

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 RESPONSIVE CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

	<u>Pages</u>
I. INTRODUCTION	1
II. PERSON OF ORDINARY SKILL IN THE ART.....	1
III. DISPUTED CLAIM TERMS	2
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)	2
B. “photodynamically diagnosing or treating a patient” (All Asserted Claims)	7
C. “nested hinges on inner side surfaces of adjacent panels” (All Asserted Claims of the ’512 Patent)	9
D. “the five panels are individually configurable to control illumination from each of the five panels” (’028 Patent: Claims 16-17, 19 and 21)	11
E. “within approximately four inches of the treatment surface” (Claims 1, 2, 4-6, 20, and 21 of the ’028 Patent).....	13
F. “a recess” (Claims 17 and 18 of the ’512 Patent)	15
IV. CONCLUSION.....	16

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Blue Calypso, LLC v. Groupon, Inc.</i> , 815 F.3d 1331 (Fed. Cir. 2016).....	4
<i>Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.</i> , 320 F.3d 1339 (Fed. Cir. 2003).....	9
<i>Certain Compact Wallets & Components Thereof</i> , Inv. No. 337-TA-1355, Ord. No. 14 (Aug. 21, 2023).....	4
<i>Cochlear Bone Anchored Solutions AB v. Oticon Medical AB</i> , 958 F.3d 1348 (Fed. Cir. 2020).....	8
<i>Daiichi Sankyo Co. v. Apotex, Inc.</i> , 501 F.3d 1254 (Fed. Cir. 2007).....	1, 2
<i>Dow Chem. Co. v. Nova Chems. Corp. (Can.)</i> , 803 F.3d 620 (Fed. Cir. 2015).....	7
<i>Eli Lilly & Co. v. Teva Pharms. Int'l GmbH</i> , 8 F.4th 1331 (Fed. Cir. 2021)	8, 9
<i>Eon Corp. IP Holdings v. Silver Spring Networks</i> , 815 F.3d 1314 (Fed. Cir. 2016).....	15
<i>Ethicon Endo-Surgery, Inc. v. Covidien, Inc.</i> , 796 F.3d 1312 (Fed. Cir. 2015).....	6
<i>GPNE Corp. v. Apple Inc.</i> , 830 F.3d 1365 (Fed. Cir. 2016).....	16
<i>Honeywell Int'l, Inc. v. Int'l Trade Comm'n</i> , 341 F.3d 1332 (Fed. Cir. 2003).....	7
<i>Indacon, Inc. v. Facebook, Inc.</i> , 824 F.3d 1352 (Fed. Cir. 2016).....	10
<i>Marrin v. Griffin</i> , 599 F.3d 1290 (Fed. Cir. 2010).....	7, 8
<i>Max Blu Techs., LLC v. Cinedigm Corp.</i> , 2016 WL 3688801 (E.D. Tex. 2016).....	15

<i>Myco Indus., Inc. v. BlephEx, LLC</i> , 955 F.3d 1 (Fed. Cir. 2020)	5, 14
<i>Mycogen Plant Sci., Inc. v. Monsanto Co.</i> , 243 F.3d 1316 (Fed. Cir. 2001).....	11
<i>Oatey Co. v. IPS Corp.</i> , 514 F.3d 1271 (Fed. Cir. 2008).....	5
<i>Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.</i> , 476 F.3d 1321, 1326 (Fed. Cir. 2007).....	15
<i>Pacing Techs., LLC v. Garmin Int’l, Inc.</i> , 778 F.3d 1021 (Fed. Cir. 2015).....	8
<i>Phase Four Indus., Inc. v. Marathon Coach, Inc.</i> , 2006 WL 3742216 (N.D. Cal. Dec. 19, 2006).....	10
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005).....	14
<i>Presidio Components, Inc. v. Am. Tech. Ceramics Corp.</i> , 875 F.3d 1369 (Fed. Cir. 2017).....	6
<i>Riddell, Inc. v. Kranos Corp.</i> , 2017 WL 2264347 (N.D. Ill. May 24, 2017).....	11
<i>Salix Pharms., Inc. v. Mylan Pharms., Inc.</i> , 2017 WL 11681685 (N.D. W. Va. Sept. 12, 2017)	2
<i>SIPCO, LLC v. Emerson Elec. Co.</i> , 980 F.3d 865 (Fed. Cir. 2020).....	14
<i>Tandon Corp. v. U.S. Int’l Trade Comm’n</i> , 831 F.2d 1017 (Fed. Cir. 1987).....	11
<i>Teva Pharms. USA, Inc. v. Sandoz, Inc.</i> , 789 F.3d 1335 (Fed. Cir. 2015).....	7
<i>Transdata, Inc. v. Centerpoint Energy Houston Electric LLC</i> , 2016 WL 3172791 (E.D. Tex. 2016)	5
<i>VR Optics, LLC v. Peloton Interactive, Inc.</i> , 2018 WL 5784546 (S.D. N.Y. 2018).....	11, 13

