

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

In the Matter of

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

Investigation No. 337-TA-1411

**RESPONDENTS BIOFRONTERA INC., BIOFRONTERA PHARMA GMBH,
BIOFRONTERA BIOSCIENCE GMBH, AND BIOFRONTERA AG'S
PETITION FOR REVIEW OF THE INITIAL DETERMINATION
FINDING VIOLATION OF SECTION 337**

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Table of Abbreviations

Abbreviation	Meaning
CX-	Complainant's Exhibit
CX-xxxxC	Confidential Complainant's Exhibit
RX-	Respondents' Exhibit
RX-xxxxC	Confidential Respondents' Exhibit
JX-	Joint Exhibit
JX-xxxxC	Confidential Joint Exhibit
'512 Patent	U.S. Patent No. 11,446,512
'028 Patent	U.S. Patent No. 11,697,028
4170D	BLU-U® 4170 or BLU-U® 4170D
4170E	BLU-U® 4170E
Asserted Method Claims	Claims 8, 17, and 18 of the '512 Patent
Asserted Patents	The '512 Patent and the '028 Patent
Complainant <i>or</i> Sun	Sun Pharmaceutical Industries, Inc.
Respondents <i>or</i> Biofrontera	Biofrontera Inc., Biofrontera Pharma GMBH, Biofrontera Bioscience GMBH, & Biofrontera AG
ITC	International Trade Commission
Comm'n Op	Commission Opinion
USPTAB or PTAB	United States Patent Trial and Appeal Board
USPTO <i>or</i> PTO	United States Patent and Trademark Office
IPR	<i>Inter Partes</i> Review
POSA	Person of Ordinary Skill in the Art at the time of the invention
DI Product	Domestic Industry Product
CMIB	Complainant's Initial Markman Brief
CMRB	Complainant's Reply Markman Brief
RMIB	Respondents' Initial Markman Brief
RMRB	Respondents' Reply Markman Brief
Order No. 18	Markman Order
CPHB	Complainant's Prehearing Brief
RPHB	Respondents' Prehearing Brief
CIB	Complainant's Initial Posthearing Brief
RIB	Respondents' Initial Posthearing Brief
CRB	Complainant's Responsive Posthearing Brief

PUBLIC VERSION

RRB	Respondents' Responsive Posthearing Brief
ID	Initial Determination
WS	Witness Statement
RWS	Rebuttal Witness Statement
PD	Photodynamic diagnosis
PDT	Photodynamic therapy
ALA	5-aminolevulinic acid
Tr.	Hearing Transcript
CIUCL	Complainant's Identification of Undisputed Claim Limitations Pursuant to Ground Rule 14.1
Prior Art References	
Lundahl	U.S. Patent No. 6,223,071 to Lundahl, et al.
Larsen	U.S. Patent Publication No. 2005/0075703 to Larsen
Kennedy	U.S. Patent No. 5,079,262 to Kennedy, et al.
Hente	U.S. Patent Publication No. 2010/0118522 to Hente
Perutz	U.S. Patent No. 4,823,858 to Perutz

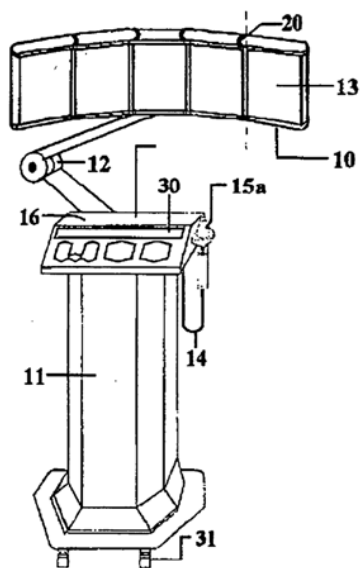
I. INTRODUCTION

Biofrontera respectfully requests that the Commission review and reverse portions of the ALJ's claim construction order, Order No. 18, finding certain claims not indefinite, and the Initial Determination ("ID"), which erroneously preserves the validity of the closely related U.S. Patent Nos. 11,446,512 ("512 Patent") and 11,697,028 ("028 Patent," collectively, the "Asserted Patents") and finds infringement of the Asserted Claims. Through compounding the misapplication of the law with a series of clearly erroneous findings of material facts, the Asserted Patents were found definite, not obvious, supported by the written description, and infringed. Not only do the ID and Order No. 18 fail to properly evaluate the facts and law presented, but on multiple occasions the ID finds certain issues waived by Biofrontera on the basis that such issues were not raised in briefing, where Biofrontera's briefs clearly and repeatedly raised such issues. Given the numerous errors throughout Order No. 18 and the ID, the Commission should review and reverse these findings.

Order No. 18 ignores well-settled Federal Circuit claim construction principles to preserve the validity of the closely related Asserted Patents. First, Order No. 18's construction of "a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges" merely replaces one uncertain term of degree ("proximate"/"not proximate") with another ("close"/"not close"). But both the plain claim language and the construction provide no objective boundaries to define the areas that need to be compared to determine whether one area emits a higher intensity of light, which improperly leaves such a determination to "the unpredictable vagaries of any one person's opinion," rendering the term indefinite. *Dow Chem. Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 635 (Fed. Cir. 2015). Second, for the claim term "nested hinges," Order No. 18 impermissibly violates basic and well-

settled canons of claim construction by rendering claim language redundant and reading out the term “nested” altogether.

Similar to Order No. 18, the ID demonstrates a systematic pattern of conspicuous errors to support its findings of non-obviousness, written description, and infringement. For instance, in its discussion of obviousness, the ID concludes that Biofrontera waived an argument that one of its key prior art references, Larsen, disclosed an illuminator with four wheels because the argument was not addressed in Biofrontera’s post-hearing briefing. ID at 116. But, the ID is simply wrong—Biofrontera addressed this point in both post-hearing briefs (RIB at 65-66; RRB at 26-27), explaining not only that four wheels were inherent in Figure 1 of the Larsen prior art reference given its perspective (pictured below), but that using four wheels would be obvious to a POSA to provide stability of movement.



In that vein, the ID further concludes that the five-panel illuminator in “Larsen does not disclose ‘a center panel configured to face the treatment surface’ . . . and Biofrontera makes no assertion to the contrary.” ID at 116. Yet again, Biofrontera plainly asserted this in its post-hearing briefs. RIB at 52-54; RRB at 20-21. As asserted in those briefs, even if it were *not* axiomatic that a series of

five objects is going to have one object in the center, and even if the figure above did not demonstrate that in black-and-white, Sun Pharma's expert admitted as much. Tr. (Jokerst), 738:13-739:2

These glaring errors in the ID relating to two of the claim limitations are emblematic of the errors relating to obviousness that infect the ID. Clear and convincing evidence of obviousness was presented during the evidentiary hearing and discussed in the briefing, yet the ID consistently either applies the wrong legal standard or makes clear errors of material fact that should be reviewed by the Commission. In one particularly striking example of factual error, the ID finds that "Biofrontera has not shown by clear and convincing evidence that the combination of Lundahl, Larsen, Hente *and Perutz* render[]" the recess and recess location limitations obvious. ID at 118 (emphasis added). However, Sun Pharma *did not dispute* that Perutz discloses the recess and recess location limitations. CIUCL at 3-4. In other words, the ID finds against Biofrontera *on an undisputed limitation*. In other instances, the ID demonstrates legally erroneous inconsistencies, such as discounting references to the BLU-U® 4170D as illustrative of the Lundahl reference in support of motivation to combine, while also crediting such references to refute a motivation to combine. ID at 118-119. Similarly, in finding that the RhodoLED® XL infringes, the ID is clear that "[t]he claims require only that the 'panels' be 'connected by' hinges; they do not specify where or how the hinges are connected to the panels." ID at 19. However, for its validity analysis, the ID finds that Larsen's disclosure of panels "flexibly *connected to each other through hinges...connecting one edge with the other*" (RX-0099, [0027] (emphasis added)) was not enough, stating that "even if one reads Larsen as having hinges between the panels, the disclosure is insufficient ..." ID at 94.

Indeed, the ALJ's claim construction order and ID are a study in contrasts of how the POSA standard for claim construction and invalidity are applied. On the one hand, when judging Section 112's standards for indefiniteness and written description, the POSA is endowed with the skill and judgment to discern uncertain boundaries of "proximate" or assess multiple variables to determine how to conduct photodynamic diagnosis. On the other hand, for assessing obviousness, the POSA cannot identify the center panel among five panels or determine that a medical device would need four wheels on its base not to topple over.

In that vein, the ID errs in finding the written description requirement was met. All asserted claims contain a preamble, properly construed as limiting, for "[a] [system for / method of] photodynamically diagnosing or treating a patient." The disclosures in the specification, however, are focused on photodynamic *therapy* while providing virtually no disclosure as to how to use the device to photodynamically *diagnose* a patient. Lacking support in the specification, in some instances, the ID adopts Sun Pharma's legally flawed position that its expert testimony can be substituted for disclosure on the "main difference" between PDT and PD when the specification provides no teaching or suggestion of this difference. Likewise, the ID uses third-party documents to fill in the lack of written description, including a later-issued Biofrontera patent and testimony from *Biofrontera's inventor* on that patent, to attempt to establish that Sun Pharma's inventors possessed the claimed invention. The Federal Circuit's case law requires an inquiry into the four corners of the specification to determine whether Sun Pharma's inventors possessed the claimed invention, not whether Biofrontera's inventor or Sun Pharma's expert possessed the invention. Contrary to Federal Circuit precedent, the ID also uses expert testimony to cherry pick examples from broad swaths of relevant variables, including wavelength of light, illumination time, fluence, and incubation time. This, too, is contrary to Federal Circuit precedent requiring, at a minimum,

“blaze marks” to allow a POSA to find a path between the specification and the claimed invention. The ID pieces together expert testimony and third-party documents not just on one variable, but on multiple variables, to manufacture a working example of PD. This is legal error.

Finally, the ID clearly errs, both legally and in its interpretation of certain material facts, in finding that Biofrontera infringes claims 8, 17, and 18 of the ’512 Patent (the “Asserted Method Claims”) and claims 16, 17, 19, and 21 of the ’028 Patent. ID at 27-33, 36-43, 67-71, 76-77. With respect to the Asserted Method Claims, the evidence and testimony in this Investigation was clear: Biofrontera encourages the use of three adjacent panels of the RhodoLED[®] XL to treat patients, which does not amount to inducing healthcare providers to infringe the Asserted Method Claims’ five-panel treatment requirement. At bottom, the ID relies on the mere fact that the RhodoLED[®] XL has five panels as evidence of Biofrontera’s intent to induce infringement, without properly assessing the evidence and testimony in the context of an *inducement* analysis, which is clear legal error and violates long-standing Federal Circuit precedent. *See, e.g.*, ID at 29-30, 38-39; *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009) (“[T]he mere knowledge of possible infringement will not suffice.”).

Further, the ID commits clear legal error by finding that Biofrontera infringes the “individually configurable” claim limitation of claims 16, 17, 19, and 21 of the ’028 Patent, while at the same time finding that Larsen does not disclose the “individually configurable” limitation even though it discloses a five-panel device where individual panels can be “switched ON or OFF.” ID at 69-71, 114-115; RX-0099, cl. 5. That is clear legal error: either Larsen discloses this limitation and renders it obvious, which it does, or Biofrontera does not infringe. *Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381 (Fed. Cir. 2021) (“We have repeatedly rejected

efforts to twist claims, like a nose of wax, in one way to avoid [invalidity] and another to find infringement”) (citation modified).

Respondents therefore respectfully request that the Commission review and reverse the ID and Order No. 18.

II. BACKGROUND

Sun Pharma and Biofrontera are currently the only two companies with FDA approved photodynamic therapy devices used in combination with a pharmaceutical compound (aminolevulinic acid, or ALA) to treat actinic keratoses. Sun Pharma is a subsidiary of a worldwide conglomerate, Sun Pharmaceutical Industries Ltd., based in India and operating in over 100 countries, sells over 2,000 products, and had over \$5.5 billion in annual sales during its last fiscal year.¹ Sun Pharma entered the PDT market in 2012 after purchasing DUSA Pharmaceuticals. Sun Pharma and its parent have spent years pursuing litigations against Biofrontera.

Biofrontera, conversely, is a small, innovative dermatology-focused company with only four product offerings: two topical pharmaceuticals, and two PDT devices. Their second device, the RhodoLED® XL, went on sale in the United States in June 2024, and days later, Sun Pharma filed the Complaint in this case, naming the Biofrontera entities as Respondents. The Commission instituted the Investigation on July 26, 2024. 89 Fed. Reg. 62790 (Aug. 1, 2024). The Complaint alleges violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. §1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same that infringe certain claims of the

¹ See Sun Pharmaceutical Industries Ltd., *Sun Pharma reports Q4 and full year results for FY24*, SUN PHARMA, (May 22, 2024) <https://sunpharma.com/wp-content/uploads/2024/05/Press-Release-Sun-Pharma-Q4FY24-Financial-Result.pdf>.

Asserted Patents, and the existence of a domestic industry and/or a domestic industry in the process of being established in its forthcoming BLU-U[®] 4170E device.

On May 2, 2025, Sun Pharma filed an opposed motion for summary determination on the satisfaction of the economic prong of the domestic industry requirement. ID at 1. On June 25, 2025, Order No. 23 (“MSD ID”), an initial determination was issued granting Sun Pharma’s motion. The evidentiary hearing was held from June 30 through July 3, 2025, and the ALJ declined to hear evidence on the economic prong in light of the MSD ID. On July 3, 2025, Biofrontera filed a petition to review the MSD ID. On July 25, 2025, the Commission determined to review the MSD ID and Commission review is pending. On September 30, 2025, ALJ Moore issued an ID finding a violation, that Biofrontera infringes the Asserted Patents, and that the Asserted Patents are not invalid.

III. STANDARD OF REVIEW

A petition for review must demonstrate that: (i) “a finding or conclusion of material fact is clearly erroneous”; (ii) “a legal conclusion is erroneous, without governing precedent, rule or law, or constitutes an abuse of discretion”; or (iii) “the determination is one affecting Commission policy.” 19 C.F.R. § 210.43(b)(1). The Commission will grant a petition and order review “if it appears that an error or abuse of the type described in paragraph (b)(1) . . . is present or if the petition raises a policy matter connected with the initial determination, which the Commission thinks it necessary or appropriate to address.” *Id.* § 210.43(d)(2). If the Commission determines to review the initial determination, it “may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part.” *Id.* § 210.45(c).

Under 19 C.F.R. § 210.42(d), “[t]he initial determination shall include: an opinion stating findings (with specific page references to principal supporting items of evidence in the record) and conclusions *and the reasons or bases therefor* necessary for the disposition of *all* material issues

of fact, law, or discretion presented in the record . . .”) (emphasis added). This requires more than a perfunctory treatment of the issues presented by the parties. Indeed, the Federal Circuit has routinely found conclusory agency decisions to be insufficient under the APA. *See, e.g., CQV Co. v. Merck Pat. GmbH*, 130 F.4th 1344, 1349 (Fed. Cir. 2025) (“[T]he Board is obligated to ‘articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made’ The Board must ‘consider the entirety of the record.’”); *Palo Alto Networks, Inc. v. Centripetal Networks, LLC*, 122 F.4th 1378, 1385 (Fed. Cir. 2024) (vacating and remanding PTAB’s decision finding no motivation to combine, and holding that “the Board erred by not addressing the evidence and the argument for the motivation to combine and by failing to provide an adequate explanation for its finding”); *Grit Energy Sols., LLC v. Oren Techs., LLC*, 957 F.3d 1309, 1324 (Fed. Cir. 2020) (vacating and remanding the Board’s non-obviousness decision for various reasons, including because “the Board failed to adequately explain its reasoning” on certain issues).

IV. ORDER NO. 18 AND THE INITIAL DETERMINATION ERR IN FINDING THE ASSERTED PATENTS NOT INVALID

A. Order No. 18 Errs in Finding the Asserted Patents Definite

1. The Claim Term “A Higher Intensity of Light Is Emitted Proximate the Second Edges Compared to the Intensity of Light Emitted Not Proximate the Second Edges” is Indefinite

Order No. 18 makes errors of both law and fact in finding that the specification of the Asserted Patents provides objective criteria for a POSA to determine the meaning of “proximate” and “not proximate” with reasonable certainty. In doing so, Order No. 18 simply replaces one term of degree with no definitional support in the specification (“proximate”) with another, equally indefinite term of degree that only appears once in the specification and not even in relation to the

second edges (“close”).² Both the plain claim language (“proximate”/“not proximate”) and the construction (“close”/“not close”) provide no objective boundaries to define the areas that need to be compared to determine whether one area emits a higher intensity of light. Instead, such a determination is left to “the unpredictable vagaries of any one person’s opinion,” rendering the term indefinite. *Dow Chem.*, 803 F.3d at 635. This clear error should be reviewed by the Commission.

The term “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” appears in every asserted independent claim, *i.e.*, claims 1, 8, and 20 of the ’512 Patent and claims 1, 5, 16, and 20-21 of the ’028 Patent. The parties disagreed on the construction of this term, with Biofrontera asserting that the term is indefinite and Sun Pharma arguing that “proximate” should be construed as “close to.” Order No. 18 at 14. Order No. 18 finds that the term is not indefinite and construed it to mean “a higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges.” *Id.* at 23.

Although Order No. 18 correctly notes that terms of degree like “proximate” are not inherently indefinite (Order No. 18 at 15), the opposite is not true either. Terms of degree *can* be definite, **but only if** the specification “provide[s] some *objective* criteria for a POSITA to determine the scope of the invention with reasonable certainty.” *Sci. Applications Int’l Corp. v. United States*, 154 Fed. Cl. 594, 635 (2021) (emphasis added). “[A] patent does not satisfy the definiteness requirement of § 112 merely because ‘a court can ascribe some meaning to a patent’s claims’ The claims, when read in light of the specification and the prosecution history, must provide

² The specification only mentions the word “close” once—in relation to what is “close” to the hinges; not what is “close” to the second/shorter edges. JX-0001, 7:8-11.

objective boundaries for those of skill in the art.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (emphasis added). Here, the particular claim language requires a higher level of precision because it requires a POSA to first identify (1) the geographic³ regions proximate to the second edges, and (2) the geographic regions not proximate to the second edges. Only after this initial determination is made can the intensity of light emitted from both regions be compared. Yet, the intrinsic record provides no objective directives to a POSA as to how to identify “proximate” and “not proximate” edges to make the recited comparison.

Although Order No. 18 expresses concern about a lack of case law stating that “a higher level of precision is required because of the ‘compared to’ language” (Order No. 18 at 17-18), the Federal Circuit explained in *Liberty Ammunition, Inc., v. United States*, 835 F.3d 1388, 1395 (Fed. Cir. 2016), that terms of degree that “necessarily call[] for a **comparison** against some baseline . . . are problematic if their baseline is unclear to those of ordinary skill in the art.” (emphasis added). The term of degree at issue in *Liberty* was a “reduced area of contact” of a projectile with the barrel of a rifle. *Id.* The Federal Circuit found that the “specification . . . saves the term ‘reduced area of contact’ from indefiniteness” only because it disclosed a single, specific model of projectile on the market (*i.e.*, the M855 round) as the baseline for comparison. *Id.* Accordingly, the Federal Circuit was able to construe the term in relation to that clear, singular baseline. *Id.* at 1396.

In contrast, the Northern District of California later applied the rationale of *Liberty* to a different set of facts and found claims indefinite where “the specification fails to clearly set out the baseline against which [the term of degree] should be compared.” *Alpha v. Force Mos Tech. Co., Ltd.*, 720 F. Supp. 3d 749, 768 (N.D. Cal. 2024). The term of degree in *Alpha* was “increased

³ During the evidentiary hearing, “geography” and “geometry” (and their derivatives) were used interchangeably in reference to the physical space on a panel. *See, e.g.*, Tr. (Jokerst), 217:1-4; 218:5-7; 219:1-9; 228:5-15.

area.” *Id.* The court rejected plaintiff’s argument that “the baseline comparison here is equally definite” to that of *Liberty*, where “the specification referred to a single specific example of a conventional projectile,” which was an actual product on the market. *Id.* Instead, the specification in *Alpha* provided only “a schematic representation of a prior art . . . semiconductor package” that would not be suitable as a baseline across the entire claim scope. *Id.* The court explained that:

While the specification here provides a clear example of what it might mean for the source and gate lead bonding area to be of “increased area” as compared to one particular instance of a conventional package, this single sample schematic is not enough There is not enough in either the claims or specification for a skilled artisan to be . . . reasonably certain of the scope of the claims. Because the specification fails to clearly set out the baseline against which “increased area” should be compared, the first claims of both the ’361 and ’265 patents are indefinite.

Id.

In the present Investigation, defining the proximate and not proximate regions is especially important because the claimed devices can have varying numbers, densities, and configurations of LEDs arranged on a panel. The Asserted Patents depict one such arrangement in Figure 2B:

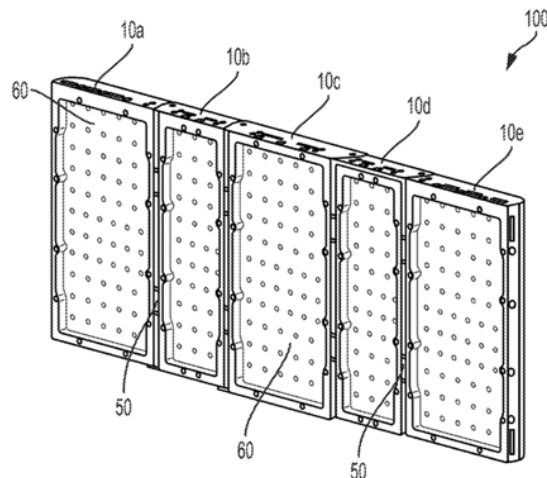


FIG. 2B

The Asserted Patents note that the intensity of light in each area of a given panel can be controlled by adjusting the current to a particular addressable string of LEDs or by varying the amount of individual LEDs within an area (*i.e.*, varying the density of LEDs in an area). JX-0001, 6:22-7:4.

Order No. 18 identifies FIG. 5 as providing the “objective boundaries” required to understand the meaning of “proximate” and “not proximate” with reasonable certainty. Order No. 18 at 16.

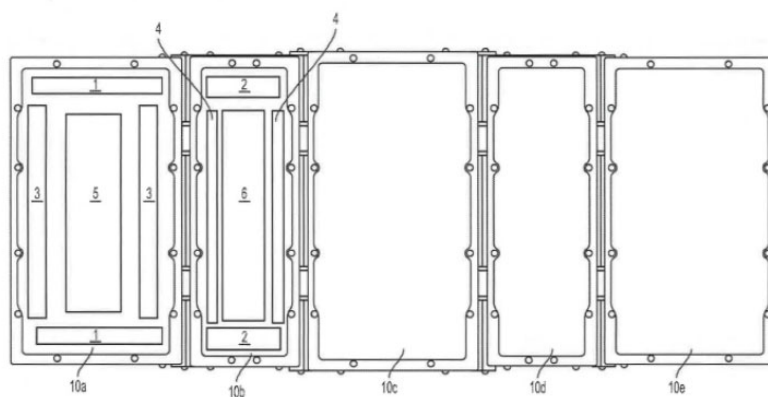


FIG. 5

Specifically, the Order agrees with Sun Pharma that the areas labeled 1 and 2 represent “proximate” areas and thus, based on FIG. 5, “one of skill can divide the panels into areas” close to the shorter edges and not close to the shorter edges. Order No. 18 at 16. But, the conclusion that areas 1 and 2 in FIG. 5 somehow create “objective boundaries” is legally erroneous. “[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.” *Hockerson-Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d 951, 956 (Fed. Cir. 2000). The specification provides no measurements, sizes, or dimensions for FIG. 5, nor does it state that the drawing is to scale. JX-0001, 6:23-38. Accordingly, even if areas 1 and 2 illustrate the “proximate areas,” FIG. 5 provides absolutely no information to inform a POSA about the size of those areas

or how to delineate between the “proximate” and “not proximate” areas. Accordingly, a POSA cannot reasonably ascertain which rows of lights in FIG. 2B would be designated areas 1 and 2 (proximate) and which rows of lights are not designated areas 1 and 2 (not proximate). In sum, FIG. 5 is no more than the “single sample schematic” that was determined to be inadequate in *Alpha*, and similarly fails to provide reasonable certainty as to the meaning of the claim term. 720 F. Supp. 3d at 768.

Absent any quantitative information as to the bounds of “proximate,” Order No. 18 first concludes that, “when the claims use the term ‘proximate,’ they do so with respect to a reference point.” Order No. 18 at 15. “Specifically, the claims state that the intensity of light ‘proximate the second edges’ is compared to the intensity of light ‘not proximate the second edges.’” *Id.* But, this simply begs the question as to the boundary between the “proximate” and “not proximate” regions, and it is a far cry from the single, fixed baseline which lent the claim term definiteness in *Liberty*.⁴

While Order No. 18 concludes that “the Commission has previously rejected a similar indefiniteness argument based on geographic location” in *Certain Electrical Connectors, Components Thereof, & Prods. Containing the Same* (“Electrical Connectors”), this single decision was cabined to the intrinsic evidence of that case—it did not provide carte blanche for all terms of degree that require comparison of geographic areas, as Order No. 18 seems to conclude.⁵ Inv. No. 337-TA-1043, Reversal of Initial Determination & Remand of Investigation (Mar. 26,

⁴ While *Liberty* and *Alpha* refer to baselines provided in the specification, and the baseline here is recited in the claims, this is not a relevant distinction. The operative question is whether the baseline (wherever it is) satisfies “the exacting ‘objective boundaries’ standard from *Interval*.” *Liberty*, 835 F.3d at 1397 (citing *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014)).

