

PUBLIC VERSION

**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**

Inv. No. 337-TA-1411

COMPLAINANT'S OPENING CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

	<u>Pages</u>
I. INTRODUCTION	1
II. LEGAL STANDARDS	2
A. Claim Construction	2
B. Indefiniteness	3
III. OVERVIEW OF THE TECHNOLOGY AND ASSERTED PATENTS.....	4
IV. PERSON OF ORDINARY SKILL IN THE ART.....	8
V. AGREED-UPON CONSTRUCTIONS	9
VI. DISPUTED CLAIM TERMS	10
A. “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges” (’512 and ’028 Patents: All Asserted Claims)	10
B. “photodynamically diagnosing or treating a patient” (Asserted Patents: All Asserted Claims).....	19
C. “nested hinges on inner side surfaces of adjacent panels” (’512 Patent: All Asserted Claims).....	21
D. “the five panels are individually configurable to control illumination from each of the five panels” (’028 Patent: Claims 16, 17, 19, and 21).....	25
E. “within approximately four inches of the treatment surface” (’028 Patent: Claims 1, 2, 4–6, 20, 21).....	28
F. “a recess” (’512 Patent: Claims 17 and 18)	30
VII. CONCLUSION.....	31

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Arctic Cat, Inc. v. GEP Power Prods.</i> , 919 F.3d 1320 (Fed. Cir. 2019).....	21
<i>BASF Corp. v. Johnson Matthey Inc.</i> , 875 F.3d 1360 (Fed. Cir. 2017).....	5
<i>Boehringer Ingelheim Pharm. Inc. v. Lupin Atlantis Holdings SA</i> , 2020 WL 1888247 (D.N.J. Apr. 16, 2020)	14
<i>Byrne v. Wood, Herron & Evans, LLP</i> , 450 F. App'x 956 (Fed. Cir. 2011)	10
<i>Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.</i> , 289 F.3d 801 (Fed. Cir. 2002).....	21
<i>Certain Bio-Layer Interferometers and Components Thereof</i> , Inv. No. 337-TA-1344, Comm'n Op. (Aug. 24, 2023).....	5
<i>Certain Multi-Stage Fuel Vapor Canister Sys. & Activated Carbon Components Thereof</i> , Inv. No. 337-TA-1140, Initial Determin. (Public) (Feb. 26, 2020)	18
<i>Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof</i> , Inv. No. 337-TA-1372, Order No. 36 (Apr. 5, 2024)	14, 15
<i>Ethicon Endo-Surgery, Inc. v. Covidien, Inc.</i> , 796 F.3d 1312 (Fed. Cir. 2015).....	18, 20
<i>GE Lighting Sols., LLC v. AgiLight, Inc.</i> , 750 F.3d 1304 (Fed. Cir. 2014).....	4
<i>Globus Medical Inc. v. Depuy Synthes Prods., LLC</i> , 2015 WL 4886050 (D.D.E. Aug. 14, 2015).....	15
<i>Invitrogen Corp. v. Biocrest Mfg., L.P.</i> , 424 F.3d 1374 (Fed. Cir. 2005).....	5
<i>Ironburg Inventions Ltd. v. Valve Corp.</i> , 64 F.4th 1274 (Fed. Cir. 2023)	5

<i>LLC v. iTouchless Housewares & Prod., Inc.</i> , 2020 WL 7342739 (N.D. Cal., Dec. 14, 2020).....	32
<i>Luminara Worldwide, LLC v. Liown Elecs. Co.</i> , 814 F.3d 1343 (Fed. Cir. 2016).....	5
<i>Mentor Graphics Corp. v. EVE-USA, Inc.</i> , 851 F.3d 1275 (Fed. Cir. 2017).....	16
<i>Nature Simulation Sys. Inc. v. Autodesk, Inc.</i> , 50 F.4th 1358 (Fed. Cir. 2022)	24, 26
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 572 U.S. 898 (2014).....	5, 24, 27
<i>On Demand Mach. Corp. v. Ingram Indus., Inc.</i> , 442 F.3d 1331 (Fed. Cir. 2006).....	3
<i>Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Lab'ys, Ltd.</i> , 476 F.3d 1321 (Fed. Cir. 2007).....	31
<i>Parker Compound Bows, Inc. v. Hunter's Mfg. Co.</i> , 2016 WL 617464 (W.D. Va. Feb. 12, 2016)	31
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005).....	2, 3, 4, 10
<i>Ridge Wallet, LLC v. 2985, LLC</i> , 2024 WL 1638654 (D. Colo. Apr. 16, 2024).....	32
<i>Teleflex, Inc. v. Ficosa N. Am. Corp.</i> , 299 F.3d 1313 (Fed. Cir. 2002).....	4
<i>Thorner v. Sony Computer Entm't Am. LLC</i> , 669 F.3d 1362 (Fed. Cir. 2012).....	4, 5
<i>THX, Ltd. v. Apple, Inc.</i> , 2016 WL 6563340 (N.D. Cal. Nov. 4, 2016)	16
<i>TomTom, Inc. v. Adolph</i> , 790 F.3d 1315 (Fed. Cir. 2015).....	22
<i>Verve, LLC v. Crane Cams, Inc.</i> , 311 F.3d 1116 (Fed. Cir. 2002).....	5, 6
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996).....	4

Statutes

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TABLE OF EXHIBITS

EXHIBIT	DESCRIPTION
A	Certified Version of U.S. Patent No. 11,446,512 to Boyajian <i>et al.</i> (Sun-ITC-0149871–91)
B	Declaration of Dr. Nan Jokerst Regarding Claim Construction, Oct. 3, 2024
C	Expert Report of Robert E. Grove, Ph.D. in Support of Respondents’ Opening Claim Construction Brief, served Oct. 3, 2024 [Confidential]
D	Rebuttal Declaration of Dr. Nan Jokerst Regarding Claim Construction with Exhibits A–C, served Oct. 17, 2024
E	Certified Version of U.S. 11,446,512 File History (Sun-ITC-0147181 – 9207) [Excerpted]
F	Certified Version of U.S. Patent No. 11,697,028 to Boyajian <i>et al.</i> (Sun-ITC-0149892)
G	Definition of “Proximate” in Merriam Webster Dictionary Website at https://www.merriam-webster.com/dictionary/proximate
J	Expert Declaration of Robert E. Grove, Ph.D., for <i>Inter Partes</i> Review of U.S. Patent No. 11,697,028 (Biofrontera Exhibit 1015 in IPR No. 2024-01312) [Excerpted]
K	Rebuttal Expert Report of Robert E. Grove, Ph.D. in Support of Respondents’ Opening Claim Construction Brief, served Oct. 17, 2024 [Confidential]
L	Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,697,028 Under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 <i>et seq.</i> (IPR No. 2024-00874) [Excerpted]
M	Expert Declaration of Eric Bretschneider, Ph.D, for <i>Inter Partes</i> Review of U.S. Patent No. 11,697,028 (Biofrontera Exhibit 1003 in IPR No. 2024-00874) [Excerpted]

Pursuant to the Procedural Schedule (Order No. 6) and Ground Rule 7.2, Complainant Sun Pharmaceutical Industries, Inc. hereby submits its opening claim construction brief.

I. INTRODUCTION

Sun Pharma’s constructions are based on “what [the inventors] actually invented and intended to envelop with the claim[s].” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005). Biofrontera, on the other hand, makes sweeping assertions of indefiniteness across all asserted claims. To support those allegations of indefiniteness, Biofrontera not only manufactures scenarios absent from the claims and specifications, but also takes positions that are fundamentally inconsistent with the declarations presented by its own expert witnesses.

