UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before The Commission

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

COMPLAINANT SUN PHARMACEUTICAL INDUSTRIES, INC.'S SUBMISSION IN RESPONSE TO COMMISSION'S NOTICE REQUESTING ADDITIONAL BRIEFING

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TABLE OF ABBREVIATIONS

Abbreviation	*Meaning*
’028 Patent	U.S. Patent No. 11,697,028
’512 Patent	U.S. Patent No. 11,446,512
ALJ	Administrative Law Judge
Asserted Claims	’028 Patent, Claims 1–2, 4, 16–17, and 19–21 and ’512 Patent, Claims 1, 3, 5, 8, 17–18, and 20
Asserted Patents	U.S. Patent No. 11,446,512 and U.S. Patent No. 11,697,028
Biofrontera	Respondents Biofrontera AG, Biofrontera Bioscience, GmbH, Biofrontera Pharma GmbH, and Biofrontera, Inc. (individually or collectively)
CRPet	Complainant’s Response to Biofrontera’s Petition for Review of the Initial Determination
CIB	Complainant’s initial post-hearing brief
CPet	Complainant’s Petition for Review of the Initial Determination
CRB	Complainant’s reply post-hearing brief
FWD	Final Written Decision (IPR2024-01312)
Hente	U.S. Patent Publication No. 2010/0118522 to Hente
ID	Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond
Larsen	U.S. Patent Publication No. 2005/0075703 to Larsen
Lundahl	U.S. Patent No. 6,223,071 to Lundahl, et al.
PDT	Photodynamic Therapy
Perutz	U.S. Patent No. 4,823,858 to Perutz
POSITA	Person of Ordinary Skill In the Art
RIB	Respondents’ Initial Post-Hearing Brief
RPet	Respondents’ Petition for Review of the Initial Determination
RPHB	Respondent’s Pre-Hearing Brief
RRB	Respondents’ Responsive Post-Hearing Brief
Sun Pharma	Complainant Sun Pharmaceutical Industries, Inc.
Tr.	Evidentiary Hearing Transcript

All emphases added, unless otherwise noted.

I. INTRODUCTION

Complainant Sun Pharmaceutical Industries, Inc. ("Sun Pharma"), hereby submits this response to the Commission's March 5, 2026, Notice of A Commission Determination Requesting Additional Briefing from the Parties ("Notice"), regarding the impact of the Patent Trial and Appeal Board's ("PTAB") Final Written Decision ("FWD"), if any, on "the Commission's determination regarding the validity of the asserted claims of both the '028 Patent and the '512 Patent," including explaining (1) whether the FWD's findings satisfy the clear and convincing standard, and (2) any differences in the records. EDIS ID 874461, at 3. For the reasons discussed below, the FWD should have no impact on the Commission's determination. The PTAB reached its decision on a different evidentiary record and under a lower, different standard of proof—distinctions the PTAB repeated throughout its decision. Consequently, the FWD lacks preclusive effect, and the Commission should uphold the ALJ's analysis in the Initial Determination.

As an initial matter, the FWD does not address the '512 Patent; the PTAB had already denied institution of *inter partes* review for that patent. *See* IPR2025-00287, Paper 10 (PTAB Jul. 2, 2025). As explained below, the '512 Patent includes claim requirements not found in the '028 Patent, and Biofrontera's obviousness arguments with respect to the '512 Patent relied on references that were not before the PTAB when it issued the FWD. Thus, the FWD should have no impact on the Commission's validity determination with respect to the '512 Patent.

Regarding the '028 Patent, the FWD rationalizes its departure from the ID on three main grounds, each rendering its findings inapplicable to the Commission's review. ***First,*** the PTAB applied a lower standard of proof. *See, e.g.*, FWD, 4 ("[T]he ITC's initial determination requires clear and convincing evidence to establish invalidity, whereas here, we need only determine whether Petitioner has established unpatentability by a preponderance of the evidence."). ***Second,*** the PTAB found that there were differences in the evidentiary records between the proceedings

that it characterized as "critical." *See, e.g.*, *id*., 4 (noting "the record before us includes ***critical*** declaration and deposition testimony not before the ITC"). ***Third,*** while the PTAB suggested its decision was "not inconsistent" with the ID's construction, the PTAB expressly declined to formally construe terms—though it then implicitly construed certain terms broadly, leaving its analysis untethered to the specific boundaries adopted by the ALJ. *See, e.g.*, *id*., 13 n.7, 27–28.

These differences led to a different outcome in the PTAB. Take the "uniformly illuminate" element, recited in every asserted claim, as an example. At the ITC, the ID adopted the parties' agreed-to construction for "uniformly illuminate," and found that it required "the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum." ID, 17. At the evidentiary hearing, the ALJ heard Biofrontera's expert, Dr. Grove, admit that Larsen did not disclose the 60% threshold. Tr. (Grove), 574:16–20 (admitting "Larsen doesn't disclose how to achieve uniformity meeting the requirements of 60 percent of the measured maximum at all points"). And in its post-hearing briefing, Biofrontera dropped any argument that Larsen alone discloses uniform illumination. *See* RIB, 48–52; RRB, 18–20. Accordingly, the ID correctly found Larsen as "lacking uniform illumination" in its analysis. ID, 103, 108. The PTAB, while arguing that it is "not inconsistent" with the parties' agreed-upon construction, went further to implicitly construe the term. The PTAB then further relied on a supplemental declaration from Dr. Grove—which Biofrontera never presented to the ALJ—and its lower burden of proof to justify reaching its differing result. FWD, 25 n.9 (asserting that Biofrontera's supplemental expert declaration "was not presented in the related ITC proceeding and directly relates to the ID's divergent determination" regarding uniformity); *id.,* 27 n.10 ("***In contrast*** with the ITC's finding that Larsen does not disclose 'uniform illumination' under a ***clear and convincing standard***, we find Larsen, ***by a preponderance of the evidence,*** discloses this element.").

The Commission's decision must be based on the record developed before the ALJ, accounting for the ways the parties chose to present their cases in this forum. 19 C.F.R. § 210.45(c) (on review, the Commission "may make any findings or conclusions … based on the record in the proceeding"). Using the dispute over motivation to combine as an example, PTAB noted that Sun Pharma "does not meaningfully dispute [Biofrontera's] proposed reasons to combine Lundahl and Larsen." FWD, 21. But the record in the ITC speaks for itself: Sun Pharma vigorously contested motivation to combine, providing testimony from its expert witness, Dr. Jokerst, as well as from the inventors and Biofrontera's own witnesses, which the ID credited to find that a POSITA would have been discouraged from combining references as Biofrontera proposed. ID, 121 ("There is no motivation to increase flexibility at the expense of uniformity"), 123 ("[A] skilled artisan would not be motivated to combine Lundahl and Larsen with Hente because the hinges in Hente are not designed to uniformly illuminate"), 124 ("The inventors' problem was specific to achieving uniform illumination in a medical setting. Perutz says nothing about how to solve that problem."). Furthermore, the ALJ repeatedly found that Biofrontera waived certain arguments or failed to rebut Sun Pharma's evidence. *See, e.g.*, ID, 105 ("Biofrontera asserts that all features other than the U-shape and spacings are 'rendered unnecessary once fluorescent tubes are replaced by superior LED technology.' … [I]t is a waived theory because it is not in Biofrontera's pre-hearing brief."); ID, 116 (finding Biofrontera "ignores the full limitation" for the "center panel" limitation); *id*. (finding Biofrontera had "abandoned or withdrawn" its argument for the "four wheels" limitation for failure to respond to rebuttal evidence). Biofrontera cannot use the FWD to resurrect waived arguments or introduce new theories it failed to properly develop at the ITC.

The FWD is not a final decision until affirmed by the Federal Circuit on appeal, and thus has no preclusive effect on the Commission's determination. *United Therapeutics Corp. v.*

Liquidia Techs., Inc., 74 F.4th 1360, 1372 (Fed. Cir. 2023) (stating that "the Board's final written decision does not cancel claims; the claims are cancelled when the Director issues a certificate confirming unpatentability, which occurs only after 'the time for appeal has expired or any appeal has terminated.'"). Moreover, Sun Pharma will soon submit a Request for Director Review to vacate the FWD. Considering the different records and standards of proof, and because the FWD lacks finality, the Commission should give no weight to the FWD and affirm the ID's finding that the Asserted Patents are valid.

II. RELEVANT PROCEDURAL BACKGROUND

A. ITC Proceedings

Sun Pharma filed its Complaint in this Investigation on June 25, 2024, asserting claims 1–3, 5, 8, and 20 of the '512 Patent and claims 1, 2, 4–6, 16, 17, and 19–21 of the '028 Patent. EDIS ID 824440. The Investigation was instituted July 26, 2024. EDIS ID 827327. On October 29, 2024, Sun Pharma filed an Amended Complaint adding claims 17 and 18 of the '512 Patent. EDIS ID 835947. On March 4, 2025, the ALJ issued an Order No. 18, Construing Certain Claim Terms. The evidentiary hearing was held from June 30–July 3, 2025, where Sun Pharma introduced evidence that 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 are infringed and valid. *See generally*, CIB. On September 30, 2025, the ALJ issued an ID finding the Asserted Claims valid and infringed. ID, 143–44. The Parties filed Petitions for Review of the ID on November 17, 2025. *See generally*, RPet; CPet. On January 28, 2026, the Commission determined to review the ALJ's construction of "nested hinges" and whether the Asserted Patents are obvious under 35 U.S.C. § 103. EDIS ID 870469.

B. PTAB Proceedings

Biofrontera filed its first IPR against the '028 Patent on April 30, 2024, but the Board denied institution on the merits. IPR2024-00874, Paper 9, 20–21. Biofrontera filed a second IPR

against the ’028 Patent on August 21, 2024, challenging claims 1, 2, 4-6, 16, 17, and 19-21 as obvious over Lundahl and Larsen. IPR2024-01312, Paper 3, 9. The Board granted institution and issued its Final Written Decision on February 23, 2026, holding those claims unpatentable as obvious over Lundahl in view of Larsen under the preponderance of the evidence standard, based on the record before the PTAB. IPR2024-01312, Paper 53, 52.

Biofrontera attempted to institute proceedings against the ’512 Patent as well. IPR2025-00287, Paper 2, 10. However, the Acting Director discretionarily denied institution of that IPR petition in view of the parallel ITC proceeding. IPR2025-00287, Paper 10, 2–3.

III. SUN PHARMA’S RESPONSE TO THE COMMISSION’S NOTICE

The Commission is not bound by the PTAB’s FWD and should make its validity determination based on the record and arguments developed and presented to the ALJ. Because the PTAB’s findings were made under a much lower preponderance of the evidence standard—which cannot demonstrate invalidity under the clear and convincing standard applied at the ITC—and because live testimonial evidence presented in the ITC are superior in credibility to the arguments presented solely through depositions and declarations at the PTAB—as the Federal Circuit has routinely recognized—the Commission should give no weight to the FWD.

