

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC

Before the Honorable Bryan F. Moore
Administrative Law Judge

In the Matter of

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

Investigation No. 337-TA-1411

RESPONDENTS BIOFRONTERA INC., BIOFRONTERA PHARMA GMBH,
BIOFRONTERA BIOSCIENCE GMBH, AND BIOFRONTERA AG'S
OPENING CLAIM CONSTRUCTION BRIEF

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1	U.S. Pat. No. 11,446,512 ("the '512 Patent")	
2	U.S. Pat. No. 11,697,028 ("the '028 Patent")	
3	Opening Expert Report of Dr. Robert E. Grove	
4	Rebuttal Expert Report of Dr. Robert E. Grove	
5	Jokerst Rebuttal Expert Report	
6	Jokerst Opening Expert Report	
7	American Heritage Dictionary Entry- Recess	
8	Merriam-Webster Collegiate Dictionary (2005)- Recess	
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10	Oxford Dictionary of Construction, Surveying, and Civil Engineering (2012)- Recess	
11	Supplemental Expert Report of Dr. Robert E. Grove	
12	Complaint Exhibit 10C	
13	U.S. Patent No. 8,216,289	
14	Complaint Exhibit 56C	
15	E-mail from B. Larivee, Rep. of Respondent, to T. Ganguly, Rep. of	



	Complainant (Oct. 3, 2024, 02:30 CST)	
16	PTAB-IPR2024-01312, Notice of Parallel Petitions	
17	PTAB-IPR2024-01312, Petition	



ASSERTED CLAIMS

Patent	Asserted Claims
U.S. Patent No. 11,446,512	1, 3, 5, 8-9, 11, 17-18, and 20
U.S. Patent No. 11,697,028	1-2, 4, 5, 6, 10-12, 16-17,19, 20, and 21

I. INTRODUCTION

Pursuant to Ground Rule 7.2 and Order No. 6, Respondents Biofrontera Inc., Biofrontera Pharma GMBH, Biofrontera Bioscience GMBH, & Biofrontera AG (“Biofrontera”) submit this claim construction brief in support of its proposed constructions for the disputed terms of claims 1, 3, 5, 8, 17-18, and 20 of United States Patent No. 11,446,512 (“’512 Patent,” Ex. 1), and claims 1-2, 4-6, 16-17, and 19-21 of United States Patent No. 11,697,028 (“’028 Patent,” Ex. 2) (collectively the “Asserted Claims” and “Asserted Patents”). The Parties have narrowed the dispute to the seven claim limitations covered herein.

The two Asserted Patents utilize existing lighting technology with the well-known area of photodynamic therapy. When it filed its Complaint, Complainant Sun Pharma (“Sun”) explained that its BLU-U 4170E device, which Sun alleges practices the Asserted Patents, is the “next generation” of the prior art BLU-U 4170D, which was first approved in 1999 and was the “predicate device for the BLU-U 4170E device.” Complaint ¶¶ 90-92 (tech prong assertions), ¶¶ 39, 43, 44. [REDACTED]

[REDACTED] In its effort to obtain patent coverage for 1990s technology [REDACTED] the patentee drafted a series of claims that employed indefinite claim language.

Biofrontera’s claim construction and indefiniteness positions are based directly on the plain and ordinary meaning of the claim language, the intrinsic evidence, and straightforward application of claim construction legal principles. In contrast, in an attempt to preserve validity in

¹ All emphasis is added unless otherwise noted.

sufficient form to press its infringement case, Sun’s claim construction positions ignore key elements of the claim language, the specification, and the intrinsic record. Accordingly, Biofrontera’s proposed claim constructions and indefiniteness positions should be adopted.

II. LEGAL STANDARDS

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390-91 (1996). “The purpose of claim construction is to determin[e] the meaning and scope of the patent claims asserted to be infringed.” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) (internal quotations omitted).

A court “look[s] to the words of the claims themselves . . . to define the scope of the patented invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (internal quotations omitted). A claim term is generally given its “ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art [“POSA”] in question at the time of the invention.” *Phillips*, 415 F.3d at 1312–13 (citation omitted). Thus, a “court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean, . . . includ[ing] the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* at 1314 (internal quotations omitted).

However, “[a] determination that a claim term ‘needs no construction’ or has the ‘plain and ordinary meaning’ may be inadequate when a term has more than one ‘ordinary’ meaning or when reliance on a term’s ‘ordinary’ meaning does not resolve the parties’ dispute.” *O2 Micro*, 521 F.3d at 1361.

In cases where the meaning of a disputed claim term in the context of the patent’s claims remains uncertain, the specification is the “single best guide to the meaning of a disputed term.”

Phillips, 415 F.3d at 1321 (quoting *Vitronics Corp. v. Cenceptronic*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Moreover, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Phillips*, 415 F.3d at 1316 (internal quotations omitted). Extrinsic evidence is inherently “less reliable” than intrinsic evidence, and “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Phillips*, 415 F.3d at 1318-19.

If a claim, “read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention” then the claim is invalid for indefiniteness under 35 U.S.C. § 112. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 898-901 (2014). The definiteness requirement of Section 112 has two main purposes. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29, 33 (1997). The first is to provide clear notice to the public as to what constitutes infringement and what does not. *Nautilus*, 572 U.S. at 909. The second purpose is to provide a clear scope of the claimed invention for purposes of patentability. *United Carbon Co. v. Binney Co.*, 317 U.S. 228, 236 (1942).

III. POSA DEFINITION

Biofrontera’s definition of the level of skill in the art should be adopted because it better aligns with the requirements of the Asserted Claims. Claims are construed according to the view of the ordinary skilled artisan at the time of the invention. *Phillips*, 415 F. 3d at 1332. Factors that may be considered in determining the level of ordinary skill in the art may include: (A) “type of problems encountered in the art;” (B) “prior art solutions to those problems;” (C) “rapidity with which innovations are made;” (D) “sophistication of the technology; and” (E) “educational level of active workers in the field. In a given case, every factor may not be present, and one or more factors may predominate.” *In re GPAC*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

Biofrontera's Position

A person of ordinary skill in the art ("POSA") at the time of the earliest effective filing date of the '028 Patent would have been an individual or member of a multi-disciplinary team with education of (1) at least a Bachelor of Science degree in one or more fields of electrical engineering, physics, biomedical engineering, computer engineering, chemical engineering or material science, in fields relating to optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), phototherapy (PT), and related technologies; and (2) a medical degree in fields relating to the diagnosis and treatment of skin conditions and related disease states. Alternatively, a POSA individually or members of the multi-disciplinary team would have had at least four years of experience in one or more fields of optics, optoelectronics, radiometry, photometry, photodynamic diagnosis (PD), photodynamic therapy (PDT), or phototherapy (PT), and at least four years of experience in one or more fields of medical treatment of skin conditions and related disease states.

Consistent with the Asserted Claims both being directed to systems and methods of treating patients employing both medication and the photodynamic illuminator, Biofrontera's definition incorporates the perspective of both an engineer and a healthcare provider treating patients in a multidisciplinary team. Sun's definition is disjunctive, allowing for *either* an MD *or* a Ph.D. in various engineering categories.² Given that Sun has asserted method of treatment claims, Biofrontera's POSA better aligns with the *GPAC* factors, especially the type of problems in the art

² Biofrontera's POSA definition is the same definition it has offered in its pending IPR, 2024-001312, filed after Sun commenced this investigation. An earlier pending IPR filed by Biofrontera, IPR 2024-00874, offered a different definition. In its Petitioner's Notice Regarding parallel Petitions, Ex. 16 (PTAB-IPR2024-01312, Notice of Parallel Petitions), Biofrontera asserted that the Patent Trial and Appeal Board should institute both petitions but noted "if the Board were to institute only one petition, then Petitioner requests the Board institute the 1312 IPR petition." *Id.* 3.