Notably, Biofrontera’s experts interpreted the claims when arguing to the PTAB that the ’028 Patent is invalidated by prior art. *See, e.g.*, Exhibit M ¶¶ 219–22 (Biofrontera’s expert explaining how the prior art allegedly teaches “a higher intensity of light is emitted proximate the second edges”), ¶¶ 285–88 (Biofrontera’s expert explaining how the prior art allegedly teaches panels that are “individually configurable to control illumination”); *see also* Exhibit J ¶¶ 175–181, 228–31. These inconsistent positions undermine Biofrontera’s arguments and highlight the definiteness of the terms at issue.

As for the two terms that Biofrontera attempts to construe—“within approximately four inches of the treatment surface” and “a recess”—each of Biofrontera’s proposed construction runs afoul of the well-established principle that terms “must be construed to implement the invention described in the specification.” *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1344 (Fed. Cir. 2006). Biofrontera’s construction of “within approximately four inches of the treatment surface,” for example, creates a non-sensical result, where the claims would include positioning the panels a mere one-tenth of an inch from the treatment surface (which could cause

severe damage to a patient's skin), yet exclude four-and-one-tenth inches (which would be a typical placement given the regular contours in a human body). As for Biofrontera's construction of "a recess," Biofrontera uses words like "indentation" nowhere to be found in either the patent claims or specification. Adoption of Biofrontera's constructions would thus "lead[] to an overall result that departs significantly from the patented invention." *Id.*

For the reasons set forth in detail below, Sun Pharma respectfully requests that the ALJ find that Biofrontera has not met its clear and convincing burden to show that any term is indefinite and adopt Sun Pharma's proposed constructions.

II. LEGAL STANDARDS

A. Claim Construction

It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. *Phillips*, 415 F.3d at 1312. "[T]he language of the claim frames and ultimately resolves all issues of claim interpretation." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). The terms of a claim are generally given their ordinary and customary meaning, which is the meaning that the term would have to one of skill in the art at the time of the invention. *Phillips*, 415 F.3d at 1312–13. The ordinary meaning of a claim term is its meaning to one of skill in the art after reading the entire patent. *Id.* at 1321.

The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The intrinsic evidence also includes the prosecution history, which consists of "the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d

at 1317. “Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent.” *Id.*

Courts may consider “extrinsic evidence,” which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Id.* While extrinsic evidence is afforded less weight than intrinsic evidence, a court may nonetheless use extrinsic evidence for guidance in ascertaining the meaning of claim terms as they would be understood by one of ordinary skill in the art, so long as it is considered “in the context of the intrinsic evidence.” *Id.* at 1317–19.

A court may depart from the plain meaning of the claims in only two scenarios: lexicography or disavowal. *Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 – 66 (Fed. Cir. 2012). The standards for finding lexicography and disavowal are “exacting.” *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). To act as a lexicographer, a patentee must “clearly set forth a definition of the disputed claim term” and “clearly express an intent to redefine the term,” *Thorner*, 669 F.3d at 1365, while disavowal requires that “the specification [or prosecution history] make[] clear that the invention does not include a particular feature.” *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016). Such disavowal must be clear and unmistakable. *Id.*

B. Indefiniteness

Demonstrating invalidity due to indefiniteness requires a showing of clear and convincing evidence. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

“A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Certain Bio-Layer Interferometers and*

Components Thereof, Inv. No. 337-TA-1344, Comm’n Op. at 11 (Aug. 24, 2023) (EDIS Doc. ID 803150), quoting *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). As the Supreme Court noted in *Nautilus*, language has “inherent limitations.” 572 U.S. at 909. The “reasonable certainty” standard exists to strike a “delicate balance,” “afford[ing] clear notice of what is claimed,” while recognizing those inherent limitations. *See id.* The definiteness requirement thus “recogniz[es] that absolute precision is unattainable.” *Id.* at 910. Thus, “a patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.” *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005). “[N]umerical precision is not always required, even when using a term of degree.” *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1285 (Fed. Cir. 2023); *see also Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002) (finding that terms of degree “are used in patent documents when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to secure the invention,” and may satisfy the definiteness requirement). The fact that the parties disagree about claim scope does not itself render a claim invalid. *See Verve*, 311 F.3d at 1120.

III. OVERVIEW OF THE TECHNOLOGY AND ASSERTED PATENTS.

The Asserted Patents, U.S. Patent No. 11,446,512 (“the ’512 Patent,” Exhibit A) and U.S. Patent No. 11,697,028 (“the ’028 Patent,” Exhibit F) share a title, “Adjustable Illuminator for Photodynamic Therapy and Diagnosis” and a common specification. Both patents claim priority to the same application with a priority date of October 15, 2015.

Claims 1–3, 5, 8, 17–18, and 20 of the ’512 Patent are at issue in this Investigation. Claims 1 and 17 of the ’512 Patent, reproduced below, contain the disputed terms (in bold):

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

an illuminator comprising at least five panels connected by *nested hinges on inner side surfaces of adjacent panels*,

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,

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,

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

17. The method of claim 8, wherein at least one panel includes *a recess* configured to receive a flange of one of the *nested hinges*.

'512 Patent at 10:22–40 (Claim 1), 11:36–38 (Claim 17).

Claims 1, 2, 4, 5, 6, 16, 17, 19, 20, and 21 of the '028 Patent are at issue in this Investigation.

Claims 1 and 16 of the '028 Patent, reproduced below, contain the disputed terms:

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

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

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,

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,

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

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*.

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

a mobile base supported by at least four wheels;

a pillar perpendicular to the base;

a controller disposed to be supported by the pillar;

an arm mounted to a top portion of the pillar; and

an illuminator connected at an end of the arm, the arm being hinged to allow adjustment of a position of the illuminator relative to the base, 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*,

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

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

'028 Patent at 10:24–44 (Claim 1), 11:45–12:7 (Claim 16) (emphasis added).

The Asserted Patents disclose a system and method for photodynamic therapy or photodynamic diagnosis of skin diseases. *See, e.g.*, '512 Patent at 10:22–40 (Claim 1), '028 Patent at 10:24–44 (Claim 1). They relate to an adjustable illumination device and method for photodynamic therapy to treat and/or diagnose several types of ailments in or near the skin or other tissues, such as those in a body cavity. '512 Patent at 1:17–27. For example, the Asserted Patents describe a system for photodynamically diagnosing or treating a patient comprising an illuminator comprising five panels connected by hinged structures with light sources disposed on surfaces of the five panels 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 being configured to be angled relative to the center panel. '512 Patent at 2:63–3:19, Claim 1. The light sources are configured to uniformly illuminate the treatment surface. *Id.*

The Asserted Patents describe how conventional adjustable illuminators could have “optical ‘dead spaces’ in certain portions of the target treatment area” which would “receive less overall light, resulting in a lower dose of treatment in those portions.” '512 Patent at 2:5–20. The Asserted Patents note that “some forms of treatment involving PDT, such as the use of ALA to treat actinic keratosis, require specific and highly uniform intensity and color of light to achieve effectiveness.” *Id.* at 2:28–31. “The optical dead space that can occur at or near the hinges of conventional adjustable illuminators reduces the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT for these specific treatments.” *Id.* at 2:39–42. The conventional illuminators also had limited effectiveness depending on the “various contours of a patient’s body.” *Id.* at 2:42–49. For example, a “‘fall off’ of light exposure tends to occur at the edges of a curved surface.” *Id.* at 6:5–6.