A. The Commission Is Not Bound By The FWD.

The FWD lacks preclusive effect on the Commission’s validity determination. ***First,*** the FWD has no finality or binding effect because patent claims are presumed valid until all appeals are exhausted and the claims found unpatentable by the PTAB are cancelled. *See Certain Network Devices, Related Software and Components Thereof (II)*, Inv. No. 337-TA-945, Comm’n Op., at 12 (Aug. 16, 2017) (explaining that “the law is clear that patent claims are valid until the PTO issues certificates cancelling … those claims, which it cannot do until the exhaustion of any appeals…take[n] from the PTAB’s final written decisions.”); *United Therapeutics*, 74 F.4th at

1372 (stating that "the Board's final written decision does not cancel claims; the claims are cancelled when the Director issues a certificate confirming unpatentability, which occurs only after 'the time for appeal has expired or any appeal has terminated.'"); *see also* 35 U.S.C. § 318(b) (noting that the Director issues a certificate cancelling claims found to be unpatentable after "the time for appeal has expired or any appeal has terminated."). Additionally, even setting aside finality, the FWD has no effect on the '512 Patent—which the ID found valid—because the PTAB's decision was limited to the '028 Patent.

Second, the PTAB applied a lower burden of proof than the ITC. At the PTAB, a petitioner bears the burden of proving unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e). At the ITC, a respondent bears the burden of proving invalidity by clear and convincing evidence. *See Guangdong Alizon Hi-Tech Co. v. Int'l Trade Comm'n*, 936 F.3d 1353, 1359 (Fed. Cir. 2019). Thus, the burden of proof applied by the ITC is more stringent than the burden applied at the PTAB. Moreover, the PTAB here went out of its way to explain that its findings were made under this lower standard, in order to explain the divergence between the FWD and the ID. *See, e.g.*, FWD, 4 ("the ITC's initial determination requires clear and convincing evidence to establish invalidity, whereas here, we need only determine whether Petitioner has established unpatentability by a ***preponderance of the evidence***."); *id*., 27 n.10. ("***In contrast*** with the ITC's finding that Larsen does not disclose 'uniform illumination' under a ***clear and convincing standard***, we find Larsen, ***by a preponderance of the evidence,*** discloses this element.").

Because of the differing burdens between the two proceedings, the PTAB's FWD is not preclusive on the Commission's validity determination. *See Certain Three-Dimensional Cinema Systems and Components Thereof*, Inv. No. 337-TA-939, Comm'n Op. at 54 (Aug. 23, 2016) ("The Supreme Court has noted that for purposes of issue preclusion, '[i]ssues are not identical if the

second action involves application of a different legal standard, even though the factual setting of both suits may be the same.'" (quoting *B & B Hardware*, 135 S. Ct. 1293, 1306 (2015)); *Certain Network Devices, Related Software and Components Thereof (II)*, Inv. No. 337-TA-945, Comm'n Op., at 8 (Aug. 16, 2017) ("a PTAB final written decision…has no collateral estoppel effect on the Commission proceeding."). For example, in reviewing the interplay between PTAB decisions and district court invalidity proceedings, the Federal Circuit has made clear that "fact findings made under a lower standard of proof (preponderance) do not have issue-preclusive effect in … proceedings where facts must be proven under a higher standard of proof (clear and convincing)." *Inland Diamond Prods. Co. v. Cherry Optical Inc.*, 155 F.4th 1365, 1368 (Fed. Cir. 2025).

Thus, the Commission should make its own determination on the validity of the Asserted Patents based on the record before the ALJ. Indeed, Commission precedent supports finding a Section 337 violation under a higher burden of proof notwithstanding a PTAB final written decision finding unpatentability. *See, e.g., Certain Semiconductor Chips With Minimized Chip Package Size and Products Containing Same,* Inv. No. 337-TA-605, at 5 (Jul. 29, 2009) (in finding a violation despite the USPTO's rejection of the asserted claims the Commission noted that "[t]here is, in fact, no harm caused by conflicting rulings between the USPTO and the Commission because the Commission does not make final binding rulings on any action relating to patents, including determining their validity…. Rather the Commission makes validity findings when considering defenses to a complainant's allegations that there has been a violation of Section 337."); *Three-Dimensional Cinema Sys.*, Comm'n Op. at 69.

B. The Commission Should Make Its Determination Based On The Record Before The ALJ—Not The FWD

Pursuant to its enabling statute, the Commission is required to make its determinations based on the evidentiary record and arguments before it: "Each determination under subsection (d)

or (e) of this section ***shall be made on the record*** after notice and opportunity for a hearing in conformity with the provisions of subchapter II of chapter 5 of title 5," 19 U.S.C. § 1337(c), —a reference to the provisions of the Administrative Procedure Act governing agency actions. Commission Rule 210.36 states that "[e]very hearing under this section shall be conducted in accordance with the Administrative Procedure Act (i.e., 5 U.S.C. §§ 554 through 556)." 19 C.F.R. 210.36(d). And under the APA, Section 554, the "***exclusive*** record" for the Commission's decision should be "[t]he transcript of testimony and exhibits, together with all papers and requests filed in the proceeding." 5 U.S.C. § 554(e).

Notwithstanding the mandates of the APA, the Commission should nevertheless make its determination on the ITC record because it is more fulsome and well-developed than the PTAB record. PTAB proceedings are constrained, resulting in a more limited presentation of evidence and argument—there are stringent word limits on the parties' papers, discovery is limited, and the oral argument is without the benefit of live testimony. Indeed, in *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186, 1190 (Fed. Cir. 2011), the Federal Circuit endorsed the district court's reliance on live testimony in making a *de novo* priority determination, stating that "while the Board is fully capable of assessing all matters presented to it, there are inherent limits to its fact finding function that arise from the sterile nature of a proceeding that is limited to documentary and declaration or deposition evidence." The Board there premised its factual findings on sworn statements that "did not allow for live credibility assessments," while the district court with "the benefit of live testimony from the declarants" found key representations not credible. *Id.*; *see also Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1582 (Fed. Cir. 1987) ("In its evaluation of the evidence on which this conclusion was based, the district court had a powerful advantage over the patent examiner and the Board, an advantage characteristic of section 145

appeals, in that the court heard and saw witnesses, testifying under examination and cross-examination, and had the benefit of extensive discussion and argument."). Moreover, to the extent there were differences between the proceedings, the FWD should not be a vehicle to inject new evidence or arguments not presented to the ALJ. *See Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 130, 1359 (Fed. Cir. 2008) (finding arguments that were not presented to the ALJ were waived); *see also Certain Ground Fault Circuit Interrupters & Prods. Containing Same*, Inv. No. 337-TA-739, Comm'n Op., at 73 (June 8, 2012) ("We find … that none of the arguments related to these four claims were presented to the ALJ, and they have therefore been waived.").

C. The FWD's Findings Under A Preponderance Standard Do Not Rise To Clear And Convincing Evidence Of Invalidity.

Sun Pharma addresses below the limitations found obvious by the PTAB based on the preponderance of evidence standard. Because none of the FWD's findings satisfy the clear and convincing evidence standard, the FWD should be given no weight. The FWD expressly relied on its preponderance standard and differences between the records to justify its findings. Moreover, as the Federal Circuit has confirmed, factual findings based on live testimony are more reliable than those based on sworn statements. *Streck*, 659 F.3d at 1190. Thus, the ID's validity findings, following a hearing with live testimony, are more reliable, and should be affirmed.

1. The ID Correctly Found No Motivation To Combine Given Contradictory Testimony, Including Self-Contradictions From Biofrontera's Own Expert.

As the FWD recognizes, Sun Pharma did not "meaningfully dispute the Petitioner's proposed reasons to combine Lundahl and Larsen" before the PTAB (because of the stricter PTAB word count). *See* FWD, 21. But here, the arguments set forth by Sun Pharma compel a different result. For example, the ID credited Sun Pharma's arguments that "introducing gaps would destroy Lundahl's goal of uniform illumination, undermining any motivation for flexibility" and that

"[w]ithout uniformity, Lundahl is not an effective medical device" and "there is no point in fitting someone into the device." ID, 120–121 (citing RX-0065 at 4:11–22; CX-0014C (Jokerst RWS) at Q511). Thus, the ID properly found that "[t]here is no motivation to increase flexibility at the expense of uniformity." Additionally, the ID quoted in full ***live inventor testimony*** from Mr. Boyajian that achieving uniformity with a multi-panel LED device was "one of the more difficult challenges" they faced, directly rebutting Biofrontera's claim that such a combination was predictable or routine. ID, 106–107; *see also* ID, 104, 121 (citing "Dr. Grove's admission that achieving uniform illumination would require undue experimentation"); *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1347 (Fed. Cir. 2000) ("[B]ecause the district court may observe witnesses under examination and cross-examination it can have a 'powerful advantage' over the Board which can never receive testimony in such a manner."); *Streck*, 659 F.3d at 1190 (noting the district court's ability to account for "live credibility assessments" which can compel different factual findings from the Board). Because Sun Pharma's arguments were not considered at the PTAB, the PTAB's conclusion as to motivation to combine should have no bearing on the Commission's decision here.

Moreover, the ITC heard from the same experts Biofrontera used at the PTAB to support its motivation to combine arguments but found their analyses insufficient under a clear and convincing burden—especially when that analysis was subject to live, cross-examination. For example, Biofrontera relied in the PTAB (as it did in the ITC) on the real-world experiences of its dermatology expert, Dr. Ehrenreich, to identify the alleged shortcomings of Lundahl's commercial embodiment, the 4170D, as a motivation to modify Lundahl's fixed U-shape with Larsen's panels. FWD, 19–20 (citing EX1016 (Dr. Ehrenreich's declaration), ¶¶42–43, 70–74, 87). The PTAB credited this theory, finding that a POSITA would incorporate Larsen's hinged panels to increase

the flexibility of Lundahl's U-shape because "there are other bodily anatomies that could use treatment for AK lesions, such as the arms, back and other body parts" and the modification would "allow for adjustment of the light panels to ensure a 2-4["] distance from the face and from other varying anatomies." *Id*. However, when Biofrontera attempted to run that same modification-motivation theory in the ITC, the ALJ squarely rejected it because Dr. Ehrenreich was confronted live with his prior deposition testimony on this very point. *See* Tr. (Ehrenreich), 648:17-650:10. Dr. Ehrenreich admitted under cross-examination that his real experience evidences no such shortcomings—in reality, he regularly uses the supposedly-inflexible 4170D to treat a variety of treatment areas and patient sizes. ID, 118 (citing Tr. (Ehrenreich), 648:1–17), 119–20 (citing Tr. (Ehrenreich), 663:12–665:18, 640:10–18). The FWD cites Dr. Ehrenreich's declaration regarding how the need to use "jury-rigged approaches" like instrument stands to fit patients when treating arms supported a motivation to modify. FWD, 19 (citing EX1016, ¶43). Dr. Ehrenreich submitted that same testimony before the ALJ but admitted under cross-examination that the same "Mayo Stands" are used in both the older 4170D device (that he claims was inflexible) and the newer, flexible 4170E device. ID, 119–20 (citing Tr. (Ehrenreich), 642:9–647:8, 663:12–665:18). Thus, because the ALJ heard live cross-examination of Dr. Ehrenreich, the ID rejected his proposal as an insufficient motivation to adapt a five-panel PDT device with hinges.