⁵ While the Commission’s decision was affirmed by the Federal Circuit, this was a non-precedential Rule 36 affirmance that did not articulate any rationale or more broadly applicable rule. *J.S.T. Corp. v. ITC*, No. 2019-2308, ECF No. 74 (Fed. Cir. 2020) (non-precedential).

2018). The indefiniteness inquiry is dependent upon the intrinsic evidence at issue in each case, including the claims, the specification, and the prosecution history. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 906-907 (2014).

Indeed, the Federal Circuit has found similar claims (*i.e.*, requiring comparison of geographical areas) indefinite where the intrinsic record fails to provide sufficient guidance as to where to draw the necessary line. For instance, in *Saso Golf*, “[t]o determine whether a golf club infringes claim 7, one must: (1) measure the radius of curvature of the ‘back side profile shape’ of the club head between the club’s ‘toe’ and its most rearwardly point; (2) measure the radius of curvature of the back side profile shape between the club’s ‘heel’ and its most rearwardly point; and (3) determine whether the first value is larger than the second value. Making these calculations requires picking a specific point on the ‘toe’ and ‘heel’ from which to measure.” *Saso Golf, Inc. v. Nike, Inc.*, 843 F. App’x 291, 293 (Fed. Cir. 2021). The Federal Circuit affirmed the indefiniteness of claim 7, where “there is no definition for the terms ‘toe’ or ‘heel’ in the patent, nor is there any instruction on how the radius of curvature calculations should be made. The prosecution history provides no guidance either—the claims regarding radius of curvature spawned from an in-person interview with the examiner, and the record does not reflect the specifics of the radius of curvature measurements.” *Id.* at 296-97.

The same is true here. “Proximate” is not defined in the specification, nor are there any instructions as to how either proximity or intensity should be measured. Also similarly, the limitation that “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” finds no verbatim support in the specification, but was first introduced during a telephone interview with the examiner during the prosecution of the ’512 Patent. JX-0004.1515-1520. As the Federal Circuit explained, where the

recited comparison “depend[s] on pinpointing the locations of the toe and heel . . . [n]othing in the record indicates that an artisan would inherently know the locations of those boundaries and the patent provides no guidance . . . [and] [t]he scope of the claim depends on these measurements,” the claim is indefinite because it “does not ‘afford clear notice of what is claimed . . .’” *Saso Golf, Inc.*, 843 F. App’x at 297.

Without any objective guidance, a determination of what is “proximate” and “not proximate” falls to “the unpredictable vagaries of any one person’s opinion,” rendering the term indefinite. *Dow Chem.*, 803 F.3d at 635. For instance, the lack of objective guidance resulted in inconsistent identification of “proximate” (or “close to”) regions by Sun Pharma’s expert Dr. Jokerst, who identified only the first row of LEDs in the BLU-U® 4170D as “proximate” but the first three rows of LEDs in the RhodoLED® XL as “proximate.” *Compare* CX-0010C.31-32, Q/A 135-141, *with* CX-0010C.99-107, Q/A 530-572.

Strikingly, with no objective boundaries as to where the “proximate” and “not proximate” (or “close to” and “not close to”) regions are located, Dr. Jokerst took the liberty to first find an area of higher intensity and then later identify the area as being “close to” the second shorter edges, which is contrary to a basic reading of the claims at issue and improperly turns the infringement inquiry on its head by first finding infringement and then later twisting the claim’s meaning to fit. *SafeTCare Mfg., Inc. v. Tele-Made, Inc.*, 497 F.3d 1262, 1268 (Fed. Cir. 2007) (“A determination of patent infringement consists of two steps: (1) . . . first interpret the claim, and (2) . . . then compare the properly construed claims to the allegedly infringing device.”).

When discussing her infringement determination, Dr. Jokerst explained during the evidentiary hearing that she did not just consider the geographic location when determining whether an area of a panel was “close to” the second shorter edges but instead considered LED

density, LED addressability, LED output intensity, and geography in order to make such a determination. Tr. (Jokerst), 216:21-217:4. When pressed, she explained:

20 Q. Under the claim construction, you first have to
 21 find an area that's close to the second shorter edge, right?
 22 A. No. I think -- I think you have to find the
 23 groupings first, to assess if there's higher intensity, and
 24 then assess if that higher intensity is close to that
 25 second -- those second shorter edges compared to areas not

 1 close to the second shorter edge. So the higher intensity
 2 is something you have to -- you have to find the areas
 3 first.

Tr. (Jokerst), 219:20-220:3. In other words, given that the Asserted Patents do not provide any guidance or definition for the “proximate” and “not proximate” regions, infringement here fell to the “unpredictable vagaries” of Dr. Jokerst’s opinion in first defining groupings of LEDs (by density, addressability, and/or intensity) and then evaluating whether any groupings provided a higher intensity of light as compared to other areas, before finally defining the “close to” and “not close to” geographic regions in order to establish infringement. The arbitrariness of such an analysis and the uncertainty it creates is the driving force behind the case law addressing indefiniteness. *See, e.g., Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 909-910 (2014) (“[A] patent must be precise enough to afford clear notice of what is claimed, thereby ‘appris[ing] the public of what is still open to them’ . . . Otherwise there would be ‘[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims.’”); *see also Dow Chem. Co.*, 803 F.3d at 635.

Dr. Jokerst’s approach is precisely the type that the Federal Circuit criticized in *Liberty*. In that case, the trial court construed “reduced area of contact” to refer to a baseline encompassing a range of projectiles, including “calibers .17 through .50 BMG.” 835 F.3d at 1394. The Federal Circuit held that this construction was incorrect and noted that “[c]laim 1 would not be definite

had the trial court’s construction been correct because there would not be a sufficient objective boundary around the term of degree . . .” *Id.* at 1397. The Federal Circuit noted that this problem was demonstrated at trial where:

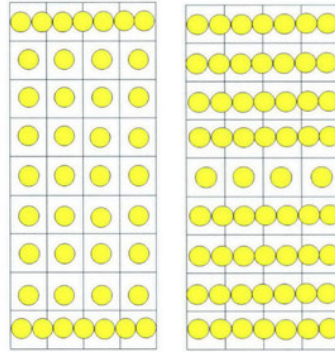
Liberty’s expert found that the accused Army projectiles had a reduced area of contact as compared to “a number”—but not all—of the tested baselines The trial court found these mixed results sufficient to show that the accused projectiles satisfy the “reduced area of contact” limitation. But ***a term of degree cannot be definite when construed in a manner that lends itself to this sort of scattershot infringement analysis*** because “a term of degree fails to provide sufficient notice of its scope if it depends ‘on the unpredictable vagaries of any one person’s opinion.’”

Id. (emphasis added). The Commission should come to the same conclusion here.

Further, the Commission’s decision in *Electrical Connectors*, on which Order No. 18 relies, actually prohibited the approach taken by Dr. Jokerst in assessing “proximate.” *Certain Electrical Connectors, Components Thereof, & Products Containing the Same*, Inv. No. 337-TA-1043 Comm’n Order at 3 (Mar. 26, 2018). Specifically, in that investigation, both parties argued at various points that the term “end region” should be construed in relation to the location of certain types of through holes in a panel. However, the Commission found that “the term ‘end regions’ is a geographic term, and therefore the type of through holes that may be located in that geographic region is not relevant to its construction in accordance with the intrinsic record.” *Id.* at 3. This contrasts sharply with the approach taken by Dr. Jokerst, who, as discussed above, repeatedly referenced non-geographical parameters to interpret the geographical term “proximate.”

The vagaries of “proximate/not proximate” and “close to/not close to” can be readily seen when looking at two hypothetical panels. For example, to the left below is a hypothetical panel consisting of nine equally-spaced rows of LEDs, where the top and bottom rows have a greater density of LEDs than the remainder of the rows on the panel. To the right below is a hypothetical

panel consisting of nine equally-spaced rows of LEDs, where the top four rows and the bottom four rows have a greater density of LEDs than the middle row on the panel.



Under these scenarios, is the boundary between the “proximate” and “not proximate” rows in the same location or does that boundary change simply because the LEDs are arranged in different densities per row? Or, should a POSA use some combination of Dr. Jokerst’s consideration of LED density, LED addressability, LED output intensity, and geography (Tr. (Jokerst), 216:21-217:4), in order to adjust the boundary between the “proximate” and “not proximate” regions to somehow account for the differences in LED configuration? And, if that is the case, how is a POSA supposed to discern when it is appropriate to give primacy to geography over LED density, addressability, and/or output intensity, and vice versa, when determining whether an area on a panel is close to (or not close to) the second shorter edges? Perhaps more importantly, these examples demonstrate that the claim terms “proximate” and “not proximate” (including under their constructions of “close to” and “not close to”) are indefinite because they provide no clear notice to the public as to what constitutes infringement and are left to the “unpredictable vagaries of any one person’s opinion.” *Dow Chem.*, 803 F.3d at 635.

Order No. 18 should have found the claim terms “proximate” and “not proximate” indefinite. RMIB, 5-14; RMRB, 3-7; RX-1275.0016-30; RX-1428C.0009-13. This was legal error that merits Commission review.

2. The Claim Term “Nested Hinges” is Indefinite

Order No. 18’s construction of “nested hinges” impermissibly violates basic and well-settled canons of claim construction by rendering claim language redundant and then reading out the term “nested” altogether. Given that the parties agree that “nested hinges” is not a known term of art and the intrinsic evidence provides no objective guidance as to what a “nested hinge” is, this claim term should have been found indefinite. This was legal error that merits review by the Commission.

The term “nested hinges” appears in every asserted independent claim of the ’512 Patent (*i.e.*, claims 1, 8, and 20) within the broader claim limitation “illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels.” The parties disagreed on the construction of this term, with Biofrontera asserting that the term is indefinite and Sun Pharma arguing that the term should have its “plain and ordinary meaning of . . . ‘hinges that fit on inner side surfaces of adjacent panels.’” Order No. 18 at 29-30. Order No. 18 agrees with Sun Pharma, concluding “that ‘nested hinges’ is [not] indefinite” and “the term ‘nested hinges on inner side surfaces of adjacent panels’ will be construed to mean ‘hinges that fit on inner side surfaces of adjacent panels.’” Order No. 18 at 35.

For context, the claims do not *just* recite “nested hinges.” Instead, they recite “nested hinges *on inner side surfaces of adjacent panels*.” *See, e.g.*, JX-0001, cl. 1. Accordingly, Order No. 18 finds “that . . . there is redundancy between ‘nested’ and ‘on inner side surfaces of adjacent panels.’” Order No. 18 at 35. Strikingly, the modifications to the claim language read out the now superfluous word “nested” from the literal claim language: “~~nested~~ hinges that fit on inner side surfaces of adjacent panels.” This type of construction is strongly disfavored because it cripples the notice function of patent claims. “Allowing a patentee to argue that physical structures and characteristics specifically described in a claim are merely superfluous would render the scope of

the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention and which language is merely superfluous, nonlimiting elaboration.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 954, 950 (Fed. Cir. 2006); *see also Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) (“It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.”); *Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1300 (Fed. Cir. 2016) (overturning a claim construction at the PTAB because “[t]he Board’s construction runs counter to the claim-construction principle that meaning should be given to all of a claim’s terms”).

Although Order No. 18 acknowledges that “a construction that introduces redundancy into a claim is disfavored,” it clings to the caveat that such a construction “is not foreclosed” where “intrinsic evidence makes it clear that the ‘redundant’ construction is correct.” Order No. 18 at 31 (quoting *VLSI Tech. LLC v. Intel Corp.*, 53 F.4th 646, 653 (Fed. Cir. 2022)). However, the narrow exception discussed in *VLSI* to the normal rule does not support the construction here. Specifically, the construction in *VLSI* did not render the construed term to be nothing more than duplicative of language already in the claims. The disputed term in *VLSI* was “force region.” *VLSI*, 53 F.4th at 648-51. The claims also recited the location of the “force region” – “a force region *at least under the bond pad*.” *Id.* at 648-51. This is analogous to the present Investigation, in which the claims recite the disputed term (“nested hinges”) and their location (“on inner side surfaces of adjacent panels”). Unlike Order No. 18 here, however, the Federal Circuit did not construe the term “force region” to mean nothing more than the recited location. Rather, the court construed “force region” to mean “a region in which the interconnect layers are susceptible to stress from the bond pad due to assembly or other processes.” *Id.* at 652. Although that construction necessarily included an area under the bond pad, it also included more than just the location recited in the rest of the claim

limitation. Accordingly, *VLSI* does not support a construction that renders a claimed element to be coextensive with, and totally superfluous to, its already recited location.

Further, the intrinsic evidence here provides far less clarity than in *VLSI*. In *VLSI*, the specification provided an explicit definition of the claim term (*i.e.*, “the force region **is** a region in which the interconnect layers are susceptible to stress from the bond pad due to assembly or other processes”), which the Federal Circuit merely adopted. *Id.*; U.S. Pat. No. 7,247,552, 6:25-29. The specification of the ’512 Patent, however, provides no such definition. Rather, the ’512 Patent only contains equivocal statements, such as “[t]he hinges 50 **may** take the form of nested hinges” or “nested hinges . . . **may include** hinges that substantially reduce or eliminate optical dead spaces.” JX-0001, 4:46-48. And, none of these statements simply equate “nested hinges” to their fitting on a location on inner side surfaces of adjacent panels. Accordingly, even under *VLSI*, Order No. 18’s importation of redundant language into the claims is improper.

Order No. 18 should have instead followed the “well-established rule that ‘claims are interpreted with an eye toward giving effect to all terms in the claim.’” *Digital-Vending Services Int’l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1275 (Fed. Cir. 2012) (quoting *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006)). As Order No. 18 concedes, “[b]y separately including the phrase ‘on inner side surfaces of adjacent panels,’ the claims imply that this requirement is different from ‘nested.’” Order No. 18 at 31.

The prosecution history also demonstrates that the patentee agreed that the term “nested hinges” had a meaning separate from “on inner side surfaces of adjacent panels.” Claim 1 originally recited “nested hinges configured to reduce optical dead space.” Order No. 18 at 34; JX-0004.552. The examiner rejected the claim language requiring that the nested hinges be configured

to “reduce optical dead space” as indefinite.⁶ *Id.* To dispense with this rejection, the patentee amended the claims as follows: “nested hinges ~~configured to reduce optical dead space~~ on inner side surfaces of adjacent panels.” *Id.* If the patentee believed these terms were redundant, it would have made one of the following amendments: “nested hinges ~~configured to reduce optical dead space~~” or “~~nested~~ hinges ~~configured to reduce optical dead space~~ on inner side surfaces of adjacent panels.”⁷ The only logical reason to add the limitation “on inner side surfaces of adjacent panels” (without removing “nested”) was that the patentee believed the “on inner side surfaces” limitation had meaning distinct from “nested hinges.”⁸

Although “nested hinges” must have its own meaning (distinct from its recited location), the intrinsic evidence provides no clear direction as to what that meaning is. As recognized by Order No. 18, “neither party introduces evidence that ‘nested hinges’ is a term that has a plain

⁶ Sun Pharma argued during claim construction that this prosecution history somehow demonstrated that the Examiner concluded that “nested hinges” was definite, but Order No. 18 correctly determines that, “contrary to Sun Pharma’s argument, this history only pertains to the definiteness of ‘on inner side surfaces of adjacent panels’ and not the term ‘nested hinges.’” Order No. 18 at 34.

⁷ The patentee clearly evidenced an intent to give meaning to “nested” when using substantively identical claim language in the related ’028 Patent but using the term “hinged structures” instead of “nested hinges.” *Compare*, JX-0001, cl. 1 (“*nested hinges* on inner side surfaces of adjacent panels”) (emphasis added), with JX-0002, cl. 1 (“*hinged structures* on inner side surfaces of adjacent panels”) (emphasis added). By using “nested hinges” instead of “hinged structures” in the nearly identical claims of the ’512 Patent, the patentee certainly signaled an intention to impart some meaning to “nested” to distinguish the claimed hinges from generic hinged structures.

⁸ Order No. 18 concludes that “[t]his history can be read either to confirm the understanding that ‘on inner side surfaces of adjacent panels’ is a separate requirement from ‘nested hinges’ or that the limitation to ‘on inner side surfaces of adjacent panels’ is redundant, but was added to satisfy an Examiner requirement for clarity. It therefore does not clearly support either party’s position.” Order No. 18 at 34. But, the ALJ’s conclusions are wrong for two reasons. First, if the history is properly read to show that “on inner side surfaces of adjacent panels” is a separate requirement from “nested hinges,” then this clearly supports Biofrontera’s position that Sun Pharma’s proposed construction (adopted by Order No. 18) cannot be correct and that “nested hinges” is thus indefinite. Second, as explained above, if “nested hinges” is redundant of its location, then, as discussed above, adding the location language provided no added clarity.

meaning to either laypersons or a person of ordinary skill in the art.” Order No. 18 at 31; RMIB at 17; RX-1275.0031. “The importance of intrinsic evidence [in ascertaining claim term meaning] reaches its zenith in cases like this when . . . the term lacks an ordinary meaning.” *IQASR LLC v. Wendt Corp.*, 825 Fed. Appx. 900, 904 (Fed. Cir. 2020). The intrinsic record here is strikingly similar to the intrinsic record in *IQASR* where the Federal Circuit found the term “magnetic fuzz” indefinite because the specification never defined the term nor provided objective boundaries:

'512 Patent (JX-0001, 4:46-48)	<i>IQASR</i> Patent At Issue (<i>Id.</i> at 905)
“[t]he hinges 50 <i>may</i> take the form of <u>nested hinges</u> ,”	“Low susceptance microparticles <i>may</i> be magnetically active disassociated particles with low or magnetic or perhaps even low sensor susceptibility, <i>such s [sic] but not limited to magnetic fuzz</i> .”
“ <u>nested hinges</u> . . . <i>may include</i> hinges that substantially reduce or eliminate optical dead spaces.”	“[L]ow susceptance microparticles <i>could be magnetic fuzz</i> , iron oxide particles, microparticles, dust, trash, ferromagnetic particles, non-or even anti-ferromagnetic particles or the like and <i>may</i> even be small perhaps less than about one inch in size or the like.”

“Because the multiple layers of definitions are all open-ended and non-limiting, a skilled artisan must wade through a morass of uncertainty and contradiction It is this word salad of inconsistent indirect definitions and examples that . . . prevents a person skilled in the art from knowing when [the claim limitation] is present and how to address it.” *Id.* at 906-906. The same applies here: the term “nested hinges” lacks an ordinary meaning. When coupled with the lack of objective boundaries in the specification, this results in an indefinite claim scope.

The proper solution was not for the ALJ to rewrite the claim, contrary to core canons of claim construction. *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 781 (Fed. Cir. 2010) (“[W]e construe claims with an eye toward giving effect to all of their terms, even if it

renders the claims inoperable or invalid.”); *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) (“This court, however, repeatedly and consistently has recognized that courts may not redraft claims, whether to make them operable or to sustain their validity.”). Instead, the ALJ should have found the claim term “nested hinges” indefinite. This was legal error that merits Commission review. RMIB at 16-19; RMRB at 9-11; RX-1275.0030-39; RX-1428C.0013-15.

B. The ID Errs in Finding the Asserted Claims Not Obvious

In failing to find the asserted claims obvious over the prior art teachings of Lundahl, Larsen, Hente, and/or Perutz, the ID adopts the positions laid out in Sun Pharma’s post-hearing briefs (often in a near word-for-word manner). But in doing so, the ID aligns itself with a one-sided analysis that is fraught with errors and omissions, and results in untenable findings. As just one example, in its discussion of the “four wheels” limitation, the ID asserts that “Biofrontera did not address this issue in its post-hearing brief,” and, because of this, “Biofrontera has abandoned or withdrawn this argument.” ID at 116. But this is incorrect, as Biofrontera dedicated multiple pages of discussion to the “four wheels” limitation across both its post-hearing initial and responsive briefing. *See infra* § IV.B.1.

As another example, during its discussion of the “recess” and “recess location” limitations, the ID determines that “Biofrontera has not shown by clear and convincing evidence that the combination of Lundahl, Larsen, Hente *and Perutz* render[.]” the recess and recess location limitations obvious. ID at 117-118 (emphasis added). But, in Complainant’s Identification of Undisputed Claim Limitations (CIUCL), Sun Pharma affirmatively stated that it *did not dispute* that Perutz discloses the recess and recess location limitations. CIUCL at 3-4. In other words, the ID finds against Biofrontera *on an undisputed limitation*.

Further, the ID applies shifting and inconsistent legal standards to support non-obviousness. For instance, the ID applies inconsistent claim scopes with respect to infringement

and validity for the “hinges limitation” (*see infra* § IV.B.4) and holds the prior art to a higher standard of disclosure than the Asserted Patents, with respect to the “uniform illumination” limitation. *See infra* § IV.B.8. These examples are but a small sampling of the type of pervasive errors present in the ID.

Whether the result of the ID’s seemingly wholesale adoption of Sun Pharma’s post-hearing briefs or the failure to give due consideration to the facts and positions laid out in Biofrontera’s briefs, the ID is rife with clear factual and legal errors that merit review by the Commission. Biofrontera addresses such errors in the following order below: (a) errors with respect to the “four wheels” limitation; (b) errors with respect to the “center panel” limitation; (c) errors with respect to the “individually configurable” limitation; (d) errors with respect to the “hinges” limitation; (e) errors with respect to the “continuous illumination” limitation; (f) errors with respect to the “recess” and “recess location” limitations; (g) errors with respect to the “higher intensity proximate second edges” limitation; (h) errors with respect to the “uniform illumination” limitation; (i) errors with respect to the analysis of motivation to combine Lundahl and Larsen; (j) errors with respect to the analysis of reasonable expectation of success in combining Lundahl and Larsen; (k) errors with respect to the analysis of combining Lundahl, Larsen, and Hente; and (l) errors with respect to the analysis of combining Lundahl, Larsen, Hente, and Pertuz.

1. The ID Errs in Finding that Biofrontera Failed to Address and Abandoned Its Argument that Larsen Disclosed or Rendered Obvious the “Four Wheels” Limitation

The ID erroneously adopts Sun Pharma’s argument that “there is no express disclosure in Larsen of four wheels . . .” (ID at 116) in concluding that the limitation “a mobile base supported by at least four wheels” set forth in claim 16 of the ’028 Patent was not disclosed by the prior art. JX-0002, cl. 16. In what can only be described as a blatant error, the ID rests its conclusion on its determination that “Biofrontera did not address this issue in its post-hearing brief. Because

Biofrontera has the burden on invalidity, I find that Biofrontera has abandoned or withdrawn this argument. G.R. 14.2.” *Id.* This clear error should be reviewed by the Commission.

In fact, Biofrontera addressed the “four wheels” limitation in **both** its initial post-hearing brief (RIB at 65-66) and its responsive post-hearing brief (RRB at 26-27).⁹ In its initial post-hearing brief, Biofrontera explained across two pages why a POSA would find four wheels inherent or obvious from Larsen and its Figure 1, stating:

Larsen teaches the 16-mobile base limitation. RX-0006C, Q/A 254. Larsen teaches that the device is “freely moveable on wheels” and ***Figure 1 suggests that the device may incorporate four wheels***, in order to provide stability. RX-0099, Fig. 1, [0027], [0069]; RX-0006C, Q/A 248. Further, during prosecution of the ’028 Patent, the examiner found that, based on Fig. 1 of U.S. Pat. No. 7,033,381 – which is the exact same image as Fig. 1 of Larsen – ***“it is inherent that there are at least two more wheels, for a total of 4, in order for the device to be stable.”*** JX-0003.130-31; RX-0006C, Q/A 249-252.

...

Further, using at least four wheels to support the stand was one of a finite number of known solutions to support a mobile stand. RX-0006C, Q/A 253. ***A POSA would have been motivated with a reasonable expectation of success to use four wheels, since the resultant stability was a well-known outcome.*** RX-0006C, Q/A 248-253. Accordingly, Larsen teaches and/or renders obvious the 16-mobile base limitation. RX-0006C, Q/A 254.

RIB at 65-66 (emphasis added). Further, in its responsive post-hearing brief, Biofrontera addressed Sun Pharma’s argument head on:

Sun’s argument that “there is no express disclosure in Larsen of four wheels – Dr. Grove points to Figure 1, but shows two wheels” (CIB at 107), merely supports Dr. Grove’s conclusion that including four wheels would be obvious . . . Although Larsen’s Figure 1 shows two wheels due to its perspective, it would be clear to a POSA that more than two wheels, e.g., four wheels would provide superior stability . . . Further, changes in the number of a component are not typically a basis for patentability. *Application of Harza*, 274 F.2d. 669, 744 (Cust. & Pat. App. 1960) (“It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced.”).

⁹ Respondents’ post-hearing brief used the “16- mobile base” term as shorthand for the claim language requiring “a mobile base supported by at least four wheels.”

RRB at 27 (emphasis added).

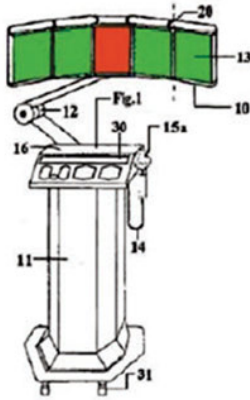
Directly contrary to the ID's statement that "Biofrontera did not address this issue in its post-hearing brief" (ID at 116), Biofrontera explicitly and unequivocally addressed it in both the initial and responsive post-hearing briefing. Overlooking or ignoring the explicit positions laid out in Biofrontera's briefing and finding that such positions were therefore abandoned or withdrawn is contrary to the Ground Rules and constitutes plain error in the ID that merits correction. *See* G.R. 14.2. The Commission should grant review to correct this clear error of material fact and legal error (in failing to properly follow the Ground Rules), instead finding that not only was the "four wheels" limitation addressed in Biofrontera's briefing (twice), but that Larsen teaches and renders obvious the "four wheels" limitation. RIB at 65-66; RRB at 26-27.