The systems and methods claimed in the '512 and '028 Patents include novel features to “to reduce or eliminate these dead spaces and provide for a more uniform light distribution in an adjustable illuminator designed for PDT or PD of a variety of targeted areas.” *Id.* at 2:50–54. For example, the Asserted Patents disclose “nested hinges” as a way to “substantially reduce or eliminate optical dead spaces.” *Id.* at 4:46–48. As another example, the Asserted Patents describes that to “increase the uniformity of light exposure to the treatment area while maintaining a practical size of the illuminator” the light sources on the panels “may be individually configured to increase the intensity of light emitting from certain diodes to compensate for this fall-off effect.” *Id.* at 6:16–21. The Asserted Patents provide the example of LED arrays that “are divided into three

general areas” where “the current to each area is adjusted in order to adjust the intensity of light emitting from each of the areas.” *Id.* at 6:22–25. In those panels, “a higher current may be supplied to areas 1 and 2”—*i.e.*, the areas proximate the shorter edges of the panel—“such that areas 1 and 2 emit a higher intensity of light than areas 3 and 4”; and “a higher current may be supplied to areas 3 and 4 than the current supplied to areas 5 and 6.” *Id.* at 6:31–36 (referencing Fig. 5). The Asserted Patents also disclose that the panels “may also include varying amounts of individual diodes mounted within the particular area.” *Id.* at 6:49–51. “By varying the arrangement of the diodes within each of the addressable strings of the LED arrays 60, power output and/or the intensity of light emitted from a given array may be better controlled and fine-tuned.” *Id.* at 7:1–4.

IV. PERSON OF ORDINARY SKILL IN THE ART

Sun Pharma proposes the following level of ordinary skill in the art, reflecting the education level of the inventors and the technical field of the patented technologies:

A POSITA with respect to the '512 and '028 Patents, and at the time of invention of the '512 and '028 Patents, would have a M.D. and/or a Ph.D. in an electrical engineering, optoelectronics, physics, optical sciences, optical engineering, or related scientific or engineering field, and at least one to two years of work or research experience in optical engineering, optics, optoelectronics, phototherapy, photodynamic therapy, or a related field.

Biofrontera, by contrast, has proposed inconsistent definitions for a POSITA. Biofrontera’s expert in this proceeding, Dr. Robert Groves, proposes in his opening claim construction report that a POSITA is required to have “(1) at least a Bachelor of Science degree . . . **and** (2) a medical degree. . . .” *See* Exhibit C, Groves Opening Claim Construction Report, ¶ 32. In his rebuttal report, he expresses his “opinion that both M.D. and **Ph.D.** backgrounds together should be considered the appropriate POSITA,” without explaining why a Bachelor of Science

and a medical degree, his original opinion, is now insufficient. *See* Exhibit K, Grove Rebuttal Claim Construction Report, ¶ 10.

Further, Dr. Grove and Biofrontera make no attempt to square the now-necessary medical degree requirement with Biofrontera’s earlier declaration from a different expert, Dr. Eric Bretschneider, Ph.D., in an IPR proceeding challenging the ’028 Patent (IPR2024-00874). There, Dr. Bretschneider, proposed a **lower** level of skill in the art and did not require an M.D. *See* Exhibit M, Bretschneider IPR Declaration, ¶ 37. Biofrontera relied on Dr. Bretschneider’s views of the patent in its IPR petition, *see* Exhibit L, IPR2024-00874 Petition, at 3, even as Dr. Bretschneider himself **lacks an M.D.** *See* Exhibit M ¶ 7.

Even setting aside the inconsistent shifts in position, Biofrontera’s new insistence that a medical degree is required to understand the claims is contrary to law because it would exclude the inventors as POSITAs on their own patents—as none of the inventors have an M.D. or four years of medical experience. *See, e.g., Phillips*, 415 F.3d at 1313 (referring to “the well-settled understanding that inventors are typically persons skilled in the field of the invention”); *Byrne v. Wood, Herron & Evans, LLP*, 450 F. App’x 956, 964 (Fed. Cir. 2011) (“[I]t will be the rare case in which an inventor is not one possessing skill in the art”), *judgment vacated on other grounds*, 568 U.S. 1190 (2013). In any event, Sun Pharma’s constructions remain the proper definitions for the disputed term under either parties’ POSITA definition.

V. AGREED-UPON CONSTRUCTIONS

The Parties have agreed to the following constructions:

Term (’512 and ’028 Patents: All Asserted Claims)	Agreed-Upon Construction
“uniformly illuminate a treatment surface”	“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”

“uniformly illuminating a treatment surface”	“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”
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VI. DISPUTED CLAIM TERMS

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

Term	Sun Pharma’s Proposed Construction	Biofrontera’s Proposed Construction
“a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges”	“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”	Indefinite.

All Asserted Claims require that “a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.” *See, e.g.*, ’512 Patent at Claim 1, ’028 Patent at Claim 1. The Asserted Patents describe how the illuminator’s panels may be divided into areas of varying intensity of light, “such that a higher intensity of light is emitted overall from the edges” in order to address the “fall-off effect” of reduced light exposure at the edges of a curved surface. *See* ’512 Patent at 5:55–6:38. Sun Pharma’s construction reflects the meaning of that term in view of the specification’s teachings, as understood by a POSITA. Biofrontera, by contrast, has failed to provide clear and convincing evidence that a POSITA would be unable to identify the scope of the claims with reasonable certainty in view of the specification and the explicit goals of the Asserted Patents.

1. Sun Pharma's Construction Reflects The Meaning Of The Claims.

The claim language and specifications of the Asserted Patents confirm that the meaning of “second edges” is “second shorter edges” and that “proximate” means “close to.” *See* Exhibit D, Jokerst Rebuttal Claim Construction Declaration, ¶ 34.

First, construing “second edges” as “second shorter edges” is consistent with the claim language: “wherein each of the at least five panels has two first edges and *two second edges shorter than the two first edges.*” Biofrontera’s expert does not contest this point; he understands that the “second edges” are the shorter edges, as seen, for example, in his identification of the “top and bottom” of the panels in Figure 5 as the “second edges.” *See* Exhibit C ¶ 54.

Second, the Asserted Patents use the term “proximate” to identify the relative arrangement of the light sources based on their intensity of light emitted, where groups of light sources (those that emit a higher intensity of light) are “close to” the second edges as compared to those not “close to” the second edges: “the light sources are *arranged such that* a higher intensity of light is emitted *proximate the second edges compared to* the intensity of light emitted *not proximate the second edges.*” ’512 Patent at Claim 1. The claims’ use of “proximate” to identify relative positioning of groups of light sources is consistent with the specification’s description of how the patented arrangement of light sources enables greater uniformity of the light illuminating a treatment surface. The Asserted Patents describe the need for “illumination to the target area and this illumination must be uniform” to achieve effective treatment, including for treating actinic keratosis. *Id.* at 2:28–42. However, there is a “fall off” of light exposure at the edges of curved surfaces (such a patient’s head), which can reduce overall uniformity. *Id.* at 5:67–6:8; *see* Exhibit B ¶ 28.

To offset that “fall-off effect,” the Asserted Patents describe that the uniformity of light exposure to the treatment area can be increased by increasing the “intensity of light emitting from certain diodes to compensate for this fall-off effect.” ’512 Patent at 6:16–21. The Asserted Patents discuss an exemplary embodiment, shown in Figure 5, where the “LED arrays” are “divided into three general areas, which may be described as ‘addressable strings.’” *Id.* at 6:22–25. Starting at the left-most panel, the areas 1—highlighted below in red—are those proximate (*i.e.*, close to) the second (shorter) edges of the panel and have higher intensity than areas 3 and 5, highlighted in blue. *See* Exhibit D ¶ 36.