(e.g., patient treatment *and* engineering) and the educational level of active workers in the field (medical *and* engineering degrees). The claim terms in dispute herein relate to engineering aspects of the claims and/or purely legal issues and thus Biofrontera’s claim construction positions are supported by the declaration of Dr. Robert Grove, Ph.D., an MIT-trained engineer who has worked in photodynamic therapy, phototherapy, and medical lasers for over forty years. Ex. 3 (Opening Expert Report of Dr. Grove) ¶¶ 6-15.

IV. DISPUTED TERMS APPEARING IN BOTH THE ’512 AND ’028 PATENTS

A. “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” (All Asserted Claims of the ’512 and ’028 Patents)

Sun’s Construction	Biofrontera’s Construction
“a higher intensity of light is emitted close the second edges compared to the intensity of light emitted not close to the second edges”	Indefinite

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” (“the proximate light limitation”) is indefinite because it fails to inform “with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus*, 572 U.S. at 901. The proximate light limitation represents multiple layers of imprecision in that it fails to reasonably inform a POSA attempting to ascertain whether a particular device infringes as to (1) what part or portion of the panel should be “compared” (*i.e.*, how to distinguish “proximate” parts of the panel from “not proximate” parts of the panel); (2) what parameter should be measured; and (3) how that parameter should be measured.³ Sun’s proposed construction – merely replacing the term “proximate” with the term

³ As explained in its 2024-01312 IPR, Ex. 17 (PTAB-IPR2024-01312, Petition) at 12, “For the purposes of this IPR, Petitioner has taken a view of the scope of the claims consistent with Patent Owner’s infringement allegations.” Biofrontera reserved its rights to present Section 112 defenses

“close” – does nothing to resolve any of these questions. The result is that a POSA is unable to draw a reliable boundary line between infringement and non-infringement, in clear violation of the definiteness requirement. *See Nautilus*, 572 U.S. at 909.

1. It is not clear what part(s) or portion of the panel should be “compared” to determine if a device falls within the claim limitation.

The proximate light limitation does not delineate what part(s) or portion of the claimed panels a POSA should “compare” in order to determine if a device emits a higher intensity of light “proximate the second edges” as compared to “not proximate the second edges.” In addition to being able to ascertain the meaning of “intensity” and appropriately and consistently measure it, a POSA must also be able to determine what is “proximate” and what is “not proximate” in order to compare them.

This is no easy task. “Proximate” is not a term of art that has a clearly defined meaning to a POSA. Ex. 3 ¶ 51. Accordingly, “the disputed term is a coined term [of degree], meaning it has no ordinary and customary meaning.” *Iridescent Networks, Inc. v. AT&T Mobility, LLC*, 933 F.3d 1345, 1353 (Fed. Cir. 2019). The question then becomes “whether the intrinsic evidence provides objective boundaries to the scope of the term.” *Iridescent*, 933 F.3d at 1353.

The intrinsic record does not do so here. The term “proximate” does not appear anywhere in the specification. Ex. 3 ¶ 51. The specification provides one example depicted in Figure 5 of an embodiment in which some areas of an illumination panel may have a “higher intensity” – but it completely fails to provide any objective boundaries, measurements, or limits for those areas. Ex. 1 and Ex. 2 at 6:22-48; Ex. 3 ¶ 52.

in this ITC matter. *Id.* Given that its Section 103 defenses are based on Sun’s infringement contentions, Biofrontera sees no inconsistency in presenting these defenses alongside each other. As noted in specific sections below, for some claim limitations, Biofrontera’s obviousness positions address the indefinite nature of the claims by addressing multiple potential meanings.

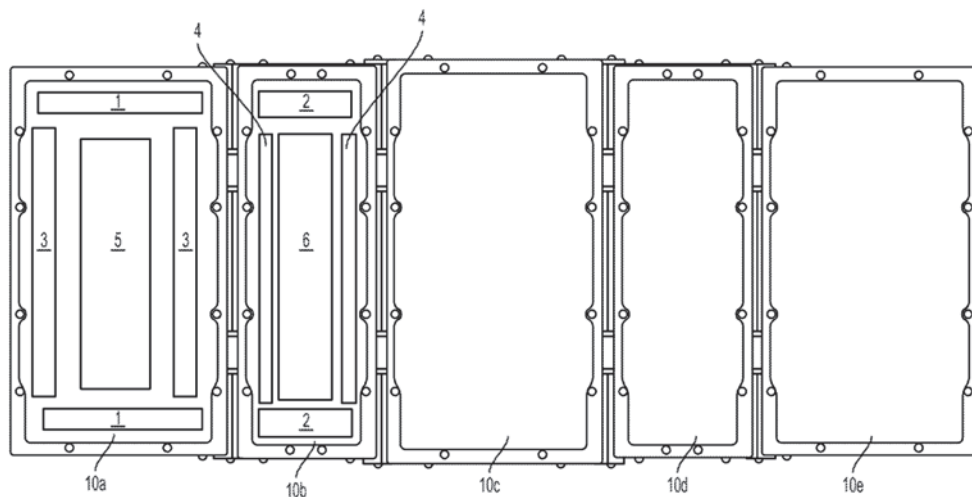


FIG. 5

Ex. 1 and Ex. 2 at Fig. 5.

The specification discloses that “[t]he current to each area is adjusted in order to adjust the intensity of light emitting from each of the areas. For example, a higher current may be supplied to areas 1 and 2 than the current supplied to areas 3 and 4 such that areas 1 and 2 emit a higher intensity of light than areas 3 and 4. Similarly, a higher current may be supplied to areas 3 and 4 than the current supplied to areas 5 and 6. Thus, a higher intensity of light is emitted overall from the edges. . . .” Ex. 1 and Ex. 2 at 6:22-38.

Sun’s expert, Dr. Jokerst, argues that this disclosure provides “objective guidance” as to what is and what is not proximate because “areas 1 are closer to the shorter edges of the panel than areas 3 and 5.” Ex. 5 (Jokerst Rebuttal Expert Report) ¶¶ 36-37. However, the specification fails to comment on the “proximity” of the areas depicted. Ex. 3 ¶ 54. In light of this silence, the entirety of sections 1 and 2 could be considered “proximate” the second edges, as they are closer to these edges than areas 3, 4, 5, and 6, as Dr. Jokerst suggests. Ex. 3 ¶ 54; Ex. 5 ¶¶ 36-37. But, it is equally plausible that only portions of areas 1 and 2 could be considered “proximate” — *e.g.*, the upper half, the upper third, the upper quarter, etc., of areas 1 and 2, as oriented in Fig. 5 — because these

portions are closer to the second edges than the lower half, the lower two-thirds, the lower three-quarters, etc. Ex. 3 ¶ 54. The specification is completely silent as to which interpretation is correct. “[A] claim is indefinite if its language might mean several different things and no informed and confident choice is available among the contending definitions.” *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d at 1366, 1373 (Fed. Cir. 2015) (internal quotations omitted).

Further, even if areas 1 and 2 could be considered to delineate “proximate” regions, the specification is silent as to the bounds, dimensions, or sizes of these areas and the drawings cannot remedy this deficiency. Ex. 3 ¶ 55. “[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).

