

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC**

**Before The Honorable Bryan F. Moore
Administrative Law Judge**

In the Matter of

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

Investigation No. 337-TA-1411

**COMPLAINANT SUN PHARMACEUTICAL INDUSTRIES, INC.'S
SUPPLEMENTAL OBJECTIONS AND RESPONSES TO RESPONDENTS' FIRST AND
SECOND SET OF INTERROGATORIES (NOS. 7, 9, 18–25)**

Pursuant to 19 C.F.R. §§ 210.27 and 210.29, Complainant Sun Pharmaceutical Industries, Inc. (“Sun Pharma”) hereby supplements its responses to Respondents Biofrontera AG, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera Inc.’s (collectively, “Biofrontera”) First and Second Set of Interrogatories (Nos. 7, 9, 18–25).

**Pages 2-120
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III. SECONDARY CONSIDERATIONS

“Objective evidence of secondary considerations [] must be considered before determining whether the claimed invention would have been obvious to one of skill in the art at the time of invention.” *Apple Inc. v. Int’l Trade Comm’n*, 725 F.3d 1356, 1365 (Fed. Cir. 2013) (citing *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1379 (Fed. Cir. 2012)). “Secondary considerations evidence can establish that ‘an invention appearing to have been obvious in light of the prior art was not’ and may be ‘the most probative and cogent evidence in the record.’” *Id.* at 1366 (quoting *Transocean*, 699 F.3d at 1349). “This evidence guards against the use of hindsight because it helps ‘turn back the clock and place the claims in the context that led to their invention.’” *Id.* (quoting *Mintz*, 679 F.3d at 1378). Here, there are objective indicia on non-obviousness, including long felt need, industry praise, commercial success, and copying.

The proponent of evidence of secondary considerations “bears the burden of showing that a nexus exists between the claimed features of the invention and the objective evidence offered to show non-obviousness.” *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). However, “there is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘is the invention disclosed and claimed in the patent.’” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016) (citing *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997)). Here, a presumption of a nexus should be found because the objective evidence discussed herein is tied to Sun Pharma’s domestic industry products and the Accused Products, and those products are the inventions disclosed and claimed in the Asserted Patents. *See Crocs, Inc. v. International Trade Com’n*, 598 F.3d 1294, 1310–11 (Fed. Cir. 2010). To the degree there are any

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unclaimed features, they amount to nothing more than additional insignificant features, such that presuming nexus is still appropriate. *Quanergy Sys., Inc. v. Velodyne Lidar USA, Inc.*, 24 F.4th 1406, 1418 (Fed. Cir. 2022). Moreover, the evidence supports finding a nexus because the objective indicia, including long-felt need, industry praise, commercial success, and copying, are tied to the claimed features of the Asserted Patents, as discussed below.

A. Legal Standards

1. Long-Felt Need

“Evidence of a long-felt but unresolved need can weigh in favor of the non-obviousness of an invention because it is reasonable to infer the need would not have persisted had the solution been obvious.” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1056 (Fed. Cir. 2016), (holding that there was substantial evidence for the jury to find that there was a long-felt but unresolved need that was solved by Apple’s patent where “documents show that Samsung, Apple’s fiercest competitor, was unsuccessfully trying to solve the same problem”). Failure of others to solve the same problem also weigh in favor of non-obviousness. *See Heidelberger Druckmaschinen AG v. Hantscho Com. Prod., Inc.*, 21 F.3d 1068, 1072 (Fed. Cir. 1994) (“Indeed, the litigation argument that an innovation is really quite ordinary carries diminished weight when offered by those who had tried and failed to solve the same problem, and then promptly adopted the solution that they are now denigrating.”).

2. Industry Praise

“Evidence that the industry praised a claimed invention or a product that embodies the patent claims weighs against an assertion that the same claimed invention would have been obvious *Apple*, 839 F.3d at 1053. As industry participants “are not likely to praise an obvious advance over the known art...if there is evidence of industry praise of the claimed invention in the

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record, it weighs in favor of the non-obviousness of the claimed invention.” *Id.* (citing *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013) (“[I]ndustry praise . . . provides probative and cogent evidence that one of ordinary skill in the art would not have reasonably expected [the claimed invention].”); *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010) (noting that industry praise, and specifically praise from a competitor, tends to indicate that the invention would not have been obvious)).