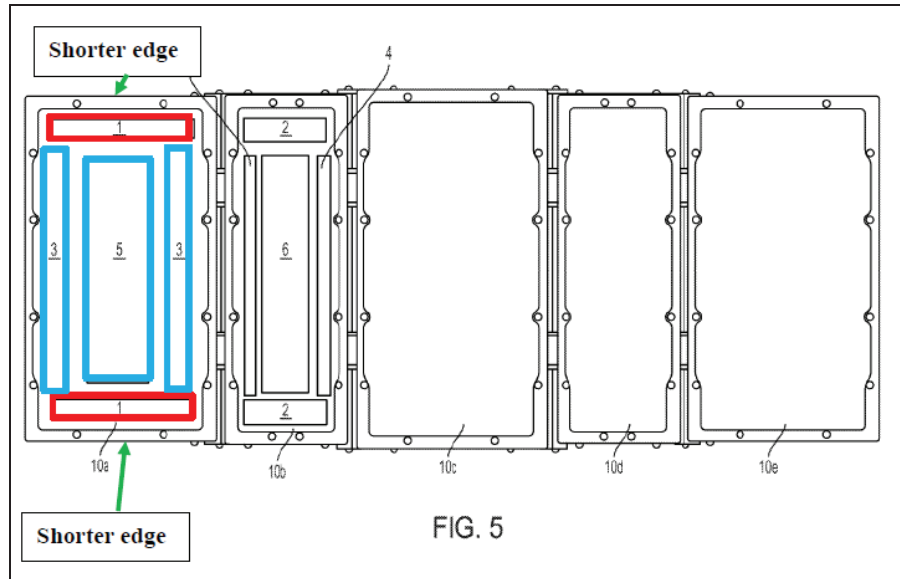


Fig. 5 (annotations added). The Asserted Patents explain that in one example, “[t]he current to each area is adjusted in order to adjust the intensity of light emitting from each of the areas.” ’512 Patent at 6:30–32. In that example, “a higher current may be supplied to areas 1 and 2 than the current supplied to areas 3 and 4 such that areas 1 and 2 emit a higher intensity of light than areas 3 and 4” and “a higher current may be supplied to areas 3 and 4 than the current supplied to areas 5 and 6.” *Id.* at 6:30–36. “Thus, a higher intensity of light is emitted overall from the edges, which may allow for a reduction in any fall-off effect.” *Id.* at 6:36–38, 7:8-11.

In an alternative example, the addressable strings (*i.e.*, the general areas 1, 3, and 5) “may also include varying amounts of individual diodes mounted within the particular area.” *Id.* at 6:49–51. Like the first example, “[b]y varying the arrangement of the diodes within each of the addressable strings of the LED arrays 60, power output and/or the intensity of light emitted from a given array may be better controlled and fine-tuned.” *Id.* at 7:1–5. The specification thus provides objective guidance regarding the meaning of “proximate” in the claim language: the claims delineate areas proximate to the second edges that have a relatively higher intensity of emitted light (*e.g.*, because of a higher current or because of the amount of LEDs in the given area) as compared to the areas not proximate the second edges. *See* Exhibit D ¶¶ 34–37.

The term “proximate” has been regularly found by courts to describe the relative positioning of components. *See, e.g., Boehringer Ingelheim Pharm. Inc. v. Lupin Atlantis Holdings SA*, 2020 WL 1888247, at *5 (D.N.J. Apr. 16, 2020) (“Courts have routinely ruled that the plain meaning of ‘proximate to’ is ‘at or near’.”); *Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof*, Inv. No. 337-TA-1372, Claim Construction Order at 12–13 (Apr. 5, 2024) (EDIS Doc. ID 817803) (finding that “the term ‘proximate’ is construed as meaning at, near, or close to, which in the context of the ’864 patent identifies relative positioning”); *Globus Medical Inc. v. Depuy Synthes Prods., LLC*, 2015 WL 4886050, at *9–10 (D. Del. Aug. 14, 2015) (construing “located proximate” as “located closer to”). The claim language here uses the term “proximate” to designate the relative position of the areas “proximate the second edges” and the areas “not proximate the second edges.”

2. The Asserted Claims Are Not Indefinite.

Biofrontera alleges that the asserted claims are indefinite because of purported uncertainty as to: (1) how to determine what is “proximate”; and (2) the meaning of “intensity” and how to

measure “intensity.” *See* Exhibit C ¶ 44. Both arguments ignore the claim language and express disclosures in the specification. Moreover, Sun Pharma’s expert explains that a POSITA reading the claims in light of the specification would understand the claim scope with reasonable certainty.

a. The Specification Provides Reasonable Certainty Regarding The Meaning Of “Proximate”

The claims of the Asserted Patents use the term “proximate” to describe the locations of light emitted relative to the second edges of the panel. *See, e.g.*, ’512 Patent at Claim 1 (“a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges”). A similar proximate-indefiniteness argument was rejected in *Certain Vaporizer Devices*, where respondents argued that “‘proximate’ is indefinite because it is a term of degree for which the patent provides absolutely no objective standard by which to determine whether something is proximate enough to meet the claims.” Inv. No. 337-TA-1372, Order No. 36 at 6. There, “proximate the first/second end” was found to provide “sufficient guidance” to a POSITA because it relied on “certain fixed points.” *Id.* at 8. Here, the “second edges” are fixed points which provides significant guidance to a POSITA for determining the relative position of the emitted light “proximate” the second edges.

Furthermore, the stated goal of the Asserted Patents—uniform illumination by eliminating the fall-off effect, discussed *supra*—also provides “reasonable certainty” to the term “proximate.” *See Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1291–92 (Fed. Cir. 2017) (finding that a skilled artisan reviewing the patent’s specification and figures and in context of the requirements necessary “for the patent’s stated objective to occur” would “understand the meaning of ‘near’ with reasonable certainty”); *THX, Ltd. v. Apple, Inc.*, 2016 WL 6563340, at *14–15 (N.D. Cal. Nov. 4, 2016) (finding that the specification provided “reasonable certainty” regarding the placement of an aperture “proximate the flat surface” in view of the goals of the claims). The

specification of the Asserted Patents instructs a POSITA that infringement can be assessed by first dividing panels into “areas” or “addressable strings” and then determining whether the areas close to the shorter edges emit a higher intensity of light as compared to the remaining areas.

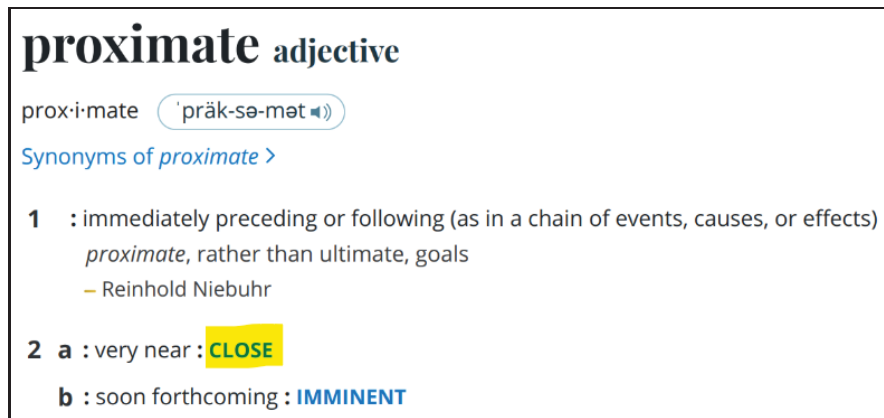
Indeed, Biofrontera’s expert understands the claims’ recitation of “proximate” to refer to increasing the intensity of light emitted in the regions near the top and bottom edges (*e.g.*, the “second edges”) to achieve the goal of uniform illumination. For example, in his declaration, he notes that a lamp can be designed to “emit light at a greater intensity” near the edges as compared to “its central region” to increase the uniformity of the illumination. Exhibit C ¶ 26. He also gives examples of reducing the spacing between light sources “*near the top and bottom* of the lamp” and “the number or density of LEDs could be increased *near the upper and lower edges* of the panel(s).” *Id.* ¶ 27.¹

Biofrontera’s expert now contends that the only understandable setup for a panel to “unambiguously seem to meet the claimed proximate light limitation” is if the row of light sources “*immediately* proximate” the edge is of higher intensity. Exhibit C ¶ 59 (“There is one scenario where a light panel would unambiguously seem to meet the claimed proximate light limitation”). But of course, the claims do not use the word “immediately” and there is no such requirement. Biofrontera provides no explanation for its unilateral importation of the word “immediately” to find indefiniteness.