The FWD did not address any of Dr. Ehrenreich's conflicting testimony when it endorsed his modification theory. Indeed, the FWD only addressed Dr. Ehrenreich's written submission, and never heard him subject to cross-examination. As the Federal Circuit has found, the PTAB's IPR process is an ill-suited vehicle for disputes that turn on credibility because the Board "makes credibility determinations based only on written declarations." *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1273 (Fed. Cir. 2017). Similarly, the Supreme Court explains that "particularly

where credibility and veracity are at issue," "written submissions are a wholly unsatisfactory basis for decision." *Goldberg v. Kelly*, 397 U.S. 254, 269 (1970). The proper course is to give special deference to trial-level credibility calls made by those who heard the live testimony, as opposed to those reviewing a cold record. *See Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 832 (Fed. Cir. 2010).

2. "Uniformly Illuminate"

The PTAB expressly acknowledged its divergence from the ID on this element based on the lower standard of proof at the PTAB. *See* FWD at 27 n.10 ("In contrast with the ITC's finding that Larsen does not disclose 'uniform illumination' under a clear and convincing standard, we find Larsen, by a preponderance of the evidence, discloses this element."). The PTAB's finding under a preponderance standard also used an incorrect construction of "uniformly illuminate" that directly contradicts both the construction in the ITC and Biofrontera's own positions on claim scope. Instead of the parties' agreed-to construction that requires "the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum" which the ALJ adopted here, *see* Order No. 18 at 13, the PTAB instead broadly construed the term implicitly to require only "uniformly illuminating a treatment area," where "the recited 'treatment area' is unspecified, and therefore includes very small and/or flat areas of a patient's body," and can even be limited to the output from "a single panel." FWD, 27–28. The FWD's construction—that "all the claim requires" is a small area of some unspecified uniformity from "a single panel," FWD, 28—is inconsistent with the understanding shared by the parties and the ALJ: namely, that "uniformly illuminate" requires uniformity when ***all five panels*** are used. Indeed, Biofrontera premised its non-infringement on that understanding of the claims. *See, e.g.*, RIB, 22 ("Consistent with the plain and ordinary meaning of this phrase, light sources disposed on all of 'the at least five panels' must be used to 'uniformly illuminate a treatment surface.' The use of fewer than five

panels to uniformly illuminate a patient does not infringe.") (citations omitted); RPet, 87 (asserting that Biofrontera's recommendation to use only three panels to treat a patient "does not infringe").

The PTAB's findings premised on that broader construction should have no bearing on the Commission's decision.[1] *Cf. Three-Dimensional Cinema Sys.*, Comm'n Op. at 19–23 (noting that broader constructions (under the PTAB's former "broadest reasonable interpretation" claim construction standard) are not preclusive on Commission determinations under the clear and convincing standard). The PTAB lacks any finding that Biofrontera's prior art discloses "uniformly illuminate" under the construction agreed to here. In fact, because of that broader construction, the PTAB found that "Larsen is configured to provide uniform illumination," FWD, 27, even as Dr. Grove admitted here that Larsen does ***not*** disclose how to achieve the 60% uniformity required by the ALJ's construction. Tr. (Grove), 574:16–20. Thus, the FWD's finding, under that improper construction and a lower burden of proof, directly conflicts with Biofrontera's expert's testimony.

Here, the ID found, under the clear and convincing evidence standard and under the agreed-to construction, that Biofrontera failed to demonstrate that the prior art disclosed this limitation. ID, 103–08. In particular, the ID found there was insufficient evidence that Biofrontera's proposed modifications to Lundahl would result in the required 60% uniformity (in contrast to the PTAB's unspecified uniformity), or that a POSITA would have a reasonable expectation of success to achieve that "claimed uniformity given those modifications all affect uniformity." ID, 104. Under the clear and convincing standard, the ID found Biofrontera relied on "the wrong assumption that

[1] The PTAB cites *In re Blue Buffalo Enters., Inc.,* No. 2024-1611, 2026 WL 100470 (Fed. Cir. Jan. 14, 2026) to support its broad construction of "uniformly illuminate." FWD, 27. However, that case addressed claim construction during patent prosecution, where the PTO applies the "broadest reasonable interpretation" standard, not the *Phillips* standard used by the PTAB and ITC.

spacing LEDs according to Lundahl's fluorescent tube spacing leads to the claimed 60% uniformity," but had "provided ***no evidence*** showing spacing alone is enough." ID, 108.

The ID's conclusion was further backed by the testimony of several witnesses regarding the difficulties in achieving that high degree of uniformity required for PDT when connecting multiple panels. ID, 106–107 (citing testimony from Biofrontera's expert, Dr. Grove; the patents' inventor, Mr. Boyajian; Biofrontera's CEO, Dr. Luebbert; and Sun Pharma's expert, Dr. Jokerst). For example, the ID found that "Dr. Grove even opined that the claimed uniformity requires 'undue experimentation'" for effective PDT treatments. ID, 104 (citing Tr. (Grove), 579:15–25). Thus, the PTAB's finding that "achieving uniformity was routine optimization within the level of ordinary skill" (FWD, 28–29) is directly at odds with the ***live testimony*** heard by the ALJ, and therefore does not meet the clear and convincing standard. Thus, the PTAB's conclusion should be given no weight, particularly because it was made under a different and broader claim construction.

3. "Hinges"[2]

The FWD found the "hinges" limitation was rendered obvious over Larsen. FWD, 23–26. However, the FWD's conclusion was rooted in an evident misinterpretation of Dr. Jokerst's written testimony, a misreading that does not bear scrutiny under a clear and convincing standard. The PTAB took Dr. Jokerst's declaration that "a POSITA [ ] would have understood that the hinges are **not necessarily** on inner side surfaces" to "impl[y] that a POSITA would have understood Larsen as at least **suggesting** that hinges **could be** on inner side surfaces." FWD, 23 (citing EX2050, ¶151). That "implication" misreads Dr. Jokerst's testimony, as her opinion clearly states

[2] The ID adopted Biofrontera's organization for § 103 where the '028 Patent's "hinged structures" and the '512 Patent's "nested hinges" were considered together, even as the ID noted the separate requirements between those patents. *See* ID, 94, 101 n. 8

that Larsen only discloses hinges on the ***bottom.*** *See* IPR2024-01312, EX2050, ¶151 (Larsen's "hinges 10" in Figure 1 "points to the bottom of the applicator 13, not any inner side surfaces"). Rather, Dr. Jokerst used the phrase "not necessarily" to dispute Biofrontera's argument that Larsen *inherently* (*i.e.*, necessarily) discloses hinges on inner side surfaces. *Id.* Under the clear and convincing standard, the ID correctly found that Larsen does not disclose or suggest the "hinges" limitation. For example, the ALJ heard Dr. Jokerst's ***live testimony*** regarding Larsen and correctly found that Larsen expressly discloses "hinges on the bottom of the applicator, ***not*** on the inner side surfaces." ID, 94–96 (citing CX-0014C (Jokerst) at Q196–231; Tr. (Jokerst), 761:7–764:19). Though the FWD leans on how "the Examiner ***originally*** understood Larsen" as teaching "hinges on inner side surfaces" FWD, 23–24, the FWD leaves unaddressed that the Examiner subsequently ***agreed*** with Sun Pharma that Larsen does ***not*** disclose this limitation—a point the ID stressed in its analysis under the higher burden standard. ID, 95 (noting three instances where the Examiner later agreed Larsen's figure did not disclose hinges on the side). The ID also relied on how Larsen used the same convention as its Figure 1 in other applications to refer to hinges on the side. ID, 96. The FWD's analysis did not address any of this contrary evidence.

The FWD's findings are further called into question because they rely heavily on Dr. Grove's testimony on the "hinges" limitation, but the ID found Dr. Grove's live testimony contradicted his obviousness analysis in two ways. First, Dr. Grove admitted live that "Larsen does not describe ***in any detail*** the hinges." Tr. (Grove), 563:1–20. Thus, "there is not sufficient evidence to show that one of ordinary skill would assume that the hinge would be on the inner side surface of the panel." ID, 100. Second, the ID found that Dr. Grove's obviousness testimony could not support invalidity under the clear and convincing standard "because it conflicts with his noninfringement testimony on hinges 'on inner side surfaces.'" ID, 101 n.8. Dr. Grove claimed

that, for infringement, it was essential to examine "the panels' internal structure and the points of attachment" between the hinges and the panels, but he never "explained how he can determine whether Larsen's or Hente's hinges disclose this limitation when those hinges are never shown, and he has no information on their structure or connection points." *Id.* Because Dr. Grove's infringement analysis was not before it, the PTAB did not meaningfully consider his contradictory testimony that the ALJ found undermined his invalidity analysis.

The FWD also found, based on the record before it, that a POSITA would be motivated to modify Larsen to put hinges on the side. FWD, 24–26. The FWD rejected as insufficient under its preponderance standard the written testimony from Dr. Jokerst that a POSITA would have been discouraged from placing hinges between panels because uniform illumination would be degraded by the resultant gaps. Instead, the FWD "credit[ed] Dr. Grove's supplemental testimony on this issue" that gaps caused by hinges are "'easily addressed' to maintain uniform illumination." FWD, 25 n.9 (asserting "[t]his testimony was not presented in the related ITC proceeding"). But that finding cannot compel a different result here for two reasons. First, Dr. Grove's proposal would ***not*** "maintain uniform illumination" under the appropriate construction of "uniformly illuminate" that both parties agreed to in the ITC. Instead, the FWD applied a broad construction of "uniformly illuminate," as discussed *supra*, § III.C.2. Second, Biofrontera never submitted that testimony before the ITC, and thus it cannot be the basis of a decision here. While the FWD found the uniformity problems would be "easily addressed" when hinges are incorporated, the ID relied on live inventor testimony that achieving uniformity with a multi-panel LED device was "one of the more difficult challenges" they faced, ID, 106–07, and cited testimony from both Biofrontera's CEO and its technical expert on how gaps between panels were known to cause uniformity problems. ID, 100 (reviewing Dr. Bretschneider's admission), 107 (reviewing Dr. Luebbert's).

4. "Continuous Illumination"

The Board's finding on the "continuous illumination" element of '028 Patent claim 16 is inapplicable here. First, as Sun Pharma explained, Biofrontera failed to argue in its post-hearing brief that the "continuous illumination" element of claim 16 of the '028 Patent was obvious over Larsen in its petition for review. CRPet, 27–29; *Philip Morris Prods. S.A. v. Int'l Trade Comm'n*, 63 F.4th 1328, 1336 (Fed. Cir. 2023) ("We have also recognized that a party's failure to make a specific argument in its petition for review of the FID before the Commission constitutes forfeiture."). Biofrontera argued the element only with respect to claim 20 of the '512 Patent, which is materially different. *See* CRPet, 27–29**.** Thus, the FWD has no bearing on the Commission's decision, and claim 16 of the '028 Patent should be found valid, regardless of any other considerations.