3. Commercial Success

Commercial success is an indicium of non-obviousness “because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.” *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). “When ‘a product attains a high degree of commercial success, there is a basis for inferring that [attempts to a solution] have been made and have failed.’” *WBIP*, 829 F.3d at 1337 (quoting *Merck*, 395 F.3d at 1376 (alteration in original); *see also id.* (citing *Magowan v. N.Y. Belting & Packing Co.*, 141 U.S. 332, 343 (1891) (“[S]uch an extensive public use [of the patented invention] as almost to supersede all packings made under other methods...was pregnant evidence of its novelty, value, and usefulness.” (alteration in original)))).

“Thus, the law deems evidence of (1) commercial success, and (2) some causal relation or ‘nexus’ between an invention and commercial success of a product embodying that invention, probative of whether an invention was non-obvious.” *Merck*, 395 F.3d at 1376 (citing *Graham*, 383 U.S. at 148 (“Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.”); *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1370

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(Fed. Cir. 2003)). “A *prima facie* case of nexus is made when the patentee shows both that there is commercial success, and that the product that is commercially successful is the invention disclosed and claimed in the patent.” *Crocs*, 598 F.3d at 1310–11 (“Because the Commission found, based on substantial evidence, that Crocs shoes practice the ’858 patent and that the Crocs shoes were commercially successful, Crocs established a *prima facie* case of nexus.”). Success of accused products can be used to establish commercial success of an invention. *Brown Williamson Tobacco v. Philip Morris*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) (“Our case law provides that the success of an infringing product is considered to be evidence of the commercial success of the claimed invention”)

4. Copying

“‘Copying may indeed be another form of flattering praise for inventive features,’ and thus evidence of copying tends to show nonobviousness.” *WBIP*, 829 F.3d at 1336 (“The fact that a competitor copied technology suggests it would not have been obvious.”).

B. Evidence of Secondary Considerations

1. Long-Felt Need

The inventions claimed in the Asserted Patents are revolutionary in the photodynamic therapy field. The inventions addressed a long-felt but unmet need for an adjustable illuminator for photodynamically diagnosing and treating a surface with substantially uniform intensity visible light. ’028 Patent (and corresponding disclosure in the ’512 Patent) at Abstract.

Prior to the time of the inventions, conventional photodynamic therapy devices left “optical dead spaces” near the edges of the device panels, which “reduce[d] the uniformity of the light along the treatment area, thereby reducing the effectiveness of PDT.” ’028 Patent (and corresponding disclosure in the ’512 Patent) at 2:41-44. “In addition, due to the various contours

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of a patient's body, the uniformity of light delivered by these conventional illuminators may vary substantially depending on the treatment area of the patient." '028 Patent (and corresponding disclosure in the '512 Patent) at 2:48-51. As such, there was a longstanding need for a photodynamic therapy device that provides uniform illumination and eliminates optical dead spaces. '028 Patent (and corresponding disclosure in the '512 Patent) at 2:41-44, 2:48-51.

Sun Pharma and its many scientists spent decades researching and developing unique technology to aid those suffering from certain skin conditions. Complainants' Initial Statement at 1-2, 4. After years of research, Sun Pharma developed a novel five-panel PDT device that provides uniform illumination during PDT treatment without optical dead spaces. *Id.*; '028 Patent (and corresponding disclosure in the '512 Patent) at 2:52-3:21; Complaint ¶ 43 ("[f]or more than eight years, Sun Pharma has been working on the development of its BLU-U® 4170E device"). In particular, the PDT device in the '028 and '512 Patents has five panels with hinges "mounted to the inner side surfaces of adjacent panels," which "reduc[e] the area in which no light source is present on the illuminator." '028 Patent (and corresponding disclosure in the '512 Patent) at 3:11-21, 4:65-5:1, FIG. 3A. The light sources are arranged on each of the five panels to provide uniform illumination such that those close to the shorter edges of each of the panels "emit a higher intensity of light" than those close to the longer edges of the panels. '028 Patent (and corresponding disclosure in the '512 Patent) at 6:18-40, FIG. 5.