Lastly, Biofrontera attempts to show why “proximate” is indefinite by using an inapposite dictionary definition: “immediately preceding or following (as in a chain of events, causes, or effects.” Exhibit C ¶ 60. However, a POSITA reading the Asserted Patents would know that, in

¹ The same expert also submitted an expert declaration on behalf of Biofrontera in the related IPR, where he had no difficulty identifying the “proximate” term within the prior art. *See* Exhibit J, Grove IPR Declaration, ¶¶ 84, 141, 175–181.

the context of the claim language describing how “the light sources are arranged,” the word “proximate” has nothing to do with non-physical concepts like “chain of events, causes, or effects.” See Exhibit D ¶ 34. Because Biofrontera’s definition in this context is non-sensical, it is inapplicable to a POSITA. *Id.* In fact, the very same dictionary cited by Biofrontera—Merriam-Webster Online Dictionary—provides the more relevant definition of “proximate” with regards to *physical elements*, “very near: *close*.”



See Exhibit G (*Proximate*, MERRIAM-WEBSTER ONLINE DICTIONARY, merriam-webster.com/dictionary/proximate (2024)). In view of the claims and the specification, as well as the supportive extrinsic evidence, the term “proximate” identifies the relative position of emitted light in relation to the fixed points of the second edges.

b. The claims use “intensity” consistent with its plain meaning.

Biofrontera further contends that the asserted claims are indefinite because of the alleged uncertainty for measuring an “intensity of light . . . emitted.” See, e.g., Exhibit C ¶ 50 (“[T]he question remains as to *where* the intensity must be measured.”). But the Asserted Patents provide objective guidance that the “intensity of light emitted” is a relative measurement—the light emitted from the areas proximate the shorter edges is of higher intensity than the light emitted elsewhere on the panels. See Exhibit D ¶ 39.

Because “an understanding of how to measure the claimed average pressures was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique.” *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015); *see Certain Multi-Stage Fuel Vapor Canister Sys. & Activated Carbon Components Thereof*, Inv. No. 337-TA-1140, Initial Det. at 63 (Mar. 22, 2022) (EDIS Doc. ID 703499) (rejecting an indefinite argument for an alleged failure to identify a specific testing method to be used, because a POSITA “would understand the value relevant to the claims . . . [and] would likely know the general means of obtaining the value, involving varying degrees of accuracy”).

Here, a POSITA would understand with reasonable certainty where to measure the emitted intensity of light. *See* Exhibit D ¶ 39. The claims expressly compare the intensity of light emitted from regions of the panel close to the shorter edges as compared to another region. A higher intensity of light may be self-evident—*e.g.*, by visually inspecting that there is a higher density of LEDs in the areas proximate the second edges as compared to not proximate the second edges. Exhibit D ¶¶ 37–38 (noting that Biofrontera’s expert made that exact visual assessment in his declaration, Exhibit C ¶ 54). Additionally, the Asserted Patents describe using a controller to set the intensities of specific addressable strings or LED arrays. Exhibit D ¶ 38; *see* ’512 Patent at 5:55–60 (“Alternatively, each panel may have a ***dedicated control unit*** to regulate power to the individual LED array on a given panel to allow for more particular fine-tuning of the illuminator, which may further enhance uniformity and increase efficiency.”) (emphasis added); *see also* ’512 Patent at 6:30–31 (“The current to each area is adjusted in order to adjust the intensity of light emitting from each of the areas.”); *id.* at 6:38–41 (“Alternatively, the illuminator may be

configured to adjust each individual diode present in a given LED array 60, allowing for an even greater fine-tuning effect.”)

A POSITA would understand with reasonable certainty how to use a sensor to measure the light. Biofrontera’s expert asserts that the claim is indefinite because “the measured intensity from the exact same light source or device will vary based on how far away (or at which angle) from the device the sensor is placed,” Exhibit C ¶ 50, as if a POSITA would not understand how to use a sensor to compare the intensity of light emitted compared to another region. To the extent there is any ambiguity about *how* to use the sensor, both experts seem to agree—through omission of any discussion on the matter—that actually taking a measurement of light is trivial for a POSITA. *See* Exhibit C ¶ 50 (“Intensity of light emitted from a source is typically measured by a sensor.”); Exhibit D ¶ 39 (“To the extent that a POSITA uses a sensor to measure the relative intensities of the areas the POSITA would understand that the sensor would need to be placed in relatively the same position with respect to the areas to get a usable comparison.”). There is no discussion, nor any evidence presented by Biofrontera’s expert, as to why a POSITA would not understand how to use a sensor to measure intensity of light emitted from the panel.

Lastly, Biofrontera argues that the claims are indefinite because “the claims fail to specify any unit or method of measurement for the recited ‘intensity.’” Exhibit C ¶ 46. But Biofrontera’s concern is with a portion of the specification—not the claims. *See id.* ¶ 47. First, there is simply no requirement in the claims to specify a unit of measurement for a POSITA to understand the *relatively* higher intensity of light emitted in one region versus another—a POSITA would use the same unit of measurement for both regions and then compare the magnitudes. *See* Exhibit D ¶ 22; *see also Ethicon Endo-Surgery*, 796 F.3d at 1319 (“If such an understanding of how to measure the claimed average pressures was within the scope of knowledge possessed by [a POSITA], there

is no requirement for the specification to identify a particular measurement technique.”). Second, Biofrontera misreads the specification, which consistently uses W/cm^2 to describe intensity emitted by the illuminator and J/cm^2 to describe light dose received by the treatment area. *See, e.g.*, ’512 Patent at 8:18–20 (“Total light dose, in terms of J/cm^2 , was measured based on emitted irradiance (W/cm^2) over time (in seconds).”); ’512 Patent at 10:48–50 (Claim 4) (“wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm^2 to 30 mW/cm^2). To the extent units play any role in the scope of the claims, a POSITA would understand how to measure a “higher intensity of light emitted.” *See* Exhibit D ¶¶ 21–39.

For the foregoing reasons, Biofrontera has not met its clear and convincing burden to show that the claims of the Asserted Patents are indefinite.

B. “photodynamically diagnosing or treating a patient” (Asserted Patents: All Asserted Claims)

Term	Sun Pharma’s Proposed Construction	Biofrontera’s Proposed Construction
“photodynamically diagnosing or treating a patient”	Preamble not limiting	Preamble is limiting.

The preambles of the Asserted Patents are not limiting because the claim elements themselves describe complete inventions, whereas the preamble only describes the claims’ intended purpose or use. *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (“[A] preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.”) The preambles here are not limiting because they do not recite “essential structure or steps” and are not necessary to give “life, meaning, and vitality to a claim.” *See Arctic Cat, Inc. v. GEP Power Prods.*, 919 F.3d 1320, 1327 (Fed. Cir. 2019).