This is further complicated because each of these areas may contain multiple LEDs or multiple rows of LEDs. Ex. 3 ¶ 56. For example, the specification teaches that “[t]he addressable strings of the LED arrays 60 may include varying amounts of individual diodes mounted within a particular area.” Ex. 1 and Ex. 2 at 6:51-53; *see also* Ex. 1 and Ex. 2 at Fig. 2B. Because multiple rows of LEDs may be included in one addressable string or area, some LEDs may be positioned closer to the second edges than others. The specification provides no boundaries or even guidelines for determining which of these LEDs are considered “proximate” and which are not. Ex. 3 ¶ 56.

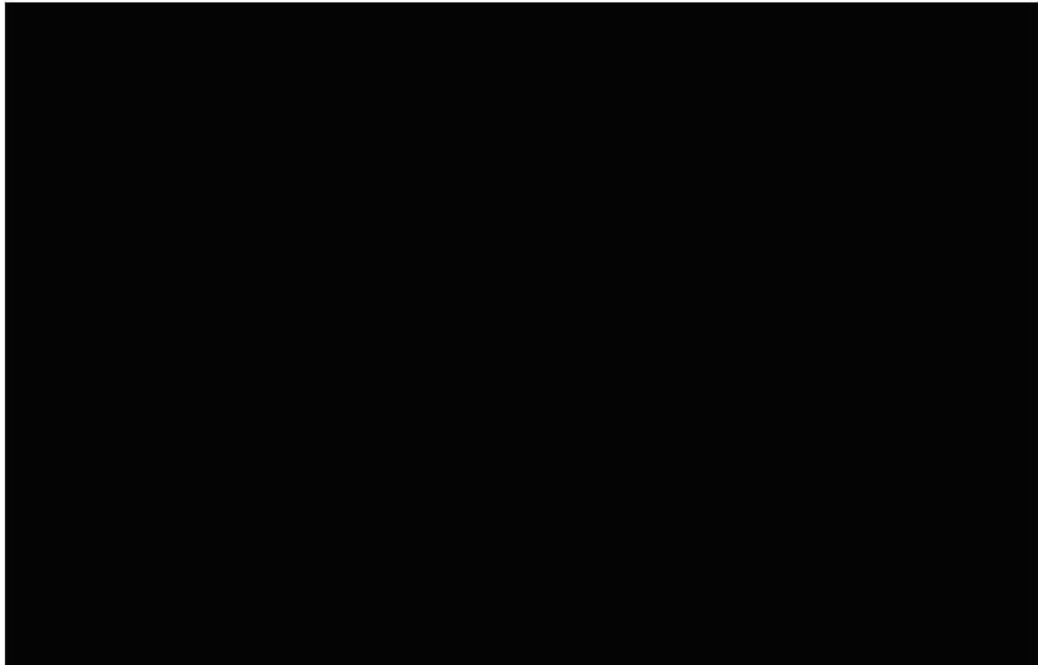
Sun’s proposed construction substituting “close” for “proximate” does nothing to resolve this problem. All Sun has proposed is to substitute one term of degree for another. This does nothing to supply the objective boundaries necessary to make the term definite. “[A] patent does not satisfy the definiteness 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

[REDACTED]

and the prosecution history, must provide objective boundaries for those of skill in the art.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). Dr. Grove opined that “one scenario where the claims might have reasonable certainty is if the claims were construed to require an increased intensity from the top and bottom rows immediately proximate/adjacent the second edges.” Ex. 4 (Rebuttal Expert Report of Dr. Robert E. Grove) ¶ 25; Ex. 3 ¶¶ 59-63. [REDACTED]

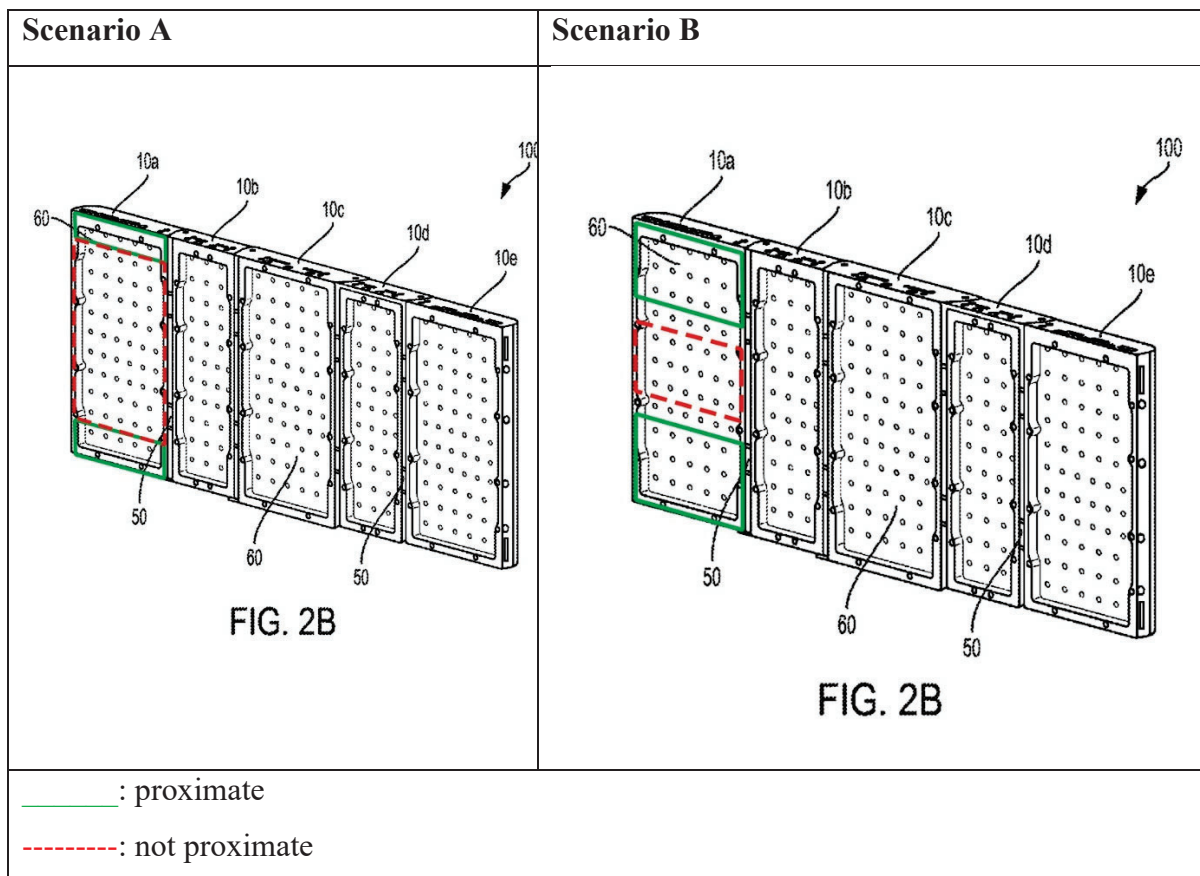
[REDACTED]

[REDACTED]



Ex. 3 ¶ 61. However, this is not the construction that Sun has asked for.

Sun’s much broader proposed construction allows for significant gray area in which a POSA is unable to draw a clear and reliable line between infringement and non-infringement. For example, it is not clear if the “proximate” or “close” region would be limited to the most proximate region (*e.g.*, Scenario A, depicted below) or if the “proximate” region could be much larger, so long as there is at least one other region that is less proximate to the second edges (Scenario B).