Sun Pharma's novel illuminator configuration produces "light output uniformity" that is "greatly enhanced across the patient's face and exhibits little to no deviation from the light output measured in the center of the patient's face to the light output measured at the edges of the patient's face. '028 Patent (and corresponding disclosure in the '512 Patent) at 8:43-67, FIG. 8. Sun achieved this light output uniformity through light sources arranged on each of the 5 panels after

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years of testing and adjustment, to address the challenges of treating a larger area during a single treatment session. *See, e.g.*, Carota Dep. Tr. 74:1–8 (uniformity is “one of the more difficult challenges that we had”), 71:20–72:10, 76:20–22, 129:3–7.

Sun’s patented illuminator provides a broader illumination area in order to treat lesions that are further apart on a patient’s face in a single illumination session, which is the principal advantage claimed by the RhodoLED XL product over the older RhodoLED lamp with a smaller illumination field. *See, e.g.*, Foguet Rough Dep. Tr. 130:24–131:3 (“[T]he [FDA] submission of the XL lamp was only an extension of the illumination field”), *id.* at 132:11–22 (“[B]ecause the BF RhodoLED illumination area didn't cover all of the lesions, a patient would have to...undergo multiple illumination sessions to treat all of the lesions”), *id.* at 132:24–133:6 (“[O]ne of the benefits of the RhodoLED XL is that because it has a larger illumination field a healthcare provider can treat multiple lesions in a single illumination session”), BF_1411_ITC_00069687 (Foguet Ex. 15), BF_1411_ITC_00069755 (Foguet Ex. 16) Luebbert Rough Dep Tr. 47:18–57:14 (“[O]ne of the reasons that Biofrontera developed the RhodoLED XL was to have a lamp with a larger treatment area so...lesions distributed over a larger area could be treated in a single illumination session”), Lyons Dep. Tr. 90:6–11 (one of the benefits of the RhodoLED XL in relation to the RhodoLED is “uniform distribution of the treatment surface that's being treated. So if you're using a face as an example where AKs predominantly arise, by treating, you know, all of the area of the face in one shot or most of it is a big benefit over treating regions”). The reason for developing the XL lamp was a long-felt need by the providers in the industry for a device capable of treating a larger area with multiple lesions in a single session. *See, e.g.*, Luebbert Rough Dep. Tr. 58:9–19 (agreeing that in the 2015/2016 time frame “there was an unmet need for a PDT lamp with a larger treatment area in the market”), Foguet Rough Dep. Tr. 102:6–15 (“[T]here were doctors that

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said that they would like to treat larger, to use larger illumination fields...to address this needs that was one of the reasons why we developed the XL”), BF_1411_ITC_00073741 (Foguet Ex. 9), BF_1411_00000992 (Luebbert Ex. 4).

Sun Pharma incorporates by reference the deposition testimony in its entirety of Mark Carota, Hermann Luebbert, and Montserrat Foguet.