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]
N	Patent Trial and Appeal Board’s Decision Denying Institution of <i>Inter Partes</i> Review of U.S. Patent No. 11,697,028 Under 35 U.S.C. § 314 (IPR No. 2024-00874)

I. INTRODUCTION

Biofrontera's indefiniteness arguments and claim construction proposals rely on hypothetical scenarios manufactured without any intrinsic evidence support. Biofrontera imagines that a person of ordinary skill in the art, with a science and medical degree, would not understand common terms such as "proximate," "intensity," "nested," and "recess." Biofrontera supports its positions using unrelated patents (Biofrontera Op. Br. at 24), irrelevant court orders (*id.*), and commercial embodiments (*id.* at 1, 9, 23), instead of focusing on the claim language and specification.

The ALJ should reject Biofrontera's constructions because its proposals are both contrary to the intrinsic evidence and basic tenets of patent law. Sun Pharma's proposed constructions, on the other hand, reflect the inventions as understood by a POSITA (under either side's definition).

II. PERSON OF ORDINARY SKILL IN THE ART

The appropriate level of ordinary skill for a POSITA is *either* a M.D. and/or a Ph.D. with experience in the fields of optical engineering, photodynamic therapy, or a related field. *See* Sun Op. Br. at 8. That level reflects the inventors' education and training, as well as the problems in the prior art they sought to solve. *See Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (factors for determining the level of ordinary skill include "the educational level of the inventor" and the "type of problems encountered in the art"). Biofrontera's definition not only excludes every inventor, but also fails to match the focus of the problems solved by the Asserted Patents.

The patents address problems in optical engineering of biomechanical instruments. For example, the patents describe how conventional illuminators could not provide the uniformity of light needed for certain treatments, including actinic keratosis. '512 Patent at 2:5–49; *see, e.g., id.*

at 2:39–42 (“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.”). The inventors solved those problems with a new design for illuminators that delivers uniform light, even with contoured treatment areas. *Id.* at 2:50–3:19. The patents simply do not require expertise in treating patients.

Daiichi is instructive. There, the lower court found that a patent directed to a “method for treating bacterial ear infections” with a novel pharmaceutical formulation required a POSITA with a “medical degree” and “experience treating patients with ear infections.” *Daiichi*, 501 F.3d at 1255–56. The Federal Circuit reversed, noting that the inventors researching drug formulations were not medical practitioners. *Id.* at 1257. *Daichii* thus rejected the argument that all patents reciting a “method of treating a physical condition” require a POSITA with a medical degree. *Id.*; *see also Salix Pharms., Inc. v. Mylan Pharms., Inc.*, 2017 WL 11681685, at *6–8 (N.D. W. Va. Sept. 12, 2017) (rejecting a medical degree requirement for method of treatment claims in view of the inventors’ education level).

Under either party’s definition, however, Sun Pharma’s constructions remain the proper definitions for the disputed terms.