Ex. 3 ¶ 57. Accordingly, given the lack of objective measurements, dimensions, or limits provided in the intrinsic record, the scope of the claim varies depending on what each individual reader considers to be “proximate” to the second edges – *e.g.*, the first row of LEDs, the first two rows, the first inch, the first two inches, the first 5% of the length of the panel, the first 15% of the length of the panel, etc. “A term of degree fails to provide sufficient notice of its scope if it depends upon the unpredictable vagaries of any one person’s opinion.” *Interval Licensing*, 766 F.3d at 1371.

2. It is unclear what parameter the proximate light limitation refers to by its recitation of “intensity.”

Setting aside the difficulties in determining what “proximate” and “not proximate” portions to compare, it is still not even clear what “intensity” the term refers to. Neither the claims nor the specification provide any explicit definition of “intensity.” Ex. 3 ¶ 46.

As normally understood by a POSA, “intensity” refers to a radiant flux density, which is a property representative of the light emitted from a *light source*, expressed in units of W/cm^2 . Ex. 3 ¶¶ 46, 47. This is consistent with the term’s usage in the Asserted Claims, which recite “a higher

intensity of light *is emitted*...” However, in certain passages, the specification refers to “intensity” as if it were a “light dose,” or “fluence” – *i.e.*, a property representative of light incident upon some *surface* placed some distance from the light source, expressed in units of J/cm^2 . Ex. 3 ¶¶ at 46, 47.⁴ For example, the specification discloses that “in some embodiments, the illuminator is configured to irradiate the lesions with a uniform blue light (*e.g.*, 417 nm) at a low *intensity* (*e.g.*, about 0.1 J/cm^2 to about 2 J/cm^2) . . . ” Ex. 1 and Ex. 2 at 9:21-31 (emphasis added). Radiant flux density (*i.e.* the normal definition of “intensity” and the way “intensity” is used in the Asserted Claims) and fluence (*i.e.* the way “intensity” is used in portions of the specification) are two different parameters. Ex. 3 ¶ 46. Accordingly, this inconsistent usage leaves a POSA at sea in determining what “intensity” the claim term refers to.

In *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1345 (Fed. Cir. 2015), the Federal Circuit held that when an applicant uses a claim term inconsistently in different portions of the intrinsic record, “the patentee has failed to inform with *reasonable certainty* those skilled in the art about the scope of the invention.” In *Teva*, the claims-at-issue recited “molecular weight” without specifying whether this referred to a peak average molecular weight (M_p), a number average molecular weight (M_n), or a weight average molecular weight (M_w). *Teva*, 789 F.3d at 1338. Further “the patentee in one instance stated that it was M_w and in the other stated that it was M_p .” *Teva*, 789 F.3d at 1338. As in *Teva*, the inconsistent usage of “intensity” in the Asserted Patents fails to provide a POSA with reasonable certainty as to what is and is not within the claim scope.

⁴ Joules (J) are a unit of energy. Watts (W) are a unit of power, equivalent to J/s. Accordingly, W represent a rate of energy emitted, while J represent an amount of energy emitted or delivered in some defined amount of time (s). An amount in J is obtainable when the rate (W) is multiplied by time (s). Ex. 3 at ¶¶ 46-47.

3. The proximate light limitation does not reasonably inform a POSA as to how “intensity” should be measured.

Even if a POSA could determine what portions of a device should be compared, and what parameter the proximate light limitation refers to, the claims still do not reasonably inform a POSA as to *how* this parameter is to be measured. This is problematic because intensity is dependent on how and where it is measured. Ex. 3 ¶ 50. “Where results can dramatically differ according to which of several quantitative techniques for applying a patent claim term is chosen, and the patent does not make clear which technique is meant, an indefiniteness problem may arise.” *Frans Nooren Afdichtingssystemen B.V. v. Stopaq Amcorr, Inc.*, 744 F.3d 715, 724 (Fed. Cir. 2014).

If “intensity” refers to a fluence in J/cm² as some portions of the specification seem to imply (Ex. 3 ¶ 46), it is referencing a *surface* placed at some distance from the light source, for a given amount of time. Ex. 3 ¶ 46. The Asserted Patents explain that the intensity, or fluence, of light on a given surface is dependent upon the angle between the incoming ray of light and the surface. Ex. 1 and Ex. 2 at 5:60-6:12. Thus, under this possible definition, the intensity depends on the shape, distance, and angle of a particular surface. The intrinsic record is silent as to any reference surface by which such an “intensity” could be defined or measured, or for how long.

The Asserted Patents are also deficient if “intensity” is given its normal meaning in the art – *i.e.* as a radiant flux density in W/cm², which is a property of a *light source*. While a radiant flux density refers to emission from a light source, in practical terms this emission must be measured by a sensor⁵, which must be placed at some position relative to the surface of the panel. Ex. 3 ¶ 50. The “intensity,” or radiant flux density, measured for the exact same light source will change based

⁵ While Dr. Jokerst alleges that “Dr. Grove had no trouble making a visual assessment of the *intensity* of light emitted from a panel...” (Ex. 5 ¶ 37 (emphasis added)), this is not accurate. Dr. Grove was able to visually assess *density* of LEDs – not their intensity. Grove Opening Report ¶ 61.

on the position of the sensor – *i.e.*, its angle and how far away it is. Ex. 3 ¶ 50. For example, “the measured intensity may differ if the sensor is placed over the center of the panel . . . as compared to placing the sensor over an upper, lower, or side region of the panel. Additionally, a sensor placed over the center of the panel, but at a distance of one-half inch from the panel surface may report a different intensity compared to a sensor placed over the center of the panel, but four inches from the panel surface.” Ex. 4 ¶ 23. The specifications do not provide examples in which an intensity was measured, nor does the intrinsic record provide any other disclosure as to how – *i.e.* at what distance, angle, or surface – intensity should be measured. Ex. 3 ¶ 50.

Because different measurement methods will produce different values for intensity even for the exact same device, whether or not a device meets the proximate light limitation will depend on where a sensor or reference surface is placed, which renders the term indefinite. Ex. 4 ¶ 23. In *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620 (Fed. Cir. 2015), three methods existed for determining a claimed parameter, and the patent owner’s expert developed a fourth method on his own. *Dow*, 803 F.3d at 633. As in the present case, “each of these methods may produce different results” and “[n]either the patent claims nor the specification here discusses the four methods or provides any guidance as to which method should be used.” *Dow*, 803 F.3d at 633-34. Accordingly, the court was confronted with the question of “whether the existence of multiple methods leading to different results without guidance in the patent or the prosecution history as to which method should be used renders the claims indefinite.” *Dow*, 803 F.3d at 634. The Federal Circuit has consistently answered that question in the affirmative. *Dow*, 803 F.3d at 634; *see also Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332 (Fed. Cir. 2003) (holding claims indefinite because the intrinsic record was silent as to which of four sample preparation methods should be used to determine whether a product was produced by the claimed method).