Pursuant to Commission Rule 210.29(c), Sun Pharma identifies documents beginning at Bates numbers Sun-ITC-0008751-Sun-ITC-0009832, Sun-ITC-0009873, Sun-ITC-0009898, Sun-ITC-0009933-Sun-ITC-0010077, Sun-ITC-0010212-Sun-ITC-0010259, Sun-ITC-0010684, Sun-ITC-0012047-Sun-ITC-0012282, Sun-ITC-0012302-Sun-ITC-0012565, Sun-ITC-0012716-Sun-ITC-0012717, Sun-ITC-0013564-Sun-ITC-0017782, Sun-ITC-0028134-Sun-ITC-0028147, Sun-ITC-0028258-Sun-ITC-0028332, Sun-ITC-0028365-Sun-ITC-0028446, Sun-ITC-0029319-Sun-ITC-0029320, Sun-ITC-0097892-Sun-ITC-0097904, Sun-ITC-0098040-Sun-ITC-0098089, Sun-ITC-0098605, Sun-ITC-0099025-Sun-ITC-0099038, Sun-ITC-0100411-Sun-ITC-0100416, Sun-ITC-0100453-Sun-ITC-0100678, Sun-ITC-0100750, Sun-ITC-0100846-Sun-ITC-0100855, Sun-ITC-0100913-Sun-ITC-0101580, Sun-ITC-0101586-Sun-ITC-0101591, Sun-ITC-0101597-Sun-ITC-0101629, Sun-ITC-0101638-Sun-ITC-0101642, Sun-ITC-0101987, Sun-ITC-0163444-Sun-ITC-0163445, Sun-ITC-0163616-Sun-ITC-0163628, Sun-ITC-0163632-Sun-ITC-0163969, Sun-ITC-0164882-Sun-ITC-0164885, Sun-ITC-0174458, Sun-ITC-0174470, and Sun-ITC-0174533.

2. Industry Praise

The inventions of the '028 and '512 Patents, which are embodied in the BLU-U® 4170E device and infringed upon by Biofrontera’s RhodoLED XL, have received recognition and praise from the industry. The RhodoLED XL was called an “innovative device [that] represents a significant advancement in the treatment of PDT with state-of-the-art engineering.”

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<https://www.benzinga.com/pressreleases/24/06/g39454636/biofrontera-announces-the-launch-of-a-new-fda-approved-red-light-source-the-rhodoled-xl-lamp> (Sun-ITC-0165275). Dr. David Cleaver of Cleaver Dermatology stated that “[t]he advanced features and versatility of [the RhodoLED XL] represent a considerable upgrade on what has been available until now and will allow us to provide our patients with the highest standard of care.” *Id.* An article by Dermatology Times called the RhodoLED XL a “state-of-the-art red light emitting LED lamp . . . designed to revolutionize photodynamic therapy . . . aimed at enhancing the ease of use for health care providers by being highly maneuverable and capable of accommodating various patient treatment positions.” <https://www.dermatologytimes.com/view/icymi-fda-approves-rhodoled-xl-lamp-red-light-source-for-use-in-actinic-keratosis-treatment> (Sun-ITC-0165292). Dermatology Times later stated that the RhodoLED XL “provides clinicians with the ability to illuminate a larger treatment area in a single session, which is particularly advantageous for treating extensive or multiple lesions. . . . [T]he RhodoLED XL lamp features 5 illumination panels versus 1, and also possesses positioning sensors.” <https://www.dermatologytimes.com/view/icymi-fda-approves-rhodoled-xl-lamp-red-light-source-for-use-in-actinic-keratosis-treatment> (Sun-ITC-0165292). The praise for the RhodoLED XL—based upon Sun Pharma’s discoveries—were the result of the inventions claimed in the ‘028 and ‘512 Patents. *See, e.g.,* Foguet Rough Dep. Tr. 132:24–133:6 (“[O]ne of the benefits of the RhodoLED XL is that because it has a larger illumination field a healthcare provider can treat multiple lesions in a single illumination session”), Luebbert Rough Dep Tr. 47:18–57:14 (“[O]ne of the reasons that Biofrontera developed the RhodoLED XL was to have a lamp with a larger treatment area so . . . lesions distributed over a larger area could be treated in a single illumination session”), Lyons Dep. Tr. 90:6-11 (one of the benefits of the RhodoLED XL in relation to the RhodoLED is “uniform distribution of the treatment surface that's being treated.

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So if you're using a face as an example where AKs predominantly arise, by treating, you know, all of the area of the face in one shot or most of it is a big benefit over treating regions"); *see also*, *e.g.*, '512 Patent at 3:2-5, 3:9–17.

Sun Pharma incorporates by reference the deposition testimony in its entirety of Jon Lyons, Hermann Luebbert, and Montserrat Foguet.