III. 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” (All Asserted Claims of the ’512 and ’028 Patents)

Biofrontera’s artificial uncertainty as to “proximate” and “intensity” cannot rise to the level of clear and convincing evidence required to invalidate all Asserted Claims. First, the claims have definite scope when read in light of the specification and the goals of the invention. Second, courts have repeatedly upheld patents that use “proximate” to denote relative positioning from a fixed

point—exactly as the claims do here. Third, there is no uncertainty around “intensity” because relative intensities are measurable and observable.

The Asserted Patents seek to irradiate curved treatment surfaces with uniform light. Every Asserted Claim recites “uniformly illuminate/illuminating a treatment surface.” *See* Sun Op. Br. at 9–10 (agreed-upon construction). The patents teach an arrangement of light sources so that areas close to the second edges emit a higher intensity of light as compared to those not close to the second edges, so that a treatment surface is uniformly illuminated. ’512 Patent at 6:22–48. As explained by Dr. Jokerst, a POSITA reading the claims in view of the specification would appreciate how the examples provided in connection with Figure 5 teach an illuminator with a higher intensity for areas close to the second edges (*e.g.*, areas 1 and 2) compared to the other areas. Ex. D ¶¶18–22. For example, the patents describe how in Figure 5, “the LED arrays 60 are divided into three general areas, which may be described as ‘addressable strings.’” ’512 Patent at 6:23–25. Through a “higher current” or by “varying the arrangement of diodes within each of the addressable strings,” areas 1 and 2 may “emit higher intensity of light.” *See generally id.* at 6:30–7:4. The Asserted Claims capture this innovative arrangement and require light sources to be arranged on each of the panels such that a higher intensity of light is emitted proximate the second, shorter edges. *See, e.g.* ’512 Patent at Claim 1.

Indeed, the PTAB recently denied institution of the first of Biofrontera’s IPR petitions against the ’028 Patent and, in doing so, provided its understanding of the “higher intensity” limitation consistent with Sun Pharma’s proposal. Ex. N at 17 (discussing how the prior art lacks a disclosure of “a higher density of light proximate to the second shorter edges of the periphery in comparison to the remaining areas of the array, which includes the first longer edges of the periphery”). That the PTAB “did not express any uncertainty as to the scope of this term or have

any apparent difficult[y] in applying the term to the prior art references” supports finding the term definite. *See Certain Compact Wallets & Components Thereof*, Inv. No. 337-TA-1355, Ord. No. 14 at *8 (Aug. 21, 2023).

“Proximate.” Biofrontera argues that “the specification fails to comment on the ‘proximity’ of the areas depicted” in Figure 5. Biofrontera Op. Br. at 7–8. But the patentee was not required to define “proximate,” as Biofrontera appears to suggest. *See Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1345 (Fed. Cir. 2016) (“[W]e have held that the exact terms appearing in the claims need not be used *in haec verba* [in the specification].”). “Proximate” is a well-accepted word in patent drafting that means close to or near a fixed point. *See Sun Op. Br.* at 13 (citing cases).

Moreover, Biofrontera provides no evidence that a POSITA would be uncertain that the areas 1 and 2 in the specification correspond to the Asserted Claims’ use of “proximate.” In describing Figure 5, the specification demonstrates how the panel is “divided” into areas that are closer to the shorter edges and those further from those edges, ’512 Patent at 6:23–25, and then uses the same words as the claims to describes how those areas “emit a higher intensity of light than” other areas. *Id.* at 6:31–34. No POSITA would assume—as Biofrontera suggests—that only a portion of area 1 is “proximate”—as the *entire purpose* of Figure 5 and the accompanying disclosure is to demonstrate that dividing the panel into areas of different current or density of light sources results in a higher intensity of light emitted close to the shorter edges.

Finally, Biofrontera pivots and suggests that the claims are definite only if they are limited to “immediately proximate.” Biofrontera Op. Br. at 9–10. That is incorrect. First, it is improper to import additional words into the claims—the claims expressly recite “proximate” and not “immediately proximate.” Second, that reading would exclude the Figure 5 embodiment, which is

described as dividing the LED arrays “into three general areas” described as “addressable strings.” ’512 Patent at 6:22–29. The description of area 1 in Figure 5 is not limited to a single row of diodes immediately near the shorter edges—instead, the specification, for example, describes how “12 diodes may be mounted in each of areas 1.” ’512 Patent at 6:52–56; *see Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008) (“At leas[t] where claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence on the contrary.”).