For example, the Federal Circuit in *Arctic Cat* held that a preamble reciting “[a] power distribution module for a personal recreational vehicle” was not limiting because it does not “impose[] any structural requirement on the claimed module beyond what is required by the bodies of the claims.” *Id.* at 1328. Like *Arctic Cat*, the preamble language does not impose any structural limitations on the invention because the structure as claimed is a complete invention. In Claim 1 of the ’512 Patent, for example, the claim discloses a system that comprises at least five panels that have light sources configured to uniformly illuminate a patient’s treatment surface, and each such element is described within the claim elements. The preamble of “photodynamically diagnosing or treating a patient” neither includes any essential structure or steps, nor breathes “life, meaning, or vitality to the claim. Moreover, as in *Arctic Cat*, the preamble does not supply any antecedent basis for the terms in the body of the claims, further evidencing that it is not limiting. *Arctic Cat*, 919 F.3d at 1329 (finding “language here does not supply ‘antecedent basis’ for terms in the body defining a module; nor does it supply structure needed to make the body itself a ‘structurally complete invention.’ . . . Rather, it merely adds structure of which the body-recited module is a part.”)

The Federal Circuit has repeatedly found that a preamble is not limiting when it “employs the standard pattern” of “a method for a purpose or intended use comprising.” *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1324 (Fed. Cir. 2015). The Asserted Patents’ use of the preamble “photodynamically diagnosing or treating a patient” follows that “standard pattern” of stating the purpose or intended use of the invention, without limiting that invention. Thus, the preambles of the Asserted Patents are not limiting because the claim elements themselves describe complete inventions; it would be inappropriate to limit the scope of the claim using the preamble where the preamble only describes the claims’ intended purpose or use.

C. “nested hinges on inner side surfaces of adjacent panels” (’512 Patent: All Asserted Claims)²

Term	Sun Pharma’s Proposed Construction	Biofrontera’s Proposed Construction
“nested hinges on inner side surfaces of adjacent panels”	Plain and ordinary meaning. Hinges that fit on inner side surfaces of adjacent panels.	Indefinite.

The Asserted Claims of the ’512 Patent recite “nested hinges on inner side surfaces of adjacent panels.” *See, e.g.*, ’512 Patent at Claim 1 (“an illuminator comprising at least five panels connected by *nested hinges on inner side surfaces of adjacent panels*”). The claim language, the specification, and prosecution history of the ’512 Patent support the plain and ordinary meaning of “nested hinges on inner side surfaces of adjacent panels” as “hinges that fit on inner side surfaces of adjacent panels.” Exhibit D ¶ 48. The term “nested hinges on inner side surfaces of adjacent panels” is not indefinite and should be given its plain and ordinary meaning. *Id.* ¶ 42.

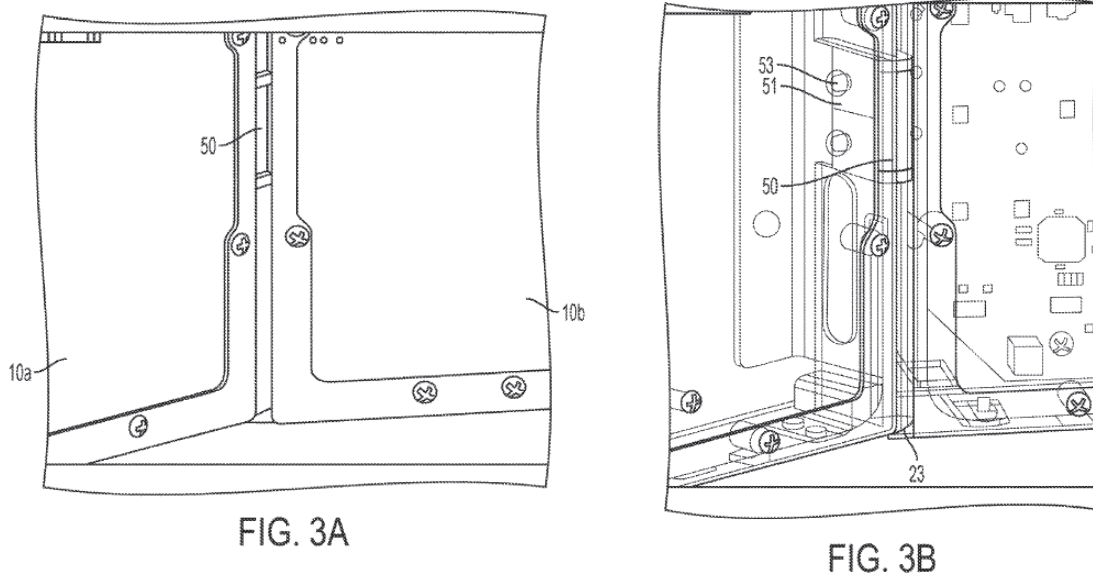
1. The Claims and Specification Support The Plain And Ordinary Meaning Of “Nested Hinges On Inner Side Surfaces Of Adjacent Panels”

The claim language of the ’512 Patent recites that the panels are “connected by nested hinges on inner side surfaces of adjacent panels.” ’512 Patent at Claim 1. A POSITA would understand, with reasonably certainty, that the plain and ordinary meaning of “nested hinges on inner side surfaces of adjacent panels” in the context of the claim language itself is hinges that fit on inner side surfaces of adjacent panels. *See* Exhibit D ¶ 44.

Moreover, the specification of the ’512 Patent further supports the plain and ordinary meaning of “nested hinges on inner side surfaces of adjacent panels.” *See id.* ¶ 45. The

² If the Court construes “nested hinges,” Sun Pharma believes that the Court should construe the phrase “nested hinges on inner side surfaces of adjacent panels” to provide full context.

specification of the '512 Patent discloses that “FIGS. 3A–3B show detailed views of the nested hinges of the main body of the illuminator of FIGS. 1A–1B.” ’512 Patent at 3:31–32. The “nested hinges 50” are shown below in Figures 3A–3B. *Id.*, Figures 3A–3B; *see id.* at 4:63–64.



Consistent with Figures 3A–3B, the specification explains that the nested hinges “are mounted to the inner side surfaces of adjacent panels (*e.g.*, 10a, 10b) to allow for rotation of the panels.” ’512 Patent at 4:64–66. The specification explains further that hinges may also contain a “flange . . . mounted to the inner side surface of a panel.” *Id.* at 4:66–67. The specification further states:

[t]he inner side surface of a panel may include a recess in which the flange 51 may be placed. The *inner side surface of the panel* may also include an additional recess to accommodate the joint of the hinge 50 such that the joint of *hinge 50 becomes substantially flush* with an outer front surface of the panel. Such configurations may allow for the outside vertical edges of adjoining panels to be positioned closer to one another. By spacing the vertical edges of adjoining panels closer, optical dead spaces may be further reduced or eliminated. In addition, the hinges 50 together with the tabs 23 may reduce the number of pinch points present in the system.