Dr. Jokerst acknowledges the problem and asserts that, even absent any disclosure in the specification, a POSA would simply know that “a sensor would need to be placed in relatively the same position with respect to the areas . . . For example . . . if the POSA wanted to compare the intensity of light emitted from areas 1, 3, and 5 [of FIG. 5 of the Asserted Patents], the POSA would place the sensor at the same distance above the emitting surface.” Ex. 5 ¶ 39. However, even if this were true, numerous questions still remain. For example, at what location “above the emitting surface” should the sensor be placed? In the center of a panel or device? At one of the second edges of a panel or device? Which one? Should the sensor be centered over proximate and non-proximate regions, respectively, depending on which is being measured? This determination is further complicated by the fact that both area 3 and area 5 (as illustrated in Fig. 5) would be considered “not proximate” as compared to area 1 – does this mean that measurement is required at multiple points across the “not proximate” area (*e.g.*, measurement at a set distance above section 3 and a set distance above section 5)? Accordingly, this does not solve the problem faced by a POSA in interpreting the claim scope – especially since it is not clear which areas are “proximate” and which are not.

B. “Photodynamically Diagnosing or Treating a Patient” – Preamble is Limiting (All Asserted Claims)

Sun’s Construction	Biofrontera’s Construction
Preamble not limiting.	Preamble is limiting, plain and ordinary meaning.

The preamble language reciting “photodynamically diagnosing or treating a patient” is a limitation of the claims, requiring that the claimed systems and methods are used or are capable of being used for photodynamically diagnosing or treating a patient.

The preamble of claims will be found limiting “when limitations in the body of the claim rely upon and derive antecedent basis from the preamble” – thus the preamble may act as a necessary and limiting component of the claimed invention. *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003). For example, in *Pacing Techs., LLC v. Garmin Int’l, Inc.*, 778 F.3d 1021, 1023–24 (Fed. Cir. 2015), the court held that the preamble “for pacing a user” was limiting because it provided antecedent basis for “the user” later in the body of the claim. *Pacing Techs.*, 778 F.3d at 1023–24. Specifically, the claim at issue recited: “A repetitive motion pacing system for pacing **a user** comprising a web site adapted to allowing **the user** to pre-select from a set of user-selectable activity types an activity they wish to perform” *Id.* at 1022. The court held that the preamble was limiting because it [is] necessary to understand positive limitations in the body of claims.” *Id.* at 1024-1026.

Similar to the facts of *Pacing Techs.*, the preamble to all of the Asserted Claims is limiting because it establishes necessary antecedent basis for the body of the claims. Specifically, the system claims recite “[a] system for photodynamically diagnosing or treating **a patient**, comprising...[an] illuminator being configured to uniformly illuminate a treatment surface of **the patient** via the light sources”.⁶ The same is true for the method claims, which recite “[a] method of photodynamically diagnosing or treating **a patient**, comprising administering 5-aminolevulinic acid (ALA) to **the patient**” (emphasis added).⁷ There is no other recitation of “a patient” anywhere in the body of the claim, and the preamble language is necessary to understand limitations in the body of the claims. Just as the Federal Circuit concluded in *Pacing Techs.*, the preamble of the Asserted Claims is also limiting and requires that the claimed methods or systems

⁶ Preamble language is present in all independent system claims, and present in the dependent system claims by virtue of their dependency.

⁷ Preamble language is present in all independent method claims, and all dependent method claims by virtue of their dependency.

are used for or capable of “photodynamically diagnosing or treating a patient.”

Additionally, the Federal Circuit has routinely concluded that statements of intended purpose in methods of using apparatuses or compositions has tended to result in a conclusion that such preamble language is limiting.” *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1341 (Fed. Cir. 2021); see *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003) (preamble was the “*raison d’être*” for the method itself). When the preamble recites “the intentional purpose for which the method must be performed . . . [the Federal Circuit] has not hesitated to hold preambles limiting when they state an intended purpose for methods of using a compound.” *Eli Lilly & Co.*, 8 F.4th at 1342.

The preamble to claim 8 of the ’512 Patent and claims 5-6 of the ’028 Patent recite methods of use (*i.e.*, “a method of photodynamically diagnosing or treating a patient”), and the preamble explicitly specifies what the method *does* (*i.e.* “photodynamically diagnosing or treating a patient”). These claims further recite method steps of “administering 5-aminolevulinic acid (ALA) to the patient.” Consequently, the asserted method claims recite the intentional purpose for which the method must be performed, and the preamble of these claims is therefore limiting. See *Eli Lilly & Co.*, 8 F.4th at 1341.

V. DISPUTED TERMS APPEARING IN ONLY THE ’512 PATENT

A. “nested hinges” (All Asserted Claims of the ’512 Patent)

Sun’s Construction	Biofrontera’s Construction
Plain and ordinary meaning	Indefinite

The “nested hinges” limitation, present in all Asserted Claims of the ’512 Patent, is indefinite because it does not inform, “with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus*, 572 U.S. at 909; *Certain High-Performance Gravity-Fed Water*

Filters & Prods. Containing the Same; Inv. No. 337-TA-1294 Comm’n Op. at 14-15, 27 (Sept. 22, 2023). A POSA does not have reasonable certainty based on the intrinsic and extrinsic evidence to distinguish a “nested hinge” from any other kind of hinge or the “hinged structure” claimed in the ’028 Patent and thus, all Asserted Claims of the ’512 Patent are indefinite.⁸

“Nested hinges” has no understood meaning or definition in the art. Ex. 3 ¶ 68. Moreover, the intrinsic evidence provides no guidance regarding the meaning of the term. The specification expressly states that “[t]he hinges 50 *may* take the form of nested hinges...” (Ex. 1 at 4:46-47), which means that a “nested” hinge must be distinct from a conventional hinge as understood in the art. Ex. 3 ¶ 69. Additionally, the specification states that “nested hinges . . . *may* include hinges that substantially reduce or eliminate optical dead spaces,” (Ex. 1 at 4:47-48), which indicates that “nested” is something different from a hinge that can “reduce or eliminate optical dead space.” *Id.* Even if a “nested hinge” is intended to “reduce or eliminate optical dead space,” the specification does not address the critical question of what the reducing or eliminating is being compared to. *Id.*

Furthermore, despite advocating for a “plain and ordinary meaning” of the claim term, Sun’s muddled and shifting position confirms that the claim term is indefinite. Dr. Jokerst does not assert that “nested hinge” is a term of art. Sun and Dr. Jokerst failed to provide what the “plain and ordinary meaning” of “nested hinges” was alleged to be. In her opening report, Dr. Jokerst quotes the specification at length and includes screenshots of Figs. 3A and 3B before finishing with a conclusory statement that “[b]ased on the foregoing, it is my opinion that a POSA would

⁸ Based on how Sun has employed the term “nested hinge” in infringement contentions and technical prong contentions, Biofrontera has served Section 103 invalidity contentions in this case. Consistent with its indefiniteness arguments, Biofrontera’s invalidity contentions contain two alternate references related to the “nested hinge” limitations addressing different hinged structures that Sun has alleged of being “nested hinges.”

understand that a nested hinge would be *as described above*.” Ex. 6 (Jokerst Opening Expert Report) ¶ 39. Finally, at paragraph 48 of Dr. Jokerst’s rebuttal report, Sun discloses for the first time that “a POSA would readily understand ‘nested hinges’ to be hinges that fit on inner side surfaces of adjacent panels.” Ex. 5 ¶ 48. A rebuttal report is no place to disclose a construction.