As its only support for reading “immediately proximate” into the claim, Biofrontera compares the claims to Sun Pharma’s own device and imports limitations from that commercial embodiment. *See* Biofrontera Op. Br. at 9. That comparison *violates a basic tenet* of claim construction: “claim construction . . . focuses on the recited limitations of the *claims*, not on the features of a commercial embodiment of the invention.” *Myco Indus., Inc. v. BlephEx, LLC*, 955 F.3d 1, 15 (Fed. Cir. 2020) (emphasis in original). Furthermore, the claims’ recitation of “proximate”—and not “immediately proximate”—reflects the disclosure in the specification, as discussed above. *See, e.g., Transdata, Inc. v. Centerpoint Energy Houston Electric LLC*, 2016 WL 3172791, at *3 (E.D. Tex. 2016) (refusing to limit scope of “proximate” to mean adjacent, in view of the specification).

“Intensity.” Biofrontera acknowledges that the normal meaning of “intensity” is emitted irradiance from a light source, expressed in W/cm^2 . Biofrontera Op. Br. at 10; *see* Ex. D ¶¶23–24 (explaining how “[t]o a POSITA, ‘intensity’ and ‘irradiance’ are interchangeable”). However, Biofrontera goes on to imagine a secondary meaning of “intensity,” as synonymous with light dose (J/cm^2). Biofrontera Op. Br. at 11.

But that secondary meaning is fabricated. As Dr. Jokerst explained, the claims are unambiguous: “a higher intensity of light is *emitted*”—which unquestionably refers to a rate of *emitted* irradiance, W/cm^2 , and not the light dose received by the treatment area over time, J/cm^2 . Ex. D ¶ 26. The one line in the specification that sparked Biofrontera’s alleged confusion *does not say* that intensity is a light dose; instead, when read in context of the preceding sentence, it simply provides the *light dose* received at the end of a period of time, *given* a low intensity of light:

In certain embodiments, the illuminator is configured to *irradiate* the lesions with a uniform blue light *for a first prescribed period* [i.e., over a *period of time*] . . . For example, in some embodiments, the illuminator is configured to irradiate the lesions with uniform blue light (e.g., 417 nm) at low intensity (e.g., about $0.1 \text{ J}/\text{cm}^2$ to about $2 \text{ J}/\text{cm}^2$). . . .

’512 Patent at 9:18–25; *see* Ex. D ¶¶28–29. A few lines down, the patent reiterates the relationship between light dose and irradiance, consistent with the ordinary meaning of those terms:

Since the total light dose (J/cm^2) is equal to irradiance (W/cm^2) multiplied by time (sec), the only additional parameter that needs to be controlled for delivery of the correct treatment light dose is exposure time.

’512 Patent at 9:53–56. As Dr. Jokerst confirmed, there is no reasonable way to read the specification as inventing a new definition of “intensity”—a POSITA reading the claims would understand “intensity” consistent with the normal meaning. Ex. D ¶¶30–32.

Regarding Biofrontera’s complaints about knowing how to measure “intensity,” the Federal Circuit has found that “there is no requirement for the specification to identify a particular measurement technique” when a POSITA understands how to conduct that measurement. *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1376 (Fed. Cir. 2017) (“[I]f a skilled person

would choose an established method of measurement, that may be sufficient to defeat a claim of indefiniteness, even if that method is not set forth *in haec verba* in the patent itself.”). Here, a POSITA knows how to determine whether one set of light sources have a higher intensity than another set, Ex. D. ¶39, especially when the illuminator has a “control unit . . . to regulate power to the lights.” ’512 Patent at 5:50–60.