3. Commercial Success

Conventional illuminators provide varying illumination based on the treatment area of the patient, depending on the natural contours of the body. *See, e.g.*, '028 Patent (and corresponding disclosure in the '512 Patent) at 2:48-51. There was need for a photodynamic therapy device which provided uniform illumination, targeted larger areas of the body, and eliminated optical dead spaces. '028 Patent (and corresponding disclosure in the '512 Patent) at 2:41-44, 2:48-51, 2:65-3:21. Sun Pharma's patents helped solve this problem with conventional illuminators, which is the principal advantage of the RhodoLED XL product over the older, smaller RhodoLED lamp. The capability of providing uniform illumination over a larger area—Sun's patented feature—is the primary driver for the commercial success of RhodoLED XL. *See, e.g.*, <https://www.dermatologytimes.com/view/icymi-fda-approves-rhodoled-xl-lamp-red-light-source-for-use-in-actinic-keratosis-treatment> (Sun-ITC-0165292) (RhodoLED XL “provides clinicians with the ability to illuminate a larger treatment area in a single session, which is particularly advantageous for treating extensive or multiple lesions”), <https://www.biospace.com/biofrontera-announces-the-launch-of-a-new-fda-approved-red-light-source-the-rhodoled-xl-lamp> (Sun-ITC-0174877) (“The introduction of the RhodoLED XL provides the option to illuminate a larger area in a single on-label Ameluz PDT treatment”), Foguet Rough Dep. Tr. at 132:22–133:6 (agreeing that “one of the benefits of the RhodoLED XL is that

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because it has a larger illumination field a healthcare provider can treat multiple lesions in a single illumination session”). There was a clear market demand for devices capable of treating a larger area in a single session. Foguet Rough Dep Tr. 102:6–15 (“[T]here were doctors that said that they would like to treat larger, to use larger illumination fields...to address this needs that was one of the reasons why we developed the XL”), BF_1411_ITC_00073741 (Foguet Ex. 9).

Biofrontera’s own documents and testimony present compelling evidence of commercial success through substantial sales and demand for their infringing RhodoLED XL product containing Sun’s patented features. *See, e.g.,* Luebbert Rough Dep. Tr.130:14-131:14 (confirming that sales of the RhodoLED XL have not been a flop); *see also* Leffler Rough Tr. 73:16-74:6. For instance, when describing the XL’s predecessor product, Biofrontera stated in an internal Marketing Plan that they aim to market their product to “[REDACTED]

[REDACTED] BF_1411_ITC_00000516 at 5. In their BF-RhodoLED XL Project Plan, Biofrontera describes their “Competitive Situation” as directly competing with Sun Pharma’s BLU-U, with a target sale quantity of [REDACTED] [REDACTED] [REDACTED] [REDACTED] BF_1411_ITC_00010393 at 6. Dr. Luebbert has described the RhodoLED XL as a device that has “advanced features” that “will undoubtedly set a new standard in photodynamic therapy.”

<https://www.stocktitan.net/news/BFRI/biofrontera-announces-the-launch-of-a-new-fda-approved-red-light-x8iqdow997ww.html> (Sun-ITC-0165266). Dr. Luebbert also noted that three

of the RhodeLED XL devices had been shipped within a week of launch, with an “encouraging” response from dermatology organizations across the United States.

<https://www.benzinga.com/pressreleases/24/06/g39454636/biofrontera-announces-the-launch-of-a-new-fda-approved-red-light-source-the-rhodoled-xl-lamp> (Sun-ITC-0165275);

<https://seekingalpha.com/article/4714932-biofrontera-inc-bfri-q2-2024-earnings-call-transcript>

[REDACTED]

(Sun-ITC-0165281). Dr. Luebbert testified that the anticipated demand of the RhodoLED XL was

“ [REDACTED] Luebbert Rough Dep. Tr. 133:8–

11. *See also* BF_1411_ITC_00042577 ([REDACTED]