2. The ID Errs in Finding That Larsen Does Not Disclose or Render Obvious the "Center Panel" Limitation

Claims 1, 17, 20, and 21 of the '028 Patent and claims 1 and 20 of the '512 Patent recite the "center panel limitation" where "one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels are configured to be angled relative to the center panel." JX-0002, cls. 1, 17, 20, 21; JX-0001, cls. 1, 20. The ID commits both clear factual and legal error in adopting Sun Pharma's belated assertion that "Biofrontera ignores the full limitation, relying only on Dr. Jokerst's testimony that Figure 1's panels are angled relative to the center panel . . . Larsen does not disclose 'a center panel configured to face the treatment surface' . . . and Biofrontera makes no assertion to the contrary." ID at 116. This clear error should be reviewed by the Commission.

First, the ID clearly makes an error of fact in finding that Larsen fails to disclose the limitation. Larsen clearly depicts two or more panels angled around a center panel in its Figure 1

(RX-0099, Fig. 1, [0072]), and Dr. Jokerst admitted that during the evidentiary hearing. Dr. Jokerst testified as follows in relation to CDX-0018C.96 (containing Fig. 1 of Larsen):



RX-0057.0002 Fig. 1 (annotations by Dr. Grove)

Q: These green panels in the figure of [Larsen] are drawn in at an angle to the orange panel in the center, correct?

A: They're at a slight arc, yes.

Q: They're at an angle, correct?

A: Yes.

Q: They're angled relative to the center panel, correct?

A: In this figure, yes.

CDX-0018C.96 (excerpt)

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

Further, Larsen is directed to a phototherapy device for the treatment of dermatological conditions by illumination of the skin. RIB at 35-36. All of its panels, including the center panel, are necessarily configured to face the treatment surface, and Dr. Jokerst admitted that Larsen teaches positioning its panels above the skin surface (*i.e.*, the treatment surface), such as to illuminate a person's back. CX-0014C.84, Q/A 327-329.

Second, the ID's statement that Biofrontera "rel[ied] only on Dr. Jokerst's testimony" is factually incorrect. ID at 116. Biofrontera also relied on Larsen, e.g., Fig. 1 and paragraph [0072], as well as on Dr. Grove's testimony (RX-0006C, Q/A 188-192), which explained, *inter alia*, "the center panel . . . is positioned to illuminate the center of the patient's back, with each adjacent side panel . . . angled relative to the center panel." RX-0006C, Q/A 190; RIB at 53.

Finally, the ID legally errs by adopting Sun Pharma's argument that "Larsen does not disclose 'a center panel configured to face the treatment surface.'" ID at 116. Beyond being factually incorrect, this argument was made by Sun Pharma for the very first time *in its post-*

hearing responsive brief. CRB at 29. Prior to that time, Sun Pharma’s dispute was limited to whether Larsen disclosed angled side panels. *Compare* CIB at 103-104 (citing CX-0014C, Q/A 327-329), *with* CRB at 29. Indeed, Sun Pharma’s initial post-hearing brief does not include a single statement or suggestion that Larsen failed to disclose “a center panel configured to face the treatment surface.” Rather, after its expert admitted during the evidentiary hearing that Larsen did indeed disclose angled panels (Tr. (Jokerst), 738:13-739:2), Sun Pharma raised this new argument for the first time in its responsive post-hearing brief. This argument is thus prohibited by the Ground Rules. G.R. 14.2 (“Any contentions that are not set forth in detail in the post-hearing initial brief shall be deemed abandoned or withdrawn.”). And it is also unsupported by Dr. Jokerst’s witness statement. CX-0014C, Q/A 327-329. Accordingly, the ID should have dismissed this argument as abandoned, rather than adopting it wholesale.

The Commission should grant review to correct these clear errors of material fact and errors of law, and should find that Larsen discloses and renders obvious the center panel limitation.

3. The ID Errs in Finding that Larsen Does Not Disclose or Render Obvious the “Individually Configurable” Limitation

Claims 16 and 21 of the ’028 Patent recite “the five panels are individually configurable to control illumination from each of the five panels” (the “individually configurable” limitation), which was construed to mean “the power output and/or light intensity of each panel can be individually controlled.” Order No. 18 at 40; JX-0002, cls. 16, 21. The ID’s finding that Larsen does not disclose the individually configurable limitation misinterprets the plain language in Larsen that “the light sources are *individually selected*—switched *ON* or *OFF*.” RX-0099, cl. 5 (emphasis added). This clear error should be reviewed by the Commission.

Larsen discloses panels that each contain multiple light sources. RX-0099, [0070]-[0072]; RX-0006C, Q/A 240-243. Claim 5 of Larsen recites “wherein the *light sources are individually*

selected—switched **ON** or **OFF**.” RX-0099, cl. 5 (emphasis added); RX-0006C, Q/A 243. Thus, Larsen teaches illuminating or darkening individual light sources within a panel, which necessarily alters or configures the power output and/or light intensity of the panel—by allowing for brightening or dimming of the panel. RX-0006C, Q/A 243; *see also* RIB at 62-64; RRB at 25-26.

There is no cogent evidentiary basis for the ID’s conclusion that “[p]ersons of ordinary skill would understand that claim 5 [of Larsen] refers to switching *between* the light source types recited in [c]laim 1¹⁰, not illuminating or darkening light sources on individual panels.” ID at 115. Claim 5 does not recite “the light source *types* are selected—switched *between semiconductor diodes and laser diodes*.” RX-0099, cl. 5.

Further, claim 1 doesn’t require multiple light source types, as the ID implies.

1. A device for the (PDT) photodynamic therapy and electromagnetic field stimulation of light sensitive substances and human cells, comprising:

light sources with suitable strength, suitable wavelength, a light conductor, an applicator, an optic lens, a polarization filter, an electromagnetic field transmitter coil, and a control and power unit, characterized by the following:

the light source consists of at least one semiconductor diode and/or at least one laser diode,

RX-0099, cl. 1 (excerpt). Claim 1 recites “at least one” as well as “and/or,” indicating that only one light source type¹¹ is required. If only one type of light source is required (*e.g.*, the applicator includes only semiconductor diodes), as is expressly contemplated in claim 1, the “ON or OFF” functionality recited in claim 5 must mean that individual semiconductor diodes can be turned on or off, which necessarily alters or configures the power output and/or light intensity of the panel.

¹⁰ Claim 5 depends from claim 1. JX-0002, cls. 1, 5.

¹¹ While the ID cites Dr. Jokerst’s testimony at CX-0014C, Q/A 436-37, this testimony is merely the same conclusory statement that reads words (*e.g.*, “types,” “between”) into claim 5 and misinterprets the scope of claim 1.

The ID's determination is predicated on the false premise that the PDT device of claim 1 must include both light sources, which is clearly contrary to the express language of claim 1. This constitutes clear factual error.

Additionally, neither claim 1 nor claim 5 specifies that whenever one light source (or light source type) is switched "OFF" another light source (or light source type) with the exact same emission characteristics is simultaneously switched "ON," which is what would be required to avoid any change to the power output and light intensity of the panel. Accordingly, the ID's determination on this issue is not supported by the disclosure of Larsen.

Further, the ID errs in finding that Larsen's disclosure that "[w]ith the help of the control mechanism 16, the invented device is adjustable" only referred to "[t]he entire device [being] adjustable, not that each of the five applicators is individually configurable." ID at 115. Larsen does not restrict its controller to only controlling the entire device. Further, Biofrontera explained in its briefing that it was known as early as 2008 that "**LED control systems** allow the user to set various parameters of system operation including brightness Controls are usually interfaced to the driver circuitry to **allow the brightness of the individual LEDs to be set.**" CX-1231.2 (emphasis added); RRB at 25. The ID fails to address this argument or explain its finding that Larsen's controller was limited to adjustment of the entire device. 19 C.F.R. § 210.42(d) ("The initial determination shall include: an opinion stating findings . . . and conclusions and **the reasons or bases** therefor necessary for the disposition of **all** material issues of fact") (emphasis added).

The Commission should grant review to correct these clear errors of material fact and find that Larsen renders obvious the individually configurable limitation.

4. The ID Errs in Finding that Larsen and Hente Do Not Disclose or Render Obvious the “Hinges” Limitations

Claims 1, 8, and 20 of the '512 Patent also recite the “hinges limitation” – *e.g.*, “an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels.” JX-0001, cls. 1, 8, 20. Claims 1, 16, 20, and 21 of the '028 Patent recite the “hinges limitation” – *e.g.*, “an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels.” JX-0002, cls. 1, 16, 20, 21. The ID concludes that the hinges limitation was not rendered obvious by Larsen individually, or by Larsen in view of Hente, by wrongly treating the limitation differently for validity analysis than it did for infringement analysis. The ID further errs by misapplication of precedent, incorrect reliance on the disclosures of unrelated foreign patent applications, and by ignoring Hente’s clear teaching of hinges between panels. Such error merits review and correction.

The ID finds that it was not obvious to place the hinges on inner side surfaces because, as Dr. Grove testified, Larsen does not provide any details about the hinges used in Larsen. ID at 100. However, this determination is the product of legal error, as the ID applies different claim requirements for infringement and validity. *Amazon.com, Inc. v. Barnesandnoble.com*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (“A patent may not, like a ‘nose of wax,’ be twisted one way to avoid [invalidity] and another to find infringement.”); *see White v. Dunbar*, 119 U.S. 47, 51 (1886) (a patent claim is not “like a nose of wax, which may be turned and twisted in any direction”); *see also SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1988) (“[T]he claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses” because the claims “measure the invention at issue.”).

In finding that the RhodoLED® XL infringed, the ID is clear: “***The claims require only that the ‘panels’ be ‘connected by’ hinges***; they do not specify where or how the hinges are

connected to the panels.” ID at 19 (emphasis added). Had the same claim scope been applied for purposes of validity, the conclusion is similarly clear—Larsen explicitly disclosed that its panels “are flexibly *connected to each other through hinges . . . connecting one edge with the other.*” RX-0099, [0027] (emphasis added); RIB at 43. But the ID does not apply the same interpretation of the hinges limitation for validity. Instead, the ID narrows the claim scope and holds the prior art to a higher standard, finding that “given the fact that . . . there is no detail about the hinges, there is not sufficient evidence to show that . . . the hinge would be on the inner side surface of the panel.” ID at 100. As a result, the ID’s findings regarding infringement and validity are at odds:

In Finding Infringement:	In Finding Validity:
“ <i>The claims</i> require only that the ‘panels’ be ‘connected by’ hinges; they <i>do not specify where or how the hinges are connected to the panels.</i> ” ID at 19 (emphasis added).	The “cited art lacks a depiction of hinges, a description of their physical structure, and ‘does not disclose hinges in any detail.’” ID at 101; <i>see also id.</i> at n.8.

Such application of disparate claim scopes is clear legal error that should be corrected. *Amazon*, 239 F.3d 1343.

Applying the same standard for infringement to the validity analysis, the ID’s criticism that Larsen “does not describe in any detail the hinges,” is irrelevant because the claims only require the hinges to connect the panels between their inner side surfaces; they do not require any particular hinge structure or mechanism of connection. ID at 99. It is also irrelevant that the ID finds that Larsen’s panels are not “nearly flush,” as this is similarly not required by the claims. ID at 99. The same is true for the ID’s reliance on Dr. Jokerst’s testimony that “[a] person of ordinary skill would have understood that there were numerous designs to connect the panels of a PDT device flexibly, including . . . different hinge designs, including overlay hinges, strap hinges, and knife hinges” ID at 100. Dr. Jokerst’s testimony about the designs and types of hinges is irrelevant because,

in its discussion of infringement, the ID explicitly establishes that hinge design and type is not a required consideration.

When properly applying a consistent standard between infringement and validity, there is only a small, closed universe of options for placing hinges to connect adjacent panels: (1) between adjacent panels; (2) on the top or bottom of the panels; or (3) on the rear surface of the panels. Tr. (Grove), 591:5-7 (“There are three locations to connect adjacent panels.”); CX-0014C (Jokerst RWS), Q/A 236 (only listing “on the top, bottom, and back of the panels” as alternate placements for hinges between panels). Choosing one out of three or four available options is not an act of invention. *Teva Pharms. U.S.A., Inc. v. Sandoz, Inc.*, 906 F.3d 1013, 1026 (Fed. Cir. 2018) (finding it obvious to select one of a “discrete number of permutations”). Although the ID dismisses Biofrontera’s reliance on *Teva* as “misplaced because there, the prior art focused on two variables . . . and provided clear direction as to choices likely to be successful,” (ID at 101) the same is true here. Within the very limited universe of possible locations for hinges, Larsen and Hente both disclosed hinges placed between panels (*supra* § IV.B.4.). Thus, the prior art “provide[s] clear direction as to choices likely to be successful.” *Teva*, 906 F.3d at 1025.

This is especially true given that, as testified by Dr. Grove, the most common option is to put “hinges between the two panels,” as people have been doing for generations prior to 2015. Tr. (Grove), 592:2-8; RRB at 13-14. The ID errs in discounting this testimony. ID at 100. Dr. Grove explicitly addressed the obviousness of placing hinges between the panels in his witness statement, and his testimony on this subject at the hearing was provided during re-direct in response to Sun Pharma’s cross examination related to what a POSA would take from Larsen regarding hinges.

RX-0006C, Q/A 69; Tr. (Grove), 589:22-592:8. Accordingly, under the same claim scope applied for infringement, Larsen clearly disclosed and renders obvious the hinges limitation.¹²

While there has been a dispute between the parties about how Larsen illustrates the hinge location in its Figure 1 (*i.e.*, at element number 20 (indicating a position between panels) or element number 10 (indicating a position at the bottom of panels)), this issue is ancillary given Larsen’s clear disclosure of “hinges...connecting one edge with the other.” RX-0099, [0027]. That said, it is clear that Larsen contains a typo with respect to element number 10 because it identifies this both as “hinges 10” and as “invented device 10.” RIB at 42; RX-0099, [0069]. [0072]. The ID relies on *LG Elecs. Inc. v. ImmerVision, Inc.*, 39 F.4th 1364 (Fed. Cir. 2022), to conclude that, in order to find for Biofrontera on this issue, “hinges 10” must be an error “so unusual” and obvious that a POSA would “mentally substitute” in the correct information. ID at 96-99. However, *LG Elecs* does not stand for that proposition. *LG Elecs* simply reaffirms the established principle that, “where a prior art reference includes an obvious error ... that would be apparent to one of ordinary skill in the art who would mentally disregard the errant information as a misprint or mentally substitute it for the correct information, the errant information cannot be said to disclose subject matter.” *Id.* at 1372. Unlike in *LG Elecs*, however, Biofrontera is not attempting to *rely* on a typographical error to establish a missing claim element as part of its obviousness grounds. Rather, Biofrontera simply points out that, given the clear inconsistency between “hinges 10” and “invented device 10,” a POSA would, at the very least, have serious doubts as to the accuracy of the disclosure of “hinges 10” pointing to the bottom of the panels. Indeed, the ID acknowledges

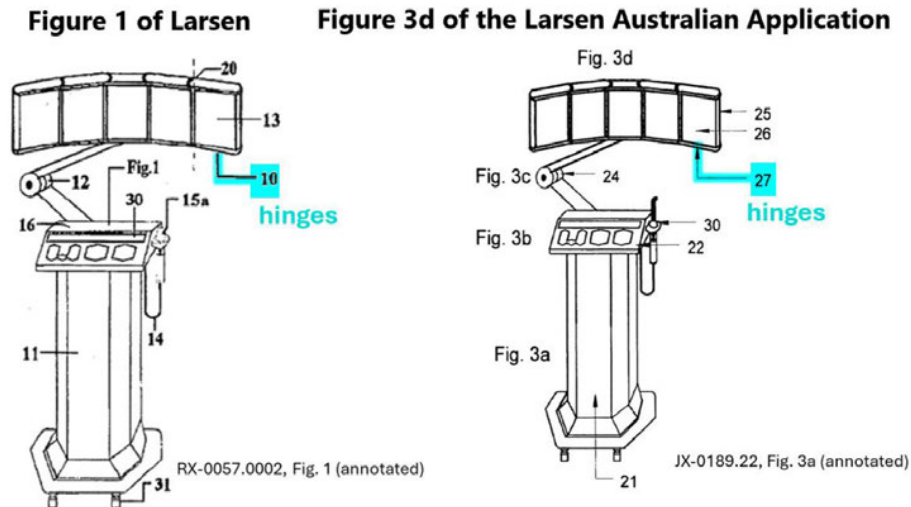
¹² The ID additionally asserts that a POSA would have no *motivation* to place hinges on inner side surfaces as they would impede the panels from being flush, create gaps, and affect uniformity (ID at 99-100 (citing CX-0014C, Q/A 233-37; Tr. (Jokerst), 765:3-25). As discussed in the section on motivation to increase flexibility (*infra* § IV.B.10), however, a POSA was motivated to incorporate hinges on inner side surfaces as a design trade off to achieve increased flexibility.

that “[i]t may be arguable that Larsen has typographical errors as to both elements ‘10’ and ‘20.’” ID at 98.

In light of this ambiguity, a POSA would consider other hinge locations, including between panels as indicated by element number 20. In fact, the Examiner did just that during prosecution of the application that became the ’512 Patent, explicitly noting that Larsen’s hinges had been erroneously labeled as element number 10 in the specification while being correctly shown as element number 20 (*i.e.*, between panels) in the Figures. JX-0004.160 (’512 File History) (“hinges 20 (indicated as 10 in the specification, but shown as element 20 in the Figures) . . .”) (emphasis added). RIB at 43. Moreover, in evaluating the ’028 Patent in its institution decision with respect to IPR2024-01312, the PTAB considered it reasonable that a POSA would have considered placing hinges on inner side surfaces as a predictable means for flexibly connecting panels, even if not expressly instructed by Figure 1 of Larsen. RX-1374.0018-19.

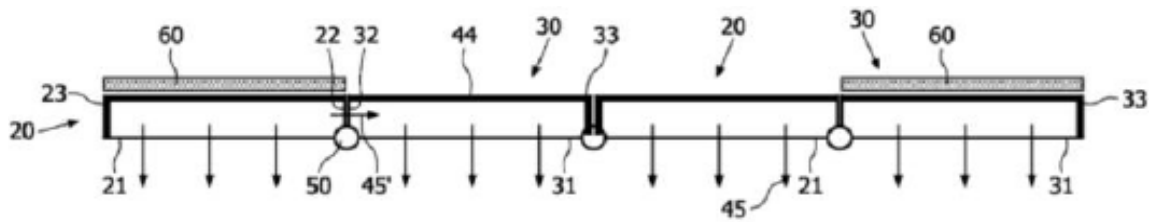
The ID further errs by looking to an unrelated patent application to address the typographical errors of Larsen. The ID states that “related applications” corroborate “Larsen’s express disclosure of hinges on the bottom of the applicator.” ID at 95. But AU 200143869 A1 (JX-0189) (“the Australian Application”) that the ID cites is not a related application under the applicable case law because it does not “stem[] from the same parent application” as Larsen. *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004); *see also AIA Eng’g Ltd. v. Magotteaux Int’l S/A*, 657 F.3d 1264, 1279 (Fed. Cir. 2011) (“[T]he varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate for consideration . . . our precedent cautions against indiscriminate reliance on the prosecution of corresponding foreign applications in the claim construction analysis.”).

Additionally, even if the Australian Application could be considered relevant, it does not support the ID's assertion that "hinges 10" is the correct annotation because "Larsen used the same [naming] convention in another application." ID at 95-96. The ID includes the following graphic to illustrate the alleged same naming convention:



ID at 96. But, the Australian Application does **not** label feature 27 as "hinges" as shown above. Rather, the Australian Application describes "a flat applicator (25) consisting of a number of individual [sic] hinged (27) flat elements (26) which can be adjusted in angles to each other." JX-0189.17. Feature 27 simply indicates that the flat elements (26) are each individually hinged (not that 27 is the location of the hinge). This is further evident by the fact that the Australian Application refers to "a number" of individually hinged flat elements 26. By the ID's flawed logic, if "individual [sic] hinged" means "hinge," feature 27 reflects the location of "a number" of hinges, which is nonsensical. Consequently, the only reasonable interpretation is that the Australian Application's reference to "individual [sic] hinged" simply indicates that the number of flat elements (26) (five in total), are each individually hinged to allow each to be adjusted in angles to each other. But, the "individual [sic] hinged" term does not reflect the location of a hinge, and the ID's logic and conclusion are the product of clear factual error.

Finally, the ID errs in stating that “Biofrontera fails to identify a single illuminator with hinges on inner side surfaces of panels.” ID at 100. With respect to infringement, the ID establishes that “the claims require only that the ‘panels’ be ‘connected by’ hinges [between panels]; they do not specify where or how the hinges are connected to the panels.” ID at 19. Larsen discloses panels that “are flexibly *connected to each other through hinges . . . connecting one edge with the other.*” RX-0099, [0027]. Hente also teaches panels connected by hinges 50, between the panels, which is clearly seen in Figure 2, depicted below. RX-0576, FIG. 2, [0015], [0048], [0052]; RIB at 37, 45-47, 70-71, 83-84, 85-86; RRB at 16-18, 36-37.



Although the ID states that “Dr. Grove ignores Hente’s disclosures that artificial light leaves the sections through the rims and side surfaces, with hinges that impede light” (ID at 102), this is not accurate. As shown in Figure 2 above, and as explained clearly on pages 17-18 of Biofrontera’s responsive post-hearing brief, Hente only depicts light emitting through rims 22 and 32 in Figure 2 (as evidenced by the arrow extending through rims 22 and 32). RRB at 17-18. In contrast, there is clearly no arrow extending through rims 33, indicating that light is not emitting through those rims. RRB at 17-18. Indeed, a POSA would understand that this perspective is explicitly reflected in the disclosure of Hente, which states that “the hinges may be positioned between two rims of the first and second section, facing each other.” RIB at 46; RX-05767, [0015]. Accordingly, it would be appropriate to locate hinges on rims 33, without any concern about blocking light, and the ID’s finding to the contrary is clear error.

The Commission should grant review to correct these legal errors and clear errors of material fact and find that Larsen and/or Hente teach and render obvious the hinges limitations.

5. The ID Errs in Finding the Continuous Illumination Limitation Was Not Obvious

Claim 20 of the '512 Patent and claim 16 of the '028 Patent recite that the nested hinges (or hinged structures) be configured so as to “allow continuous illumination across” the at least five panels. JX-0001, cl. 20; JX-0002, cl. 16. The ID errs with respect to this limitation by failing to recognize the full context in which statements were made, ignoring the evidence that was submitted in concluding that merely “attorney argument” was being made by Biofrontera, and, once again, improperly applying different claim scopes for invalidity and infringement.

The ID incorrectly states that “Biofrontera’s expert confirmed Larsen cannot have ‘continuous illumination’ because it has ‘lower irradiance regions at the junction of two of Larsen’s panels.’” ID at 102-103. The “expert” in question here is not Dr. Grove, who testified in this Investigation, but Dr. Bretschneider, who submitted a declaration in support of an IPR petition on the '028 Patent that was not instituted by the PTAB (as opposed to IPR2024-01312, which *was* instituted by the PTAB). JX-0188.1. Regardless, the ID mischaracterizes this statement and takes it out of context. The full statement explains just the opposite: while “[a] person of ordinary skill in the art would understand that the gaps between adjacent panels *could* lead to regions of low irradiance on the patient’s skin[,] *Larsen’s applicators are designed to provide an even and gap free radiation* of the surface with multiple wavelengths of light.” JX-0188.66 (emphasis added).

Further, while the ID calls Biofrontera’s position on this point “attorney argument,” (ID at 102) this is incorrect. Dr. Grove explained that:

[T]he '512 patent does not state or define what is meant by “continuous illumination” across the at least five panels. However, it my understanding that the “continuous illumination across the at least five panels” is simply the result of the configuration of the “nested hinges,” which the '512 patent owner alleges to simply

be “hinges that fit on inner side surfaces of adjacent panels.” In view of this, it is my understanding that “nested hinges” configured in a way to minimize the gap between adjacent panels would “allow continuous illumination across the at least five panels.”

RX-0006C, Q/A 158.

With respect to infringement, the ID finds that the RhodoLED[®] XL meets this limitation because “[t]he hinges fit between adjacent panels and do not interfere with the continuous illumination across the five panels.” ID at 34. Larsen and/or Hente disclose and render obvious hinges that fit between adjacent panels. RIB at 40-47; *supra* § IV.B.4. Although the ID cites Dr. Grove’s statement that, “in Figure 1 of Larsen, you can’t actually see what Larsen’s hinges look like,” (ID at 102) with respect to infringement, the ID finds that “the claims require only that the ‘panels’ be ‘connected by’ hinges; they do not specify where or how the hinges are connected to the panels.” ID at 19. Accordingly, the ID should have found this limitation disclosed for the same reason it found the limitation met for infringement. Once again, the ID erred by applying a narrower claim scope for validity than it did for infringement. *Supra* § IV.B.4.

These clear errors of material fact and errors of law merit review by the Commission, especially in light of Larsen’s clear statement that its device provides “*an even and gap free radiation.*” RX-0099, [0028] (emphasis added).