Sun’s shifting positions prove too much because there has never been a dispute as to *where* the nested hinge is located. The claim language makes it abundantly clear that the nested hinge is “on inner side surfaces of adjacent panels.” *See, e.g.*, Ex. 1 at Claim 1. A comparison of the relevant language from the ’512 and ’028 patents is provided below:

'512 Patent	'028 Patent
“connected by <i>nested hinges</i> on inner side surfaces of adjacent panels”	“connected by <i>hinged structures</i> on inner side surfaces of adjacent panels”

The well-established rule that “all claim terms are presumed to have meaning in a claim,” *Innova/Pure Water v. Safari Water Filtration*, 381 F. 3d 1111, 1119 (Fed. Cir. 2004), as well as the presence of the same language in the ’028 Patent claims means that the “on inner side surfaces of adjacent panels” language stands alone. *See id.* (rejecting a claim construction that would read “operatively” out of “operatively connected”); *Neville et al. v. Foundation Constructors, Inc.*, 972 F.3d 1350, 1357 (Fed. Cir. 2020) (“While the ‘protrusion’ and ‘end plate’ structures must be connected in some fashion, the use of these two terms in a claim requires that they connote different meanings.”); *see also Merck & Co., Inc v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“a claim construction that gives meaning to all the terms of the claims is preferred over one that does not do so”).

That leaves the crux of the matter: what is meant by a “nested hinge.” Between the ’028 Patent and the ’512 Patent, Sun Pharma has obtained two claim sets that derive from the same

specification and vary in only a handful of ways, including the difference between the '028 Patent's "*hinged structures* on inner side surfaces" and the '512 Patent's "*nested hinges* on inner side surfaces." A "hinged structure" is a term understood to be a "hinge," encompassing various potential sub-types of hinges. Ex. 3 ¶ 75. A "nested hinge" must mean something different than a "hinged structure" if the claims are to be read consistently with each other. *See AstraZeneca AB v. Mylan Pharms., Inc.*, No. 1:22-CV-35, 2022 WL 17178691, at *6 (N.D.W. Va. Nov. 23, 2022) ("Where, as here, multiple patents derive from the same parent application and share many common terms, the court must interpret the claims consistently across all asserted patents.") (internal quotations omitted); *In re Rambus Inc.*, 694 F.3d 42, 48 (Fed. Cir. 2012) (affirming USPTO's analysis of claim differentiation across related patents); *Clare v. Chrysler Grp. LLC*, 819 F.3d 1323, 1330 (Fed. Cir. 2016) (appropriate to apply the rule of claim differentiation across related patents); *see also* Ex. 3 ¶ 75 (Sun's "plain and ordinary meaning" definition fails to explain how the "nested hinges" of the '512 Patent differ from the "hinged structures" of the '028 Patent). Sun's newly asserted position that "nested hinges" are "hinges that fit on inner side surfaces of adjacent panels" (Ex. 5 ¶ 48) reads out the "nested" claim term, which is improper. Thus, Sun's position and expert reports provide no explanation or meaningful construction of the term "nested hinges," and particularly how a "nested hinge" differs from a "hinged structure." Ex. 3 ¶ 68.

After reviewing all the intrinsic evidence, a POSA would still have no understanding of what makes a "nested hinge" different from a hinge. Thus, "nested hinges" is indefinite because it does not inform those skilled in the art about the scope of the invention with reasonable certainty. *Nautilus*, 572 U.S. at 909.

B. "a recess" (Claims 17 and 18 of the '512 Patent)

Sun's Construction	Biofrontera's Construction
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No construction provided to date	Plain and ordinary meaning of “an indentation in a surface”
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Although the claims and specification of the '512 Patent reference “a recess” as part of the claimed panels, they do not provide definitive guidance as to what a “recess” is. The specification makes several references to “a recess,” stating that (1) the recess is on the inner side surface of the panel; (2) that a flange may be placed in the recess; and (3) the recess may also accommodate the hinge joint. Ex. 1 at 4:66-67, 5:1-6. While this disclosure provides guidance on the location of the “recess” and potential functions of a “recess” (accommodating a flange or hinge joint), in none of these instances is “a recess” defined.

Because the '512 Patent's intrinsic evidence does not provide any guidance regarding the proposed meaning of the term “recess,” the Commission should turn to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Phillips*, 415 F.3d at 1314, 1322. “Dictionaries or comparable sources are often useful to assist in understanding the commonly understood meaning of words and have been used both by our court and the Supreme Court in claim interpretation.” *Id.*; see also *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299 (Fed. Cir. 2006) (reverting to dictionary definitions when specification and claim language were insufficient to define the claim).

The American Heritage Dictionary defines “recess” as “an indentation or small hollow.” Ex. 7 (American Heritage Dictionary Entry- Recess). The term “recess” is further defined as “indentation, cleft” (Ex. 8 (Merriam-Webster Collegiate Dictionary (2005)- Recess); Ex. 9 (Merriam-Webster Dictionary (2024)- Recess), and “an indent in a wall or surface” (Ex. 10 (Oxford Dictionary of Construction, Surveying, and Civil Engineering (2012)- Recess). Based on these dictionary definitions for the term “recess,” a POSA would understand this term to have the plain and ordinary meaning of “an indentation in a surface.” Ex. 11 (Supplemental Expert Report

of Dr. Robert E. Grove) ¶¶ 45-46.

VI. DISPUTED TERMS APPEARING IN ONLY THE '028 PATENT

A. “within approximately four inches of the treatment surface” (Claims 1, 2, 4-6, 20, and 21 of the '028 Patent)

Sun’s Construction	Biofrontera’s Construction
Plain and ordinary meaning.	“less than or equal to four inches from the treatment surface”

Biofrontera’s construction is supported by the claim language specification of the '028 Patent. The claims of the '028 Patent state that the claimed systems and methods must provide uniform illumination of the treatment surface “within approximately four inches” of the treatment surface. Specifically, claims 1, 20, and 21 require “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...wherein the five panels are positioned to allow treatment *within approximately four inches of the treatment surface.*” Claim 5 requires “*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.*”

As an initial matter, the patentee’s use of “within” modifies the phrase “approximately four inches” to mean “less than or equal to four inches from the treatment surface.” This construction fits most closely with a plain reading of the claims.

Additionally, the claim language directly ties the “within approximately four inches” treatment distance with the coexistent requirement that the claimed systems and methods must provide “uniform illumination” of the treatment surface.

In other words, a POSA would construe the term “within approximately four inches”

consistent with the evidence in the specification that demonstrates “uniform illumination” of the treatment surface. The parties have agreed that the “uniformly illuminate” / “uniformly illuminating” terms are construed as “irradiate light over the active emitted area such that the measured irradiance is at least within 60% of the measured maximum” / “irradiating light over the active emitted area such that the measured irradiance is at least within 60% of the measured maximum.” Ex. 15 (E-mail from B. Larivee, Rep. of Respondent, to T. Ganguly, Rep. of Complainant (Oct. 3, 2024, 02:30 CST)). Consequently, a POSA would look to the specification for discussion of treatment distances that allow for “uniform illumination” of the treatment surface.

Dr. Grove agrees, identifying the following passage as critical to the interpretation of the claim term:

“In one embodiment, the measured output over the active emitting area (over the entire active emitting area) is within 60% of the measured maximum (over the entire active emitting area) measured with a cosine response detector *over all operation distances*. More preferably, the measured output over the emitting area is within 70% of the measured maximum *over a distance of two and four inches*. Even more preferably, the measured output over the emitting area is within 80% of the measured maximum *over a distance of two and four inches*.”