[REDACTED] The positive reception and sales of Biofrontera's infringing product at a comparable price point to Sun Pharma's product necessarily mean that there are consumers for their product which uses Sun's patented features, including a “larger illumination area with five panels” and “positioning sensors to ensure the patient receives the optimal energy delivery”, <https://www.stocktitan.net/news/BFRI/biofrontera-announces-the-launch-of-a-new-fda-approved-red-light-x8iqdow997ww.html> (Sun-ITC-0165266), especially given that currently Sun Pharma and Biofrontera are the only two companies with FDA-approved lamps in the U.S. market in the photodynamic therapy space. *See, e.g.*, Luebbert Rough Dep. Tr. 44:16–45:1 (Sun Pharma is “Biofrontera's biggest competitor” in the PDT market since there are no “other companies in the U.S. that have FDA-approved lamps for PDT besides Sun Pharma and Biofrontera”). Dr. Luebbert also testified that [REDACTED]

[REDACTED]

[REDACTED].

The RhodoLED XL device is also priced higher than the original, non-infringing RhodoLED device, demonstrating that the commercial success of the XL product is due to the patented features. *See, e.g.*, Luebbert Rough Dep. Tr. 134:17–135:5 ([REDACTED]

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(Foguet Rough Dep. Tr. 132:24–133:6 (“[O]ne of the benefits of the RhodoLED XL is that because it has a larger illumination field a healthcare provider can treat multiple lesions in a single illumination session”), *id.* 130:24–131:3 (“[T]he [FDA] submission of the XL lamp was only an

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extension of the illumination field”), *id.* at 132:11–22 (“[B]ecause the BF RhodoLED illumination area didn't cover all of the lesions, a patient would have to...undergo multiple illumination sessions to treat all of the lesions”), Luebbert Rough Dep. Tr. 47:18–57:14 (“[O]ne of the reasons that Biofrontera developed the RhodoLED XL was to have a lamp with a larger treatment area so...lesions distributed over a larger area could be treated in a single illumination session”), Lyons Dep. Tr. 90:6-11 (one of the benefits of the RhodoLED XL in relation to the RhodoLED is “uniform distribution of the treatment surface that's being treated. So if you're using a face as an example where AKs predominantly arise, by treating, you know, all of the area of the face in one shot or most of it is a big benefit over treating regions”).

Sun Pharma incorporates by reference the deposition testimony in its entirety of Eugene Leffler, Hermann Luebbert, and Montserrat Foguet.

Pursuant to Commission Rule 210.29(c), Sun Pharma also identifies Biofrontera’s Exhibit A to its Response to Sun Pharma’s Complaint and documents beginning at Bates numbers BF_1411_ITC_00000020, BF_1411_ITC_00000386, BF_1411_ITC_00000388, BF_1411_ITC_00000441, BF_1411_ITC_00000454, BF_1411_ITC_00000515, BF_1411_ITC_00000516, BF_1411_ITC_00011047, BF_1411_ITC_00022693, BF_1411_ITC_00023287, BF_1411_ITC_00023299, BF_1411_ITC_00040477, BF_1411_ITC_00040268, BF_1411_ITC_00039522, BF_1411_ITC_00145384 (Leffler Ex. 3), Sun-ITC-0159456, Sun-ITC-0159490, Sun-ITC-0159558.

4. Copying

Throughout the entire development of the accused BF-RhodoLED XL, Biofrontera had access to prior Sun Pharma employees, Sun Pharma documents, and Sun Pharma’s patent applications, including patent applications directed to the Sun Pharma BLU-U 4170E.