6. The ID Errs in Finding that Hente and Perutz Do Not Disclose or Render Obvious the “Recess” and “Recess Location” Limitations

Claim 17 of the ’512 Patent recites the “recess limitation” – *e.g.*, “at least one panel includes a recess configured to receive a flange of one of the nested hinges.” JX-0001, cl. 17. Claim 18 of the ’512 Patent recites the “recess location limitation” – *e.g.*, “the recess is positioned at an inner side surface of the at least one panel.” JX-0001, cl. 18. The ID appears to refer to the recess limitation of claim 17 and the recess location limitation of claim 18 collectively as the “recess and flange” limitation. ID at 116. To distinguish between the two limitations, this brief

will use the “recess” and “recess location” terminology. Biofrontera previously asserted two grounds for obviousness of claims 17-18 of the ’512 Patent: (1) Lundahl, Larsen, and Hente, and (2) Lundahl, Larsen, Hente, and Perutz. At this stage, Biofrontera withdraws the first ground (1) in view of Lundahl, Larsen, and Hente, but ***maintains*** the second ground (2) in view of Lundahl, Larsen, Hente, and Perutz.¹³

Notably, it is undisputed between the parties that Perutz provides a teaching of the recess and recess location limitations. Consequently, the ID commits legal error in finding that “Biofrontera has not shown by clear and convincing evidence that the combination of Lundahl, Larsen, Hente ***and Perutz*** render[]” the recess and recess location limitations obvious. ID at 118 (emphasis added). Following the evidentiary hearing, Sun Pharma filed its Identification of Undisputed Claim Limitations, in which Sun Pharma ***does not dispute*** that Perutz discloses the recess and recess location limitations. CIUCL at 3-4. The ID incorrectly states that “Biofrontera argues that Perutz . . . disclose[s] ‘the recess limitation and recess location limitations.’ . . . ***Complainant disagrees.***” ID at 116-117 (emphasis added). Sun Pharma ***conceded*** that Perutz discloses the recess and recess location limitations. CIUCL at 3-4. The ID clearly errs in ***finding against Biofrontera on an undisputed issue.***

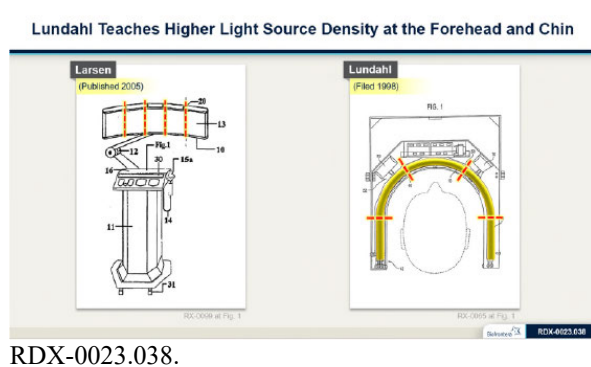
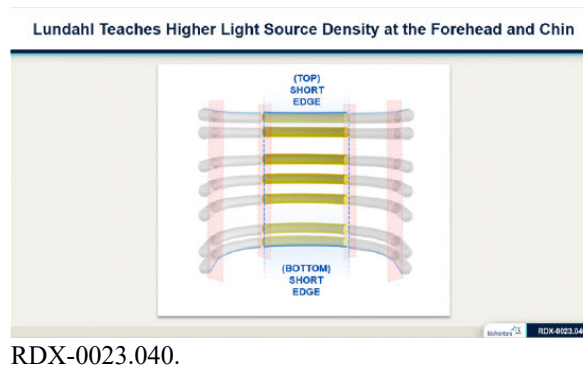
The Commission should grant review to correct this clear error of material fact, and find that Larsen, Lundahl, Hente, ***and Perutz*** teach and render obvious the recess and recess location limitations. RIB at 69-71; RRB at 27-28.

¹³ For clarity, Biofrontera also ***maintains*** the grounds of obviousness in view of Lundahl, Larsen, and Hente for all other Asserted Claims, aside from claims 17-18 of the ’512 Patent. This ground is withdrawn ***only*** for claims 17-18 of the ’512 Patent.

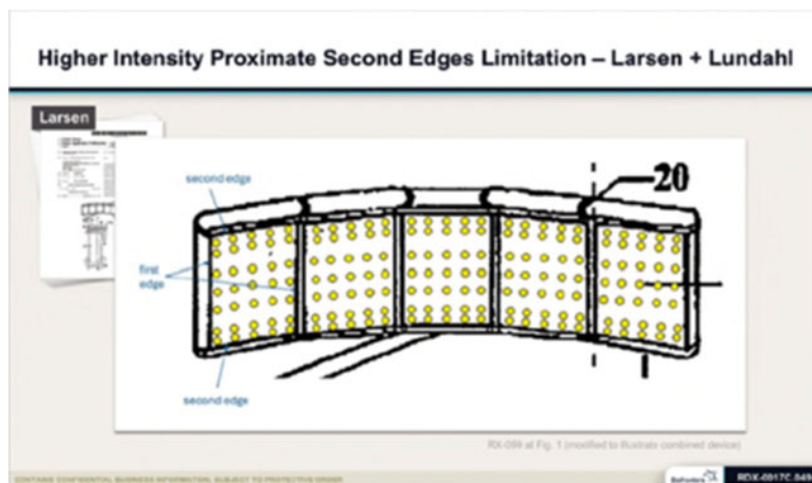
7. The ID Errs in Finding that the “Higher Intensity Proximate Second Edges” Limitation Was Not Obvious

All of the asserted claims recite “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” (the “higher intensity proximate second edges” limitation). JX-0002, cls. 1, 16, 20, 21; JX-0001, cls. 1, 8, 20. The ID once again copies language from Sun Pharma’s post-hearing briefs, nearly word-for-word, with no consideration of the analysis provided in Biofrontera’s post-hearing briefs, to find that this limitation was not rendered obvious by Lundahl and Larsen. ID at 109-114. In doing so, the ID errs by ignoring key arguments made by Biofrontera and by applying incorrect legal standards. These errors merit review by the Commission.

As an initial matter, the ID’s statement that “Biofrontera never explains how combining Lundahl’s disclosures with Larsen would satisfy the full limitation” is simply inaccurate. ID at 114. Biofrontera (and Dr. Grove in his testimony) explained extensively in both initial and responsive post-hearing briefs that, because Lundahl teaches the benefits of providing higher intensity near a patient’s forehead and chin, as illustrated in its Fig. 1, it would be obvious to apply this principle in combination with Larsen’s five panels. RIB at 32-34, 56-61; RRB at 21-25; *see also* RX-0006C, Q/A 94-95, 97, 209-220, 321.



For instance, Dr. Grove explained that, “[g]iven the design of the device, Lundahl teaches a higher density [of] light sources near the forehead and chin regions of the head, that is nearer the top and bottom of the head,” (RX-0006C, Q/A 97) and “[b]y combining the design principles of Larsen related to hinged panels and LED lights with the PDT device and light distribution of Lundahl, a POSITA would expect the resulting device to have a design similar to what I have provided in RDX-0017C.49, with the yellow circles representing LEDs.” *Id.*, Q/A 215.

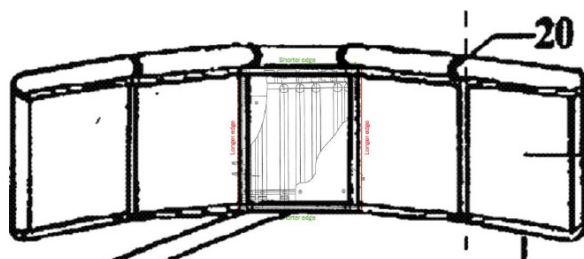


RDX-0017C.049. The ID commits error in simply ignoring all of this testimony and Biofrontera’s arguments.

The ID also legally errs by misapplying *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016), to its analysis of this limitation. ID at 110. *Arendi* dealt with the application of common sense to supply a claim limitation that was completely missing from the prior art. 832 F.3d at 1361 (“The single question at issue here is whether the Board misused ‘common sense’ to . . . supply a missing limitation . . .”). There is no such missing claim limitation here. Lundahl discloses a device that emits higher intensity at the edges near a patient’s forehead and chin. RIB at 32-34, 56-61; RX-0065, Figs. 1-2, 6:16-30, 6:48-57; RX-0006C, Q/A 93-95, 97, 321. Both Dr. Grove and Dr. Jokerst agree that this is the case. Tr. (Grove), 565:4-8; Tr. (Jokerst), 740:25-741:5

(answering that Lundahl teaches a higher intensity, “near the forehead and chin . . .”). Larsen discloses panels having shorter edges near the patient’s forehead and chin. RIB at 55-56; RX-0099, Fig. 1; RX-0006C, Q/A 206. Thus, all aspects of the claim limitation are disclosed in the art—the parties merely disagree as to how a POSA would combine them.

In addressing the combination, the ID incorrectly eschews the “expansive and flexible approach” to obviousness prescribed by the Federal Circuit (*KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007)) to adopt Sun Pharma’s assertions that a POSA would only understand and combine these elements as literally disclosed, rigidly applying the teachings as an automaton. For instance, the ID adopts Sun Pharma’s argument that a POSA “[a]pplying Lundahl’s light distribution to Larsen’s five panels yields a higher intensity of light on the longer edges of each panel.” ID at 109.



CDX-0018C.77. Biofrontera, on the other hand, recognizes that “a person of ordinary skill is also a person of ordinary creativity, not an automaton,” and would exercise common sense in how to combine the disclosures of the prior art. *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 978-79 (Fed. Cir. 2014); *KSR*, 550 U.S. at 420-21 (2007) (“[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle . . .”). For example, a POSA would be able to exercise logic and reason to apply Lundahl’s teaching of the beneficial effects of a higher intensity near the forehead and chin to apply this principle in combination with Larsen. RIB at 32-34, 56-61. Notably, the PTAB agreed with

Biofrontera’s position when instituting *inter partes* review of the ’028 Patent, finding that applying Lundahl’s teaching of “greater light intensity at the top and bottom sides,” near the forehead and chin, would translate to “the top and bottom sides of Larsen, which are the shorter edges in Larsen.” RX-1374, 18-19; *see Certain Unmanned Aerial Vehicles & Components Thereof*; Inv. No. 337-TA-1133, Comm’n Op. at 37 (Sep. 8, 2020) (recognizing the “PTO’s role as the lead agency in assessing the patentability, or validity, of proposed or issued claims.”).

The ID similarly errs legally by rigidly requiring physical incorporation of exact structures in combining the devices. Specifically, the ID notes that “Lundahl’s curved center is the only portion with higher intensity at the top and bottom as ‘[o]nly the more uniform center portion of the tube output is used for patient treatment’ Combining Lundahl’s light distribution with Larsen’s five panels yields higher intensity at the shorter edges only in the center of the device, not on each of the five panels.” ID at 112. Essentially, the ID finds that the higher intensity proximate second edges limitation was not obvious because Lundahl’s emitting area for patient treatment would be too small to map perfectly onto a five-panel device. However, “[i]t is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements.” *In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012); *see also Apple Inc. v. Gesture Tech. Partners, LLC*, 127 F.4th 364 , 371 (Fed. Cir. 2025); *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981) (“The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.”); *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973) (“Combining the teachings of references does not involve an ability to combine their specific structures.”).

Finally, the ID makes a clear error of material fact in giving credence to Sun Pharma's argument that "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." ID at 114. As an initial matter, Biofrontera (and its expert, Dr. Grove) has not once asserted that the scan engine is a *necessary* component of the resulting device formed by the combination of Lundahl and Larsen. *See* RIB at 56-61; RRB at 24-25. Additionally, this argument is wholly unsupported by Larsen and is simply a fabricated construct by Dr. Jokerst about the supposed movement of Larsen's scan engine. In fact, at the evidentiary hearing, Dr. Jokerst admitted that Larsen fails to disclose whether the scan engine causes movement up or down or side to side, any pattern of movement for the scan engine, any range of movement for the scan engine, any rate of movement for the scan engine, or any specific time points. Tr. (Jokerst), 741:22-742:20. Dr. Jokerst further admitted that she did not provide any units, dimensions, or measurements for her analysis of the scan engine. Tr. (Jokerst), 742:22-743:5; CDX-0018C.83. Given the complete absence of any supporting details related to Larsen's scan engine as far as the nature of the movements, the range of movements, and the timing of movements, and Dr. Jokerst's express admission that Larsen does not disclose any of these details, the ID errs in relying on these positions to support its finding that the scan engine would lead to higher intensity of light emitted from the center of panels.

The Commission should grant review to correct these clear factual and legal errors and find that Lundahl and Larsen render obvious the "higher intensity proximate second edges" limitation. RIB at 56-61; RRB at 21-25.

8. The ID Errs in Finding That Lundahl and Larsen Do Not Render Obvious Uniform Illumination

Claims 1, 16, 20, and 21 of the '028 Patent and claims 1, 8, and 20 of the '512 Patent each recite the “uniform illumination limitation.” JX-0002, cls. 1, 16, 20, 21; JX-0001, cls. 1, 8, 20; RIB at 48-49. “Uniformly illuminate”/“uniformly illuminating” was agreed to mean “irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum.” Order No. 18 at 13. Lundahl discloses this limitation verbatim. RX-0065, 15:22-26; *see also* RX-0065, 1:9-11; RX-0006C, Q/A 176-185. The parties dispute only whether there is a reasonable expectation of success in maintaining the disclosed uniformity once the PDT device of Lundahl is combined with the LEDs and hinged panels of Larsen.

In finding that the uniform illumination limitation was not rendered obvious, the ID errs by raising the standard for “uniform illumination” beyond what the claims or the law require and by requiring the prior art to disclose uniformity in more detail than the Asserted Patents did to enable it. And the ID overlooks significant portions of Biofrontera’s briefing, resulting in reliance on out-of-context statements and citations. Review and correction of these errors is warranted.

The ID errs by applying a standard of uniformity beyond what was required by the claims. ID at 103-104. Biofrontera pointed out that “the level of uniformity required by the claims is not high” (RIB at 31), referring to the “within 60%” standard established at *Markman*. Order No. 18 at 13. The ID rejects Biofrontera’s position, stating that it “is contradicted by Lundahl, which states there are ‘biological requirements imposed on a PDT light source’ that meant conventional illuminators were insufficient” ID at 103-104. But the ID does not just reject the contention that the level of uniformity is not high, it went a step further and determined, based on *the prior*

art reference *Lundahl*¹⁴ that “instead, the invention was required to provide ‘a highly uniform output irradiance.’” ID at 103-104; RX-0065, 6:54-57. The claim construction agreed to by the parties and adopted by Order No. 18 for “uniformly illuminate”/“uniformly illuminating” was not an elevated “highly uniform” standard but the “within 60%” standard. It was plain legal error for the ID to deviate from the claim construction for purposes of evaluating obviousness. *SmithKline*, 859 F.2d at 882 (“[T]he claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses” because the claims “measure the invention at issue.”).

The ID also improperly elevates the standard for reasonable expectation of success by relying heavily on inventor testimony as to the so-called “difficulty” that they had in developing the invention. ID at 104, 106-107. The appropriate viewpoint for evaluating reasonable expectation of success, however, is that of a POSA, not that of the inventor. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (“The issue of obviousness is determined entirely with reference to a hypothetical ‘person having ordinary skill in the art.’... The actual inventor's skill is irrelevant to the inquiry, and this is for a very important reason.”); *see also Intercontinental Great Brands LLC v. Kellogg North America Company*, 118 F. Supp. 3d 1022, 1036 (N.D. Ill. 2015) (“[T]he obviousness analysis does not focus on what the inventors said or did, but what a person skilled in the art would have known.”). That is especially true in this case where some inventors, like Mr. Mazejka (JX-0006C, 38:9-16), do not meet the definition of a POSA. Order No. 18 at 13. Inventor testimony should also be looked at with skepticism given their

¹⁴ Although *Lundahl* is incorporated by reference in the Asserted Patents, “import[ing] limitations from the specification into the claims” should be avoided. *Imaginal Systematic, LLC v. Leggett & Platt, Inc.*, 805 F.3d 1102, 1108-1111 (Fed. Cir. 2015) (refusing to import limitations from the specification into the claims because “nothing in the written description of the [patent at issue] indicate[d] that the claims should be read to refer only to” a system as described in a patent incorporated by reference in the specification).

personal interest in having the patents found non-obvious. *Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 860 (Fed. Cir. 1991) (noting that “[c]ourts have commented on the inherent discredit that may be placed upon an inventor’s testimony, especially when relating to the teachings of the prior art or to the inventor’s recollection of the act of invention.”).

Further, the ID legally errs by requiring that Biofrontera present actual measurements to “*prove* the combination maintained the measured uniformity.” ID at 104 (emphasis added). It is well-established that “expectation of success need only be reasonable, not absolute,” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007), and “conclusive proof of efficacy” is not required. *Acorda Therapeutics, Inc. v. Roxane Labs, Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018). As the Federal Circuit has explained, “expert and other evidence indicates that a person of ordinary skill . . . can draw reasonable inferences about the likelihood of success even without a perfectly designed clinical trial . . .” or other test. *Id.* at 1334. The ID ignores this black letter law to instead rely on a nonprecedential Federal Circuit case. ID at 103-104 (citing *Juniper Networks, Inc. v. Correct Transmission, LLC*, 2024 WL 3517862, at *6 (Fed. Cir. July 24, 2024)). Unlike the expert in *Juniper*, however, Dr. Grove did more than simply state that it would be “very simple” to achieve uniform illumination in combining Lundahl and Larsen. Rather, Dr. Grove clearly explained that Lundahl taught a light source distribution that provided uniformity benefits and why application of this light source distribution with LEDs would lead to uniform illumination within the meaning of the claims. RX-0006C, Q/A 321, 324-325, 329. Further, unlike in *Juniper*, the claimed limitation at issue here—uniformity within 60% of the maximum—was already achieved by Lundahl *15 years before the priority date* of the Asserted Patents. RX-0065, 15:22-26. The only modification needed was to maintain this result with a light source (LEDs) that was not

plagued with the numerous shortcomings associated with fluorescent tubes. RIB at 80-81; RX-0006C, Q/A 321, 324-325, 329.

Additionally, the ID's criticism and characterization of Biofrontera's arguments related to reasonable expectation of success in achieving uniformity as "conclusory" (ID at 108) is the product of applying a different standard to the Asserted Patents than to the prior art, contrary to well-established precedent. Specifically, while the Asserted Patents themselves routinely discuss "uniform illumination" in both the specification and claims, the Asserted Patents are entirely devoid of any particular details related to the necessary spacing of light sources needed to achieve uniform illumination and also lack any explicit instruction as to the LED characteristics necessary for achieving uniform illumination in the recited five panel illuminator. This silence is both telling and relevant, as Federal Circuit precedent has held that the standard for establishing an expectation of success should be consistent between the patent and the prior art. *Alcon Research, Ltd. v. Apotex, Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012).

In *Alcon*, for example, the asserted claims recited methods of treating human eyes using olopatadine. *Id.* at 1364. The Federal Circuit explained that:

Although [patentee] argues that [the prior art] would not give a skilled artisan an expectation of success because it does not teach that olopatadine is safe for the human eye, we find this contention to be without merit. *Id.* While it is true that [the prior art] does not expressly disclose that olopatadine would be safe for use in human eyes, neither does the [asserted] patent We conclude that, just as a skilled artisan would be able to practice the invention claimed in the [asserted] patent despite its lack of explicit instruction that olopatadine is safe for human ophthalmic use, the artisan would have a reasonable expectation of success for adapting [the prior art] formulation for the same use in a human eye.

Id. at 1369. The ID should have applied the same standard in this instance. Applying the standard set in *Alcon*, if a POSA "would be able to practice the invention claimed in the [Asserted] [P]atent[s] despite its lack of explicit instructions" as to the spacing or details for uniform

illumination in a paneled device, the same POSA would have a reasonable expectation of success for combining Lundahl and Larsen to achieve the same. *Id.* at 1369.

Similarly, although the ID criticizes Biofrontera for “ignor[ing] the optical dead spaces created by breaking Lundahl’s device into five panels,” and further asserts that “[n]either Lundahl nor Larsen teaches how to maintain uniformity when introducing multi-panel gaps” (ID at 107), the claimed five panel illuminator of the Asserted Patents also necessarily includes these multi-panel gaps, and not once do the Asserted Patents discuss or provide any details for how to provide uniform illumination.

Perhaps most tellingly, the Asserted Patents themselves indicate that fluorescents and LEDs are interchangeable within the context of the claimed illuminators, stating:

Each panel contains an array of light emitting diodes (LED) 60, which may be configured in an evenly spaced pattern across the face of the panel. The number of individual LEDs arranged in a given array is not particularly limited. Alternatively, ***other types of light sources may be used, such as fluorescent and halogen lamps.***

JX-0002, 3:56-62 (emphasis added). The Asserted Patents state that either LEDs or fluorescent light sources may be used in the illuminator, yet provide no discussion regarding the alleged difficulties the ID asserts to argue that a POSA would not have a reasonable expectation going from one light source to the other.

Moreover, the Asserted Patents rely on and incorporate the teachings of the prior art, including Lundahl, to provide guidance on how to achieve uniform illumination with the claimed illuminators:

For effective treatment, it is desirable to have a power output that is ***uniform in intensity and color.*** Illuminators, such as those disclosed in U.S. Pat. Nos. 8,758,418; 8,216,289; 8,030,836; 7,723,910; 7,190,109; 6,709,446; ***6,223,071***, which are incorporated by reference in their entireties for the techniques, methods, compositions, and devices related to PDT and PD, are typically used to provide ***the proper uniformity of light for treatment purposes.***

'028 Patent, 1:50-57 (emphasis added).¹⁵

If achieving uniform illumination required anything more than the disclosure provided in Lundahl and the other prior art patents, the Asserted Patents would have provided additional guidance on the transition from fluorescents to LEDs. They did not. Consequently, as repeatedly stated in Biofrontera's briefing, and as supported by the repeated testimony of Dr. Grove, a POSA had at least a reasonable expectation that uniform illumination could be achieved by combining the teachings of Lundahl and Larsen. The ID errs in finding otherwise.

Additionally, the ID appears to have completely overlooked large swaths of Biofrontera's briefing. For instance, the ID errs by stating, in its analysis of reasonable expectation of success, that "Dr. Grove even opined that the claimed uniformity requires 'undue experimentation.'" ID at 104. However, this overlooks Biofrontera's briefing that explained:

Although Sun points to a statement Dr. Grove made that a POSA would be required to "perform undue experimentation to make and use an illuminator that provides uniform illumination over the full scope of the claims," this statement is ***taken out of context***. CIB at 99 (emphasis added); Tr. (Grove), 579:15-25 (Q: you said that in your opening expert report, right? A: ***In a different context, I did, yes.***"). Dr. Grove's statement was in relation to the difficulty of providing uniform illumination to the far reaches of the claim scope – e.g., of providing uniform illumination to a patient's extremities and torso. Tr. (Grove), 587:4-588:21. This statement was not made in relation to providing uniform illumination of, e.g., the face, which is both within the claim scope and clearly disclosed in Lundahl. RX-0006C, Q/A 92, 96, 328; RX-0065, 2:35-40, 2:60-67, 3:29-38.

RRB at 19-20 (emphasis added).

The ID also improperly discounts Biofrontera's argument that:

While Sun has asserted that, to achieve uniformity, four features of Lundahl must be incorporated in combination with Larsen's LED panels (CPHB, 147-149), this argument is logically flawed . . . three of these – the reflector, specific electrical control system, and specific cooling system – are only needed to solve uniformity

¹⁵ The other patents cited and incorporated in the background of the Asserted Patents are all in the same family as Lundahl (6,223,071) and include identical disclosures.

issues specific to fluorescent tubes, meaning that they would be rendered unnecessary once fluorescent tubes are replaced by superior LED technology.

RIB at 50-52. The ID incorrectly finds that this argument was waived for not being in Biofrontera's pre-hearing brief. ID at 105. However, Biofrontera argued in its pre-hearing brief that the combination of Lundahl's principles of light source spacing along with Larsen's LED panels would be sufficient to provide the claimed uniformity. RPHB at 155-159. For instance, Biofrontera argued in its pre-hearing brief that:

[T]he light pattern and arrangement of Fig. 2 would provide a measured output over the active emitting area of within 70% of the measured maximum...In view of this understanding established by Lundahl, the device resulting from combining the teachings of Lundahl and Larsen, which is illustrated in RDX-0017C.100 and shown above, has effectively the same light arrangement and pattern as Fig. 2 of Lundahl. RX-0006C, Q/A 321. Because of this, a POSA would at least reasonably expect that this resulting device would provide an irradiance of at least 60% of the measured maximum over the entire treatment surface, as required by the Asserted Claims. RX-0006C, Q/A 321. In fact, the motivation to combine Lundahl and Larsen is at least partly based on the desire to even further increase light output consistency by changing the light source from fluorescent tubes to LEDs.

RPHB at 157-158. This argument necessarily encompasses the negative—that various and sundry additional components are not necessary. Further, these arguments were made in direct response to Sun Pharma's assertion in its pre-hearing brief that five factors (i.e., U-shaped tubes, reflectors, a specific electrical system, and a specific cooling system) must be integrated to achieve uniform illumination. CPHB at 147-150.¹⁶

Finally, the ID incorrectly accuses Biofrontera of relying on the BLU-U[®] 4170E and the RhodoLED[®] XL as prior art and/or as evidence to motivation and reasonable expectation of

¹⁶ As explained in Biofrontera's Motion in Limine No. 4, this argument by Sun Pharma was asserted for the first time in its pre-hearing brief and in the accompanying witness statement and demonstratives of Dr. Jokerst, extending beyond the scope of her expert reports. This motion was denied in Order No. 25, with no explanation as to the basis for denial. Order No. 25, 7. It would seem particularly unfair to Biofrontera to both allow new arguments by Sun Pharma and then prevent Biofrontera from entering any response.

success. ID at 107-108. The ID's characterization is wholly inaccurate. Biofrontera merely pointed to these devices to refute Sun Pharma's false implication, *e.g.*, in CDX-0018C.81, that gaps between LEDs would necessarily produce gaps in illumination. RIB at 77. It is well-established that "[e]xtrinsic evidence can be used to demonstrate what is 'necessarily present' in a prior art embodiment even if the extrinsic evidence is not itself prior art." *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1329 (Fed. Cir. 2020) (citing *Monsanto Tech. LLC v. E.I. DuPont De Nemours & Co.*, 878 F.3d 1336 (Fed. Cir. 2018)). Biofrontera simply used the BLU-U® 4170E and the RhodoLED® XL for the opposite purpose—to show what would *not* have necessarily been present (*i.e.*, gaps in illumination) in an LED device such as the one disclosed in Larsen.