Second, the PTAB's decision does not support finding invalidity under the clear and convincing standard. The ID properly understood that, as recited in the claims, it is the hinges that "allow continuous illumination across the five panels." ID, 102. Thus, if Larsen, the only reference before PTAB with hinges, does not disclose those hinges in any detail, it likewise does not disclose that any supposed continuous illumination is a function of those hinges under the higher burden of proof. The ID correctly credited Dr. Grove's live testimony where he admitted that "Larsen doesn't provide a description of the physical structure of the hinge" and "in Figure 1 of Larsen, you can't actually see what Larsen's hinges look like." ID, 102 (citing Tr. (Grove), 563:1–23). Therefore, the ID correctly found "Larsen never teaches nested hinges that 'allow for minimization of the gap between panels' to in turn 'allow continuous illumination.'" ID, 102. The FWD never contended with Dr. Grove's admissions that Larsen lacks details on its hinges, and thus, its analysis of this element is insufficient under the clear and convincing standard.

5. "Higher Intensity"

Biofrontera presented different arguments as to the "higher intensity" limitation before the PTAB and the ITC. For example, at the PTAB, the FWD predicated its decision on finding that Larsen's scan engine was not necessary in Biofrontera's combination of Lundahl and Larsen. *See* FWD, 32. Here, however, Biofrontera explicitly and continuously relied on Larsen's scan engine in the combination of Lundahl and Larsen. In his analysis, Dr. Grove repeatedly invoked the scan engine feature in his combination, particularly for allegedly disclosing "uniform" illumination. *See, e.g.*, RX-0006C, Q113 (relying on "scan engine 66" in Larsen), Q180 (same), Q263 (same). Therefore, it was appropriate for the ID to analyze how the incorporation of the scan engine would impact the "higher intensity" limitation. ID, 114. Additionally, Dr. Jokerst fully supported her analysis of how Larsen's scan engine in the Lundahl/Larsen combination would lead to higher intensity of light emitted from the center of the panels. *See* CX-0014C, Q275–78; Tr. (Jokerst), 757:16–760:13 (Dr. Jokerst live testimony on how the engine moves up and down); CDX-0018C.82, .83. Notably, the "higher intensity" limitation is the only limitation where the FWD disagreed with the ID's conclusion, FWD, n.14, due to the difference in Biofrontera's arguments regarding Larsen's scan engine. *Compare* ID at 114 ("…incorporating Larsen's scan engine in the Lundahl/Larsen combination would lead to higher intensity of light emitted from the center of the panels, not near the second shorter edges as claimed.") *with* FWD at 32 ("However, we agree with Petitioner that Larsen's scan engine is not required in the combination, which modifies Lundahl with the concept of Larsen's five adjustable, hinged LED panels."). Because Biofrontera changed how its Lundahl/Larsen combination worked in the PTAB, the FWD should have no bearing on the Commission's decision as to the "higher intensity" limitation.

6. "A Center Panel Configured To Face The Treatment Surface"

Due to word count limitations, Sun Pharma's arguments on "a center panel configured to

face the treatment surface" made to the ALJ were not presented at the PTAB. In light of this, the PTAB found that Biofrontera met the preponderance standard. *See* FWD at 30 ("Patent Owner does not contest this, and we determine that Petitioner's contention is supported by a preponderance of evidence."), n.12 ("Our determination differs from the ITC's ID, which agreed with Patent Owner's argument that Larsen does not teach a center panel configured to face the treatment surface…"). On a fulsome record, the ID, on the other hand, correctly found that "Biofrontera has not shown by clear and convincing evidence that Larsen discloses the center panel limitation" because Biofrontera "ignore[d] the full limitation" and therefore made "no assertion" that all parts of the element were disclosed in Larsen. ID, 116. The FWD should not be an avenue to cure this deficiency. Therefore, the FWD should be given no weight, and the Commission should affirm the ID on its record. ID, 116; CIB, 103–04; CRB, 29; CRPet, 48–51.

7. "Four Wheels"

Like the "center panel" limitation, the FWD recognizes that Sun Pharma's arguments regarding "four wheels" were not presented at the PTAB though they were considered in the ID. *See* FWD at 47 ("Patent Owner does not dispute Petitioner's identification of teachings in Lundahl and Larsen for the remaining limitations of claim 16."). Therefore, the FWD found this element met by a preponderance of the evidence. *Id.* Because the ITC has a more developed record, the ID properly found that Biofrontera did not show that "four wheels" was obvious; the PTAB's contrary conclusion on a different record should be afforded no weight by the Commission.

Here, Biofrontera failed to present clear and convincing evidence that Larsen, which is silent on how many wheels it has, discloses this limitation. Biofrontera argued that Larsen's Figure 1, which shows only two wheels in its perspective view, "suggests that the device may incorporate four wheels," and that "[a] POSA would have been motivated with a reasonable expectation of success to use four wheels." RIB, 65–66. Biofrontera's brief, however, ignored Dr. Jokerst's

rebuttal testimony, submitted at the hearing, that there was no inherent disclosure of four wheels because Figure 1 shows only two wheels and "[a] POSITA would have understood that the device would have been stable and freely moveable on only three wheels." CX-0014C, Q449; *see* CIB, 107 (citing CX-0014C, Q448–52; CX-1028). The ID found that Biofrontera failed to address Sun Pharma's rebuttal evidence and therefore abandoned the argument. ID, 116. The PTAB's decision should not be used to revive Biofrontera's argument and therefore should have no bearing on the Commission. The Commission should make its determination on the ITC record and affirm the ID. ID, 116, CIB, 107; CRB, 36; CRPet, 52–53.

8. "Individually Configurable"

The PTAB's decision on the "individually configurable" limitation should not impact the Commission's determination. ***First***, EX2011 (CX-1231 in the ITC), on which the FWD relies for its decision (FWD, 45), was not supported by expert testimony in the ITC. At the ITC, Biofrontera belatedly attempted to introduce CX-1231 as new prior art. And, as Sun Pharma explained in its Response to Biofrontera's Petition for Review, CX-1231 was not relied on by Biofrontera's expert here, and its analysis therefore lacks any expert testimony for this claim limitation. CRPet, 47. Moreover, as Sun Pharma explained, any arguments related to CX-1231 are waived because Biofrontera failed to include any argument that CX-1231 disclosed this limitation in its pre-hearing brief. CRPet, 47. ***Second***, the FWD credits "Petitioner's declarant that, where each panel includes its own sensor, Larsen at least suggests that applicators are individually adjusted by the controller based on feedback from their respective sensors." FWD, 46. This argument was absent from Biofrontera's briefing and petition for review in the ITC and is therefore inapplicable here. Moreover, a "suggestion" that Larsen's applicators are individually adjusted does not rise to clear and convincing evidence. Because the PTAB credited arguments Biofrontera did not make in this proceeding, the FWD should be given no weight, and the Commission should affirm the ID based

on its record. ID, 116, CIB, 100–101; CRB, 35; CRPet, 46–48.

D. Secondary Considerations Defeat Any Prima Facie Showing Of Obviousness

The FWD's findings on secondary considerations do not bear on the record here, which includes relevant ***Biofrontera*** confidential information—not before the PTAB—foreclosing any finding of invalidity. For example, Sun Pharma here submitted detailed analyses of Biofrontera's infringement of multiple claims, relying on Biofrontera internal documents, and robust commercial success using Biofrontera's confidential sales data. Indeed, Biofrontera failed to rebut almost all of that evidence; its Petition for Review includes only conclusory incorporation by reference, not any substantive rebuttal. RPet, 69–70; CRPet, 65–68. That failing is dispositive because objective indicia "must be considered before determining" obviousness. *Apple Inc. v. ITC*, 725 F.3d 1356, 1365 (Fed. Cir. 2013); *see Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) ("Objective indicia of nonobviousness must be considered in every case where present.").

1. Nexus

Because the RhodoLED® XL is coextensive with the Asserted Claims, Sun Pharma is entitled to a presumption of nexus between the claimed invention and the product's commercial success. *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329–30 (Fed. Cir. 2016). Biofrontera did not preserve any argument in the ITC record that the RhodoLED® XL is not coextensive with the asserted claims, and it cannot resurrect that theory now. For example, Biofrontera's Petition for Review contains no rebuttal to Sun Pharma's coextensiveness argument based on the detailed, and now unrebutted, infringement analysis. *See* RPet, 69–70. Nor does the PTAB's FWD alter the analysis. The FWD characterized the record before it —Sun Pharma's claim-by-claim analysis and claim charts incorporated into its briefs—as conclusory. FWD 35–36. However, the PTAB record was limited to publicly available information, as Biofrontera would not permit Sun Pharma to submit Biofrontera confidential information before the PTAB. Therefore, the FWD's criticism

has no application to the ITC proceeding, where there was extensive, claim-specific evidence establishing that RhodoLED® XL meets each asserted claim. ID, 18–43, 53–77; *see Three-Dimensional Cinema Sys.*, Comm'n Op., at 57–58 (finding that technical prong evidence not required by the PTAB demonstrated nexus and "supports a different conclusion than the PTAB with respect to secondary considerations"). Indeed, Biofrontera's Petition let stand the ID's infringement finding for Claims 1 of both patents. The claim language itself likewise reinforces coextensiveness: the Asserted Claims recite the RhodoLED® XL as a whole (*e.g.,* Claim 16 of the '028 patent; Claim 1 of the '512 patent), not specific, narrow features.

The FWD's remaining rationales do not undermine nexus on this record. The FWD states that because RhodoLED® XL is embodied by a different patent, the presumption of nexus was not available, FWD, 36, but the PTAB came up with that argument on its own—Biofrontera never made that argument at either the PTAB or the ITC. And to the extent Biofrontera suggests that "unclaimed features" drive sales, the ITC record refutes that suggestion, as this was directly addressed through expert testimony. For example, the FWD calls out the RhodoLED® XL's user interface as a distinguishing, unclaimed feature. FWD, 38. But as Dr. Vander Veen testified, both RhodoLED® XL and the older RhodoLED® include touchscreen user interfaces, which therefore cannot explain the higher demand for the RhodoLED® XL. Tr. (Vander Veen), 297:16–298:14. Thus, the ITC record—including arguments that Biofrontera never rebuts—supports a presumption of nexus.

2. Commercial success

The PTAB's findings regarding commercial success do not overcome the extensive ITC record, supported by confidential sales data not before the PTAB. The FWD found that "the lack of overall market share data" cut against commercial success. FWD, 42. But that evidence was before the ITC. RhodoLED® XL sales materially outperformed both the older BLU-U® 4170D

and the original RhodoLED®—neither of which practices the Asserted Claims—even though the XL sold at roughly twice the price of the original RhodoLED®. CX-1249; CX-1225.3; Tr. (Leffler), 288:16–290:19; CX-0012C, Q132, Q165. In its first year, the XL's annualized sales exceeded BLU-U® 4170D sales by approximately [redacted], despite Sun Pharma having [redacted] of the PDT market. CX.0012C, Q165, Q180. Market demand for RhodoLED® XL caused Biofrontera to significantly expand inventory, and Biofrontera touted the XL launch as a success to its shareholders. CX-0356.1; Tr. (Luebbert), 336:2–8; CX-0012C, Q111–12.