Id. at 5:1–12 (emphasis added). In view of the plain language of the claims, consistent with the specification’s disclosure above, a POSITA would understand that the term “nested hinges on

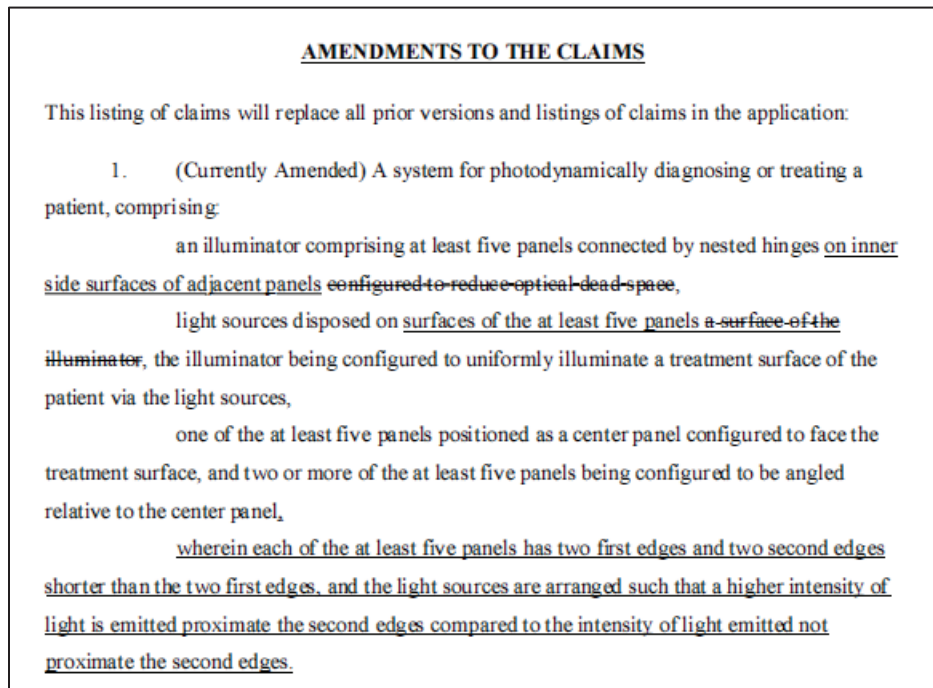
inner side surfaces of adjacent panels” has its plain and ordinary meaning: hinges that fit on the inner side surfaces of adjacent panels. *See* Exhibit D ¶ 44.

2. The Prosecution History Support The Plain And Ordinary Meaning Of “Nested Hinges On Inner Side Surfaces Of Adjacent Panels”

The prosecution history of the ’512 Patent further supports Sun Pharma’s construction. *See* Exhibit D ¶ 44; *see also* *Nautilus*, 572 U.S. at 910. The Federal Circuit recently confirmed that the prosecution history of a patent is significant where a patent examiner initially rejects a claim on the ground of indefiniteness, and the applicant later amends the claims to overcome the rejection. *See Nature Simulation Sys. Inc. v. Autodesk, Inc.*, 50 F.4th 1358, 1366 (Fed. Cir. 2022) (“The prosecution history here is significant, for the patent examiner had initially rejected the claims on the ground of indefiniteness.”). There, the court found that the district court erred when it “gave no weight to the prosecution history showing the resolution of indefiniteness by adding the designated technologic limitations to the claims.” *See id.* at 1367–68.

Here, the understanding of “nested hinges on inner side surfaces of adjacent panels” is supported by the interaction of the Examiner and Applicant. During prosecution, the Examiner initially rejected the claims of the ’512 Patent “under 35 U.S.C. 112(b) (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor . . . regards as the invention.” Exhibit E, ’512 Patent File History, at Sun-ITC-0147732. Specifically, the Examiner stated that “Claim 1 recites the limitation ‘nested hinges configured to reduce optical dead space’ in lines 2–3. The metes and bounds of the claim are unclear as it is not known what the optical dead space is compared to in order to known [sic] that it has been ‘reduced’.” *Id.* In response, the Applicant, in consultation with the Examiner,

amended the term “nested hinges” as shown in the prosecution record to recite “nested hinges *on inner side surfaces of adjacent panels*”:



Id. at -8818, 8823. After the amendment, the Examiner withdrew the rejection for indefiniteness and allowed the claims, stating “[i]t is in the opinion of the examiner that *the art of record neither anticipates nor renders obvious ‘nested hinges on inner side surfaces of adjacent panels. . . .’*”

Id. at -8911 (emphasis added). The Examiner’s allowance of the claims following Applicant’s amendment further supports that a POSITA would understand the metes and bounds of the term “nested hinges on inner side surfaces of adjacent panels.” *See Nature Simulation*, 50 F.4th at 1366–67.

Biofrontera’s additional arguments also fail. In his expert report, Dr. Grove attempts to show how the inclusion of additional “tab” and “recess” features of the ’512 Patent do not shed light on the meaning of “nested hinges.” *See* Exhibit C ¶¶ 76–79. But, as if to answer his own question, he later states “further inspection of this passage and the accompanying figures illustrates

that *the tabs and ‘nested hinges’ are unrelated elements of this device,*” *id.* ¶ 77 (emphasis added), and later acknowledges that the “disclosure suggests that a recess to receive the joint of the hinge *is an additional configuration.*” *Id.* ¶ 80 (emphasis added). Both the “tab” and “recess” features in the ’512 Patent specification are additional features of the *panels* and not of the “nested hinges,” and therefore are not meant (nor are necessary) to provide a POSITA with an understanding of the plain and ordinary meaning of the term “nested hinges on inner side surfaces of adjacent panels.”

For the foregoing reasons, Biofrontera has not met its clear and convincing burden to show that the claims of the ’512 Patent are indefinite, and the term “nested hinges on inner side surfaces of adjacent panels” should be given its plain and ordinary meaning: “hinges that fit on inner side surfaces of adjacent panels.”

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

Term	Sun Pharma’s Proposed Construction	Biofrontera’s Proposed Construction
“the five panels are individually configurable to control illumination from each of the five panels”	Plain and ordinary meaning: The power output and/or light intensity of each panel can be individually controlled.	Indefinite.

Claims 16 and 21 of the ’028 Patent recite that “the five panels are individually configurable to control illumination from each of the five panels.” *See, e.g.*, ’028 Patent Claims 16 and 21. Biofrontera has not—and cannot—overcome its clear and convincing burden to demonstrate that this term is indefinite.

A POSITA would understand with reasonable certainty that “individually configurable to control illumination” means that the *illumination from each panel* can be individually controlled, *i.e.*, the power output and/or the light intensity emitted *from* the panel can be individually

controlled. *See Nautilus*, 572 U.S. at 901. Biofrontera alleges that the claims are indefinite because “individually configurable to control illumination” could somehow include physically moving the panels. Biofrontera’s hypothetical construction is not contemplated by the claims or the specification; it broadens the scope of the claims in an effort to prove indefiniteness, but lacks any intrinsic support for such a broadening.

First, as to “configurable,” a POSITA would understand the meaning of such a word because the ’028 Patent always uses the word “configure” and its variants in accordance with its standard meaning—“to set up for operation especially in a particular way.” *See* Exhibit D ¶ 58 (reviewing exemplary dictionary definitions). In context of the claims, the word “configurable” refers to the ability of the panels to be individually set up with respect to the illumination from the panel—*i.e.*, as Sun Pharma proposes in its construction, that “the power output and/or light intensity of each panel can be individually controlled.”

Second, the ’028 Patent consistently uses the term “individually configurable,” or some variation thereof, in relation to controlling the illumination emitted from the panels’ light sources. *See* Exhibit D ¶ 59. The claim language itself supports this: “wherein the five panels are ***individually configurable to control illumination from*** each of the five panels.” ’028 Patent at Claim 16 (emphasis added). The claim itself states that “individually configurable” refers to the ability to control the illumination from the panels, which contradicts entirely Biofrontera expert’s statement that “the language of claims 16 and 21 does not provide any guide regarding what is meant by ‘configurable.’” *See* Exhibit C ¶ 89.