The Commission should grant review to correct these errors of law and clear errors of material fact and to find that the uniform illumination limitation is rendered obvious. RIB at 30-31, 48-52, 79-82; RRB at 18-20, 34-36.

9. The ID Errs in Finding a Lack of Motivation to Replace Fluorescent Tubes

Biofrontera made two arguments as to why a motivation existed to replace the fluorescent tubes of Lundahl with the LEDs of Larsen: (i) fluorescent tubes had known *performance* issues that were solved by LEDs; and (ii) fluorescents were becoming *disfavored* in the industry and by the government. The ID errs by completely ignoring (i) and applying an incorrect legal standard with respect to (ii). This is clear factual and legal error that merits review by the Commission.

In yet another instance of the ID copying near verbatim from Sun Pharma's post-hearing briefs with no consideration of the analysis provided in Biofrontera's post-hearing briefs, the ID found a lack of motivation to replace fluorescent tubes based solely on Sun Pharma's asserted position that Biofrontera waived arguments related to the *safety* issues of fluorescents (ID at 121).

This is both inaccurate¹⁷ and inapposite. Even if waiver did apply to the discussion of safety, it is irrelevant given that the safety issue is at best merely ancillary to the issues of (i) *performance* and (ii) fluorescents being *disfavored*, which were not waived, as discussed below.

With respect to (i), Biofrontera argued in its pre-hearing brief and its initial post-hearing brief that there would have been a motivation to replace fluorescents to improve light source *performance*, *i.e.*, with respect to uniformity, efficiency, cost, and design flexibility. RPHB at 160-162; RIB at 30-31 (“[T]he Lundahl device had two key drawbacks . . . (2) use of ‘fluorescent tubes [that were] in some ways not well suited for PDT.’”), 77-79. For instance, in its pre-hearing brief, Biofrontera argued that:

LEDs have a lower cost and a longer lifetime than fluorescent tubes. RX-0006C, Q/A 325. Second, fluorescent tubes are known to have inconsistent light output within the tube itself, as acknowledged in Lundahl (the tubes have “non-emitting area at their ends” (6:31-42) and that “tube output may vary over its length” (4:41-42). RX-0006C, Q/A 324-325. This was acknowledged by Dr. Jokerst, who recognized this problem and stated during her deposition that “[the fluorescent tubes] have a dark [] area.” RX-1379C (Jokerst Tr.), 141:5-10; RX-0006C, Q/A 324 Fourth, the relatively narrow output spectrum of LEDs allows for an illuminator with an output wavelength ideally matched to an absorption band of the photosensitizer. RX-0006C, Q/A 325.

RPHB at 160-161. Biofrontera similarly argued in its initial post-hearing brief:

Regarding performance, Mr. Lundahl noted “[t]he output from fluorescent tubes is not inherently uniform. The fluorescent tubes have low output areas (*i.e.*, areas of reduced emission) near the end of the tubes. Fluorescent tubes are also temperature sensitive. For example, fluorescent lights lose output when they get too hot or cold.” CX-0011C, Q/A 26. These difficulties are acknowledged in the Lundahl reference, which itself notes that: “output from a fluorescent tube is not inherently uniform” (RX-0065, 6:10-11), “tube output may vary over its length” (RX-0065, 4:41-42), tubes have a “non-emitting area at their ends” (RX-0065, 6:31-42), and “tube wall temperatures strongly affect output distribution” (RX-0065, 9:13-15). Dr. Jokerst similarly admitted that “[i]t was known that fluorescent

¹⁷ Biofrontera argued in its prehearing brief that there was adverse regulatory action against fluorescents prior to 2015. RPHB at 5, 161. One of the reasons for this was safety issues. RPHB at 5 (“[F]luorescent bulbs were becoming disfavored across the industry and government regulatory agencies due to their *toxic mercury content*.”) (emphasis added)). Biofrontera merely elaborated on this argument in its post-hearing brief. RIB at 77-79.

tubes had dark areas.” Tr. (Jokerst), 732:7-10. LEDs also provided **performance advantages** over fluorescents, including higher efficiencies, longer lifetimes, and “unprecedented flexibility in lighting fixture design.” CX-1231.1-2 (“A properly designed LED light system is capable of providing performance and a lifetime well beyond any traditional lighting source.”); Tr. (Jokerst), 736:5-7 For these reasons, LEDs became widely used as their costs came down and had become the industry preferred light source for PDT by the early 2010s. Tr. (Jokerst), 736:8-10; RX-0006C (Grove), Q/A 38-40, 310.

RIB at 160-161 (emphasis added). The ID completely fails to address this argument or explain why a motivation did not exist in view of the compelling evidence provided above.¹⁸

With respect to (ii), the ID dismisses the argument in one sentence, stating that “fluorescent tubes did not ‘become obsolete by the 2015 priority date.’” ID at 121. However, the legal standard for motivation does not require that the prior art become obsolete or unavailable. Instead, the desire to **improve** already functional technology can be sufficient. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006) (“motivation to combine exists . . . [when] the combination of references results in a product or process that is **more desirable**, for example because it is **stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient**[;] . . . the desire to **enhance** commercial opportunities by **improving** a product or process is universal . . .”) (emphasis added); *see also Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023) (“[U]niversal motivations known in a particular field to **improve** technology provide a motivation to combine . . .”) (emphasis added) (internal quotations and citations omitted). Biofrontera presented evidence showing that fluorescent tubes were becoming disfavored by the 2015 priority date, providing the requisite motivation to switch in addition to the known performance issues. RIB at 30-31, 77-78.

¹⁸ The PTAB agreed with Biofrontera that “a skilled artisan would have been motivated to use Larsen’s LEDs as they are *more cost-efficient* and *last longer*.” RX-1374, 20 (emphasis added).

What's more, *Sun Pharma* failed to address either (i) performance or (ii) fluorescents being disfavored in its initial post-hearing brief. CIB at 108-114. The Ground Rules are clear that "[a]ny contentions that are not set forth in detail in the post-hearing initial brief shall be deemed abandoned or withdrawn." G.R. 14.2 Not only has Sun Pharma abandoned any counterargument, per Ground Rule 14.2, the ID should have found in favor of Biofrontera on this issue.

The ID fails to address Biofrontera's fulsome discussion of the motivation to replace fluorescent tubes with LEDs based on known *performance* issues and applied an incorrect legal standard to assess whether fluorescents becoming *disfavored* in the industry and by the government could serve as motivation to replace fluorescent tubes. The Commission should grant review to correct these errors of law and clear errors of material fact.

10. The ID Errs in Finding a Lack of Motivation to Increase Flexibility

In finding a lack of motivation to increase the flexibility of Lundahl's PDT device, the ID relies on a series of incorrect legal standards, unsubstantiated conclusions, and mischaracterizations of the facts by Sun Pharma. The ID finds that, because the BLU-U® 4170D is still used and sold to this day, there was no motivation to modify Lundahl's design (as embodied in the 4170D) to include hinges (ID at 121), but this overlooks the bedrock principle that an implicit motivation always exists to improve upon the prior art, particularly in view of known shortcomings and inefficiencies.

The ID also finds that the availability of other connection means between panels, including "without hinges," works against the motivation to add hinges to Lundahl's device. ID at 120. But the ID overlooks that Dr. Jokerst was unable to identify any actual examples of connecting panels without hinges (and, in fact, includes paragraphs of discussion regarding the different types of hinges that could be used). ID at 100-101. The ID's finding that the gaps introduced by hinges between panels would "destroy Lundahl's goal of uniform illumination" is both unsupported by

Sun Pharma’s briefing and experts, and also fails to consider Dr. Grove’s discussion and explanation that the impact of “gaps” between panels is minimized or eliminated in a PDT device with panels that can be angled with respect to one another (as is expressly taught by Larsen). ID at 120; RIB at 77. Indeed, the PTAB also disagrees with the ID, finding that a motivation existed to increase the flexibility of the Lundahl device by incorporating Larsen’s hinged panels. RX-1374, 20. These clear factual and legal errors merit review by the Commission.

The ID’s criticism of Biofrontera’s discussion of the BLU-U[®] 4170D is misplaced and mischaracterizes the purpose for which the device was cited. The ID states that “Biofrontera never identified BLU-U[®] 4170D as a prior art system in its contentions or in its prehearing brief.” ID at 118, n. 12. However, Biofrontera does not rely on the BLU-U[®] 4170D as prior art—Biofrontera relies on Lundahl as prior art. But, because the 4170D embodies the fixed U-shape device disclosed in Lundahl, it is illustrative of the real-world advantages and drawbacks of that design.¹⁹ Biofrontera has been consistent about this position throughout this Investigation, as set forth in Dr. Grove’s Expert Report (CX-1324C, ¶ 582), Biofrontera’s prehearing brief (RPHB at 147-148), and Biofrontera’s post-hearing briefing (RIB at 74-75). Further, the fact that the 4170D embodies Lundahl’s fixed U-shape device is not controversial—this was readily admitted by Sun Pharma’s expert, Dr. Jokerst, and its Associate VP of Regulatory Affairs and IP, Scott Lundahl, who is also the first named inventor on the Lundahl reference. Tr. (Jokerst), 731:24-732:3; JX-0017C, 37:6-9,

¹⁹ It is well-established that, to show anticipation, “[e]xtrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a reference.” *Ciba-Geigy Corp. v. Alza Corp.*, 1995 U.S. App. LEXIS 28214 at *6 (Fed. Cir. 1995); *see also Monsanto Tech. LLC v. E.I. DuPont De Nemours & Co.*, 878 F.3d 1336 (Fed. Cir. 2018). Importantly, unlike in the anticipation context, Biofrontera is not relying on the 4170D to supply missing structure or claim elements – only to illustrate and explain how a POSA would view the advantages and disadvantages of the structure already fully disclosed in Lundahl.

41:7-10, 41:13-16. Nonetheless, the ID apparently dismisses large swaths of Biofrontera's arguments in support of motivation on this basis.

Paradoxically, the ID was quite willing to rely on the 4170D as persuasive evidence to *refute* motivation. For instance, in finding that there would not be motivation to increase Lundahl's flexibility with panels, the ID extensively relies upon testimony by Drs. Schmuylovich and Ehrenreich regarding their experiences treating patients with the 4170D. ID at 118-119. The ID also relies on statements made by Dr. Roberts about her experiences using the 4170D for "treating patients' faces, necks, arms, hands, chests, and backs without any issues." ID at 118. Dr. Roberts was an expert engaged by Sun Pharma in IPR2024-01312 (challenging the '028 Patent). CX-1063.1. Thus, not only were her statements based on the 4170D device, but Dr. Roberts was not present at the evidentiary hearing and was not available for cross-examination or deposition.²⁰ Nevertheless, the ID finds her declaration to be reliable evidence for the purposes of refuting motivation. This treatment of the evidence is uneven and should be corrected.

Moreover, the ID relies on the fact that the BLU-U® 4170D could be used to provide PDT to different parts of the body including hands and arms (via "[j]ury-rigging' with a Mayo stand") to suggest that no motivation existed to improve and increase flexibility of the device. ID at 119. But this flawed view and interpretation is wholly inconsistent with well-established case law precedent. In *DyStar*, for example, the Federal Circuit held:

²⁰ Biofrontera moved to exclude the testimony of Dr. Roberts and Dr. Bretschneider in its *Motion In Limine* No. 2. This motion was denied in Order No. 25 because "declarations filed during an IPR is [sic] part of the intrinsic record of the that [sic] patent. *Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1266-67 (Fed. Cir. 2012) . . ." Order No. 25, 5-6. However, *Krippelz* is not supportive of the proposition it is cited for. The declaration at issue in *Krippelz* was submitted as part of a completed reexam. *Id.* at 1266-67. Further, the declarant in that case also appeared and testified at trial. *Id.* In contrast, Dr. Roberts did not appear in the present case or at the evidentiary hearing. Additionally, Order No. 25 provides no supporting case law or rationale as to why this case involving a completed reexamination proceeding should be applicable in the context of a pending IPR.

Indeed, we have repeatedly held that an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the “improvement” is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical—we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves.

DyStar, 464 F.3d at 1368. This implicit motivation to develop more desirable products flows logically from the “self-evident proposition that mankind, in particular, inventors, strive to improve that which already exists.” *Pro-Mold & Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed.Cir.1996); *see also Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1160-61 (Fed. Cir. 2007) (affirming district court’s finding of obviousness and agreeing with accused defendant’s arguments that claim merely updated an existing toy with then-common electronics, and that a specific motivation to combine need not appear in the prior art when the improvement stems from a general desire to improve a known device using newer technology).

The ID suggests that simply because the BLU-U® 4170D *could* be used to provide PDT (no matter how inconvenient or difficult), such use would nullify any motivation to increase the flexibility or otherwise improve the prior art device described in Lundahl. But this approach is legally deficient and ignores the well-established implicit motivation to improve that which already exists. Simply because Dr. Ehrenreich and Dr. Roberts were able to devise methods for treating other parts of the body such as hands, arms, and back does not mean that an improved device with enhanced flexibility was not desirable. *See* RX-0007C (Ehrenreich WS), Q/A 159 (“dermatologists . . . would have been motivated to modify the fixed U-shaped lamps to be more flexible and adaptable to each patient’s physiology”); *see also id.*, Q/A 168, 186, 190-91, 194, 198. Indeed, even the inventors of the Asserted Patents and of the Lundahl reference itself acknowledged that the fixed U-shape of the prior art Lundahl PDT device (as exemplified in the

BLU-U® 4170D) was limiting. RX-0015C (Carota), 37:2-6 (“Q: And were there problems with a rigid curved device? A: It was limiting.”); JX-0017C (Lundahl), 42:19-43:2 (“[f]or certain people, especially shall we say larger people, that posed a problem.”).

Further, the ID relies on Dr. Ehrenreich’s testimony that he had not encountered a scenario where the shape and dimensions of the patient would not allow him to perform PDT treatment to support its conclusion that no motivation existed to increase the flexibility of Lundahl’s PDT device. ID at 118. However, by focusing on this one statement in isolation, the ID overlooks the full context of what Dr. Ehrenreich previously testified: “[w]ith the BLU-U that I used to treat patients, I typically resort to using pillows, instrument stands, and other jury-rigged approaches to fit arms or hands into the treatment area. ***But this can be awkward and uncomfortable for patients, and it can make setting and controlling the distance between the light and the treatment area difficult, especially on a convex surface such as a forearm.***” RIB at 76, citing RX-0007C (Ehrenreich WS), Q/A 159 (emphasis added). Again, the law is clear that an implicit motivation exists to improve upon known prior art devices and to make such devices more efficient. Despite the fact that it may be possible to perform PDT with Lundahl’s device for various parts of the body, Dr. Ehrenreich clearly identified inefficiencies associated with the device, including the “awkward and uncomfortable” nature of treating other parts of the body. The ID focuses on a single statement made by Dr. Ehrenreich and did not give consideration to the full scope of his testimony. This represents clear factual and legal error.

The ID further asserts that Biofrontera’s proposal to modify Lundahl with hinges to increase flexibility is the product of hindsight because Biofrontera ignores “that there were numerous other designs to connect the panels of a PDT device flexibly, including without hinges ...” ID at 120 (citing CX-0014C (Jokerst RWS), Q/A 236). However, the ID (1) fails to review

and consider the full testimony of Dr. Jokerst, which failed to identify any alternative attachment means other than hinges; and (2) overtly ignores the express teachings of Larsen relied upon by Biofrontera. As an initial matter, the ID cites to the Rebuttal Witness Statement of Dr. Jokerst (CX-0014C) to support its position that “there were numerous other designs to connect the panels of a PDT device flexibly, including without hinges,” however, while Dr. Jokerst alludes to attachment of panels “without hinges,” she fails to provide a single example of how the panels could be attached without hinges. ID at 120; CX-0014C, Q/A 236. In fact, in the follow-up question and answer, Dr. Jokerst dedicates an entire paragraph discussing the various types of hinges, including butt hinges, overlay hinges, strap hinges, offset hinges, and knife hinges, and does not include a single mention of potential means of connecting panels without hinges. *Id.*, Q/A 237. Moreover, even if Dr. Jokerst had provided any support for her notion that numerous non-hinge options were available to connect the panels of a PDT device flexibly (which she does not), the issue is irrelevant because Larsen expressly teaches panels “flexibly connected to each other through hinges . . . connecting one edge with the other.” RX-0099, [0027]. The ID’s finding that Biofrontera’s positions are the product of hindsight based on the alleged availability of numerous other design options, including without hinges, lacks supporting evidence and is ultimately immaterial in view of Larsen’s express disclosure. This constitutes clear factual error.

The ID also finds that the gaps introduced by including hinges between panels would defeat any motivation to increase flexibility, and that “introducing gaps would destroy Lundahl’s goal of uniform illumination.” ID at 120. But this strained conclusion finds no support—the ID does not include a single citation to Sun Pharma’s briefing or the testimony of any of its experts for this point. In its discussion of the hinges limitation, the ID states that “placing hinges on the inner side...would impede the panels from being flush, create gaps, and affect uniformity.” ID at 99-100.

However, “affect[ing] uniformity” is a far cry from the ID’s later conclusion that “gaps would destroy Lundahl’s goal of uniform illumination.” Additionally, nowhere in Dr. Jokerst’s testimony cited for support of the hinges limitation discussion does she state or suggest that uniform illumination would be destroyed by incorporating hinges between panels. *See* CX-0014C (Jokerst RWS), Q/A 233-37; Tr. (Jokerst), 765: 3-25.

The ID also cites to the declaration of Dr. Bretschneider, who the ID states “concluded the same: ‘A person of ordinary skill in the art would understand that the gaps between adjacent panels could lead to regions of low irradiance on the patient’s skin.’” ID at 100 (citing JX-0188.66). But, a statement that gaps between adjacent panels *could* lead to regions of low irradiance is significantly short of stating or implying that gaps will destroy uniform illumination. Further, as discussed above, this statement is taken out of context. The full statement explains just the opposite – that while “[a] person of ordinary skill in the art would understand that the gaps between adjacent panels *could* lead to regions of low irradiance on the patient’s skin[,] **Larsen’s applicators are designed to provide an even and gap free radiation** of the surface with multiple wavelengths of light.” JX-0188.66 (emphasis added).

Importantly, as Dr. Grove explained, the argument that gaps associated with hinges between panels would discourage a POSA from modifying Lundahl’s device to include hinged panels overlooks the fundamental design aspects of Larsen. RX-0006C, Q/A 317; RIB at 76-77. As Larsen explains, the PDT devices described therein comprise applicators (panels) that are “*hinged together so as to be adjustable at angles with respect to one another.*” RIB at 77; RX-0099, cl. 11 (emphasis added). Dr. Grove rightly clarifies that the hinged-panel illuminator of Larsen may be positioned in a “flat” orientation, or may also be positioned in an orientation where the adjacent panels are angled toward one another, creating a curved orientation (approximating a

U-shape). RX-0006C, Q/A 317. Based on this disclosure, Dr. Grove explained that, by positioning the panels at angles (*e.g.*, in a bent/curve orientation), any gaps between panels will be minimized or eliminated. RIB at 77; RX-0006C, Q/A 317.

Indeed, the PTAB agreed with Dr. Grove's position, finding that a motivation existed to increase flexibility:

Based on our review of the Petition, Petitioner explains that a driving motivation for a POSITA to modify Lundahl to include Larsen's five panels is "to increase the flexibility of the device to ensure the light panels could be maintained at a distance of 2-4" from the surface of the treatment area, whether the face, arm, or back, etc." Pet. 29 (emphasis added). As Lundahl's device is not flexible, and such flexibility would improve its ability to treat areas other than an average sized face, we determine, at this stage in the proceeding, that this motivation for the combination is sufficient.

RX-1374, 20. Consequently, contrary to the ID's unsupported findings that gaps associated with hinges between panels would "destroy" the motivation to increase flexibility, the PTAB agreed with Dr. Grove, correctly finding that Lundahl's device was not flexible, and increasing flexibility (by incorporating hinged panels) would improve the resulting device's ability to treat various areas of the body.

Further, the ID's prioritization of inventor testimony constitutes legal error. For instance, the ID credits the inventors' testimony over Dr. Grove's testimony (RX-0006C, Q/A 314, 317-318, 320-321, 329) that it would be routine to maintain uniformity when incorporating hinged panels. ID at 121. However, "[t]he actual inventor's skill is irrelevant to the inquiry [of obviousness], and this is for a very important reason. The statutory emphasis is on a person of ordinary skill." *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985); *see also Intercontinental Great Brands LLC v. Kellogg North America Company*, 118 F. Supp. 3d 1022, 1036 (N.D. Ill. 2015) ("[T]he obviousness analysis does not focus on what the inventors said or did, but what a person skilled in the art would have known."). As noted above, *supra* § IV.B.8,

this is an especially relevant consideration here, where the inventors do not all meet the established definition of a POSA. Dr. Grove was testifying from the perspective of a POSA and such testimony should not have been discounted in favor of the perspective of the inventors.

Additionally, in this discussion, the ID once again erroneously cites Dr. Grove's statement about undue experimentation. As discussed in detail above, *supra* § IV.B.8, this statement was taken out of context and is not applicable to the issue of uniform illumination of the face and scalp.

The ID's finding of a lack of motivation to increase flexibility is plagued with a series of clear factual and legal errors. The Commission should grant review to correct these errors and find that a motivation did exist to increase flexibility of the Lundahl PDT device to include Larsen's hinged panels. *See* RIB at 74-77; RRB at 30-34.

11. The ID Errs in Finding that there Would Not Have Been a Reasonable Expectation of Success in Combining Lundahl and Larsen

The ID limits its findings regarding reasonable expectation of success to a lack of "reasonable expectation of success that [the] combination of Lundahl and Larsen would meet the uniform illumination limitation . . ." ID at 121-122. This issue is discussed in detail above. *Supra* § IV.B.8. However, Biofrontera additionally notes that in its discussion of reasonable expectation of success, the ID incorrectly cites Dr. Grove's out-of-context statement regarding undue experimentation, *for the third time*. ID at 122. As discussed in detail above, *supra* § IV.V.8, this statement was taken out of context and is not applicable to the issue of uniform illumination of the face and scalp.

12. The ID Errs in Finding that there Would Not Have Been a Motivation and Reasonable Expectation of Success in Combining Lundahl, Larsen, and Hente

The ID legally errs by finding that Hente is not analogous art. ID at 122-124. Prior art is considered analogous if either (1) the prior art is from the same field of endeavor, or (2) the prior

art is reasonably pertinent to a problem with which the inventor is involved, regardless of the field of endeavor. *Sci. Plastic Prods. v. Biotage AB*, 766 F.3d 1355, 1359 (Fed. Cir. 2014); *LKQ Corp. v. GM Global Tech. Ops. LLC*, 102 F.4th 1280, 1297 (Fed. Cir. 2024).

Hente is directed to adjustable illumination devices that are bendable or foldable via hinges. RX-0576 (Hente), Abstract; RIB at 36-37. The ID incorrectly states that Hente’s solution of an illuminator with panels that are rotatable with respect to one another via hinges is not “reasonably pertinent” to the problem faced by the inventors of the Asserted Patents. ID at 122. While the ID states that the “inventors’ problem was specific to achieving uniform illumination in a medical setting,” (ID at 124), this view is too narrow under *In re Paulsen*, 30 F.3d 1475, 1481-482 (Fed. Cir. 1994). In *Paulsen*, reviewing a rejection for obviousness, the Federal Circuit upheld a rejection of a claim reciting a portable computer with hinges over “reasonably pertinent” art that included hinges “used in a desktop telephone directory, a piano lid, a kitchen cabinet, a washing machine cabinet, a wooden furniture cabinet, or a two-part housing for storing audio cassettes.” *Id.* at 1478. The Federal Circuit found that the inventors’ concern for “how to connect” with hinges is a “problem[s] that [is] not unique” to a specific hinge use, making prior art that “discloses various means of connecting” reasonably pertinent. *Id.* at 1481-482. This view of whether “the subject matter as a whole would have been obvious” allows a court to “take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Although the ID cites *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992) in support of its narrow view of the prior art a POSA would have considered (ID at 122), as the PTAB articulated in *Ex Parte Gayathri et al.*, No. 2015-003785, 2016 WL 4775729 at *6 (P.T.A.B. Sep. 9, 2016), it is important not to “cite to *Oetiker* . . . and other decisions by the Court of Appeals without

acknowledging that these holdings were modified by the Supreme Court’s holding in *KSR*....” In *KSR*, the Supreme Court “repudiated strict application of the ‘teaching, suggestion, or motivation’ test to show obviousness” and encouraged an expansive view of combinable prior art. *Ex Parte Gayathri*, 2016 WL 4775729 at *6; *KSR*, 550 U.S. at 415. The flexible view set out in *Paulsen* and encouraged in *KSR* should be applied here.

Additionally, the ID’s requirement that the hinges in Hente be “designed to uniformly illuminate” in order to find motivation to combine is incorrect. ID at 123-124. The claims merely require “hinges that fit on inner side surfaces of adjacent panels.” Order No. 18 at 35. Hente teaches hinges positioned between panels, such as on their inner side surfaces. RX-0576, FIG. 2, [0015], [0048], [0052]; RIB at 37, 45-47, 70-71, 83-84, 85-86; RRB at 16-18, 36-37. Further, Hente teaches hinges that allow for adjustment of adjacent panels/sections, while minimizing the gap between them, providing motivation to apply these teachings in combination with Lundahl and Larsen. RX-0576, Title, Abstract; RX-0006C, Q/A 336; RIB at 83. “[A]s long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor.” *In re Fulton*, 391 F.3d 1195, 1202 (Fed. Cir. 2004).