Biofrontera’s cited cases regarding “intensity” miss the mark. In *Teva*, the parties agreed that the term “molecular weight” could refer to three different measurements that have three different results. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). There, “the claim on its face offers no guidance on which measure of ‘molecular weight’ the claims cover.” *Id.* Here, the claims are explicit that intensity—which has only one accepted meaning—is “emitted.” Moreover, the measurement here is a relative one—“a higher intensity of light is emitted proximate the second edges *compared to* the intensity of light emitted not proximate the second edges.” That alone distinguishes these patents from those at issue in *Teva*, *Dow*, and *Honeywell*, which all did not involve *comparative* measurements. *See id.*; *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620 (Fed. Cir. 2015); *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332 (Fed. Cir. 2003).

Because Biofrontera has failed to provide clear and convincing evidence of indefiniteness, the ALJ should reject its proposal and adopt Sun Pharma’s construction.

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

The preambles merely recite the goals of the invention and should not be treated as limiting. *See Marrin v. Griffin*, 599 F.3d 1290, 1294–95 (Fed. Cir. 2010) (applying the “presumption against reading a statement of purpose in the preamble as a claim limitation”). Biofrontera argues it must be limiting because (1) the preambles’ “a patient” provides an antecedent basis for “the patient” in

the body of the Asserted Claims and (2) the preambles recite an intended purpose, which, under Biofrontera's flawed reading of the case law, requires finding the preambles limiting. Both of those reasons fail.

First, the full preamble does not provide an antecedent basis for the body of the Asserted Claims—at most, “a patient” is later referenced as “the patient.” But the full phrase, “photodynamically diagnosis or treating a patient” is not a necessary component of the invention and does not provide any antecedent basis for the body of the Asserted Claims. In *Cochlear Bone*, the Federal Circuit analyzed a similar claim—where the preamble included “a patient” that provided antecedent basis, but the other phrases in the preamble were “merely a statement of intended use”—and found that such a statement is not limiting. *Cochlear Bone Anchored Solutions AB v. Oticon Medical AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020); *see also Marrin*, 599 F.3d at 1294–95 (finding preamble's statement of purpose not limiting even as the preamble provided antecedent basis for the word “label”). In Biofrontera's cited case, *Pacing Technologies*, the court, by contrast, found that *all* phrases in the preamble were limiting because *each* provided antecedent basis for the claims. *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015) (both “a user” and “repetitive motion pacing system” provide antecedent bases).

Second, Biofrontera overstates Federal Circuit precedent as to when a preamble reciting the invention's purpose is limiting. “[P]reamble language merely extolling benefits or features of the claimed invention *does not* limit the claim scope without clear reliance on those benefits or features as patentably significant.” *Cochlear Bone*, 958 F.3d at 1355 (Fed. Cir. 2020). In *Eli Lilly*, cited by Biofrontera, the Federal Circuit “stressed that there is no ‘litmus test’ for determining whether a preamble is limiting Rather, whether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described

in the patent.” *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1340 (Fed. Cir. 2021). Based on the facts of that case, where the “method comprises a single step of administering an effective amount of a composition,” the Federal Circuit found the preamble limiting because it instructed a POSITA what the antibody was intended to treat. *Id.* The court went on to explain that “more general claims directed to apparatuses” with preambles that “merely state[] the purpose of intended use of an invention [are] generally not treated as limiting the scope of the claims.” *Id.* Biofrontera also cites *Boehringer*, but the preamble at issue there recited a specific virus to be grown and isolated. *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003). That is, the preamble recited “the essence of the invention without which performance of the recited steps is nothing but an academic exercise.” *Id.*

Given that Biofrontera has failed to show that the claims rely on the preambles’ recitation of the goal of the invention as patentably significant, the preambles are not limiting.

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

In the context of the ’512 Patent, this term simply means hinges that fit on inner side surfaces of adjacent panels, as explained by Dr. Jokerst. *See generally* Ex. D. ¶¶ 44–54. “Nested” is an ordinary word that, according to dictionaries supplied by Biofrontera’s own expert, means “to fit compactly together.” Ex. D ¶53. Despite this straightforward meaning of “nested hinges,” Biofrontera manufactures yet another indefiniteness argument through a strained reading of the specification and an improper invocation of the claim differentiation doctrine.