The specification further supports Sun Pharma’s proposed construction. The patent describes that the illumination of the panels is created by the light sources, *e.g.*, LED arrays contained in the panels. ’028 Patent at 3:56–57 (“Each panel contains an array of light emitting

diodes . . . which may be configured in an evenly spaced pattern across the face of the panel.”). Every instance of the phrase “individually configurable” or its variation in the specification supports Sun Pharma’s understanding of the claim language. The phrase is always used in relation to the panel’s light sources and describes either controlling the power output or light intensity—*i.e.*, “illumination **from** each of the five panels.” Exhibit D ¶ 59. That output is controlled by means of a control unit “to regulate power to the lights.” ’028 Patent at 5:52–54. Examples of the specification’s use of “individually configurable” are copied below:

- “In order to even further reduce or eliminate optical dead spaces, it is preferable that 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. For example, the ***power outputted*** to each individual diode in an array of light emitting diodes (LED) may be individually adjusted.” ’028 Patent at 3:14–21 (emphasis added).
- “In order to increase the uniformity of light exposure to the treatment area while maintaining a practical size of the illuminator, the LED arrays **60** may be ***individually configured to increase the intensity of light emitting from*** certain diodes to compensate for this fall-off effect.” *Id.* at 6:18–23 (emphasis added).
- “An example in which the LED arrays **60** may be ***individually configured*** is shown in Fig. 5. Here, the LED arrays **60** are divided into three general areas, which may be described as ‘addressable strings.’ . . . The current to each area is adjusted in order to ***adjust the intensity of light emitting from*** each of the areas.” *Id.* at 6:24–33 (emphasis added).
- “Furthermore, by using either pre-programmed settings or sensors to detect the curvature of the surface to be treated, the LED arrays **60** can be ***individually configured to emit more intense light*** to only those areas that require it. This allows for an increase in uniformity of light exposure in an efficient manner as power output and/or light intensity is increased to only certain diodes, in accordance with need.” *Id.* at 6:43–50 (emphasis added).

In view of the specification, a POSITA would understand with reasonable certainty that “individually configurable to control illumination from each of the five panels” refers to controlling the illumination emitted from the panel—not the panel’s physical positioning or

movement. Therefore, the term should be given its plain and ordinary meaning: the power output and/or light intensity of each panel can be individually controlled.

For the foregoing reasons, a POSITA would understand with reasonable certainty that the term “the five panels are individually configurable to control illumination from each of the five panels” should be given its plain and ordinary meaning of “the power output and/or light intensity of each panel can be individually controlled,” and Biofrontera has not met their clear and convincing burden to show that the claim term is indefinite.

E. “within approximately four inches of the treatment surface” (’028 Patent: Claims 1, 2, 4–6, 20, 21)

Term	Sun Pharma’s Proposed Construction	Biofrontera’s Proposed Construction
“within approximately four inches of the treatment surface”	Plain and ordinary meaning.	“less than or equal to four inches from the treatment surface”

A POSITA reading the claims in context would understand what it means to position the five panels “to allow treatment *within approximately* four inches of the treatment surface.” Because “approximately” modifies “four inches,” a POSITA would understand that the invention does not require an exact measurement of four inches—rather, the panels can be positioned within *more or less* four inches of the treatment surface. Biofrontera’s construction, by putting a hard upper limit on four inches, reads out the word “approximately” from the claim language. And by Biofrontera’s logic, the claims include positioning the panels a mere one-tenth of an inch from the treatment surface—which could cause severe damage to a patient’s skin—but somehow exclude four-and-one-tenth inches as outside the scope.

The claim language of the ’028 Patent directs that the five panels are “*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” to allow the illuminator to “uniformly illuminate a treatment surface of the patient via the light sources.” ’028 Patent at 10:32–35; 10:29–31. With that context, a POSITA would understand that the limitation “wherein the five panels are *positioned* to *allow treatment* within approximately four inches of the treatment surface” means that the panels must be positioned at an appropriate distance from the patient’s skin—about four inches—to allow adequate treatment, including by accounting for the contours and potential movement of a patient’s body. That distance, according to the claims, may be less than four inches, but may also be more than four inches.

The specification of the ’028 Patent similarly reflects that the phrase “within approximately four inches of the treatment surface” has a reasonable variance—both less than and greater than—of four inches from the treatment surface. *See* Exhibit B ¶ 40. Specifically, there are at least three variations at play: (1) variation in the contours of a related treatment area of a single patient, such as their face (*e.g.*, the variation from the tip of a person’s nose to the depth of their eye lids); (2) variation in different treatment areas across a single patient (*e.g.*, the variation between their arm and their face); and (3) variation in the same treatment areas between different patients (*e.g.*, Person A’s face and Person B’s face). *See* Exhibit B ¶ 40; ’028 Patent at 2:56–64 (“[I]t 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.”). If the phrase “within approximately four inches” is limited to “less than or equal to four inches,” then it would not account for necessary variation to handle the contours across human features.

Contrary to Biofrontera’s construction, “within *approximately* four inches” necessarily includes a range *above* four inches, as “approximately” has been regularly defined by courts as

synonymous with “about.” *See, e.g., Parker Compound Bows, Inc. v. Hunter’s Mfg. Co.*, 2016 WL 617464, at *23 (W.D. Va. Feb. 12, 2016) (in finding “approximately 13 inches” as not indefinite, the court stated that “[w]ords of approximation are ‘ubiquitous in patent claims’ and, ‘when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention . . . have been accepted in patent examination and upheld by the courts.’”). A patentee may use “about” and “approximately” as claim terms to avoid a strict numerical boundary to the specified parameter. *See Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Lab’ys, Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007) (affirming that claim limitation of weight ratio of “about 1:5” meant approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1).

In a litigation-inspired attempt to limit the claim language, Biofrontera’s construction reads out the word “approximately” from the disputed phrase and should be rejected.

F. “a recess” (’512 Patent: Claims 17 and 18)

Term	Sun Pharma’s Proposed Construction	Biofrontera’s Proposed Construction
“a recess”	Plain and ordinary meaning.	“an indentation in a surface”

The term “a recess” is straightforward and requires no construction beyond its plain and ordinary meaning. In the ’512 Patent, the term describes a physical feature on the panel that receives a flange of one of the nested hinges:

17. The method of claim 8, wherein at least one panel includes **a recess** configured to receive a flange of one of the nested hinges.

18. The method of claim 17, wherein **the recess** is positioned at an inner side surface of the at least one panel.

’512 Patent at 11:36–12:2 (Claims 17–18) (emphasis added). Similarly, the specification further supports the claim language. The ’512 Patent explains how a recess of the panel enables a

particular configuration of panels fitting closer together, to assist with the goal of reducing optical dead spaces during treatment:

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

'512 Patent at 5:1–10 (emphasis added).

Other courts have likewise determined that the term “recess” does not require a construction. For example, one court stated that the term “a recess” should be given its plain and ordinary meaning because it is “readily apparent even to lay judges.” *simplehuman, LLC v. iTouchless Housewares & Prod., Inc.*, 2020 WL 7342739, at *840 (N.D. Cal. Dec. 14, 2020). Similarly, another court found that no construction was required for the term “recess” because “the term ‘recess’ is not subject to multiple interpretations that affect the scope of the term.” *Ridge Wallet, LLC v. 2985, LLC*, 2024 WL 1638654, at *4 (D. Colo. Apr. 16, 2024).

Biofrontera has no justification, other than advancing an apparent noninfringement position, for its proposal to replace a simple word with a construction that does not appear anywhere in the specification. The term “a recess” should be given its plain and ordinary meaning.

VII. CONCLUSION

For the foregoing reasons, Complainant respectfully requests that the ALJ construe the disputed terms of the Asserted Patents consistent with Sun Pharma’s constructions, and find that Biofrontera has not met its clear and convincing burden to show that any term is indefinite.

CERTIFICATE OF COMPLIANCE

Pursuant to Ground Rules 1.6 and 7.2, the undersigned certifies that this brief contains 9,729 words, exclusive of the exempted portions of the brief, as calculated by the “Word Count” feature on Microsoft Word Office 365, the word processing program used to create it.

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