Additionally, the ID improperly applies *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021), to state that Hente was not “suitable” for combination. ID at 123. The discussion of suitability in *Intel* is in the context of a motivation to combine prior art references, not the evaluation of a reasonable expectation of success. *Id.* Yet, *Intel* establishes that a prior art combination need only be a *suitable* option, not the best option, to show obviousness. *Id.* Thus, not only does *Intel* not stand for the proposition the ID cites it for, but it actually underscores the

proper expansive approach to obviousness—that the hinges taught by Hente are only required to be a *suitable* option for connecting adjacent panels of an illuminator, not the *best* option.

Finally, the ID errs by requiring hinges “for a very thin stretchable device like Hente’s” to physically connect the “rigid, thick panels” of Lundahl and Larsen. ID at 123. The hinges taught by Hente are not required to be “bodily incorporated into the structure of the primary reference[s].” *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1294 (Fed. Cir. 2015). And, Biofrontera is not suggesting that Hente’s exact hinge structure be physically incorporated into Larsen’s device. Larsen already teaches a paneled device including hinges appropriate for such a device. *Supra*, § IV.B.4. To the extent there is a lack of clarity in Larsen as to where to *locate* those hinges, Hente clearly teaches a *location* for hinges—between panels.

The Commission should grant review to correct these clear factual and legal errors, and find that it would be obvious to combine Hente with Lundahl and Larsen with a reasonable expectation of success. RIB at 82-84; RRB at 36-37.

13. The ID Errs in Finding that there Would Not Have Been a Motivation and Reasonable Expectation of Success in Combining Lundahl, Larsen, Hente, and Perutz

Similar to its erroneous conclusion with respect to Hente, the ID legally errs by finding that Perutz is not analogous art. ID at 123-124. As explicitly stated in the ID, Perutz provides “a connection of display panels.” ID at 123. The problem of how to connect adjacent panels with hinges is not unique to a specific hinge use, making prior art that “discloses various means of connecting” reasonably pertinent. *In re Paulsen*, 30 F.3d at 1481-482. Thus, similar to the erroneous conclusion on Hente, the ID errs by too narrowly defining the problem faced by the inventors in concluding Perutz was not analogous art. *Supra*, § IV.B.12.

Additionally, the ID errs in its statement that “[h]ere, unlike *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1365 (Fed. Cir. 2022) ... there was no known need

for a recess configured to receive a flange of one of the nested hinges or recesses positioned at an inner side surface of the at least one panel.” ID at 124. *Adapt Pharma* establishes that motivation to combine may be found in “any need or problem known in the field of endeavor at the time of invention and addressed by the patent.” *Adapt Pharma*, 25 F.4th at 1365. Here, minimizing space between adjacent panels was a known need. RIB at 70-71; RX-0006C, Q/A 338, 344, 348. It was well known at the time of filing that minimizing the space between panels had beneficial effects on illumination of the treatment area. RX-0006C, Q/A 302, 334, 338. This known need would have motivated a POSA to locate hinges within recesses in order to minimize spaces between panels. RX-0006C, Q/A 334, 338.

Finally, the ID errs by discounting Perutz as unsuitable based on the “size of features.” ID at 124. As previously stated, the law does not require the features of Perutz to be “bodily incorporated into the structure of the primary reference[s]” of Lundahl and Larsen. *MCM Portfolio LLC*, 812 F.3d at 1294; *see In re Mouttet*, 686 F.3d 1322 (Fed. Cir. 2012) (“It is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of elements.”).

The Commission should grant review to correct these errors and find that it would be obvious to combine Perutz and Hente with Lundahl and Larsen with a reasonable expectation of success. RIB at 84-86; RRB at 37-38.

14. Secondary Considerations

Although the ID does not address secondary considerations, Sun Pharma’s alleged secondary considerations were not supported by the evidence. For instance, while Sun Pharma asserts that aspects of the asserted claims were copied and incorporated into Biofrontera’s RhodoLED® XL, Dr. Jokerst admitted that she had seen no direct evidence to support copying or indeed any reliance by Biofrontera on knowledge gleaned from Sun Pharma or its patents, in

developing its own products. Tr. (Jokerst), 746:21-748:5. Similarly, although Sun Pharma alleged commercial success, [REDACTED]

[REDACTED] Thus, Sun Pharma instead relies on roughly a years' worth of mediocre RhodoLED[®] XL sales to attempt to establish commercial success. RIB at 88. Such examples are reflective of the unsupported nature of Sun Pharma's secondary considerations arguments as a whole. Accordingly, the alleged secondary considerations do not render the asserted claims non-obvious, as discussed in full in Biofrontera's briefing. RIB at 86-90; RRB at 38-40.

C. The ID Errs in Finding the Asserted Claims Not Invalid for Lack of Written Description

The ID commits clear errors, both legally and in its conclusions on certain material facts, in finding that the Asserted Patents are not invalid for lack of written description under 35 U.S.C. § 112. All asserted claims contain a preamble reciting “[a] [system for / method of] *photodynamically diagnosing* or treating a patient.” The claim construction order correctly determined that the preamble was limiting. Order No. 18 at 29. In addition to the limiting preamble, the claims, including the system claims recite broad ranges of variables related to photodynamic diagnosis (“PD”) and photodynamic therapy (“PDT”). The specification does not demonstrate that the inventors possessed PD. For instance, the respective experts agree that the illumination times contained in the working example cited by Sun Pharma *do not work for PD*. RIB at 98 (citing CX-0013C, Q/A 18; Tr. (Shmuylovich), 681:11-684:9; RX-0007C (Ehrenreich WS), Q/A 111, 232, 277-78, 300-02, 356). Lacking support in the specification, Sun Pharma reached for expert testimony and third-party documents, including a later-issued Biofrontera patent and testimony from *a Biofrontera inventor* on that patent, to attempt to establish possession by the Sun Pharma inventors. ID at 126. The ID ignores Federal Circuit precedent that provides that silence is not

disclosure and prohibits relying on expert testimony inconsistent with the specification to support written description. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010); *Zoho Corp. v. Sentius Int'l, LLC*, 494 F. Supp. 3d 693, 705 (N.D. Cal. 2020); *Maytag Corp. v. Electrolux Home Prods., Inc.*, 448 F. Supp. 2d 1034 (N.D. Iowa 2006), *aff'd*, 224 F. App'x 972, 1078 (Fed. Cir. 2007). The legal error was consequential, as it permitted Sun Pharma to re-write its specification by, for instance, substituting Sun Pharma's expert opinion that a "millisecond" or "nearly instantaneous" exposure to light would permit photodynamic diagnosis, when the specification *only discloses* exposure times of minutes or hours. ID at 130-31; JX-0001 at 9:21-43.

The ID erroneously erases the distinction between photodynamic therapy (PDT) and photodynamic diagnosis (PD). The Asserted Patents and Accused Product relate to *photodynamic therapy (PDT)*, whereby a photosensitizing compound is applied to a patient's skin, left to incubate for a prescribed period, and then exposed to light energy for a period of time, which the specification states ranges from minutes to three hours. JX-00001, 9:21-43. The irradiation causes a photochemical reaction, releasing a reactive oxygen species that destroys the cells where the photosensitizing compound has accumulated. RIB at 5. The brightness of the light is called irradiance and the product of time multiplied by irradiance is called fluence, meaning the dose of light at the treatment surface. JX-00001, 9:53-56. "Brighter" irradiance or longer exposure times result in greater fluence. Like gas in an engine, the photosensitizing compound is effectively consumed or "burned up" by fluence. The greater the irradiance or the longer the exposure time, the more of the photosensitizing compound is consumed through a process called photobleaching. RRB at 53; Tr. (Shmuylovich) 706:16-20 ("... as you do this process, these photosensitizers get used up. That is called photobleaching. So you run out of energy."). The experts agree that the

length of exposure time disclosed in the specification (a) is appropriate for PDT; and (b) leads to photobleaching, a process whereby the photosensitizing compound is consumed. RX-0007C (Ehrenreich WS), Q/A 111, 132, 232, 252-256, 302; CX-0009C, Q/A 162; CX-0013C, Q/A 43.

Photodynamic diagnosis (“PD”), in contrast, uses the application of a photosensitizing compound and light to detect diseased tissue. The problem is that the specification does not provide a working example of how to conduct PD. And it does not define the characteristics of the system—illumination time, wavelength, irradiance, fluence—that would permit a system to be useful for PD. The disclosure does not, for instance, speak about fluorescence, the method the experts agree is used to detect diseased tissue. Finally, and most starkly, the Asserted Patents speak to irradiating the treatment surface for a period of minutes or hours, as is appropriate for PDT. Contradicting the specification, which states that PD or PDT can be accomplished by practicing the example set out in 9:1-43 which speaks to minutes or hours of illumination, Sun Pharma’s expert states that PD must be conducted over the course of milliseconds, “nearly instantaneously,” or “a few seconds.” CX-0013C Q/A170 (“photobleaching, where the light fluence is high that the PpIX molecules become deactivated, is not really a concern for the illumination times used during PD. The light used to excite the fluorophore is typically applied only briefly—often for just a few seconds—so the amount of light exposure is insufficient to cause significant photobleaching.”).

In contrast to the specification’s silence about what wavelengths, intensities, and fluences of light can be used effectively for diagnosis, RX-0007C (Ehrenreich WS), Q/A 221-227, the dependent claims are directed to broad ranges of each variable:

- “light having a wavelength in a range of 400 nm to 700 nm.” JX-0001, claim 5; JX-0002, claim 4.

- “output red light at a dose of about 30 J/cm² to 150 J/cm² .” JX-0001, claim 3; JX-0002, claim 2.
- “output light at an irradiance density of 10 mW/cm² to 30 mW/cm² .” JX-0001, claim 4; JX-0002, claim 3.

RIB at 91-92. Thus, the asserted claims must encompass at least these ranges. RX-0007C (Ehrenreich WS), Q/A 222-224. Moreover, the specification teaches, and Sun Pharma’s expert Dr. Shmuylovich agrees, that the Asserted Patents are directed to treating and diagnosing with visible light, commonly understood to be in the 400 to 700 nm wavelength. CX-0013C, Q/A 151-152.

As discussed below, the ID disregards that the bedrock principle of the written description requirement is possession as demonstrated through an inquiry directed to the four corners of the specification. Instead, by substituting expert testimony and outside documents, the ID is contrary to at least three principles outlined by the Federal Circuit. **First**, the Federal Circuit states: “[w]here, however, the ‘four corners of the specification directly contradict information that the patentee alleges is ‘well-known’ to a person of skill at the effective filing date, no reasonable jury could conclude that the patentee possessed the invention.”” *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012); quoting *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) (holding claims invalid over expert testimony). **Second**, “[s]ilence is generally not disclosure.” *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1017 (Fed. Cir. 2022). **Third**, “[i]t is not enough that a claimed invention is ‘an obvious variant of that which is disclosed in the specification.’” *Id.* at 1016. Thus, the Federal Circuit has made it clear that the four corners of the disclosure must demonstrate possession through disclosure, not silence, not suggestion, and certainly not through expert testimony at odds with the specification.

The ID adopts Sun Pharma’s argument—copied virtually verbatim from Sun Pharma’s post-hearing briefs—that knowledge of a POSA can supplement the teachings of the specification. However, far from merely supplementing the specification with knowledge of a POSA, the ID relies on expert testimony and documents that contradict both each other and the specification itself, thus effectively rewriting the specification to preserve the validity of the claims. Such an approach is contrary to Federal Circuit law and contrary to the evidence in this Investigation. In its post hearing reply brief, Sun Pharma argued that the specification’s lack of written description and examples of PD can be excused by reference to what is “well known in the art.” CRB, 50-51 (citing *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005); *Streck*, 665 F.3d at 1285). The guidance in *Streck* and *Capon*, however, is inapplicable to this case. By its own terms, *Streck* states “this is not a case where a patentee attempts to claim a broad genus without defining a specific species.” *Streck*, 665 F.3d at 1287; *see also Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1338 (Fed. Cir. 2021) (“*Capon* does not support Juno's arguments regarding its exceedingly broad functional claim limitations.”); *FWP IP ApS v. Biogen MA, Inc.*, 749 F. App'x 969, 976–77 (Fed. Cir. 2018) (distinguishing *Streck* and affirming invalidity where key variable was not disclosed and conditions to be treated were “open ended”). In this case, unlike *Streck* and *Capon*, Sun Pharma does indeed broadly claim a genus of photodynamic diagnosis, including with claims encompassing broad ranges of wavelengths and fluences, without defining a specific species.

Furthermore, the Federal Circuit has cautioned that “when the four corners of the specification directly contradict information that the patentee alleges is “well-known” to a person of skill at the effective filing date, no reasonable jury could conclude that the patentee possessed the invention. *Bos. Sci. Corp.*, 647 F.3d at 1366 (finding claims invalid). Just as contradicting the

specification shows a lack of written description, silence in the specification cannot constitute disclosure.

1. The ID Errs by Ignoring the Plain Language of the Specification, Which Lacks Written Description Support for PD

The ID commits legal and factual errors by collapsing the differences between PDT and PD, even though the specification and claims distinguish between them. Sun Pharma and the ID correctly point out that there is only one working example in the specification:

The specification provides an exemplary method of using the claimed illuminator with ALA. JX-0001 at 9:1-43. ***While the specification references PDT at the start, it concludes by confirming that the method is also for photodynamic diagnosis using the illuminator***, JX-0001 at 9:44-48, consistent with the known overlap between photodynamic therapy and photodynamic diagnosis.

ID at 127. In introducing this example, the specification states that it is specific for PDT. JX-0001, 8:64-67 (“One example of a ***treatment method*** for precancerous lesions such as actinic keratosis ***by PDT*** utilizing an adjustable illuminator described above in conjunction with ALA will now be described.”). Then, following the example at 9:1-43, the specification states at 9:44-48 that “[t]he invention ***thus provides a method for photodynamically diagnosing*** or treating a contoured surface of a patient, which includes providing the adjustable illuminator described above, placing the patient in the illuminator, ***and illuminating the patient to diagnose*** or treat ***the patient***.”²¹ By its terms, the specification itself is inconsistent on whether the sole example is just for treatment or for treatment and diagnosis.

²¹ Several areas of the specification discussed PD and PDT as goals. ID at 126 (citing JX-0001 at 1:17-20, 1:34-47). But “[a] written description sufficient to satisfy the requirement of the law requires a statement of an invention, not an invitation to go on a hunting expedition to patch together after the fact a synthetic definition of an invention.” *Indivior UK Ltd. v. Dr. Reddy's Lab's S.A.*, 18 F.4th 1323, 1329 (Fed. Cir. 2021) (finding no written description support where ranges were not disclosed); RRB at 47-48.

The problem, however, is that the example at 9:1-43 teaches a series of variables around wavelength, incubation time, illumination time, and fluence that are directed to PDT and, in many cases, will not work for PD. RIB at 94, 97-101; RRB at 44-46. As discussed below, the ID frequently substitutes expert testimony where the specification is silent or is contradicted by the plain terms of the specification. The Federal Circuit has repeatedly found failure to disclose a critical variable demonstrates lack of possession. And to find the written description requirement satisfied in spite of multiple missing variables is clear error.

a. Illumination Time

The ID commits legal error by substituting a different illumination time for those provided for in the specification, thus violating the Federal Circuit tenet that expert testimony in service of preserving validity must be consistent with the specification. *Boston Sci. Corp.*, 647 F.3d at 1366. Sun Pharma's expert Dr. Shmuylovich testified that "[t]he main difference between PDT and PD is the length of time that the treatment area is illuminated," and that "[f]or PD, it is nearly an instantaneous process from illumination to detecting fluorescence." CX-0013C, Q/A 18-20. This "main difference" appears nowhere in the specification. Dr. Shmuylovich's testimony characterized the illumination time necessary for PD as "nearly instantaneous," "milliseconds," or a matter of seconds. CX-0013C, Q/A 20, 93, 168. But, as Sun Pharma's expert confirmed, there is simply ***no reference*** to illumination times of seconds or milliseconds in the specification. Tr. (Shmuylovich), 681:11-684:9. In *Indivior UK Ltd. v. Dr. Reddy's Lab's S.A.*, 18 F.4th 1323, 1328-29 (Fed. Cir. 2021), the Federal Circuit affirmed a finding of lack of written description when the claims were directed to a particular range of weights for certain drug formulations, but neither the specific range or even the endpoints of the range were disclosed in the specification. Similar to *Indivior*, the specification here teaches illumination times on the order of approximately 8 minutes to 16 minutes, 20 minutes, 30-40 minutes, "one to about three hours," not the "nearly

instantaneous” or millisecond process required for PD. *See* 9:65-10:4; 9:16-43. The ID, at 130, commits legal error by relying on the specification’s vague mention of a “prescribed period,” amidst the expressly described times of minutes and hours, to conclude that illumination times suitable for PD are disclosed. RIB at 97-99, RRB at 44-45; *see also Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 923 (Fed. Cir. 2004) (“generalized language may not suffice if it does not convey the detailed identity of an invention”) (holding claims invalid); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000) (claims invalid for failing to provide a blaze mark consistent with claimed range).

The experts agree that the illumination times recited in the Asserted Patents relate to PDT, JX-0001, 9:35-43; *see also* CX-0013C, Q/A 18-20, but the ID essentially permits Sun Pharma to rewrite the specification to incorporate Dr. Schmuylovich’s opinion that a POSA would know that photodynamic diagnosis occurred over the course of milliseconds. ID at 130. This is inconsistent with the specification, which does not disclose anything about illumination of seconds or milliseconds, and instead states that the illumination times of minutes or hours recited in the asserted patents, JX-0001, 9:1-43 “***thus provides a method for photodynamically diagnosing . . . patient, which includes . . . illuminating the patient to diagnose or treat the patient.***” But, as the evidence showed, exposure to higher intensities and durations of light can lead to photobleaching, a situation where PpIX no longer fluoresces, thus rendering it ineffective for PD. RIB at 94, 97-99; RX-0007C (Ehrenreich WS), Q/A 111, 132, 232, 252-256, 302. “[W]hen the four corners of the specification directly contradict information that the patentee alleges is ‘well-known’ to a person of skill at the effective filing date, no reasonable jury could conclude that the patentee possessed the invention.” *Bos. Sci. Corp.*, 647 F.3d at 1366. Even if the ID had concluded the specification to be silent on illumination time, the Federal Circuit has been clear that silence is not

disclosure. *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1017 (Fed. Cir. 2022).

The Federal Circuit’s case law provides that in situations where, as here, a patentee describes one method in the specification but claims something broader, the claims are invalid for failing to meet the written description requirement. Specifically, in *Boston Scientific*, the Federal Circuit affirmed a finding of invalidity where the patentee relied on an expert witness to claim a genus of macrocyclic lactone analogs. *Bos. Sci. Corp.*, 647 F.3d at 1366 (“both the Choi article and [patentee’s expert’s] declaration directly conflict with the shared specification of the 1997 patents, which explicitly states that ‘the precise mechanism of rapamycin *is still under active investigation.*’”). As the ID did here, the patentee in *Boston Scientific* argued that because information regarding the claimed analogs was present in the prior art, one skilled in the art would know what fell within the scope of the claims. *Id.* at 1362. The Federal Circuit concluded that there was insufficient support in the specification to support that the inventors were in possession of the genus of claimed analogs. *Id.* at 1366. Here, given the specification’s disclosed illumination times, there is nothing in the specification to indicate the inventors were in possession of a system or method for photodynamic diagnosis.

Likewise, in *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344 (Fed. Cir. 2005), the Federal Circuit affirmed written description invalidity where the specification disclosed a single method of image transformation called “seamless DWT,” but lacked disclosure as to non-seamless DWT or other forms of seamless DWT. *Id.* (“The trouble with allowing claim 21 to cover all ways of performing DWT-based compression processes that lead to a seamless DWT is that there is no support for such a broad claim in the specification.”); *see also Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1018 (Fed. Cir. 2022) (claims invalid

where patentee's expert testimony was contrary where it was "inconsistent with plain text of the specification"). Relying on the expert testimony that milliseconds is required for PD over the plain language of the specification's range of minutes or hours is legal error.

Dr. Shmuylovich's testimony as to illumination times was unsupported expert testimony, uncorroborated by any prior art documents. Reliance on his testimony was particularly troublesome as Dr. Shmuylovich admitted that he had never conducted PD with the type of photodynamic illuminator claimed in this case. RIB at 96; RRB at 47-48. Similar to the holding in *Allergan USA, Inc. v. MSN Lab's Priv. Ltd.*, 111 F.4th 1358, 1376 (Fed. Cir. 2024), "reliance on such [expert] testimony, untethered to the inventors' own description of the invention, would improperly take the written description inquiry outside the four corners of the specification."

b. Fluence

Fluence, as discussed above, is a function of irradiance multiplied by time. Here, the ID commits the same error in relying on Sun Pharma's expert testimony, stating that, "[b]ecause visualizing fluorescence requires only seconds of light exposure, CX-0013C, Q/A 168-69, a skilled artisan would understand that the PDT-sufficient fluence applied for a shorter duration would activate PpIX for PD." ID at 131. Just as the ID commits error by importing the time limitation, here, the ID again ignores the specification and the claims to rescue the asserted claims from invalidity. There is no disclosure in the specification of what fluences are appropriate for PD, as the ID acknowledges. ID at 130. As with illumination time, the ID concludes "a skilled artisan would understand that the PDT-sufficient fluence applied for a shorter duration would activate PpIX for PD." *Id.* As with illumination time, discussed above, there is nothing in the specification that explains that lower fluences or illumination times are necessary to support PD, let alone what those amounts are.

c. Wavelength

The ID errs by allowing expert testimony to identify a specific value or values for use in PD, when the specification references a broad range of wavelengths of light for use in PDT. ID at 129; RIB at 100-101; RRB at 47. There are several errors in the ID. First, the ID relies on a portion of the specification that expressly calls out specific wavelengths of light as being useful for *treatment*, not diagnosis. ID at 129-30; RIB at 94-95 (citing JX-0001, 4:2-13). But disclosure of wavelengths useful in treatment does not demonstrate the inventors were in possession of wavelengths useful in diagnosis. *See LizardTech*, 424 F.3d at 1345-46 (affirming no written description when the claims were directed to nonseamless DWT transformation and the specification only provided support for seamless DWT transformation). As the testimony at trial confirmed, the wavelength most useful for creating fluorescence—405 nm—is not identified in the specification as useful for treatment, let alone for diagnosis. RIB 101.

Second, even if one ignores this error, by claiming a broad range of wavelengths (400-700 nm) and stating that certain are effective for treatment, the specification runs afoul of the Federal Circuit’s blaze marks case law. RIB at 101; RRB at 47; *In re Ruschig*, 379 F.2d 991, 995 (C.C.P.A. 1967); *see also Novozymes A/S v. Dupont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013). The Federal Circuit has found that allowing an expert to identify a preferred variable from among many does not satisfy the blaze marks case law. In *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000), the Federal Circuit affirmed a finding of invalidity where the claims were directed to a particular ratio which could be “pieced together” from certain disclosures, but was not explicitly emphasized. (“Although the examples provide the data from which one can piece together the $C_{\max}/C_{24}$ limitation, neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasizes the $C_{\max}/C_{24}$ ratio.”). The ID once again relies on expert testimony to arrive at its conclusion. ID at 129-30. Third, the

test for written description is whether the inventors themselves had possession, as demonstrated by the specification. “[T]he fact that an invention may be enabled does not mean it is adequately described, and vice versa.” *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1382 (Fed. Cir. 2019). By relying on expert testimony to pluck a working blaze mark from amidst the forest of disclosure, the ID commits legal error. *Id.* (“there is no similar hook or disclosure in the specification that an ordinarily skilled artisan can rely on to understand that the inventor possessed effective uncoated PPI.”).

d. Incubation Time

The ID errs by ignoring yet another indication that the specification’s examples do not work for, and in some cases undermine, PD. The specification’s only example for applying ALA and incubating on a patient’s skin teaches a 14–18-hour incubation time. RIB at 100 (citing JX-0001, 9:6-13). During the hearing, Sun Pharma called Dr. Montserrat Foguet, Biofrontera’s head of regulatory affairs and a scientist, affirmatively and adversely in its case, and posed questions regarding Dr. Foguet’s patents on ALA formulations. On the one hand, the ID relies on that testimony for the legally and factually erroneous proposition that, because ***Dr. Foguet and her patents*** demonstrated possession of PD, the inventors must have been in possession as well. ID at 126 (citing to Tr. (Foguet), 372:4-14 questions regarding Dr. Foguet’s U.S. Patent Number 11,540,981); ID at 130 (citing to Tr. (Foguet), 375:2-14, posing questions regarding Dr. Foguet’s WO 2024/209064A1). On the other hand, the ID adopts Sun Pharma’s characterization of Dr. Foguet’s testimony that the Asserted Patents’ 14-18 hour incubation time was “attorney argument through its fact witness who inserted the new theory in response to a closed-ended question.” ID at 130. This is factual error. Dr. Foguet’s testimony was in response to open-ended questions and came only after Sun Pharma’s adverse direct questions opened the door to Dr. Foguet’s knowledge of PD by asking her questions about her patents. Sun Pharma did not object to the redirect questions

and thus waived the argument that the questions were improper. Expert testimony and Sun Pharma's own exhibits corroborated Dr. Foguet's testimony that the long incubation times recited in the Asserted Patents were incompatible with PD.²² Likewise, the ID faults Biofrontera for not including in its pre-hearing brief reference to testimony that only came into evidence *after Sun Pharma opened the door to her testimony during adverse examination* of Dr. Foguet using her own patents, which were not even included on Sun Pharma's exhibit list. ID at 130. Of course, Biofrontera cannot, and was under no obligation to, anticipate what Sun Pharma would ask witnesses that it called adversely.