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Around 2015, Sun Pharma had been working on the development of its BLU-U® 4170E device, which practices the claims of the '512 and '028 Patents. Complaint ¶¶ 43, 92. On October 15, 2015, Sun Pharma filed its U.S. Provisional Application No. 62/241,902 (“902 Provisional Application”), which led to the '512 and '028 Patents. Sun-ITC-0147139 - Sun-ITC-0147180. The 902 Provisional Application described a novel PDT device that has five panels with hinges “mounted to the inner side surfaces of adjacent panels,” which “substantially reduce or eliminate optical dead spaces.” Sun-ITC-0147139 at 150, 161 (902 Provisional Application, [0022]-[0023], FIG. 3A). In addition, the 902 Provisional Application described light sources that are arranged on each of the five panels to provide uniform illumination such that those close to the shorter edges of each of the panels “emit a higher intensity of light” than those close to the longer edges of the panels. Sun-ITC-0147139 at 152, 163-164 (902 Provisional Application [0027], FIG. 5). On April 20, 2017, Sun Pharma’s U.S. Patent Application No. 15/292,731 on its BLU-U® 4170E device published as U.S. 2017/0106205 A1. BF_1411_ITC_00000780, FOLEY-1411ITC-0000523. On August 3, 2017, Sun Pharma’s U.S. Patent Application No. 15/487,991 also published as U.S. 2017/0216616 A1. BF_1411_ITC_00000794, FOLEY-1411ITC-0001584.

On October 31, 2016, Biofrontera stated in a news article that DUSA Pharmaceuticals (owned by Sun Pharma) was its “main competitor in the U.S.” Sun-ITC-0173896, Sun-ITC-0174086 (*DUSA Pharmaceuticals, Inc. v. Biofrontera, Inc. et al.*, Case No. 1:18-cv-10568-RGS, Dkt. No. 1, ¶ 37 (D. Mass. 2018) (citing Ex. 6, MedCityNews Article)).

In late 2016, Biofrontera hired over 20+ employees from Sun Pharma who took at least 600 Sun Pharma documents. Complainants Initial Statement at 2 (citing *DUSA Pharmaceuticals, Inc. v. Biofrontera Inc. et al.*, Case No. 1:18-cv-10568-RGS, Dkt. No. 123 (D. Mass. 2018)). Sun Pharma sued Biofrontera in the Federal District Court for the District of Massachusetts and

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asserted that Biofrontera had misappropriated confidential and trade secret information from Sun Pharma, improperly obtained confidential Sun Pharma information from former Sun Pharma employees to sell and market its own products, and infringed two of Sun Pharma's photodynamic therapy patents by making, using, offering to sell, and selling the BF-RhodoLED. Sun-ITC-0174234 - Sun-ITC-0174290 (*DUSA Pharmaceuticals, Inc. v. Biofrontera, Inc. et al.*, Case No. 1:18-cv-10568-RGS, Dkt. No. 44 (D. Mass. 2018)). On December, 2018, the Federal District Court for the District of Massachusetts found that Biofrontera was in possession of at least 600 Sun Pharma documents that contained "confidential and proprietary information" and enjoined Biofrontera from "making use of or disseminating DUSA's sales and financial information, customer lists and customer target lists, training and marketing materials, standard operating procedures, technical information, and unpublished clinical data, and any derivations thereof." Complaint ¶ 68 (citing *DUSA Pharmaceuticals, Inc. v. Biofrontera, Inc. et al.*, Case No. 1:18-cv-10568-RGS, Dkt. No. 123 (D. Mass. 2018)) ("Biofrontera by its own admission is in possession of at least 600 DUSA documents obtained from 20+ employees that have left DUSA for Biofrontera in recent years. These documents include an extensive target customer list, sales analyses, training and marketing materials, operating procedures, technical information, and unpublished clinical data."). In November 2021, the parties a Settlement and Release Agreement, where Sun Pharma released Biofrontera of certain claims, including "DUSA Released Patent Claims" with the following definition:

"DUSA Released Patent Claims" shall mean all claims, demands, liens, actions, suits, causes of action, obligations, controversies, debts, costs, attorneys' fees, expenses, damages, judgments, orders, and liabilities, whether known or unknown to DUSA, that accrued on or before the Effective Date of this Agreement, and that are based on (1) infringement of any claim of the Asserted Patents; or (2) infringement of any claim of any patent that issued on or before the Effective Date, but only to the extent that the infringement claim is