Ex. 4 ¶ 36, citing the '028 Patent, 8:58-67 (emphasis added). Thus, the '028 Patent indicates that the uniform illumination (*i.e.*, all irradiation measurements across the active emitted area are at least within 60% measured maximum) occurs over treatment distances of *two and four inches*. The explicit reference to treatment distances of two inches and four inches is reflective of the range of treatment distances, with four inches being the upper limit. Ex. 4 ¶ 36. The passage above also refers to “all operation distances,” which represents all treatment distances ranging from two inches to four inches, and that distances outside this range (*e.g.*, greater than four inches) are not an acceptable “operation distance” for the device. *Id.*

Further, the examples provided in the '028 Patent only demonstrate “uniform illumination” at a treatment distance of two inches. Ex. 4 ¶ 37. In its discussion of Figs. 7 and 8, the '028 Patent specification states that the comparison of light uniformity between a conventional illuminator (Fig. 7) and the light uniformity achieved with the current device (Fig. 8) was assessed using “a cosine response detector, which mimics the response of a patient's skin to the incident of light as described above, at *a distance of two inches.*” Ex. 2 at 8:15-21 (emphasis added). Moreover, the '028 Patent does not provide any disclosure suggesting that the device can or should be operated at distances greater than four inches. Ex. 4 ¶ 37.

Moreover, Biofrontera’s construction is consistent with Sun Pharma’s own assertions as to why its product meets the claimed requirements. Specifically, as part of their initial Complaint, Sun Pharmaceuticals (the owner of the Asserted Patents) asserted that its BLU-U® 4170E device and accompanying User Manual meets the claimed requirements that the device “uniformly illuminate[s] a treatment surface” (Ex. 12 (Complaint Exhibit 10C) at 15) and that the panels of the device are positioned “within approximately four inches” of the treatment surface. *Id.* 31. When providing evidence from the BLU-U® 4170E User Manual supporting the treatment distance of “within approximately four inches,” Sun cites portions of the User Manual stating that the treatment surface (*i.e.*, the patient’s forehead/cheeks, scalp, or other upper extremities) “should be *no further* than 4” from the surface.” Ex. 12 at 31-32 (citing Complaint Ex. 28 at 18-20) (emphasis original). In other words, BLU-U® 4170E expressly instructs users that the device should not be used at treatment distances of greater than four inches. A POSA would view these statements as consistent with the disclosure of the '028 Patent, establishing that the claimed device only provides “uniform illumination” at operation distances up to four inches from the treatment surface (*i.e.*, there is no support that uniform illumination can be achieved at treatment distances greater than

four inches). Ex. 4 ¶ 38.

Additionally, Biofrontera's construction is supported by a previous Memorandum and Order on Claim Construction in *DUSA Pharmaceuticals, Inc. v. Biofrontera Inc.*, No. CV 18-10568-RGS, 2019 WL 1208805 (D. Mass. Mar. 14, 2019).⁹ In that case, U.S. Patent No. 8,216,289 (the '289 Patent, Ex. 13) was asserted against Biofrontera. The '289 Patent is related to the BLU-U® device that has been on the market since the late 1990's/early 2000's. Like the '028 Patent, the device of the '289 Patent is designed for photodynamic treatment of patients, and much of the disclosure provided in the '289 Patent is the same/similar to the disclosure provided in the '028 Patent. In fact, the claims of the '289 Patent similarly require "an illuminator whose measured output over an active emitting area is at least 60% of the measured maximum over all operation distances" (*i.e.*, a similar limitation as the construction for the claimed "uniform illumination" recited in the '028 Patent). The '289 Patent states that "according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4" and 2", and within 60% of the measured maximum **over all operation distances.**" Ex. 13 at 15:6-11 (emphasis added). The Court construed the term "all operation distances" to mean "the range of distances between 2" and 4" because it determined that "the asserted patents reasonably clearly set out the operational range of an illuminator [where the] patents identify 2" and 4" as the only specific operation distances at which maximum output is to be measured." *DUSA Pharmaceuticals, Inc. v. Biofrontera Inc.*, WL 1208805 at *7.

Consequently, when construing the term "all operation distances" in the '289 Patent (for a device that is similar to the claimed device of the '028 Patent and is used for the same purpose to

⁹ It is our understanding that Sun Pharma acquired or merged with Dusa Pharmaceuticals, and Sun Pharma is now the owner of the Asserted Patents.

provide “uniform illumination” to a treatment surface), the Court found that “the asserted patents reasonably clearly set out the operational range of an illuminator” of between two and four inches. *Id.* Again, a POSA would view these findings as consistent with the disclosure of the ’028 Patent, establishing that the claimed device only provides “uniform illumination” at operation distances up to, but not exceeding four inches from the treatment surface. Ex. 4 ¶ 38.

The specification of the ’028 Patent makes clear that the claimed “uniform illumination” is only achieved at treatment distances of two inches and four inches. A POSA would interpret this disclosure as establishing that the claimed treatment distance of “approximately four inches” has an upper limit of four inches from the treatment surface, and “within” this treatment distance is properly construed as “less than or equal to four inches” from the treatment surface.

Sun Pharma has asserted that the term should be given its plain and ordinary meaning to provide a “reasonable variance” based on factors such as variation in facial contours, variation in treatment areas (*e.g.*, arm vs. face), and variation in treatment areas between persons (*e.g.*, Person A’s face vs. Person B’s face). Ex. 6 ¶ 41. However, Sun fails to provide any guidance regarding what a “reasonable variance” of four inches would be. Additionally, Sun argues that Biofrontera’s construction is seemingly improper because the construction “read[s] the word ‘approximately’ out of the disputed term because a POSA would understand that ‘approximately four inches’ could be greater than or less than four inches.” Ex. 6 ¶ 41. However, the specification is “always highly relevant to the claim construction analysis,” and “the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The specification of the ’028 Patent is clear that the claimed “uniform illumination” is only achieved at treatment distances of two inches and four inches as the ’028 Patent specification “denote[d] a range” with a maximum treatment distance of four inches from

the treatment surface (*i.e.*, the upper limit of “all operation distances”) for the term “within approximately four inches.” *Max Blu Techs., LLC v. Cinedigm Corp.*, 2016 WL 3688801 at *30 (E.D. Tx. 2016) (construing the claim term “less than approximately” to only encompass values “less than” a maximum denoted in the specification); *see* Ex. 4 ¶ 41.

Further, to the extent Sun Pharma were to obtain a construction encompassing treatment distances greater than four inches, the claims would be invalid for lack of written description support and enablement. The '028 Patent specification does not include a single reference to the term “approximately four.”¹⁰ As noted, the specification only references treatment distances ranging from two inches to four inches. Additionally, Sun Pharma is claiming a specific result in its claims—“uniformly illuminat[ing] a treatment surface”—but the '028 Patent specification *only* provides written description for uniformly illuminating a treatment surface at a distance of two to four inches. There is nothing suggesting patentee was in possession of a device that could uniformly illuminate a treatment surface at distances greater than four inches. When possible, claims are construed to preserve their validity. *See Phillips*, 415 F.3d at 1327. If “within approximately four inches” is construed to encompass treatment distances greater than four inches, the claims are invalid for lack of written description support and/or enablement. Consequently, Biofrontera’s construction should be adopted.

B. “the five panels are individually configurable to control illumination from each of the five panels” ('028 Patent: Claims 16-17, 19, and 21)

Sun’s Construction	Biofrontera’s Construction
Plain and ordinary meaning: The power output and/or light intensity of each panel can be individually controlled.	Indefinite.

¹⁰ The term “approximately four” was included in the originally submitted claims of the '028 patent application, but the term is found nowhere in the specifications of the priority applications cited by the '028 Patent.