As with wavelength, fluence, and illumination time, the ID once again ignores the express teaching of the specification and pieces together a working example of an important PD variable from expert testimony, prior art articles, and conjecture. ID at 131. In particular, the ID states that POSAs "were aware that fluorescence can be detected following shorter incubation times, e.g., 3 hours (CX-1084.4, CX-1076.2, CX-1079.3), and 4-6 hours (CX-0342.2, CX-0343.11)." ID at 131. As with wavelength, fluence, and illumination time, this is legal error to rely on expert testimony and third party articles "untethered to the inventors' own description of the invention." *Allergan*, 111 F.4th at 1376; see also *Bos. Sci.*, 647 F.3d at 1366; *Purdue Pharma*, 230 F.3d at 1326.

e. Multiple Wavelengths

The ID's errors with respect to the multiple variables necessary to conduct PD compound atop one another. Instead of filling in the specification's gap on a single variable, as the Federal Circuit did in *Capon*, the ID accepts an illumination time not even hinted at by the specification,

²² Over Biofrontera's motion *in limine* objection, Sun Pharma submitted an expert declaration from its expert, Dr. Heather Roberts, MD, in the parallel IPR. CX-1063. The ID relies on that declaration. ID at 118, 121. At her IPR deposition, which occurred after the hearing, Dr. Roberts testified "So I have never used the 14-to-18-hour incubation time. Anytime the LEVULAN is on the skin for more than six hours, it gets into the sheath around the nerve, and the patient will be in exquisite agony while we do the treatment." Ex. 1, Tr. (Roberts, July 25, 2025), 87:12-88:11.

and then layers on assumption after assumption until it arrives at something approaching a working example of PD. This is a significant departure from the Federal Circuit’s precedent on written description and legal error.

2. The ID Errs by Misconstruing the Law Around “Generic Claims” and, Under the Properly Applied Standard, Biofrontera’s Analysis Addresses the Disputed Claims, Including the System and Method Claims

The ID errs by adopting Sun Pharma’s flawed argument that “[t]he inventors never claimed to have invented photodynamic diagnosis . . . [r]ather, the inventors invented an adjustable illuminator that provides uniform illumination and ‘is suitable for use in photodynamic dynamic therapy and diagnosis.’” ID at 126 (quoting JX-0001 at 1:17-20). It is black letter law that “the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of *the claimed subject matter* as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (emphasis added). “The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed.*” *In re Hunter*, 1995 WL 364375, at *5 (Fed. Cir. 1995) (emphasis in the original); *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295 (Fed. Cir. 2002) (“the disclosure must show [the inventor] had invented each feature that is included as a claim limitation.”); RRB at 42. The claimed subject matter is not “an adjustable illuminator,” as the ID has it, but rather a “[a] [system for / method of] photodynamically diagnosing or treating a patient.” RRB at 41. Pursuant to the claim construction order, this preamble is limiting.

Second, the claims are directed to a *generic invention* under the Federal Circuit’s precedents. RIB at 92 (citing *Juno*, 10 F.4th at 1335; RRB at 41-42. The ID commits legal error by concluding that “generic invention” has a colloquial meaning opposite to “specific” rather than a meaning under the Federal Circuit’s precedents. ID at 127 (“The system Asserted Claims recite an illuminator with *specific features*, such as (1) five panels; (2) connected by hinges...”). In

particular, the claim limitations place Sun Pharma's claims in the category of a "generic invention" because it recites a "function"—conducting photodynamic therapy and photodynamic diagnosis—in the limiting preamble. *Juno*, 10 F.4th at 1335. To satisfy written description for a generic invention using functional language in the preamble, "the written description 'must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.'" *Juno*, 10 F.4th at 1335 (quoting *Ariad*, 598 F.3d at 1349). The "claimed result," in this case, would be "photodynamic diagnosis" and "photodynamic therapy." *See id.* The ID ignores this case law and, in a statement that proves too much, states that applying PDT disclosures would be sufficient: "Biofrontera divides PDT and PD, ignoring that persons of ordinary skill would readily apply PDT disclosures to implement PD using the disclosed illuminator." ID at 128. Sun Pharma's claims, not Biofrontera, divided PDT and PD and, having done so, must provide written description support for each aspect of its claimed invention.

The ID errs when it faults Biofrontera for failing to distinguish adequately between system and method claims. First, as a factual matter, the system claims actually incorporate the very concepts related to wavelength, fluence and time exposure under dispute. RIB at 91-92 (citing JX-0001, claim 5 and JX-0002, claim 4 related to wavelength; JX-0001, claim 3 and JX-0002, claim 2). Fluence, which incorporates time of exposure, and wavelength are at the core of the dispute about whether there is adequate written description support. As Biofrontera explained, the asserted claims, including the independent system claims, must encompass at least the ranges of wavelength and fluence recited in the dependent claims. As to fluence, the expert testimony confirmed that the range of fluence would not work for photodynamic diagnosis. RIB at 94, 97-99; RRB at 53, RX-0007C, Q/A 111, 132, 232, 252-256, 302. The broad range of claimed wavelengths does not show

possession of PD. *Purdue Pharma*, 230 F.3d at 1326 (“[O]ne cannot disclose a forest ... and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the [specification].”). The ID does not address this fact or argument. While the ID concedes that written description is necessary and indeed, provided, for PDT, the ID incorrectly concludes that description is not necessary for PD. Between the limiting preamble and the dependent claims, therefore, both the system and method claims must provide adequate written description for time, fluence, and wavelength.

Second, the failure to consider the Federal Circuit’s “generic invention” case law also infects other findings within the ID related to alleged deficiencies in Biofrontera’s analysis. ID at 127. The Federal Circuit’s case law makes clear that, when there is a generic invention claim that recites *a function*, such as photodynamic diagnosis, the court looks to the specification to see whether there is adequate written description to support that claimed function. RIB at 92; RRB at 41-42; *Juno*, 10 F.4th at 1335 (quoting *Ariad*, 598 F.3d at 1351). Indeed, in examining generic claims, the Federal Circuit has found generic claims directed to both compositions of matter or systems as well as method claims invalid for failing to satisfy the written description requirement when the specification did not include adequate written description for the claimed function. *Lizardtech*, 424 F.3d at 1345-46 (applying generic case law to method claims for data compression). At a minimum, even if the Commission were to find adequate written description support for the system claims, a failure to distinguish between system and method claims does not moot the arguments as to the method claims. *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1383 (Fed. Cir. 2011) (holding failure to distinguish applicable to method claims, but considering arguments as applied to method claims).

Finally, the ID commits error on both the law and the facts when it dismisses Biofrontera's arguments, stating that the written description inquiry must be analyzed on a claim-by-claim basis. ID at 125. The ID misreads *In re Hunter*, 1995 WL 364375, at *5 (Fed. Cir. 1995), which states that "one must analyze *each claim* for compliance with the written description requirement." That is what Biofrontera did. *Each claim* of the asserted patents includes the limitation directed to a system or method for photodynamically diagnosing a patient. Biofrontera analyzed the relevant limitations in each claim, which is the limiting preamble, read in view of the specification, and further informed by the dependent claims. Biofrontera's analysis draws upon the relevant dependent claims directed to wavelength, time, and fluence. RIB at 91-92. Instead, the ID reads *In re Hunter* to require a limitation-by-limitation analysis, which is not required. As Biofrontera did in its briefing, the *In re Hunter* opinion proceeds by analyzing the possession of only the limitations in dispute and relevant to the seven disputed claims: simultaneous filling and nonsimultaneous filling. *Id.* at *7-8. Instructive for this case, where PDT is disclosed but PD is not, the Federal Circuit confirmed the invalidity of the claims for failing to provide written description support when the claims were directed to nonsimultaneous filling but the specification only provided description of simultaneous filling. *Id.* at *8. The Federal Circuit has consistently analyzed written description by reference to the disputed limitations common to a set of claims, just as Biofrontera did here. *See, e.g., Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab 'ys Inc.*, 923 F.3d 1368, 1375, 1384 (Fed. Cir. 2019) (holding nine asserted claims from two related patents invalid for failure to satisfy written description based on analysis of representative claims); *Ariad*, 598 F.3d at 1340-41 (holding four claims invalid by analyzing common element); *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997) (same).

V. THE ID ERRS IN FINDING THAT BIOFRONTERA INFRINGES CLAIMS 8, 17, AND 18 OF THE '512 PATENT AND CLAIMS 16, 17, 19, AND 21 OF THE '028 PATENT²³

A. The ID Errs in Finding that Biofrontera Induces Healthcare Providers to Infringe Limitation 8[c] of the Asserted Method Claims of the '512 Patent

The ID clearly errs, legally and factually, in finding that Biofrontera infringes the Asserted Method Claims of the '512 Patent because Biofrontera does not induce healthcare providers (“HCPs”) to use “at least five panels” of the RhodoLED[®] XL to treat patients, as required by limitation 8[c]. Claims 8, 17, and 18 of the '512 Patent are method claims—they recite “[a] method of photodynamically ... treating a patient” by following certain treatment steps, including limitation 8[c], which requires “*uniformly illuminating a treatment surface of the patient with light sources disposed on the **at least five panels** of the illuminator.*” JX-0001, Claim 8. The ID improperly finds that Biofrontera indirectly infringes the Asserted Method Claims by inducing HCPs to use all five panels of the RhodoLED[®] XL to treat patients. ID at 28-31, 36-43. There is no dispute that the RhodoLED[®] XL is a five-panel illuminator. But Biofrontera only *recommends* for HCPs to use *three* adjacent panels to treat patients, which does not infringe limitation 8[c]. In similar contexts, the Federal Circuit has held that the fact that a device is *capable* of infringing (*i.e.*, the RhodoLED[®] XL has five panels) does not necessarily mean the accused infringer *intends*

²³ The ID also finds that Biofrontera infringes the Asserted Claims of both Asserted Patents with respect to the “nested hinges” claim term (all Asserted Claims), the “a recess” claim term (claims 17 and 18 of the '028 Patent), and the “within approximately four inches” claim term (claims 1, 2, 4-6, and 20-21 of the '028 Patent). Biofrontera does not petition for review of the ID’s noninfringement findings on any of these claim terms or issues, but reserves its right to pursue these noninfringement positions in other tribunals (including in federal district court) or to the extent the Commission or any appellate court construes any of these claim terms or phrases to have a different meaning than the ALJ’s constructions.

for the device to be used in an infringing manner (*i.e.*, Biofrontera only encourages HCPs to use three adjacent panels).

Induced infringement requires proof that: (1) there is underlying direct infringement; (2) respondent intended to cause the direct infringement; and (3) respondent knew the acts of the directly infringing party would constitute direct infringement. 35 U.S.C. § 271(b); *see also Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 843 F.3d 1315, 1332 (Fed. Cir. 2016). The parties’ dispute on this issue centers on the second inducement requirement—whether Biofrontera *intends* for HCPs to use all five panels of the RhodoLED® XL to treat patients.

The Federal Circuit has made it clear that the intent element of inducement requires “evidence [of] ‘intent to *encourage* infringement.’” *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (quoting *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009)) (emphasis in original). In contrast, merely describing an infringing use or presenting an infringing use as an option to the user, is not the same as encouraging, recommending, or promoting “an infringing use, or suggesting that an infringing use ‘should’ be performed.” *Takeda*, 785 F.3d at 630-631; *see also HZNP Medicines LLC v. Actavis Lab’ys UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019) (“Merely describing the infringing use, or knowing of the possibility of infringement, will not suffice; specific intent and action to induce infringement must be shown.”); *Vita-Mix*, 581 F.3d at 1328 (“[T]he mere knowledge of possible infringement will not suffice.”).

The ID’s finding that Biofrontera induces HCPs to infringe the Asserted Method Claims is clear error because it misunderstands material facts about how Biofrontera markets or instructs HCPs to use the RhodoLED® XL. And the ID commits multiple legal errors by misapplying Federal Circuit precedent on what constitutes intent. For example, the ID fails to distinguish

between the *capabilities* of the device and how Biofrontera actually *encourages* HCPs to use the device. The ID relies on various statements in Biofrontera’s documents that merely describe the RhodoLED® XL as a PDT device that has five panels as evidence of intent. ID at 29 (citing JX-0086.7 and stating “[t]he User Manual notes that ‘RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light.’”); 30 (citing JX-0073C as evidence that patients have been treated using “all five RhodoLED® XL panels”); 38-39 (citing various documents and testimony for the point that the RhodoLED® XL must be used “in accordance with the instructions in the User Manual”). It is clear legal error to rely on those objective descriptions as evidence of Biofrontera’s intent because they merely describe the structure and function of the device without encouraging HCPs to use a specific number of panels when treating patients. *Takeda*, 785 F.3d at 631 (“Merely describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use should be performed”) (citation modified).

The ID also misconstrues the instructions from the RhodoLED® XL user manual on how to operate the device as evidence of Biofrontera’s intent. *See, e.g.*, ID at 28-30. The RhodoLED® XL user manual is clear: Biofrontera’s *intent* is to *encourage* the use of three adjacent panels. *See, e.g.*, JX-0086.17 (“[I]t must be ensured that at least **three adjacent panels** are used”). The ID overlooks that critical fact, never even addressing the user manual’s *instruction* to use three adjacent panels and instead adopting Sun Pharma’s mischaracterizations of the document. For example, the ID relies on the RhodoLED® XL user manual’s step-by-step instructions on how to use the device to treat patients. ID at 28-29 (quoting JX-0086.9). The ID finds that “steps 5, 7, and 9 instruct positioning the patient and the lamp, and starting the illumination.” *Id.* at 29. But the ID

overlooks step 6, which **instructs** HCPs to “[s]elect active panels” **before** treating a patient, which begins three steps later in step 9:

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

Id.; see also JX-0086.9. Before step 9, the illuminator is not being used for treatment but rather is on at a low power for adjustment. JX-0086.9. Nothing in the step-by-step instructions shows an intent to encourage HCPs to use five panels to treat patients—to the contrary, HCPs are expressly instructed to **choose** the number of active panels **before** initiating treatment, as long as at least three adjacent panels are used. JX-0086.9; RX-0011C (Ehrenreich RWS), Q/A 51, 57, 104-110; Tr. (Ehrenreich), 543:21-545:15; Tr. (Shmuylovich), 154:22-155:20; Tr. (Thompson), 107:7-108:19, 134:18-135:16; RX-0004C (Luebbert WS), Q/A 102.

Likewise, the ID clearly errs by relying on “chapter 8.4.5” of the RhodoLED® XL user manual (referenced in “step 6”) as evidence of intent to encourage HCPs to use five panels:

8.4.5 Selecting Active LED Panels

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

ID at 29-30; see also JX-0086.16. Chapter 8.4.5 merely describes the structure and function of the device without encouraging HCPs to use a specific number of panels, which does not amount to

intent under Federal Circuit precedent. *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023) (“In order to support inducement liability, instructions may not merely describe an infringing mode; they must ‘evidence “intent to encourage infringement.”’)” (quoting *Takeda*, 785 F.3d at 631). And Chapter 8.4.5 explains that HCPs can *choose* which panels are “activated” or “deactivated,” not that all five panels should be active for treatment.²⁴ JX-0086.16; RX-0011C (Ehrenreich RWS), Q/A 51, 57, 104-110; Tr. (Ehrenreich), 543:21-545:15; Tr. (Shmuylovich), 154:22-155:20; Tr. (Thompson), 107:7-108:19, 134:18-135:16; RX-0004C (Luebbert WS), Q/A 102.

The ID also errs by adopting Sun Pharma’s mischaracterization of the word “default” in the RhodoLED® XL user manual. ID at 29-30. Contrary to the ID’s finding, “default” does not mean that patients are *treated* with all five panels as some sort of automatic or default setting. Rather, the RhodoLED® XL user manual and other documents are clear that “default” means that when the RhodoLED® XL is initially powered on by a user (*i.e.*, plugged in and turned on via the user interface), all five panels are active. JX-0086.16-17; RX-0011C (Ehrenreich RWS), Q/A 105-107; Tr. (Shmuylovich), 154:22-155:20; Tr. (Thompson), 107:7-108:19, 134:18-135:16; Tr. (Ehrenreich), 543:25-545:15. In other words, the “default” status of all five panels being active at a low power level is what happens *before* a patient treatment session is started—HCPs have the option to choose how many panels stay active when they are ready to start a treatment, as long as three adjacent panels are used. Biofrontera never encourages HCPs to leave all five panels in the active state for treatment purposes—they expressly instruct and encourage the use of three adjacent

²⁴ The ID also shows Figure 10 from Chapter 8.4.5, which merely illustrates what the software displays when “all panels are activated,” without using any language to encourage HCPs to activate all five panels for treatment. ID at 29; JX-0086.16. And the ID omits Figure 12 from Chapter 8.4.5, which illustrates what the software shows when a panel is *deactivated*. JX-0086.16.

panels, not all five. JX-0086.16; RX-0011C (Ehrenreich RWS), Q/A 51, 57, 104-110; Tr. (Ehrenreich), 543:21-545:15; Tr. (Shmuylovich), 154:22-155:20; Tr. (Thompson), 107:7-108:19, 134:18-135:16; RX-0004C (Luebbert WS), Q/A 102.

Even setting those material fact errors aside, the Federal Circuit has held that “arguing that the ‘default’” configuration of an accused product *necessarily* “leads to infringing use ... is insufficient as a matter of law.” *Vita-Mix*, 581 F.3d at 1329. Thus, the ID also committed clear legal error by relying on the “default” configuration of the RhodoLED® XL to find that Biofrontera *intends* for HCPs to infringe the Asserted Method Claims. *Id.* (holding that “[a]lthough the ‘default’” configuration of the accused product “may lead to infringing use under certain conditions, there is no evidence that [the accused infringer] *intends* users to maintain the” infringing configuration of the accused product).

The ID also relied on a purported “warning” message that appears if HCPs start a treatment session with fewer than five panels:

11	Not all panels are activated. Please check whether the surface to be treated is adequately irradiated. If necessary, reposition the patient or activate more panels!	Message before starting a treatment if not all LED units are active
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ID at 30, 42 (citing JX-0066C.29). This is also clear error because this message never uses the word “warning,” does not use any language to encourage HCPs to use *five* panels as required by the claims, merely informs HCPs that they should ensure the patient’s treatment surface is adequately illuminated with the panels that are active, and in no way stops HCPs from using fewer than five panels. JX-0066C.29; RX-0011C, Q/A 57, 105-106, 133; Tr. (Thompson), 107:7-108:19, 134:18-135:16. Indeed, Biofrontera has expressly categorized this message under “[i]nformation messages,” which are different from *warning* messages:

5.2 User messages

The software enables the display of various user messages. They can be divided into three categories:

- 1) Information messages
- 2) Warning or error messages
- 3) Queries

JX-0066C.29. Thus, the *intent* of this message is to *encourage* HCPs to “check whether the surface to be treated is adequately irradiated,” and at most it encourages HCPs to “activate more panels” if the surface is not adequately irradiated, without specifically encouraging HCPs to use *five panels*. *Id.*

The ID clearly errs in finding that this message encourages HCPs to use five panels, but it goes even further when it concludes from Mr. Thompson’s general testimony about “warning” messages in the context of source code that the specific message from the RhodoLED® XL is used “to alert the user that they are doing something that is not intended.” ID at 30 (citing Tr. (Thompson) at 121:18-122:5, 131:3-132:15). The ID’s finding that Biofrontera does “not intend[.]” for HCPs to use fewer than five panels of the RhodoLED® XL to treat patients is flatly incorrect and inconsistent with Biofrontera’s express recommendation to use *three panels* to treat patients. And the ID commits clear legal error by relying on this message because it reads in if/then form: “*If* necessary, [*then*] reposition the patient or activate more panels.” JX-0066C.29. The Federal Circuit has held that language that “operates in an ‘if/then’ manner ... does not encourage infringement.” *HZNP*, 940 F.3d at 702. For that additional reason, the ID clearly errs.

Further, the ID relies on various marketing materials, including a promotional video in which all five panels of the RhodoLED® XL were used for PDT. ID at 30 (citing JX-0073C (Ted Lain Video)); 39-41 (citing JX-0104, JX-0105C, JX-0078). But these marketing materials never *encourage or instruct* HCPs to use five panels to treat patients. RX-0011C (Ehrenreich RWS), Q/A 118-133. They merely show that the device has five panels, without encouraging HCPs to use

a specific number of panels when treating patients, which does not amount to inducement. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1323-1324 (Fed. Cir. 2009) (finding no inducement where a medical device “can be used in an infringing manner ... as opposed to the noninfringing manner disclosed in” instruction manual) (citation modified).

The ID also misinterprets language from the Ameluz[®] label and incorrectly finds that Biofrontera “focus[ed] on the label alone” for inducement issues. ID at 42. Biofrontera never argued that the inducement issues here should be decided based on the label alone. *See, e.g.*, RIB at 23 (discussing why RhodoLED[®] XL user manual “reinforces that HCPs may *choose* to use five panels and that three adjacent panels *must* be used”); 23-24 (discussing why “FDA correspondence, internal discussions at Biofrontera, and other marketing or promotional materials,” including the video of Dr. Ted Lain, do not show that Biofrontera has induced HCPs to infringe); *see also* RRB at 7 (explaining that Biofrontera’s marketing materials “merely demonstrate that the device *has* five panels, not that all five should be used”); 8 (discussing RhodoLED[®] XL user manual and the purported “warning message” relied on by Sun Pharm and the ID). And the ID’s apparent disregard of ***binding Federal Circuit precedent*** on inducement law, whether from pharmaceutical cases or not, is clear legal error. Indeed, the Federal Circuit has relied on inducement precedent from pharmaceutical cases in non-pharmaceutical cases. *See, e.g.*, *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, 30 F.4th 1109, 1120 (Fed. Cir. 2022) (relying on *Takeda*, 785 F.3d at 630). Thus, the difference between non-pharmaceutical cases and pharmaceutical cases is the type of evidence that may be considered—there is no difference in the legal standards on inducement. *See, e.g.*, *Vita-Mix*, 581 F.3d at 1328-1329 (non-pharmaceutical case holding that “the mere knowledge of possible infringement will not suffice” and that “product instructions do not evidence a specific intent to encourage infringement” when they recommend a

non-infringing use); *Exergen*, 575 F.3d at 1323 (finding no inducement where a medical device “can be used in an infringing manner ... as opposed to the noninfringing manner disclosed in” instruction manual) (citation modified).

In any case, the ID’s analysis of the Ameluz® label is limited to the following excerpt:

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

ID at 42 (citing JX-0074.4). The ID’s finding that this language means “[t]hree is the minimum and five is within the ‘recommended number of panels,’” is clear error because this language “recommend[s]” HCPs to use “3 adjacent panels,” while “5 panels” is presented as *optional*. ID at 42; *see also* JX-0074.4; RX-0011C, Q/A 95-98.

The ID also clearly errs in finding that “the only technical data provided is for five-panel treatments” and that “Biofrontera does not provide examples in its promotional and instructional materials where fewer [than five] panels are recommended.” ID at 39, 42. Biofrontera *does* “provide examples” in which “fewer [than five] panels are recommended,” as discussed above: the RhodoLED® XL user manual and the Ameluz® label “*recommend[]*” the use of *three panels*, and discuss the illumination area of the device when three panels are used. RX-0011C, Q/A 114-133; Tr. (Shmuylovich), 147:8-151:23; JX-0074.4; JX-0086.17.

Further, as to “technical data ... for five-panel treatments,” Biofrontera’s illumination data, which was submitted to the FDA, expressly relied on data obtained from *three* panels. JX-0067C.2-4; RX-0011C, Q/A 131-133; JX-0009C (Lyons) at 47:16-48:11. Regardless, the ID commits clear legal error by relying on non-public FDA correspondence and data in the context of inducement. ID at 43 (citing JX-0067C). Indeed, the ID never addresses the Federal Circuit case law Biofrontera cited, which expressly held that “nonpublic statements,” including “FDA

submissions,” “are not available to downstream users and therefore cannot cause inducement.” *Metacel Pharms. LLC v. Rubicon Rsch. Priv. Ltd.*, 2025 WL 1178384, at *4 (Fed. Cir. Apr. 23, 2025); *see also Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1324 (Fed. Cir. 2012) (circumstantial evidence, including FDA materials, offered to show specific intent could not overcome a clear omission of an infringing instruction, precluding an inducement finding).

Finally, the ID finds that Biofrontera’s VP of sales and marketing testified that certain marketing slides, including an internal draft, were “presented to third-party customers to advertise the device’s features, including five panels.” ID at 41 (citing JX-0010C (Baldyga Dep. Tr.) at 44:18-21, 45:7-11; JX-0078); 43 (citing JX-0010C (Baldyga Dep. Tr.) at 22:20-23:8, 20:4-14; JX-0105C). But Mr. Baldyga never testified that Biofrontera encouraged HCPs to use a specific number of panels to treat patients, he merely agreed that the RhodoLED® XL “includes five panels.” JX-0010C (Baldyga Dep. Tr.) at 22:20-23:8, 20:4-14, 44:18-21, 45:7-11. And contrary to the ID’s finding, Mr. Baldyga was never asked if the specific talking point about the use of “5 panels” referenced in JX-0105C were communicated to customers. ID at 43; *see also* JX-0010C (Baldyga Dep. Tr.) at 20:4-14; 22:20-23:8.

Accordingly, the ID clearly errs in its interpretation of material facts and Federal Circuit precedent in finding that Biofrontera induces infringement of the Asserted Method Claims.

B. The ID Errs in Finding that Biofrontera Infringes the “Individually Configurable” Limitation of Claims 16, 17, 19, and 21 of the ’028 Patent

The ID clearly errs in finding that Biofrontera infringes claims 16, 17, 19, and 21 of the ’028 Patent because the RhodoLED® XL’s panels are not “individually configurable to control illumination from each of the five panels,” as required by limitations 16[g] and 21[e]. The phrase “individually configurable to control illumination from each of the five panels” was construed to mean “the power output and/or light intensity of each panel can be individually controlled.” Order

No. 18 at 40. The ID finds that the RhodoLED[®] XL infringes for three distinct reasons: (1) because the device’s panels can be individually turned on or off; (2) because, during manufacturing in Germany, each panel’s light intensity can be calibrated and set; and (3) because, in the context of device maintenance (but not treatment), the device’s lights can be temporarily adjusted. That is clear legal error.