Moreover, Biofrontera's attorney's arguments were contradicted by its own witnesses at the ITC hearing. For example, Biofrontera argued in briefing that "sales have not reached a level sufficient to conclude that the RhodoLED® XL has been commercially successful" and that the RhodoLED® XL "has not even sold anywhere near what was projected." RPHB, 177. But Biofrontera's CEO, Dr. Luebbert, rejected that position when he was confronted with his own statements to Biofrontera's investors. When asked whether he agreed with Biofrontera's contention that the RhodoLED® XL "has not even sold anywhere near what was projected," he answered, "No." Tr. (Luebbert), 318:10–13. The contemporaneous sales data, Biofrontera's own inventory expansion, and its shareholder communications confirm that the RhodoLED® XL achieved commercial success attributable to the claimed invention.

Not only did the PTAB not address the testimony presented in the ITC, it also advanced arguments on commercial success that Biofrontera never advanced here, or even at the PTAB. For example, the PTAB *sua sponte* credited evidence that the increased sales for the RhodoLED® XL were driven by the FDA's approval of larger doses of the drug Ameluz®. FWD, 38–40. There is no briefing or expert testimony to support that argument, in either the PTAB or the ITC, and thus that PTAB finding is insufficient to defeat a finding of commercial success here.

3. Industry Praise

Biofrontera does not address Sun Pharma's industry-praise evidence anywhere in its Petition for Review. *See* RPet, 69–70. That silence leaves Sun Pharma's showing uncontested on the ITC record and thus independently supports the patents' validity. *See* CRPet, 67–68.

The PTAB criticized Sun Pharma's evidence of praise because it included Biofrontera's self-referential praise, which is not "from industry." FWD at 41. But the ITC record contains multiple examples of industry participants praising the relevant devices and the technological advances tied to the claimed invention. For example, doctors praised the RhodoLED® XL for the patented features. CX-0356.1 (dermatologist stating RhodoLED®-XL's "larger illumination area has significantly increased our patient throughput"); JX-0177.4 (dermatologist praising RhodoLED® XL for its "multi-panel lamp head [that] fits nicely over a patient's face or scalp for the short treatment, while providing better coverage").

Similarly, Mr. Lundahl testified that market feedback on the BLU-U® 4170E, which is also coextensive with the Asserted Patents, was very positive, including a doctor saying, "we'd hit a home run with this light source." CX-0011C (Lundahl), Q161–64; JX-0094C.2; *see also* CIB, 120–121. The FWD's analysis also turned on the PTAB's view that the "extent" of the praise evidence for the BLU-U® 4170E was "a single article" and that it was merely an announcement of FDA approval, not "praise from industry participants." FWD 34. However, Sun Pharma relied on an updated version of the article here, which quotes a practicing dermatologist and expressly describes the device's new features as advancing PDT. CX-1346.2; *see also* CX-1346.4 (author calling the 4170E a step forward in PDT). As evidenced above, the ITC record includes additional, independent evidence of praise from market participants beyond a single publication. On this record, industry praise provides further objective evidence supporting nonobviousness.

E. The PTAB Did Not Address The '512 Patent.

The FWD addressed only the '028 Patent. The '512 Patent was not at issue and is therefore unaffected by the FWD. The '512 Patent contains materially different claim requirements, not found in the '028 Patent including "nested hinges on inner side surfaces" ('512 Patent, all claims), "a recess" ('512 Patent, Claims 17-18), and "the nested hinges being configured so as to allow continuous illumination across the at least five panels" ('512 Patent, Claim 20). The ALJ construed both "nested hinges on inner side surfaces" and "a recess" (Order No. 18) and found that Biofrontera's combinations did not teach either claim element as construed for every asserted claim of the '512 Patent (ID, 17, 94–103, 116–18). None of these terms unique to the '512 Patent, nor their constructions, were before the PTAB, further distancing the '512 Patent from the FWD.

With respect to the "continuous illumination" limitation, Biofrontera offered attorney argument only and did not provide substantive proof addressing the limitation. ID, 102. That argument was contradicted by Biofrontera's own expert. *Id.,* 102–103. As to the "nested hinges" and "recess" limitations, Biofrontera attempted to demonstrate obviousness by relying on additional prior-art references, specifically Hente and Perutz, that were not before the PTAB, but the ID found no motivation to combine those references with Lundahl and Larsen. ID, 122–124. Indeed, Biofrontera's assertions at the ITC against claims 17 and 18 of the '512 Patent, which include the "recess" term and have no corollary in the '028 Patent, depend ***entirely*** on Hente and Perutz. RIB, 69–71; RRB, 27–28. Because neither reference was before the PTAB, the FWD can have no impact on the Commission's determination on the validity of those claims.

Thus, the FWD does not impact the Commission's '512 Patent validity determination, which should affirm the ID on the evidence and arguments before the ALJ.

IV. CONCLUSION

For the foregoing reasons, the FWD does not impact the Commission's determination.

Dated: March 12, 2026

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before The Commission

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

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

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TABLE OF ABBREVIATIONS

Abbreviation	*Meaning*
’028 Patent	U.S. Patent No. 11,697,028
’512 Patent	U.S. Patent No. 11,446,512
ALJ	Administrative Law Judge
Asserted Claims	’028 Patent, Claims 1–2, 4, 16–17, and 19–21 and ’512 Patent, Claims 1, 3, 5, 8, 17–18, and 20
Asserted Patents	U.S. Patent No. 11,446,512 and U.S. Patent No. 11,697,028
Biofrontera	Respondents Biofrontera AG, Biofrontera Bioscience, GmbH, Biofrontera Pharma GmbH, and Biofrontera, Inc. (individually or collectively)
CBR	Complainant’s Response to the Commission’s Request for Additional Briefing
CRPet	Complainant’s Response to Biofrontera’s Petition for Review of the Initial Determination
CIB	Complainant’s Initial Post-Hearing Brief
CPet	Complainant’s Petition for Review of the Initial Determination
CPHB	Complainant’s Pre-Hearing Brief
CRB	Complainant’s Reply Post-Hearing brief
FWD	Final Written Decision (IPR2024-01312)
Hente	U.S. Patent Publication No. 2010/0118522 to Hente
ID	Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond
Larsen	U.S. Patent Publication No. 2005/0075703 to Larsen
Lundahl	U.S. Patent No. 6,223,071 to Lundahl, et al.
PDT	Photodynamic Therapy
Perutz	U.S. Patent No. 4,823,858 to Perutz
POSITA	Person of Ordinary Skill In the Art
RIB	Respondents’ Initial Post-Hearing Brief
RPet	Respondents’ Petition for Review of the Initial Determination
RPHB	Respondents’ Pre-Hearing Brief
RRB	Respondents’ Responsive Post-Hearing Brief
RBR	Respondents’ Response to the Commission’s Request for Additional Briefing
Sun Pharma	Complainant Sun Pharmaceutical Industries, Inc.
Tr.	Evidentiary Hearing Transcript

All emphases added, unless otherwise noted.

I. INTRODUCTION

The Commission must determine the validity of the Asserted Patents based on the record developed in this Investigation. The ID correctly found that Biofrontera failed here to carry its burden to prove invalidity by clear and convincing evidence, including because it failed to preserve arguments in its briefing and timely rebut contrary evidence. Biofrontera should not be permitted to use the FWD to sidestep the ITC's procedural requirements and deadlines and introduce arguments and evidence that it failed to properly submit before the ALJ.

Biofrontera's response to the Commission's Request ("RBR") attempts to convert the FWD into a finding of clear and convincing evidence by asserting that the PTAB was "clearly convinced" of the claims' invalidity and that it found a "strong case of obviousness." RBR, 1. But that ignores the PTAB expressly predicating its findings on its lower standard of proof to explain why it did not reach the same result as the ID. *See, e.g.*, FWD, 27, n.10 (contrasting the ITC's finding a failure to disclose the element "under a clear and convincing standard" with the FWD finding disclosure "by a preponderance of the evidence"). Similarly, Biofrontera quotes the FWD's cursory review of secondary considerations and attempts to draw an "inference that, ***whatever evidentiary standard applies***, the PTAB found the obviousness case presented in the IPR to be compelling." RBR, 5. But that "inference" is contradicted by the PTAB's own words, as the PTAB's reference to a "strong case" was limited to the preponderance standard—as no other standard was considered. *See* FWD, 33 (referring to the need for "substantial weight" required for secondary considerations "in order to determine that the claims have not been shown to be unpatentable ***by a preponderance of the evidence***."). Biofrontera's brief offers no substantive analysis of those secondary-considerations findings under the clear-and-convincing standard. As reviewed in Sun Pharma's opening brief ("CBR"), the FWD's cursory review of its limited record does not disturb the clear objective evidence presented here. CBR, 21–24.

Likewise, Biofrontera claims that the "full quote" of a colloquy by one PTAB judge is "worth the Commission's attention," RBR, 1, but Biofrontera fails to explain why the Commission should accord any weight to what that judge called his "***first impression*** of this case"—not a reasoned, written analysis—that it seems "simple" to substitute fluorescent tubes with LEDs. Ex. A, 51:15–23. Regardless, the proper analysis under the clear and convincing standard is not whether it is "simple" using hindsight to swap in LEDs or put hinges on the side of a panel in the ***abstract***, but whether the claimed arrangement of features was obvious for a ***medical-grade*** illuminator with strict uniform intensity requirements. The full record here demonstrates that, before the Asserted Patents were filed, persons of ordinary skill would have been discouraged from making a medical-grade illuminator with the claimed arrangement of features. CBR, 3.

The Commission asked whether the FWD's analysis—not soundbites—should impact review of the ID. Because nothing in Biofrontera's brief demonstrates that the PTAB's invalidity analysis meets the clear and convincing standard, the Commission should affirm the ID.

II. THE FWD IS NOT BINDING OR PERSUASIVE

First, Biofrontera never argues that the FWD has preclusive effect on this Investigation. Federal Circuit and Commission precedent confirm that a FWD (a non-final decision) does not bind ITC validity determinations because of the PTAB's lower standard of proof. CBR, 5–7.

Second, the Commission should reject Biofrontera's invitation to "accord substantial persuasive weight" to the FWD's finding to overcome the ID's analysis. RBR, 1. Not one of Biofrontera's cited cases suggests otherwise—Biofrontera notably does not cite a single Commission Opinion in support.[1] Instead, Biofrontera cites two district court decisions regarding whether to stay proceedings during pending IPRs. *See, e.g.*, *Tas Energy, Inc. v. San Diego Gas &*

[1] Biofrontera's brief claims the Court of Federal Claims has "regularly recognized the persuasive value of PTAB decisions," RBR, 3, but fails to cite a single Court of Federal Claims case.