First, the specification provides a POSITA sufficient context for the meaning of “nested hinges on inner side surfaces of adjacent panels.” While “conventional adjustable illuminators” include “hinges” to rotate panels, the presence of hinges may cause an “optical dead space” where light is not emitted from a “gap” between the light sources. ’512 Patent at 2:5–15. The ’512 Patent

teaches that using “nested hinges” to connect the panels can reduce “optical dead spaces.” *Id.* at 3:9–12, 4:45–48. For example, the patent describes how hinges fitting within the inner side surface of adjacent panels allows for “the outside vertical edges of adjoining panels to be positioned closer to one another.” *Id.* at 4:63–5:10. Biofrontera focuses on the specification’s use of the word “may” to imply that nested hinges must also include hinges that do **not** reduce or eliminate optical dead space. Biofrontera Op. Br. at 17. But “may” here simply means “can”: “The hinges 50 may take the form of nested hinges, which may include hinges that substantially reduce or eliminate optical dead spaces.” ’512 Patent at 4:46–48; *see Phase Four Indus., Inc. v. Marathon Coach, Inc.*, 2006 WL 3742216, at *5 (N.D. Cal. Dec. 19, 2006) (construing “may flow” as “can flow,” as opposed to “not required” because “‘may’ is also commonly used to mean ‘can’ or ‘having the ability or power’”). Biofrontera has not provided clear and convincing evidence that a POSITA reading the claims would be uncertain as to claim scope because of the one sentence in the specification.

Second, Biofrontera invokes the ’028 Patent’s “hinged structure” to invalidate the ’512 Patent claims, reciting “nested hinge” as indefinite by relying on the doctrine of claim differentiation. In Biofrontera’s view, the ’512 Patent is invalid because the terms in the two patents cannot have identical meanings. That is wrong. Biofrontera ignores that the two patents’ claims are different in scope, such that claim differentiation does not apply. *Indacon, Inc. v. Facebook, Inc.*, 824 F.3d 1352, 1358 (Fed. Cir. 2016) (“[W]e have declined to apply the doctrine of claim differentiation where, as here, the claims are not otherwise identical in scope.”). For example, Claim 1 of the ’028 Patent includes “wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface”—a limitation absent from the Asserted Claims of the ’512 Patent.

The Asserted Patents may use similar terms to convey the same meaning without invalidating the claims. Indeed, “[i]t is not unusual that separate claims may define the invention using different terminology, especially where (as here) independent claims are involved.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1329 (Fed. Cir. 2001). Therefore, “two claims which read differently can cover the same subject matter.” *Tandon Corp. v. U.S. Int’l Trade Comm’n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987); *see, e.g., Riddell, Inc. v. Kranos Corp.*, 2017 WL 2264347, at *11 (N.D. Ill. May 24, 2017) (claims using different terms interchangeably were not indefinite); *VR Optics, LLC v. Peloton Interactive, Inc.*, 2018 WL 5784546, *401–02 (S.D. N.Y. 2018) (finding that “the patentee simply chose to use a different word, namely ‘drive’ instead of ‘control,’ to describe the same otherwise clear function”).

For the foregoing reasons, Sun Pharma respectfully requests the ALJ to adopt the plain and ordinary meaning of the term “nested hinges 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)

The ALJ should reject Biofrontera’s attempt to invalidate claims of the ’028 Patent because there is no clear and convincing evidence that a POSITA would lack reasonable certainty about its scope. There should be no real dispute that the term is directed to controlling the illumination from each of the five panels, rather than physically moving any of the five panels.

Biofrontera offers two reasons why, in its view, that straightforward meaning cannot be. First, it argues that the claims’ invocation of “configurable” somehow includes physically moving or manipulating the panels. That argument runs contrary to the plain meaning of the claim term, which describes controlling “illumination from” each panel and says nothing about moving the panels. Furthermore, the only connection between Biofrontera’s specification quotes regarding physical positioning and the claim term at issue here is the word “configuring/configuration.”