The limitation that “the five panels are individually configurable to control illumination from each of the five panels” (“the individually configurable limitation”) is indefinite because it fails to inform “with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus*, 572 U.S. at 909. The specification of the ’028 Patent repeatedly uses the words “configure,” “configured,” “configurable,” and other variations, but uses these terms in a manner where it is not clear whether the claimed term “individually configurable” relates to the physical manipulation of the panels to control illumination (*e.g.*, by angling the panels relative to each other), or to the altering of the wavelength and/or current of the individual LED diodes.¹¹

The ’028 Patent specification repeatedly references configuring the panels in a manner that suggests the “configuring” is directed to physical manipulation of the panels, some of which are provided below:

- This panel is positioned between two other panels and, in a way, acts as a ‘lighted hinge’ to provide enough ‘fill-in’ light to reduce or eliminate the optical dead spaces when the panels *are bent* into a certain **configuration**.” Ex. 2 at 2:65-68, 3:1-4 (emphasis added).
- “the illuminator may be automatically positioned into the proper **configuration** by the actuators without requiring the user *to move the system by hand*.” Ex. 2 at 7:40-43 (emphasis added).

¹¹ To clarify the relationship between “wavelength and/or current” and “power output and/or light intensity,” the lamp emits light with the same color (*i.e.*, wavelength) and intensity across the entire surface of the lamp. Different color light output corresponds to different wavelengths, where LEDs with blue light output will have wavelengths around 400-450 nm and LEDs with red light output will have wavelengths around 600-690 nm. *See* Ex. 3 ¶¶ 24, 26 The intensity of light corresponds to the light output, where the light intensity may be increased by either increasing the current to certain LEDs (increasing the light output per LED) or increasing the number of LEDs in a given row or space (*i.e.* the density of LEDs). Ex. 3 ¶ 59.

- “[c]onfiguring an illuminator *to conform to the curved surface* (e.g., a U-shaped configuration designed to ‘wrap around’ the curvature of the surface)... Ex. 2 at 6:11-14 (emphasis added).
- “The **configurations** may range from *a flat-plane emitter* (as shown in FIGS. 1B and 2B) to *a substantially U-shaped configuration* (as shown in FIGS. 1A and 2A). The adjustable illuminator may also be **configured** such that *the two end panels* 10a, 10e *can be pulled back relative to the three middle panels* 10b, 10c, 10d, such that a smaller U-shaped configuration may be created by the middle panels.” Ex. 2 at 7:50-58 (emphasis added).

A POSA would understand that these passages reflect “configuring” the illuminator panels to represent the physical positioning or manipulation of the panels on the device. Ex. 3 ¶ 90. The ’028 Patent specification further states “it is an object of some embodiments of the present invention to provide an infinitely adjustable illuminator that can effectively deliver a uniformity of light across various areas of a patient’s body, such as a patient’s extremities (e.g., arms and legs) or torso, in addition to a patient’s face and scalp. Thus, a uniform light may be delivered to a targeted treatment area regardless of the shape and location of the contoured surface of the patient’s body.” Ex. 2 at 2:56-64. This supports a POSA’s understanding that “individually configurable to control illumination from each of the five panels” could be construed to mean controlling illumination from each of the five panels by physical manipulation of the panels, so as to provide for uniform illumination of differently shaped body parts across different locations of the patient’s body. See Ex. 3 ¶ 90.

But, the ’028 Patent also repeatedly suggests that the “configuring” may relate to the altering of the wavelength of and/or current to the LEDs, stating:

- “In addition, the LED arrays **60** may be **configured** to emit light continuously or the LED arrays **60** may be **configured** to *flash the diodes on and off* based on a predetermined interval. Furthermore, the LED arrays **60** may be **configured** such that only one *wavelength of light* (e.g., blue) is emitted. Alternatively, the LED arrays **60** may be **configured** such that two or more *wavelengths of light* are emitted from the arrays.” Ex. 2 at 4:15-22 (emphasis added).
- “...the light sources on each of the panels are individually **configurable** to *provide specific power output* to certain areas of the light sources on the panels to compensate for decreased uniformity.” Ex. 2 at 3:16-19 (emphasis added).
- “...the LED arrays **60** can be individually **configured** to *emit more intense light* to only those areas that require it.” Ex. 2 at 6:43-50 (emphasis added).

These passages reflect “configuring” the LED arrays and light sources to alter the wavelength of the LEDs and/or altering the current to the LEDs (Ex. 3 ¶ 91), which is distinct and unrelated to “configuring” the panels via physical manipulation of the panels, as described above.

Sun asserts that the individually configurable limitation should be construed as “the power output and/or light intensity of each panel can be individually controlled,” and cites to various passages similar to those above, stating that the “light sources” and “LED arrays” may be configured or adjusted. Ex. 5 ¶ 59. The explicit language of the claims, however, states that “the five *panels* are individually configurable to control illumination,” directly referring to the *panels* as the component that is “configurable.” All evidence provided by Sun in support of its position specifically calls out the LED arrays or individual diodes on the panels as being configurable, not the panels. Accordingly, Sun’s construction fails to address this claim language or to capture the other disclosures on “configuring” by physical manipulation of the panels.

Additionally, where Sun intended for the light sources to be “configurable,” the claims

were drafted to reflect this. For instance, claim 16 also recites “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.” This claim language reflects an express intent for the “light sources” to be configurable. Had the ’028 Patent applicant intended for the “individually configurable to control illumination” language to be solely directed to power output and/or light intensity of the light sources, as asserted by Sun, it could have drafted the claim language in a manner to reflect this intent, but it did not. In fact, if Sun’s construction were to be adopted, the “light sources being configured” limitation of claim 16 would be redundant. But, it is improper to adopt a claim construction that renders certain claim limitations redundant. *See Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1237 (Fed. Cir. 2016) (“Ideally, claim constructions give meaning to all of a claim’s terms. Construing a claim term to include features of that term already recited in the claims would make those expressly recited features redundant.”) (internal citation omitted); *see also CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) (“In the absence of any evidence to the contrary, ... different terms in the claims connote[] different meanings.”).

When claim language might mean several different things with no informed and confident choice among the definitions, the claims are indefinite. *Interval Licensing*, 766 F.3d at 1371. In *Interval Licensing LLC v. AOL, Inc.* the term “unobtrusive manner” was described in the specification relating to two distinct embodiments: wallpaper displays and screensaver displays. *Id.* at 1373. The Court held that “the ‘unobtrusive manner’ phrase has too uncertain a relationship to the patents’ embodiments,” and, because of this, “fails to ‘inform those skilled in the art about the scope of the invention with reasonable certainty.’” *Id.* at 1371, 1373 (quoting *Nautilus*, 134

S.Ct. at 2130 & n. 8). Similar to *Interval Licensing LLC*, the “individually configurable” term has too uncertain a relationship to the embodiments described in the ’028 patent, which suggests that that the term “individually configurable” may refer to physical manipulation of the panels, or to the altering of the wavelength and/or current of the individual LEDs. Ex. 3 ¶¶ 89-92. Because of these competing embodiments, a POSITA is left to guess which definition is required by the claim language, and the claims fail to inform the scope of the claims with reasonable certainty.

VII. CONCLUSION

For at least the foregoing reasons, the ALJ should adopt Biofrontera’s proposed constructions for all disputed terms.

Ground Rule 1.6 (Word Limit) Certification

The undersigned hereby certifies that this brief contains 9,891 words, and therefore complies with Ground Rules 1.6 and 7.2.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

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