Elec. Co., 2014 WL 794215, at *6 (S.D. Cal. Feb. 26, 2014) (staying district court litigation pending IPR); *DSS Tech. Mgmt., Inc. v. Apple, Inc.*, 2015 WL 1967878, at *5 (N.D. Cal. May 1, 2015) (same). The cases also lack any discussion on reconciling any inconsistencies with the PTAB's findings, as those stays were ordered before any *Markman* hearing or invalidity findings.

Biofrontera argues that PTAB findings are "strong evidence" that must be considered, but its brief's selective quotations omit a key caveat. RBR, 2, 4. For example, the full quote from *Tas Energy* actually reads: "Lastly, **even if the PTO affirms the claims**, the PTO's decision 'is strong evidence that the court must consider in assessing whether the party asserting invalidity has met its burden of clear and convincing evidence.'" *Tas Energy*, 2014 WL 794215, at *4 (S.D. Cal. Feb. 26, 2014) (internal citation referring to "the PTO's upholding of the claims" as "strong evidence"). That full statement is logical: the PTO's ***affirmance*** of claims under its preponderance of the evidence standard, where the challenger ***failed*** to meet its burden under a lower standard, is "strong evidence" that must be addressed when determining invalidity under a higher burden of clear and convincing evidence. Likewise, Biofrontera cites *Ultratec*—which at least addresses invalidity on the merits—but there too, the district court found persuasive the PTAB's decision ***not*** to institute because of a ***failure*** to show unpatentability under the lower standard, where the "same argument" of invalidity was then made to the court. *Ultratec, Inc. v. Sorenson Commc'ns, Inc.*, 2015 WL 5330284, at *14 (W.D. Wis. Sept. 11, 2015).

What is lacking from Biofrontera's brief is any support that the PTO's finding of ***un***patentability can persuade here when the standard heightens—not to mention when the PTAB applies a different claim construction and reviews different evidence. Indeed, the Federal Circuit recently reaffirmed that PTAB findings should not be simply ported to a forum with a heightened

standard, as doing so would bypass "the statutorily prescribed clear-and-convincing evidence standard." *Kroy IP Holdings, LLC v. Groupon, Inc*., 127 F.4th 1376, 1381 (Fed. Cir. 2025).

III. THE FWD DOES NOT REMEDY BIOFRONTERA'S FAILURE TO MEET ITS BURDEN OF CLEAR AND CONVINCING EVIDENCE OF INVALIDITY

A. Sun Pharma's PTAB Briefing Decisions Do Not Impact Validity Here.

Biofrontera's attempt to draw a purported "reasonable inference" from Sun Pharma's selection of issues to brief in the IPR should be ignored. RBR, 7. The Investigation here included robust *Markman* proceedings, exchange of confidential exhibits, live testimony, and extensive briefing on all issues, including infringement and invalidity. The PTAB's procedures are narrower in each respect—for example, Sun Pharma's word count limit for its Patent Owner Response was less than a fourth of the limit for the ITC's Pre-Hearing Brief. Sun Pharma never conceded that the limitations it did not brief in the PTAB had been demonstrated to be obvious by clear and convincing evidence—indeed, Sun Pharma contested many of those limitations here, and the ALJ sided with Sun Pharma's presentation of the evidence.

B. The FWD Cannot Impact The '512 Patent.

The FWD reaches only the '028 Patent, not the '512 Patent. Biofrontera's brief fails to address the material differences between the two patents that render the FWD inapplicable to the '512 Patent. ***First***, Biofrontera argues that there should be no distinction between "nested hinges" and "hinged structures." RBR, 8. But the terms are demonstrably different. The ALJ correctly gave effect to "nested," construing the term to require "hinges that **fit** on inner side surfaces"—signifying a particular configuration and placement of the hinge. Order No. 18 at 31–32. Even Biofrontera acknowledged the difference for "nested hinges" in its prior art analysis. For the '028 Patent, Biofrontera relied on Larsen alone to teach a "hinged structure on inner side surfaces." But for the '512 Patent, Biofrontera introduced Hente—art not included in the FWD—as allegedly

teaching the "nested hinge" term. RX-0006C, Q161 (Hente disclosed "nested hinge"), Q333 (identifying Hente only for '512 Patent claims). Biofrontera chose new art for the '512 Patent's "nested hinges" because the validity analysis was not coextensive with the '028 Patent.[2]

Second, Biofrontera apparently concedes that the claims analyzed in the FWD have no analog for claims 17 and 18 of the '512 Patent, which require a "recess." RBR, 9. That accords with Biofrontera's reliance here on new art, Hente and Perutz, to teach the "recess" limitation—art that the FWD never addressed.

Third, the FWD has no bearing on the element, "the nested hinges being configured so as to allow continuous illumination across the at least five panels," recited in Claim 20 of the '512 Patent because it has no analog in the '028 Patent. While Biofrontera notes the alleged overlap with "nested hinges" and "hinged structures," its chart for the '512 Patent states there is no overlap with the term, "five panels connected by hinged structures to allow continuous illumination across the five panels," recited in Claim 16 of the '028 Patent. *See* RBR, 5.

C. Review of Limitations In The '028 Patent Addressed By The FWD

1. "Hinged Structures On Inner Side Surfaces"

In both proceedings, Biofrontera failed to identify any reference predating the Asserted Patents that disclosed using inner-side hinges to connect PDT panels. The PTAB instead adopted Biofrontera's claim that it was common sense to put hinges on the inner side. FWD, 26. But that only underscores the hindsight-driven nature of the analysis and cannot come close to meeting the clear and convincing standard. The Federal Circuit warns "common sense" cannot be used as a "wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with

[2] Biofrontera twice repeats its false contention that the ID broadened the claims for infringement to require any hinge on any panel, without regard to the location. RBR, 8, 11. That contention has no basis—the ID did not delete "hinges on inner side surfaces" from the claims; it merely rejected Biofrontera's theory that "on" required directly mounting to a surface. CRPet, 22–24.

a limitation missing from the prior art references specified." *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362–63 (Fed. Cir. 2016). That is the case here, as Biofrontera's expert admitted that the references do not describe or disclose their hinges "in any detail." Tr. 563:1–20, 585:8–12.

The FWD divorced the Asserted Patents from their proper context—medical-grade illuminators with highly uniform light required to evenly activate the PDT drug. Instead, the FWD found the "hinged structure" limitations obvious by analogizing to the sort of ordinary design choice one might make for door hinges, reasoning that there are only a finite number of ways to connect panels. FWD, 25–26. The claimed invention, though, is not directed to merely connecting generic light panels. The ALJ heard from both fact and expert witnesses how hinges on the inner sides were at odds with the high degree of uniformity required for an effective medical device and how a POSITA would be discouraged from placing hinges on the inner sides and would opt for other possible connection means. *See* CRPet, 20–21, 23–25.

The FWD claimed that trying to achieve a nearly flush arrangement to eliminate gaps would motivate one to arrive at the claims. FWD, 24–25. However, neither Biofrontera nor the PTAB identified evidence showing that Larsen discloses a nearly flush configuration that would motivate selecting inner-side hinges. Instead, both rely on Dr. Grove's testimony, *id*., the same expert who told the ALJ that Larsen did not disclose hinges in any detail—and thus could not support a conclusion that Larsen discloses a flush arrangement. ID, 99–101. When there is no motivation to place hinges on the inner side surfaces, as opposed to other locations where there would be no uniformity drawbacks, one cannot simply point to "common sense" as evidence of obviousness, let alone clear and convincing evidence, under *Arendi*.

Biofrontera again returns to its assertion that "the available evidence shows clearly and convincingly that it is obvious for a POSA to place hinges between panels," but cites only Dr.

Grove's unsupported testimony regarding the "most logical" hinge design. RBR, 10–11. The ID rejected that testimony as both conclusory and absent from Dr. Grove's witness statement. ID 100–01. Moreover, the ALJ found that Dr. Grove's opinions on obviousness lacked credibility because they could not be reconciled with his own noninfringement testimony. ID, 101 n.8. The PTAB never addressed that inconsistency, underscoring the differences in the record.

2. "Uniformly Illuminate" (All Claims)

Biofrontera's brief ignores how the PTAB itself distinguished its FWD from the analysis required in this Investigation. The PTAB re-interpreted "uniformly illuminate" to be a "functional limitation" with a broad construction that required only the output from a "single panel" and where a treatment area could encompass very small or flat areas.[3] FWD, 27–28. Neither party ever advocated for that construction here and the ID did not adopt it, but Biofrontera's brief fails to address the PTAB's divergence. By broadening the construction, the PTAB made its findings regarding "uniformly illuminate" irrelevant to this Investigation, which must apply the parties' agreed-upon construction. *See Application of Swinehart*, 439 F.2d 210, 213 (C.C.P.A. 1971) ("'Functional' terminology may render a claim quite broad."). Moreover, the PTAB's finding conflicts with Biofrontera's noninfringement argument that all five panels must be used to meet the claims. CBR, 12–13.[4]

[3] In a footnote, the PTAB declined to "expressly construe claim terms" but stated, without explanation, that the FWD "is not inconsistent with the claim constructions set forth in the ID." FWD, 13, n.7. The PTAB's analysis, however, shows the opposite. For example, the FWD asserts Larsen ***alone*** discloses "uniformly illuminate." *Id.*, 27–28. Biofrontera does not, and cannot, argue that finding is applicable here, as Biofrontera has already admitted that Larsen does not disclose the degree of uniformity required under the ID's construction. CBR, 13.

[4] Sun Pharma is seeking Director Review of the FWD for these exact reasons. As the Director recently explained, the PTAB should "correctly construe[] claim terms and [] minimize inconsistency in claim construction between forums" to "discourage petitioners from seeking broader constructions at the Board to support a patentability challenge while seeking narrower constructions in litigation to avoid infringement liability." *Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 at 4 (Director Nov. 3, 2025) (precedential) (Ex. 2).

Biofrontera briefly acknowledges that the PTAB relied on Dr. Grove's supplemental declaration which was not part of the ITC record. Dr. Grove there asserted that POSITAs could position LEDs so that the divergence angles of individual lights overlapped to prevent gaps. But that arrangement only leads to illumination generally, not the claimed uniformity of intensity; Dr. Grove admitted he never analyzed or estimated what the levels of ***intensities*** would be at the treatment surface, Ex. 1, 29:1–30:8, 52:22–53:21, and that his analysis uses a flat surface, as opposed to a curved surface as typically seen in PDT, *id*., 55:4–20.

Biofrontera's remaining arguments fare no better.[5] As Sun Pharma previously explained, *Alcon* is inapposite because there is no dispute that the Asserted Patents adequately disclosed uniformly illuminating using the claimed illuminator. CRPet 41–42. Nor did the ID's analysis consider the POSITA to be an automaton. The problem was Biofrontera's failure to demonstrate that its proposed combination preserved the uniformity achieved by Lundahl's integrated system after introducing fundamental changes (like introducing gaps between panels). CRPet 43–44. The PTAB addressed those difficulties by relying on its lower standard of proof, a broader construction, and purportedly new arguments and evidence; but that cannot constitute clear and convincing evidence here.