[REDACTED]

directed to a Biofrontera product that was first sold commercially on or before the Effective Date and further only to the extent of the country or territory in which said product was sold on or before the Effective Date. For the avoidance of doubt, DUSA Released Patent Claims do not include (1) claims based on patents that had not issued on or before the Effective Date; (2) claims against a Biofrontera product that had not been first sold commercially on or before the Effective Date; or (3) claims asserted in countries or territories against a Biofrontera product where that product had not been first sold commercially in that country or territory on or before the Effective Date. For the purposes of this definition, "Biofrontera product includes, without limitation, (1) any product made for or on behalf of Biofrontera or its Affiliates and (2) any product made by Biofrontera or its Affiliates for a third party. For clarity, a "product" under this definition refers to a product line or specific model, and not individual units.

BF_1411_ITC_00180216 at -219. Therefore, Biofrontera was not released from claims based on patents that did not issue as of the Effective Date of the Settlement Agreement. Furthermore,

[REDACTED]

[REDACTED]

[REDACTED]. *See, e.g.,* Foguet Rough Dep. Tr. 39:18–24, 167:12–21; Luebbert Rough Dep. Tr. 193:6–18, BF_1411_00010399 (Luebbert Ex. 3, “Project Plan BF-RhodoLED XL”).

On October 20, 2020, Biofrontera filed U.S. Patent Application No. 17/071,496 relating to a 5-panel “improved” illumination device for photodynamic therapy. Sun-ITC-0174854 - Sun-ITC-0174874. In 2021, Biofrontera announced its new BF-RhodoLED®XL device and obtained FDA approval. Complainant’s Initial Statement at 2; Complaint ¶ 70 (citing Ex. 30, *Biofrontera AG Receives FDA-Approval of the BF-Rhodoled® XL Lamp* (Oct. 22, 2021)). On February 2, 2022, Biofrontera filed an Information Disclosure Statement in the prosecution of its U.S. Patent Application No. 17/071,496, citing Sun Pharma’s U.S. Publication No. 2017-0216616. Sun-ITC-0174854 (IDS dated February 10, 2022). Biofrontera cited U.S. Patent Application Publication

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No. 2017/0216616 (“’616 Application”) during the prosecution of its U.S. Patent No. 11,235,169 (the “’169 Patent”, Sun-ITC-0157028)—a patent that, according to Biofrontera, covers the BF-RhodoLED® XL product according to Biofrontera, *see, e.g.*, Foguet Rough Dep. Tr. 162:23–163:6, BF_1411_ITC_00121389; BF_1411_ITC_00060629 at -633; BF_1411_ITC_00039986; BF_1411_ITC_00043844; BF_1411_ITC_00043859; Sun-ITC-0168522; Sun-ITC-0168475 at 10; Sun-ITC-0168527, and is listed in the U.S. Food and Drug Administration (FDA) publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (“the Orange Book”) for BF-RhodoLED® XL. The 2017/0216616 Application and ’028 Patent are in the same patent family, both claiming priority to U.S. Application No. 15/292,731. On June 25, 2024, Sun Pharma filed this proceeding asserting that Biofrontera’s BF-RhodoLED®XL device infringes the claims of Sun Pharma’s ’512 and ’028 Patents. Complaint ¶¶ 65.

Sun Pharma incorporates by reference Biofrontera’s response to Sun Pharma’s Interrogatory No. 28.

Pursuant to Commission Rule 210.29(c), Sun Pharma also identifies documents beginning at Bates numbers BF_1411_ITC_00000388, BF_1411_ITC_00000634, and BF_1411_ITC_00011060, Sun-ITC-0168529, BF_1411_ITC_00043844 at -846, BF_1411_ITC_00072341; BF_1411_ITC_00055669 at -55679 (noting that the two FDA approved drug/device combinations for PDT in the U.S. are BF-RhodoLED with Ameluz® and BLU-U with Levulan).

IV. THE ASSERTED PATENTS NAME THE PROPER INVENTORS

An “inventor” is the person or persons who conceived the patented invention. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998). Conception is the “touchstone of inventorship”, *id.* (citing *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1227–28

**Pages 137-138
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Respectfully submitted,

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