First, regarding turning panels on and off, the ID errs because it reads the “individually configurable” limitation to have two different and inconsistent meanings. For purposes of infringement, the ID finds that because the lights on the RhodoLED[®] XL’s panels can be turned on and off, Biofrontera infringes. ID at 69-71. But in the context of obviousness, the ID finds that Larsen’s disclosure of light sources on panels that can be “switched ON or OFF” does *not* render this limitation obvious. ID at 114-115. The ID’s conflicting applications of the *same* claim phrase and construction is clear legal error—it is black-letter law that “[c]laim terms must be construed the same way for the purpose of determining invalidity and infringement.” *TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017); *see also Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381 (Fed. Cir. 2021) (“We have repeatedly rejected efforts to twist claims, ‘like “a nose of wax,”’ in ‘one way to avoid [invalidity] and another to find infringement’”) (quoting *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (citation omitted)); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (“It is axiomatic that claims are construed the same way for both invalidity and infringement.”). *Supra* § IV.B.3.

Second, for calibrating lights during manufacturing or adjusting lights [REDACTED], the ID’s finding that Biofrontera infringes the “individually configurable” limitation relies on a clearly erroneous application of the construed phrase in the context of the claims as a whole. The

ID finds that the RhodoLED® XL infringes the “individually configurable” limitation because the individual panels can be turned on and off, *and* because the intensity of light of each panel can be adjusted in [REDACTED]. ID at 69-71. But the “individually configurable” limitation must be read in the context of the claims as a whole, not in a vacuum. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (“[T]he context in which a term is used in the asserted claim can be highly instructive”); *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (“While certain terms may be at the center of the claim construction debate, the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms”).

Here, the “individually configurable” limitation must be read together with the limiting preamble, which recites “[a] system for photodynamically diagnosing or treating a patient.” JX-0002, claims 16, 21; Order No. 18 at 29. Read together, the claims require controlling “the power output and/or light intensity of each panel” of an illuminator that is a “system for photodynamically ... treating a patient.” The ID’s finding that controlling the light intensity of each panel in maintenance or service mode (*i.e.*, when the device is not being used as a system for photodynamically treating a patient) infringes is clear error because it fails to read the “individually configurable” limitation in the context of the claims as a whole. ID at 69-71; *see also* CX-0017C, Q/A 30-35; JX-0118C.7; JX-0086.25; RX-0011C, Q/A 185-191; RX-0002C (Foguet WS), Q/A 69-81; Tr. (Thompson), 119:17-120:22, 133:2-19.

VI. THE ALJ MADE ERRONEOUS AND PREJUDICIAL PRE-HEARING RULINGS

Order No. 25 commits legal error by admitting and relying on declarations from an ongoing IPR. The ID compounds that error by relying on the Roberts declaration in support of its obviousness conclusions. ID at 118, 121. Biofrontera moved to exclude the testimony of Dr. Roberts and Dr. Bretschneider in its Motion *in Limine* No. 2. This motion was denied in Order No.

25 on the basis that “declarations filed during an IPR is [sic] part of the intrinsic record of the that [sic] patent. *Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1266-67 (Fed. Cir. 2012) . . .” Order No. 25, 5-6. However, *Krippelz* is not supportive of the proposition it is cited for. The declaration at issue in *Krippelz* was submitted as part of a *completed* post-grant proceeding. *Krippelz*, 667 F.3d at 1266-67. Further, the declarant in that case also appeared and testified at trial. *Id.* In contrast, Dr. Roberts was not deposed nor did she appear at the evidentiary hearing. Additionally, Order No. 25 provides no supporting case law or rationale as to why a case involving a completed reexamination proceeding should be applicable to the record in a still-pending IPR. ITC ALJs and the Patent Office have determined that reliance on declarations from witnesses that do not testify at trial is improper. *See, e.g., Certain Wiper Blades*, 337-TA-816, Order No. 97 at 1-2 (Sep. 26, 2013) (granting staff’s motion to exclude declarations from witnesses who could not testify at the evidentiary hearing); *Certain Semiconductor Devices & Prods. Containing the Same*, Inv. No. 337-TA-1414, Order No. 55 at 1 (May 15, 2025) (granting motion to “exclude declarations from witnesses who were not identified on Respondents’ witness list, did not submit witness statements, and are not available for cross-examination on the witness stand”). Likewise, reliance on materials from an ongoing IPR is improper. *See Ex Parte Kelly K. Houston*, No. Appeal 2017-006142, 2017 WL 2303255, at *6, n.1 (P.T.A.B. May 24, 2017) (“Appellant’s contention that the current reexamination proceeding can be used to construe the claims, and in particular its reliance on *Krippelz* . . . is misplaced.”). Both because Dr. Roberts was not present at trial and because the declaration is part of an ongoing IPR proceeding, Order No. 25’s decision to admit the Roberts

and Bretschneider declarations was legal error and the ID's reliance on the Roberts declaration was therefore improper and prejudicial.

VII. CONCLUSION

The Commission should review and reverse the erroneous conclusions of law and fact in the Order No. 18 and ID and find: (i) the asserted claims are indefinite; (ii) the asserted claims are invalid as obvious; (iii) the asserted claims are invalid for failing to satisfy the written description requirement; (iv) claims 8, 17, and 18 of the '512 Patent and claims 16, 17, 19, and 21 of the '028 Patent are not infringed; and (v) the pre-trial ruling that permitted reliance on the Roberts declaration was erroneous and prejudicial.

PUBLIC VERSION

Dated: November 17, 2025

Respectfully submitted,

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PUBLIC VERSION

Appendix A

APPENDIX A:**TABLES OF CLAIM ELEMENT IDENTIFIERS**

Asserted Claims from U.S. Patent No. 11, 446, 512 ('512 Patent)	
Identifier	Claim/Element
Claim 1	
1[p]	A system for photodynamically diagnosing or treating a patient, comprising:
1[a]	an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels,
1[b]	light sources disposed on surfaces of the at least five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
1[c]	one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,
1[d]	wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.
Claim 2	
2[p]	The system of claim 1,
2[a]	wherein the illuminator is configured to uniformly illuminate the treatment surface when the treatment surface is at a distance of two to four inches from the illuminator.
Claim 3	
3[p]	The system of claim 1,
3[a]	wherein the illuminator is configured to output red light at a dose of about 30 J/cm ² to about 150 J/cm ² .
Claims 4	
4[p]	The system of claim 1,
4[a]	wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm ² to 30 mW/cm ² .
Claim 5	
5[p]	The system of claim 1,
5[a]	wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.
Claim 8	
8[p]	A method of photodynamically diagnosing or treating a patient, comprising:
8[a]	administering 5-aminolevulinic acid (ALA) to the patient;
8[b]	positioning an illuminator proximate to the patient, the illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels; and
8[c]	uniformly illuminating a treatment surface of the patient with light sources

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

Asserted Claims from U.S. Patent No. 11,697,028 ('028 Patent)	
Identifier	Claim/Element
Claim 1	
1[p]	A system for photodynamically diagnosing or treating a patient, comprising:
1[a]	an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
1[b]	light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
1[c]	one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
1[d]	wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
1[e]	wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.
Claim 2	
2[p]	The system of claim 1,
2[a]	wherein the illuminator is configured to output red light at a dose of 30 J/cm ² to 150 J/cm ² .
Claim 3	
3[p]	The system of claim 1,
3[a]	wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm ² to 30 mW/cm ² .
Claim 4	
4[p]	The system of claim 1,
4[a]	wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm.
Claim 5	
5[p]	A method of photodynamically diagnosing or treating a patient, comprising:
5[a]	administering 5-aminolevulinic acid (ALA) to the patient;
5[b]	positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
5[c]	uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,
5[d]	wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

Claim 7	
7[p]	The method of claim 5,
7[a]	wherein the illuminating comprises outputting blue light during at least part of the time when the treatment surface is illuminated.
Claim 9	
9[p]	The method of claim 5, wherein:
9[a]	the illuminator comprises at least three first panels having first widths, at least two second panels having second widths, wherein each of the second widths of the at least two second panels is narrower than each of the first widths of the at least three first panels; and
9[b]	the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side connected to a respective one of the at least three first panels and a second lateral side connected to another respective one of the at least three first panels.
Claim 16	
16[p]	A system for photodynamically diagnosing or treating a patient, comprising:
16[a]	a mobile base supported by at least four wheels;
16[b]	a pillar perpendicular to the base;
16[c]	a controller disposed to be supported by the pillar;
16[d]	an arm mounted to a top portion of the pillar; and
16[e]	an illuminator connected at an end of the arm,
16[f]	the arm being hinged to allow adjustment of a position of the illuminator relative to the base,
16[g]	the illuminator comprising: five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels,
16[h]	light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and
16[i]	one or more fans mounted to at least one of the five panels.
Claim 17	
17[p]	The system of claim 16,
17[a]	wherein one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels are configured to be angled relative to the center panel.
Claim 18	
18[p]	The system of claim 16,
18[a]	wherein the light sources are configured to output blue light during at least part of the time when the treatment surface is illuminated.

Claim 19	
19[p]	The system of claim 16,
19[a]	wherein the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated.
Claim 20	
20[p]	A system for photodynamically diagnosing or treating a patient, comprising:
20[a]	an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the illuminator is configured to output light at a variable irradiance density during treatment; and
20[b]	light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
20[c]	one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
20[d]	wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and
20[e]	wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.
Claim 21	
21[p]	A system for photodynamically diagnosing or treating a patient, comprising:
21[a]	an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and
21[b]	light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,
21[c]	one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,
21[d]	wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,
21[e]	Wherein the five panels are individually configurable to control illumination from each of the five panels, and
21[f]	wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.

CLAIM CONSTRUCTION

Terms & Claims	Parties' Agreed Construction
<p>“uniformly illuminate a treatment surface” / “uniformly illuminating a treatment surface”</p> <p>'512 and '028 Patents: All Asserted Claims</p>	<p>“irradiating light over the active emitting area such that the measured irradiance at a treatment surface of the patient is at least within 60% of the measured maximum”</p>
Terms & Claims	ALJ Moore's Construction
<p>“a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges”</p> <p>'512 and '028 Patents: All Asserted Claims</p>	<p>Not indefinite.</p> <p>“a higher intensity of light is emitted close to the second shorter edges compared to the intensity of light emitted not close to the second shorter edges”</p>
<p>“photodynamically diagnosing or treating a patient”</p> <p>'512 and '028 Patents: All Asserted Claims</p>	<p>Preamble is limiting</p>
<p>“nested hinges on inner side surfaces”</p> <p>'512 Patent: All Asserted Claims</p>	<p>Not indefinite.</p> <p>“hinges that fit on inner side surfaces of adjacent panels”</p>
<p>“a recess”</p> <p>'512 Patent: Claims 17-18</p>	<p>“indentation, small hollow, or cleft”</p>
<p>“within approximately four inches of the treatment surface”</p> <p>'028 Patent: Claims 1, 2, 4-6, and 20-21</p>	<p>“less than or equal to approximately four inches from the treatment surface”</p>
<p>“the five panels are individually configurable to control illumination from each of the five panels”</p> <p>'028 Patent: Claims 16-17, 19, and 21</p>	<p>Not indefinite.</p> <p>Plain and ordinary meaning, which is “the power output and/or light intensity of each panel can be individually controlled”</p>

See Order No. 18; ID at 17.

PUBLIC VERSION

Exhibit 1



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Transcript of Heather J. Roberts, M.D., FAAD

Date: July 25, 2025

Case: Biofrontera, Inc., et al. -v- Sun Pharmaceutical Industries, Inc. (PTAB)

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1 UNITED STATES PATENT AND TRADEMARK OFFICE

2
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4 BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH,
5 BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG
6 Petitioner,

7 v.
8 SUN PHARMACEUTICAL INDUSTRIES, INC.
9 Patent Owner.

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Case IPR2024-01312
Patent 11,697,028

14 ORAL AND VIDEOCONFERENCED DEPOSITION OF

15 HEATHER J. ROBERTS, M.D., FAAD

16 JULY 25, 2025

17 (Reported remotely.)

18 *****

1
2
3 ORAL AND VIDEOCONFERENCED DEPOSITION OF
4 HEATHER J. ROBERTS, M.D., FAAD, produced as a
5 witness at the instance of the Petitioner, taken
6 in the above-styled and -numbered cause on the
7 25th day of July, 2025, A.D., beginning at 9:07
8 a.m. CDT to 12:55 p.m., before Kelly Hassell, RPR,
9 CLR, CSR, in and for the State of Texas, located
10 in San Francisco, California, in accordance with
11 the PTAB Rules of Civil Procedure and the
12 agreement hereinafter set forth.
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1 If counsel could please state their
2 appearances for the record.

3 MR. LARIVEE: I'm Brian Larivee for
4 the Biofrontera Petitioners. With me is James
5 Murphy.

6 MS. HIGGINS: This is Gabrielle
7 Higgins from the Desmarais firm. With me is
8 Dr. Bridget Belcher and Mr. Raymond Habbaz,
9 representing the Patent Owner, Sun Pharma.

10 MR. LARIVEE: Good morning,
11 again --

12 THE COURT REPORTER: I'm sorry.

13 MR. LARIVEE: -- Doctor --

14 THE COURT REPORTER: I'm sorry.

15 I'm Kelly Hassell, Certified
16 Shorthand Reporter, located in Dallas, Texas.
17 The witness is located in San Francisco,
18 California. My Texas CSR number is 5729.

19 If you could raise your right hand,
20 please.

21 (The witness was duly sworn.)

22 THE COURT REPORTER: Thank you.

1 You may proceed.

2 HEATHER J. ROBERTS, M.D., FAAD,
3 having been first duly cautioned and sworn to
4 testify the truth, the whole truth and nothing but
5 the truth, testified on her oath as follows:

6 DIRECT EXAMINATION

7 BY MR. LARIVEE:

8 Q Good morning, again, Dr. Roberts. I'm
9 Brian Larivee from Polsinelli. Again, I'm
10 representing Biofrontera.

11 Are you being represented by
12 counsel today?

13 A Yes.

14 Q And who is representing you?

15 A Desmarais.

16 MS. HIGGINS: To -- to be clear, we
17 are representing the Patent Owner, Sun Pharma.

18 MR. LARIVEE: Okay.

19 Q (BY MR. LARIVEE) And, Dr. Roberts, you
20 understand that you're being deposed today in
21 the -- in the inter partes review numbered
22 IPR 202401312 pertaining to U.S. Patent

1 Number 11,697,028 that is presently before the
2 United States Patent and Trademark Office,
3 correct?

4 A Yes, that is correct.

5 Q And before we get started today, I've
6 got some instructions for you, to try to help the
7 deposition go more smoothly.

8 First, I'm going to be asking you
9 some questions, and you're going to be answering
10 the questions under oath.

11 Do you understand?

12 A Yes, I understand.

13 Q And so you understand you've been
14 sworn -- you've been -- you have been sworn to
15 tell the truth, and the effect is the same as if
16 you were testifying in court, right?

17 A Yes.

18 Q And, now, the court reporter will be
19 taking everything down that is being said here
20 today, so it's important that we don't talk over
21 each other. Instead, you should wait until I
22 finish my question before you start your answer,

1 and I will wait until you finish your answer
2 before starting my next question.

3 Do you understand?

4 A Yes, I understand.

5 Q We'll be taking breaks periodically
6 throughout the day. And if you feel you need a
7 break, for the restroom or for any other reason,
8 please ask. However, if a question is pending, I
9 just would ask that you answer the question before
10 we take the break.

11 Do you understand?

12 A Yes, I understand.

13 Q Sun Pharma's attorneys may be making
14 objections today, which are for the Patent Office
15 to consider at a later date. You're required to
16 answer my questions, even if there is an
17 objection, unless your attorney instructs you not
18 to answer.

19 Is that clear?

20 A Yes, that's clear.

21 Q Now, after the deposition is over, the
22 court reporter will repair -- will prepare a

1 transcript that contains the questions and the
2 answers and the objections. And at that point,
3 you'll have an opportunity to review the
4 transcript and prepare a statement of changes.

5 Do you understand that?

6 A Yes, I do.

7 Q Okay. Finally, this is a remote
8 deposition. You understand that we'll be
9 presenting exhibits on the screen before you,
10 right?

11 A Yes, I do.

12 Q And I will ask the reporter to put up
13 the exhibit and give you control of the exhibit so
14 that you can scroll through it and see what it is.
15 And then I -- after you've had a chance to look, I
16 will direct you to certain areas of the document,
17 and you'll have an opportunity to answer questions
18 about the document. Okay?

19 A Yes. That sounds fine.

20 Q And do you have any paper documents in
21 the room with you this morning?

22 A I have the copies of my declarations.

1 Q Okay. Could you please state your full
2 name for the record?

3 A My full name is Heather Joy Roberts.

4 Q And, Dr. Roberts, have you used any
5 other names professionally?

6 A No, I have not.

7 Q And, Dr. Roberts, is there any reason,
8 such as a physical or mental condition, unusual
9 stress, being under the influence of a substance,
10 that would prevent you from answering my questions
11 fully and truthfully today?

12 A No, there is not.

13 Q Okay. Dr. Roberts, have you ever had
14 your deposition taken before?

15 A Once before.

16 Q And when -- when was that time you had
17 your deposition taken?

18 A That was around 1999.

19 Q And what was the case about?

20 MS. HIGGINS: And I caution the
21 witness not to reveal any confidential information
22 about that case. You can identify the case.

1 A That case was a chemical exposure, and I
2 was called in to give my opinion as to whether the
3 chemical exposure caused a subsequent rash years
4 later.

5 Q (BY MR. LARIVEE) Okay. Do you recall
6 who the parties were in that case?

7 A Yes.

8 Q And who were those parties?

9 A I'm not at liberty to say.

10 Q Okay. And were you serving as an -- as
11 an expert witness in that case?

12 A Yes.

13 Q Have you served as an expert witness in
14 any other cases?

15 A Yes, I have.

16 Q And what types of cases have you served
17 as an expert witness in?

18 A Mainly medical malpractice cases.

19 Q And have you ever served as an expert
20 witness in a patent case before?

21 A No, I have not.

22 Q Okay. Now, with -- you -- you mentioned

1 you only had one deposition. Have you ever
2 testified in court?

3 A No, I have not.

4 Q What did you do to prepare for today's
5 deposition?

6 MS. HIGGINS: And I caution the
7 witness not to reveal any communications with
8 counsel.

9 A I met with counsel and reviewed
10 documents listed in my declaration.

11 Q (BY MR. LARIVEE) Okay. Were there --
12 about how long did you meet with counsel for?

13 A Less than 15 hours.

14 Q And who was present during those
15 meetings?

16 A Myself, Gabrielle Higgins, and Bridget
17 Belcher.

18 Q Was anyone else present by phone or
19 videoconference?

20 A No.

21 Q Did any of the documents you reviewed
22 during your preparation refresh your recollection

1 about the opinions you offered in this case?

2 A It refreshed some items of technology in
3 general.

4 Q And -- and what were those items of
5 technology in general?

6 A Just some of the studies that have been
7 done in the past.

8 Q What kind of studies?

9 A Studies by Dr. Gold pertaining to using
10 BLU-U for acne.

11 Q Okay. Just generally, Dr. Roberts, what
12 documents pertaining to this case have you
13 reviewed?

14 MS. HIGGINS: And I'm going to
15 caution the witness to -- you can answer the
16 question generally. You're not to reveal
17 communications with counsel.

18 A So the documents that I've reviewed is
19 information regarding the BLU-U, the paper by
20 Dr. Gold titled "Therapeutic and Aesthetic Uses of
21 Photodynamic Therapy, Part Two of a Five-Part
22 Series" on lasers and light treatments for acne

1 vulgaris.

2 I reviewed Dr. Michael Ehrenreich's
3 declaration.

4 And then I did a -- I had a cursory
5 look at the '028 patent.

6 And then any other exhibits that we
7 cite -- that I cite in my declaration as noted.

8 Q (BY MR. LARIVEE) Okay. Do you know
9 Dr. Michael Ehrenreich professionally?

10 A No, I do not.

11 Q You mentioned that you -- you met with
12 counsel for less than 15 hours in preparation for
13 this deposition. On how many occasions did you
14 meet with counsel?

15 A We started meeting last --

16 MS. HIGGINS: Before this
17 deposition, correct?

18 MR. LARIVEE: Yes, before this
19 deposition.

20 MS. HIGGINS: You can answer the
21 question.

22 THE WITNESS: Okay.

1 A We started meeting around last December,
2 periodically, by Zoom.

3 Q (BY MR. LARIVEE) So when you mentioned
4 less than 15 hours, that's inclusive of -- is that
5 inclusive of all the work you've done in this
6 case?

7 A That's inclusive of all the work I've
8 done up until arriving here for the deposition.

9 Q Okay. So to be clear, in total,
10 you've -- you've billed about 15 hours to this
11 case up until this morning?

12 A Less than 15.

13 Q Thank you.

14 Have you spoken to anyone, other
15 than your attorneys, about this case?

16 A No, I have not.

17 Q Have you -- have you posted to social
18 media at all about this case?

19 A No, I have not.

20 Q Dr. Roberts, do you recall when
21 Desmarais LLP approached you about serving as an
22 expert witness in this case?

1 A I believe it was around November of
2 2024.

3 Q And were you formally retained in
4 November 2024 as well?

5 A I don't recall if it was -- I don't
6 know.

7 Q Before November 2024, had you had any
8 contact with -- with the Desmarais law firm or
9 Attorney Higgins?

10 A We may have spoken in October, but it
11 was not before October, that I can recall.

12 MR. LARIVÉE: Could we please
13 have -- Ms. Reif, could we please have
14 Exhibit 2015 published for the witness?

15 THE REMOTE TECHNICIAN: Absolutely.
16 Stand by.

17 (Exhibit 2015 marked.)

18 Q (BY MR. LARIVÉE) Dr. Roberts, the --
19 the exhibit tech has -- has put Exhibit 2015 up on
20 the screen. Do you have the ability to scroll
21 through that exhibit?

22 THE REMOTE TECHNICIAN: So all you

1 can read the small text a bit better. I want to
2 direct your attention to the portion of the -- of
3 the website that says "Step 1," the paragraph and
4 the text underneath that.

5 Do you see that?

6 A Yes. Can you enlarge it?

7 Q Absolutely. How is that?

8 A Better. Thank you.

9 Q Could you just nod when you have --
10 you've had a chance to read that text?

11 A Okay. Okay.

12 Q And there's a portion here that says,
13 "Incubation Times: Face --

14 A Right.

15 Q -- or scalp: 14 to 18 hours."

16 Do you see that?

17 A Yes.

18 Q And with the 18 -- 14-to-18-hour
19 incubation time, is it your practice to apply the
20 LEVULAN to one of your patients one day and do the
21 treatment the next?

22 A So I have never used the 14-to-18-hour

1 incubation time. Anytime the LEVULAN is on the
2 skin for more than six hours, it gets into the
3 sheath around the nerve, and the patient will be
4 in exquisite agony while we do the treatment.

5 So I only know one person 20 years
6 ago who was a professor of mine at USC who tried
7 using that incubation time and came into the
8 clinic white as a sheet because he had a gentleman
9 in his office screaming as if he was being killed.
10 And so I don't know anybody since that time that
11 uses a 14-to-18-hour incubation.

12 Q How did you know not to use the
13 14-to-18-hour incubation time?

14 A Well, from that professor, but more
15 importantly when I bought my device I was trained
16 -- we were trained to do the 90-minute incubation,
17 how to do it.

18 Q Trained -- trained by the company?

19 A Yes.

20 Q Now let me zoom back out for a moment,
21 Dr. Roberts. I'm going to show you another page
22 on this exhibit.

Conducted on July 25, 2025

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CHANGES AND SIGNATURE

PAGE/LINE	CORRECTION	REASON FOR CHANGE
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I, _____, have read the foregoing deposition and hereby affix my signature that same is true and correct except as noted herein.

HEATHER J. ROBERTS, M.D.,
FAAD
STATE OF _____)

Subscribed and sworn to before me by the said witness, HEATHER J. ROBERTS, M.D., FAAD, on this the _____ day of _____, 2025.

My Commission Expires: NOTARY PUBLIC IN AND FOR THE STATE OF _____

Conducted on July 25, 2025

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1 I, Kelly Hassell, Certified Reporter and
2 Notary Public within and for the State of Texas
3 do hereby certify:

4 That HEATHER J. ROBERTS, M.D., FAAD, the
5 witness whose deposition is hereinbefore set
6 forth, was duly sworn by me before the
7 commencement of such deposition and that such
8 deposition was taken before me and is a true
9 record of the testimony given by such witness.

10 I further certify that the adverse party,
11 Sun Pharmaceutical Industries, Inc., was
12 represented by counsel at the deposition.

13 I further certify that the deposition of
14 HEATHER J. ROBERTS, M.D., FAAD, occurred in the
15 City of San Francisco, State of California, on the
16 25th of July, 2025, commencing at 9:07 a.m. CDT to
17 12:55 p.m.

18 I further certify that I am not related to
19 any of the parties to this action by blood or
20 marriage, I am not employed by or an attorney to
21 any of the parties to this action, and that I am
22 in no way interested, financially or otherwise, in

Conducted on July 25, 2025

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1 the outcome of this matter.

2

3

4 IN WITNESS WHEREOF, I have hereunto set my
5 hand this 27th day of July, 2025.

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Kelly Hassell

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CERTIFICATE OF SERVICE

I, Antoine R. Bland, hereby certify that on December 5, 2025, copies of the foregoing were served upon the following as indicated:

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Brian F. Moore Administrative Law Judge U.S. INTERNATIONAL TRADE COMMISSION 500 E Street, SW Washington, DC 20436	☒ VIA ELECTRONIC MAIL
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/s/ Antoine R. Bland

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