3. "Higher Intensity. . . ." (All Claims)

Instead of explaining why the FWD's treatment of this limitation constituted clear and convincing evidence, Biofrontera's brief simply recycles its arguments to overturn the ID. Sun Pharma has already addressed those arguments in full. CRPet, 31–37. Biofrontera claims the ID

[5] Biofrontera introduces a new argument to attempt to rebut inventor testimony regarding the challenges of achieving uniformity. Biofrontera now claims the inventor was only testifying about the challenges of achieving "regulatory compliance," but not the uniformity required by the claims. RBR, 12. Not only is that new argument waived, but it is also contradicted by the record evidence here: Sun Pharma demonstrated to the FDA that its new, patent-practicing 4170E device achieved at least the same 60% uniformity as the older, 4170D device. CPHB, 200.

ignored its illustrations of how the combination meets this element, RBR, 16–18, but the ID reviewed Biofrontera's illustrations and found them conclusory and at odds with the references. ID, 111–14. Similarly, neither reference teaches higher intensity at the shorter edges of panels, as Lundahl lacked panels and taught higher intensity at its long edges (and only in the center portion), and Larsen had equidistant spacing of lights on all panels. Biofrontera tried to fill that gap by appealing to common sense, but the ID reviewed how Dr. Grove's admissions reflected a failure to persuade by clear and convincing evidence. *Id*. That the PTAB accepted Biofrontera's theory under a lower standard, and without the benefit of hearing Dr. Grove's undermining admissions live, does not amount to evidence sufficient to satisfy the clear-and-convincing standard.

4. "Continuous Illumination" (Claim 16)

Biofrontera tries to say the FWD on this element constitutes clear and convincing evidence, but that attempt comes too late: neither the FWD nor Biofrontera's brief can backfill the gap in Biofrontera's ITC briefing, where Biofrontera failed to argue that the prior art disclosed "five panels connected by hinged structures to allow continuous illumination." CRPet, 27–29.

5. "Individually Configurable" (Claims 16, 21)

The FWD's analysis credited an exhibit, CX-1231, that Biofrontera failed to identify as prior art before the ITC's evidentiary hearing. CRB, 20; CRPet, 47. Biofrontera identified Larsen alone for this limitation. RPHB, 124–26. That procedural failing is not fixed by the PTAB's analysis under its different record. Here, Biofrontera's expert never addressed it or explained how it teaches this limitation, and CX-1231 itself says nothing about controlling PDT illuminators on a panel-by-panel basis—thus, there is no clear and convincing evidence disclosing this claim limitation. *Id*. Similarly, Larsen only discloses device-wide control, where the switch mechanism controlled light sources of a particular ***type***; nothing in Larsen discloses panel-by-panel control. CRPet 46–48.

6. Motivation to Combine

Biofrontera again suggests that because the PTAB found a motivation under a lower standard, that analysis should override the ID's careful findings under the higher burden. The PTAB's findings were reached without rebuttal argument from Sun Pharma and therefore, did not consider the same fulsome record as analyzed by the ALJ under a higher burden of proof.

First, Biofrontera wrongly claims "Sun Pharma did not comment" on whether fluorescent tubes had known performance issues. RBR, 22. Sun Pharma indeed addressed that argument here, explaining the lack of convincing evidence for that motivation, given the continued use of PDT fluorescent devices. *See* CRPet, 59–60; CRB 40.

Second, Biofrontera claims it was legal error for the ID to require the prior art to be "obsolete," RBR, 22, but that mischaracterizes the record. It was ***Biofrontera*** who first argued that a motivation existed because fluorescent tubes were becoming "obsolete." *See* RIB, 2, 31, 79. The ID disagreed on the ***facts***, not the law, in part because such tubes were still used in PDT devices to this day, including by Biofrontera's own expert. ID, 121.

Third, Biofrontera's "increased flexibility" argument was thoroughly litigated and rejected in the ITC, in part because of contradictory, live testimony from Biofrontera's experts. Biofrontera never addresses those failings and points to nothing in the record that would justify adopting the PTAB's finding on a more limited record of evidence submitted and rebuttal arguments presented.

Finally, the ALJ did not require that the prior art be "inoperable"—the ID expressly found that "[t]here is no motivation to increase flexibility ***at the expense of uniformity***." ID, 121. That is a factual finding based on the extensive record, not a legal error.

IV. CONCLUSION

For all these reasons, the FWD does not provide a basis to disturb the ID, given the differences in record, burden applied, and Biofrontera's failure to preserve its arguments here.

Dated: March 19, 2026

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PUBLIC VERSION

EXHIBIT 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioner

V.

SUN PHARMACEUTICAL INDUSTRIES, INC.,

Patent Owner.

Case IPR2024-01312

Patent 11,697,028

Virtual Deposition of ROBERT GROVE, Ph.D.

Thursday, September 11, 2025

9:05 a.m. CST

Job No.: 598792

Pages: 1 - 66

Reported Stenographically by:

Tiffany M. Pietrzyk, CSR RPR CRR

Virtual deposition of ROBERT GROVE, Ph.D., pursuant to notice, before Tiffany M. Pietrzyk, a Certified Shorthand Reporter in the States of Illinois, Texas, and California, Registered Professional Reporter, Certified Realtime Reporter, and a Notary Public in and for the State of Illinois.

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C O N T E N T S

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E X H I B I T S

(Retained by counsel unless otherwise specified.)

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P R O C E E D I N G S

(Witness sworn.)

WHEREUPON:

ROBERT GROVE, Ph.D.,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. HABBAZ:

Q. Good morning, Dr. Grove.

A. Good morning, sir.

Q. We've met before, but my name is Raymond Habbaz of Desmarais LLP. I represent patent owner, Sun Pharma. With me remotely is my colleague Bridget Belcher who is also with Desmarais LLP.

Can you state your full name for the record.

A. Yes. First name Robert, middle name Earle, E-a-r-l-e, last name Grove, G-r-o-v-e.

Q. And where are you today?

A. I am located in Pleasanton, California, P-l-e-a-s-a-n-t-o-n, California, which is about 40 miles east of San Francisco.

Q. Okay. And you were last deposed in

Q. Do you see the paragraph all the way at the bottom of the page that starts, "In the design"?

A. I do.

Q. So page 8 of Exhibit 2013 states, "In the design of the light distribution by LEDs, some other parameters to be thoroughly analyzed are the luminous spatial intensity distribution, the optical power, and the spectral density."

Do you see that?

A. I do.

Q. And you agree that there are multiple factors that go into the design of LED light distribution; true?

A. Yes.

Q. And one of those factors is luminous spatial intensity distribution; right?

A. That's correct.

Q. And luminous spatial intensity is the concentration of light emitted for solid unit of angle; true?

A. Yeah, I think that's a fair definition. It refers to the divergence of the output of the LED.

Q. Okay. And can you explain what you mean by "divergence of the output of the LED"?

A. Yes. The -- among optics technology people, the divergence is a way to describe what actually is defined technically, as was stated here, I think, on the previous page, as a Lambertian output. So the -- for LEDs, as they are manufactured, certainly as they were manufactured prior to 2015, although the output is not a perfect Lambertian, which would mean that the emitted intensity falls off precisely as the cosine of the angle between the normal to the LED and the angle pointed back toward the LED, it very closely approximates that formula.

And so when I talk about the divergence, I'm talking about the spread of light emitted from the LED.

Q. Okay. And when you say, "the spread of light emitted from the LED," that's, as I understand it -- well, let me strike that and ask my question this way.

The intensity of light can be different at each angle from the LED; right?

A. Yes. It is, in fact, different at each angle with the highest intensity directly below, if you will, the LED. And then the intensity decreases as you move one side or the other, looking back toward the LED. And that decrease in intensity is what follows the simple formula, which is that the intensity is equal to the intensity directly below the LED times the cosine of that angle.

Q. Now -- I'm going to -- you can set that aside.

A. Thank you.

Q. I'm sorry. I can't see you on video, but I assume you have it open in front of you, so you can set that aside.

A. Yeah. I do have it open in front of me, yeah.

Q. Okay. It's your opinion that you can achieve the 60 percent uniformity required by the '028 patent using Lundahl's basing of light sources as applied to LEDs; true?

A. Yes, I would say that the -- it's my professional opinion that a POSA would be able to

know when you're there.

A. I have it.

Q. And can you turn to paragraph 12, which I have it on page 5.

A. I have it.

Q. And there's a figure on the next page, page 6.

Do you see that?

A. I do.

Q. And here, you're drawing an illustration of LEDs with a wider divergence angle than Dr. Jokerst did in her illustration; right?

A. Yes.

Q. And how did you come up with the angles represented in the drawing in paragraph 12?

A. The -- the gray angles are what Dr. Jokerst drew as the emitted light from LEDs. The pinkish color or purplish color is the correct drawing of -- or the correct representation of a Lambertian source.

Q. Okay. And how did you calculate the exact angles you used in your illustration?

A. The LEDs, which produce near Lambertian or almost perfect Lambertian output, as stated by Dr. Jokerst, are drawn showing a spread or a divergence angle where each ray, for example, looking at the LED represented by the black box next to that right arrow -- red arrow, the lines emanating from that LED to the left and the right are shown at an angle which represents an intensity that is exactly half of the intensity or the radiance, which would be measured directly underneath the LED.

So a Lambertian source is always shown with a divergence angle represented like this, if it's done exactly to the definition of Lambertian emitter.

Q. Okay. And if you go back to the prior page, you have an equation in that last sentence there.

Do you see that?

A. Yes, I do.

Q. Okay. And what is that equation?

A. Excuse me. It is the equation that I just referenced verbally, which is that the rays shown

represent an intensity along that ray, which is exactly half of the intensity that would be measured directly below the LED.

Q. Okay. And so the lightly black shaded line in your drawing at the edges of the pink distribution, those are the rays you're referring to which has an intensity that's half of the intensity directly under the LED; is that right?

A. Those rays are drawn at an angle, which is 60 degrees from the vertical, if you will, or 60 degrees from directly below the LED, and the cosine of 60 degrees is one-half, so your statement is correct.

Q. Okay. And in you're equation, I represents the intensity of the light; is that right?

A. That's right.

Q. Is that I0 or IO in the right-hand side of the equation?

A. Yeah, this formula states mathematically that the intensity, at a particular viewing angle, which is represented by the capital I, is equal to -- well, in case of the ray that I showed, it is

equal to the intensity directly below the LED divided by 2. And that is the appropriate formula for an angle of 60 degrees.

So the general formula is I equals I0 cosine theta, where theta is the angle between the ray in this drawing vertical -- vertically below the LED and out to some angle to one side or the other. When that angle --

Q. Okay.

A. -- reaches 60 degrees, it's -- the cosine of 60 degrees is one-half, and you get the formula I equals I0 divided by 2.

Q. Thank you. And I appreciate the explanation. My question is a lot simpler.

I0 represents the intensity directly underneath the LED; true?

A. Yes, that's -- correct, yes.

Q. Thank you.

If you can turn to paragraph 15, which starts on page 6. I'm interested in the drawing that's on page 8.