However, those quotes do not discuss “configurable *to control illumination from* each of the five panels,” and are thus inapplicable to the claim term at issue.

Second, Biofrontera takes issue with Sun Pharma’s proposed construction because it reads the specification as only describing the light sources on the panels as being configurable, as opposed to the panels themselves. But that semantic game does not work here—the panels illuminate *through* the “light sources disposed on surfaces of the five panels.” *See* ’028 Patent, Claim 16. For example, Claim 16 recites that the panels are “connected by hinged structures *to allow continuous illumination across the five panels*” while the illuminator too is “configured to *uniformly illuminate . . . via the light sources.*”¹ Therefore, a POSITA reading the claims’ reference “individually configurable to control illumination from each of the five panels” would connect those claims to the specification’s description of light sources—*disposed on panels*—being individually configured.

Moreover, the portion of the specification that discussed “individually configurable” (’028 Patent at 5:52–7:6) opens with a direct reference to the panels’ power output being configurable: “At least one control unit is also connected to the panels to regulate power to the lights. . . .” ’028 Patent at 5:52–54. The specification is clear that the light sources on each individual panels—*i.e.*, the LED array 60—can be configured on a panel-by-panel basis using a “dedicated control unit”: “each panel may have a dedicated control unit to regulate power to the individual LED array on a given panel” ’028 Patent at 5:57–59.

¹ Biofrontera argues that the continuation of this limitation, “the light sources being configured to output light uniformly” would be redundant in view of Sun Pharma’s construction. Biofrontera Op. Br. at 30. But Biofrontera fails to provide any explanation as to *how* Sun Pharma’s construction leads to a redundancy in the claim language.

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

Biofrontera's proposed construction of “less than or equal to four inches” introduces an upper bound on the positioning of the panels. This construction not only reads out the word “approximately” from the claims, but it also violates Federal Circuit law by excluding embodiments provided in the specification. As Dr. Jokerst explains, a POSITA would understand that “within approximately four inches” conveys a “reasonable variance” and includes distances greater than or less than four inches. Ex. B ¶¶ 40–41.

First, Biofrontera attempts to use a different claim term—“uniformly illuminates”—to limit the plain meaning of “within approximately four inches” to under four inches. But those terms are separately recited in the Asserted Claims. To the extent Biofrontera wishes to dispute whether an illuminator can successfully “uniformly illuminate” if the panels are positioned to allow treatment within four-and-a-tenth inches, for example, that is a non-infringement argument that should not be resolved as a matter of claim construction.

Moreover, Biofrontera misreads the specification when it argues that achieving at least 60% uniformity is limited to distances between two and four inches. On the contrary, the specification provides an example where the measured output is “within 60% of the measured maximum . . . over *all operational distances*”—not just between two and four inches. ’028 Patent at 8:58–62 (emphasis added). The reference to distances of two to four inches appears in the context of “more preferably” embodiments, *see id.* at 8:62–67, and is separately claimed, *see* ’512 Patent at 10:43–44 (unasserted Claim 2 reciting “when the treatment surface is at a *distance of two*

to four inches from the illuminator”).² Moreover, it is well-established that limitations from preferred embodiments should not be imported into the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.”). Nor is it appropriate for Biofrontera to rely on Sun Pharma’s commercial embodiment to support importing an upper limit into the claims. *See Myco*, 955 F.3d at 15 (“[C]laim construction . . . focuses on the recited limitations of the *claims*, not on the features of a commercial embodiment of the invention.”) (emphasis in original).³

Regardless, there is no suggestion in the specification that the invention would be inoperable at distances slightly over four inches. Instead, the specification explicitly discloses using the device on *curved* surfaces with variable distances, such that approximation is required. *See* ’028 Patent at 2:56–64 (discussing “deliver[ing] 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.”), 5:62–6:23 (describing how the invention can be used to overcome shortcomings of conventional illuminators when treating curved surfaces, such as a patient’s head). As Dr. Jokerst explained, the claims convey “a reasonable variance based on the technological context and application of the patented technology” including “variation in the contours of a treatment area such as a person’s face.” *See* Exhibit B ¶ 40.