Let me know when you're there.

A. I have it.

Q. Okay. And here, you are illustrating the divergence angles, which are in red, that overlap at the treatment surface on the bottom of the illustration; right?

A. Yes.

Q. And earlier in the paragraph 15, you state that, "a POSITA would simply ensure that the divergence angles of the adjacent LEDs overlap at the desired treatment distance to ensure no 'gaps' between the light emission of the individual LEDs"; right?

A. I'm sorry. You were reading from paragraph 15?

Q. Yeah, just the text right above.

A. Yeah. One moment here.

Yeah, "a POSA would simply ensure that the divergence angles of the adjacent LEDs overlap at the desired treatment distance to ensure no 'gaps' between the light emission of the individual LEDs."

Correct.

Q. And the divergence angles you're drawing in

paragraph 15, those are, again, the 60-degree angles that we were discussing earlier; right?

A. Yes.

Q. And the intensity at those divergence angles will be half of the intensity directly underneath the LED; right?

A. From that particular -- from an individual LED. Obviously, the intensity on this treatment surface is the sum of the radiance produced by a particular LED and all of its neighbors.

Q. Right. And you haven't calculated the intensity of light received at the treatment surface in the example you're providing in figure -- in paragraph 15; true?

A. I have not calculated it mathematically, but from the drawing it's easy to estimate a degree of uniformity.

Q. Okay. You have not provided an estimate of the degree of uniformity for the illustrations you've provided in your declaration; right?

A. No, I have not.

Q. Okay. And again, looking at the text just

above your drawing, you stated that a POSA would simply ensure that the divergence angles of the adjacent LEDs overlap at the desired treatment distance to ensure no "gaps" between the emission -- the light emission of the individual LEDs; right?

A. Correct.

Q. That's what you state here?

In your opinion, it's simple to achieve gap-free illumination at the treatment surface using LEDs; right?

A. If the treatment surface is located at a distance that's, for example, not immediately adjacent to the LEDs, that statement is true.

Q. At a treatment distance of about four inches, your statement is true; right?

A. It's true at distances of -- if it's true at two inches, then it's true, very likely, at four inches because you get simply further overlap from adjacent LEDs.

Q. Okay. So let me say it this way. In your opinion, it's simple to achieve gap-free illumination at the treatment surface using LEDs at

distances of around two inches to four inches; right?

A. Yes, that's true.

Q. And your drawing here in paragraph 15 depicts a flat treatment surface; right?

A. I attempted to replicate what Dr. Jokerst drew in her drawing, yes.

Q. Right, but the drawing that you're providing your opinions on in your declaration, that drawing shows a flat treatment surface; right?

A. Yes.

Q. And in the PDT context, the treatment surface such as a face is often not a flat surface; right?

A. True.

Q. It's your opinion that the amount of experimentation and testing necessary to achieve a specific design goal increases when the treatment surface is not flat; right?

A. In general, that's true, yes.

MR. HABBAZ: I think we can take a break now if that works for you, Dr. Grove.

CERTIFICATE OF COURT REPORTER - NOTARY PUBLIC

I, TIFFANY M. PIETRZYK, Certified Shorthand Reporter No. 084-004371, CSR, RPR, CRR, and a Notary Public within and for the State of Illinois, do hereby certify:

That ROBERT GROVE, Ph.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition and that such deposition was taken before me and is a true record of the testimony given by such witness.

I further certify that the adverse party, BIOFRONTERA, was represented by counsel at the deposition.

I further certify that the deposition of ROBERT GROVE, Ph.D. occurred virtually, via Zoom videoconference, on Thursday September 11, 2025, commencing at 9:05 a.m. CST to 10:50 a.m. CST.

I further certify that I am not related to any of the parties to this action by blood or marriage, I am not employed by or an attorney to any of the parties to this action, and that I am in no way interested, financially or otherwise, in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 12th day of September, 2025.

My commission expires: February 28th, 2028

Tiffany M. Petrenko

NOTARY PUBLIC IN AND FOR THE
STATE OF ILLINOIS

PUBLIC VERSION

EXHIBIT 2

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Paper 20
Date: November 3, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDER SECRETARY OF COMMERCE
FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE

REVVO TECHNOLOGIES, INC.,
Petitioner,

v.

CEREBRUM SENSOR TECHNOLOGIES, INC.,
Patent Owner.

IPR2025-00632
Patent 11,835,421 B2

Before JOHN A. SQUIRES, *Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

ORDER
Vacating the Decision Granting Institution, and
Remanding to the Board for Further Proceedings
after *Sua Sponte* Director Review

On September 15, 2025, the Board issued a Decision granting institution of *inter partes* review in the above-referenced proceeding. Paper 13 ("Decision"). On October 20, 2025, *sua sponte* Director Review of the Board's Decision granting institution was initiated to address the claim construction issues implicated in this case. Paper 19. For the reasons provided below, the Decision granting institution is vacated, and the case is remanded for further proceedings consistent with this decision.

In this case, Revvo Technologies, Inc. ("Petitioner") did not propose its own constructions for claim terms in the Petition, but instead accepted Cerebrum Sensor Technologies, Inc.'s ("Patent Owner") proposed constructions from the parties' district court litigation. Paper 1 ("Pet.") at 9–10 (citing Ex. 1017, Exhibit A at 5–7, 10, Exhibit B at 10–15). Although Petitioner proposed different constructions for the claim terms in the district court litigation, Petitioner did not explain why it was taking a different position here. *Id.* Petitioner did argue, however, that the Petition complied with 37 C.F.R. § 42.104(b)(3)[1] because Petitioner had adopted Patent Owner's proposed constructions from the district court litigation. *See* Paper 10 at 17, n.5 (citing, *e.g.*, *Western Digital Corp. v. Spex Techs., Inc.*, IPR2018-00084, Paper 14 at 11 (PTAB Apr. 25, 2018) (determining that a petition complies with Rule 104(b)(3) by identifying the claim constructions it proposes as the basis for requesting an *inter partes* review)).

Patent Owner argued that the Board should deny the Petition because Petitioner's different positions before the Board and the district court amounted to gamesmanship and the Petition, therefore, failed to comply

[1] Section 104(b)(3) requires a petition to identify "[h]ow the challenged claim is to be construed."

with Rule 42.104(b)(3). Paper 9 ("Prelim. Resp.") at 14–15 (citing *10X Genomics, Inc. v. President & Fellows of Harvard College*, IPR2023-01299, Paper 15 at 13 (PTAB Mar. 7, 2024); *Orthopediatrics Corp. v. K2M, Inc.*, IPR2018-01546, Paper 10 at 11 (PTAB Feb, 14, 2019) (both denying institution for failing to comply with Rule 42.104(b)(3) where a petitioner, without adequate explanation, proposed different claim constructions before the Board and in district court).

The Board acknowledged Patent Owner's gamesmanship accusation but was not persuaded that any gamesmanship occurred because Patent Owner did not dispute any of the claim constructions provided in the Petition. Decision 6. The Board determined that Petitioner complied with Rule 42.104(b)(3) because the Petition identified "how the claim language is to be construed," which is all the rule requires. *Id.* at 7. The Board explained that Patent Owner's cited cases—*10X Genomics* and *Orthopediatrics*—were limited to a petitioner's alleged inconsistent arguments about whether a claim term is subject to interpretation as a means-plus-function element under 35 U.S.C. § 112(f), which this case did not implicate. *Id.* at 7–8 & n.7. Finding no dispute as to Petitioner's proposed constructions, the Board proceeded to apply them in deciding whether to institute trial. *Id.* at 8.

The Board erred by limiting its consideration of a petitioner's differing claim construction positions to instances that implicate means-plus-function interpretation under Section 112(f). Although the Board's trial rules "do not necessarily prohibit petitioners from taking inconsistent claim construction positions before the Board and a district court," when a petitioner takes alternative positions before the Board and a district court,

that petitioner should, at a minimum, explain why alternative positions are warranted. *Cambridge Mobile Telematics, Inc. v. Sfara, Inc.*, IPR2024-00952, Paper 12 at 8–9 (PTAB Dec. 13, 2024) (informative); *accord Sun Pharm. Indus. Inc. v. Nivagen Pharm., Inc.*, IPR2025-00893, Paper 18 at 3 (Director Sept. 19, 2025) ("Although a party is not necessarily precluded from arguing different claim construction positions before a district court and the Board, a party should explain why different positions are warranted.").

The Board's claim construction rules are designed to ensure that the Board correctly construes claim terms and to minimize inconsistency in claim construction between forums. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,349 (Oct. 11, 2018). To that end, the rules discourage petitioners from seeking broader constructions at the Board to support a patentability challenge while seeking narrower constructions in litigation to avoid infringement liability. *See id.* at 51,350. As the Office explained when it changed the claim construction standard used in *inter partes* reviews and post-grant reviews to match the standard used in litigation, "[petitioners] will have less flexibility to advance inconsistent arguments about claim scope, and will instead be required to choose a single claim construction that best captures the true meaning of the patent claim." *Id.* That is not the case here, however, as petitioners continue to propose different claim constructions in the two forums.

Allowing petitioners to continue this practice does not further the Office's goal of "providing greater predictability and certainty in the patent system." 83 Fed. Reg. at 51,342–43. This is true even where, as here, the

claim terms do not implicate Section 112(f). Thus, although a petitioner is not necessarily precluded from arguing different claim construction positions before a district court and the Board, the petitioner should explain sufficiently why the different positions are warranted, even in instances that do not implicate Section 112(f). *See Sun Pharm.*, IPR2025-00893, Paper 18 at 3. "For example, if a party advances a narrow construction in the district court and the district court declines to adopt the narrow construction, the party would have sufficient reason for advancing the broader, court-adopted construction in a proceeding before the Board." *Id.* Simply noting that the petitioner is adopting a patent owner's claim construction proposals from district court, however, is not a sufficient reason for advancing different positions in the two forums.

Here, Petitioner's statement that it "accepts Patent Owner's proposed constructions" from the district court litigation, Pet. 9, does not explain sufficiently why the different positions were warranted, and the Board erred when it determined that Petitioner complied with Rule 42.104(b)(3) by proposing Patent Owner's district court constructions. The Board also erred when it found that a petitioner is only required to explain its different positions when Section 112(f) is implicated. Ordinarily, that would mean a denial of institution. Because this decision clarifies how a petitioner should approach different claim construction positions and how the Office will assess those positions, the appropriate course of action is to vacate the Board's decision and remand the case to the Board. The Board may authorize additional briefing, as necessary, to determine whether Petitioner has provided a sufficient reason why different claim construction positions are warranted.

Absent good cause, the Board shall issue a decision on remand within 30 days of this decision, or within 30 days of receiving additional briefing if ordered.

Accordingly, based on the foregoing, it is

ORDERED that the Board's Decision granting institution (Paper 13) is vacated; and

FURTHER ORDERED that the case is remanded to the Board for further proceedings consistent with this decision.

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CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2026, copies of the foregoing were filed and served upon the following as indicated:

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