² Sun Pharma’s Opening Brief on page 4 included a typographical error (“claims 1-3”): claims 1 and 3 of the ’512 Patent are asserted. Claim 2 is not asserted. Sun Pharma informed Biofrontera of the typographical error during several meet and confers.

³ Similarly, the construction of a prior art patent, unrelated to the Asserted Patents and with different claim language, is irrelevant. *Cf. SIPCO, LLC v. Emerson Elec. Co.*, 980 F.3d 865, 870 n.2 (Fed. Cir. 2020) (rejecting the relevance of a prior construction for the same claim term where the earlier “case involved different patents, in entirely different patent families, with different specifications”).

Finally, Biofrontera's citation of *Max Blu Technologies* shows the weakness of its position. There, the district court construed "***less than*** approximately" as having its plain and ordinary meaning. That is, "less than" was literally in the claims and was not manufactured out of thin air. *Max Blu Techs., LLC v. Cinedigm Corp.*, 2016 WL 3688801 at *30 (E.D. Tex. 2016). Instead, the court found that "approximately" was appropriately used to "avoid a strict numerical boundary to the specified parameter." *Id.* (citing *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007)). The court highlighted that "approximately" is the correct term when the "technological impact" of deviating slightly above or below the parameter was negligible. *Id.* Likewise, Biofrontera cannot support its argument that the specification's disclosures regarding treatment distances of four inches are somehow limited to ***exactly*** 4.0 inches and no more (but potentially much less).

Sun Pharma requests that the ALJ adopt the plain and ordinary meaning of the term "within approximately four inches," which allows for reasonable variations and encompasses distances slightly less than and greater than four inches.

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

The term "a recess" is an ordinary and well-understood word that requires no construction. Biofrontera argues that it must import a definition from a dictionary, because the '512 Patent does not itself define the word "recess." Biofrontera Op. Br. at 20. The case law rejects that position: defining or construing every word in a claim is not necessary. *Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1318 (Fed. Cir. 2016) ("A court need not attempt the impossible task of resolving all questions of meaning with absolute, univocal finality."). "This is because such an endeavor could proceed ad infinitum, as every word—whether a claim term itself, or the

words a court uses to construe a claim term—is susceptible to further definition.” *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1373 (Fed. Cir. 2016).

The term “a recess” does not need to be replaced with a dictionary definition because there is no evidence that a POSITA needs that definition to understand the term.

IV. CONCLUSION

For the foregoing reasons, Sun Pharma respectfully requests that the ALJ adopt its 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 4965 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.

Dated: November 15, 2024

/s/ Betty Chen

Betty Chen

DESMARAIS LLP

101 California Street, Suite 3000

San Francisco, CA 94111

Telephone: (415) 573-1900

Facsimile: (415) 573-1901

Email: Sun-biofronteraITCService@desmaraisllp.com

PUBLIC VERSION

Dated: November 15, 2024

Respectfully submitted,

/s/ Betty Chen

Betty Chen

Kurt Fredrickson

DESMARAIS LLP

101 California Street, Suite 3000

San Francisco, CA 94111

Telephone: (415) 573-1900

Facsimile: (415) 573-1901

Email: Sun-biofronteraITCService@desmaraisllp.com

Goutam Patnaik

Tuhin Ganguly

Atifah Safi

DESMARAIS LLP

1899 Pennsylvania Avenue, NW, Suite 400

Washington, DC 20006

Telephone: (202) 451-4900

Facsimile: (202) 451-4901

Email: Sun-BiofronteraITCService@desmaraisllp.com

Raymond Habbaz

DESMARAIS LLP

230 Park Avenue, 26th Floor

New York, NY 10169

Telephone: (212) 351-3400

Facsimile: (212) 351-3401

Email: Sun-BiofronteraITCService@desmaraisllp.com

*Counsel for Complainant Sun Pharmaceutical
Industries, Inc.*