

**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

Motion No. 1411-013

**COMPLAINANT SUN PHARMACEUTICAL INDUSTRIES, INC.'S MOTION AND
MEMORANDUM OF POINTS AND AUTHORITIES ON SATISFACTION OF THE
ECONOMIC PRONG OF DOMESTIC INDUSTRY**

Pursuant to Commission Rule 210.18 and Ground Rule 5.4.2, Complainant Sun Pharmaceutical Industries, Inc. ("Sun Pharma") respectfully moves for summary determination on satisfaction of the economic prong of the domestic industry requirement under 19 U.S.C. § 1337(a)(3)(B)-(C).

GROUND RULE 5.1 CERTIFICATION

Sun Pharmaceutical Industries, Inc. certifies that it has complied with Ground Rule 5.1 and has conferred with Respondents Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Bioscience GmbH at least two days before filing this motion. Respondents will oppose the motion.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	LEGAL STANDARDS	4
III.	SUN PHARMA’S DOMESTIC INDUSTRY INVESTMENTS SATISY THE ECONOMIC PRONG UNDER EACH OF SUBSECTIONS 337(A)(3)(B) AND (C).....	6
A.	Sun Pharma’s U.S. Investments in Labor and Capital Under Section 337(a)(3)(B).....	7
1.	Sun Pharma’s Internal Labor Expenditure.....	8
2.	Payments to [REDACTED]	13
3.	Payments to [REDACTED]	15
4.	Payments to [REDACTED]	16
5.	Payments to [REDACTED]	17
6.	Payments to Other Contractors	19
7.	Payments to [REDACTED]	21
B.	Sun Pharma’s U.S. Investments in R&D Under Section 337(a)(3)(C).....	22
C.	Sun Pharma’s U.S. Investments Specific to the BLU-U® 4170E Are Significant and Substantial.....	23
1.	100% Of Sun Pharma’s R&D And Manufacturing For The BLU-U® 4170E Takes Place In The United States	24
2.	Sun Pharma’s Domestic Investments Related to the BLU-U® 4170E Have Been Increasing Over Time	26
3.	Sun Pharma’s Investments Represent a Substantial Reinvestment of Revenue Into the Development of the BLU-U® 4170E	29
4.	Sun Pharma’s Investments in The Development Of The 4170E Are Greater Than or In Line With Industry Standards	31
D.	Sun Pharma Has Demonstrated a Domestic Industry In The Process Of Being Established 32	
E.	Biofrontera’s Arguments Lack Merit.....	34
IV.	CONCLUSION.....	37

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Alloc, Inc. v. Intl Trade Comm’n</i> , 342 F.3d 1361 (Fed. Cir. 2003).....	5
<i>Anderson v. Liberty Lobby, Inc.</i> , 477 U.S. 242 (1986).....	4
<i>Celotex Corp. v. Catrett</i> , 477 U.S. 317 (1986).....	4
<i>Certain Active Matrix Organic Light-Emitting Diode Display Panels And Modules For Mobile Devices, And Components Thereof</i> , Inv. No. 337-TA-1351	7
<i>Certain Bone Cements Components Thereof and Products Containing the Same</i> , Inv. No. 337-TA-1153, Comm’n Op. at 26-27 (Jan. 25, 2021)	24
<i>Certain Cartridges for Electronic Nicotine Delivery Systems and Components Thereof</i> , Inv. No. 337-TA-1141	6
<i>Certain Child Resistant Closures with Slider Devices Having Actuated Insertable Torpedo for Selectively Opening the Closures and Slider Devices Thereof</i> , Inv. No. 337-TA-1171, Comm’n Op., 2020 WL 5701025 (Sept. 18, 2020)	5
<i>Certain Gas Spring Nailer Prods. and Components Thereof</i> , Inv. No. 337-TA-1082, Comm’n Op. at 80 (Apr. 28, 2020)	23
<i>Certain Magnetic Data Storage Tapes and Cartridges Containing the Same</i> , Inv. No. 337-TA-1012, Comm’n Op., 2018 WL 8648372 (Apr. 2, 2018)	5
<i>Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Products Containing the Same, and Components Thereof</i> , Inv. No. 337-TA-921, Comm’n Op. at 63 (Jan. 6, 2016)	28, 35
<i>Certain Mobile Electronic Devices</i> , Inv. No. 337-TA-794, Initial Determination at 604–05 (Oct. 3, 2012)	36
<i>Certain Non-Volatile Memory Devices & Prods. Containing the Same</i> , Inv. No. 337-TA-1046, Comm’n Op. at 41–42 (Oct. 26, 2018)	5, 32
<i>Certain Plant-Derived Recombinant Human Serum Albumins (“rHSA”) and Products Containing Same</i> , USITC Inv. No. 337-TA-1238, ID (April 7, 2022).....	24, 25, 31

<i>Certain Pouch-Type Battery Cells, Battery Modules, and Battery Packs, Components Thereof, and Products Containing the Same, 337-TA-1179, ID (Dec. 14, 2020)</i>	6, 24
<i>Certain Pre-Filled Syringes for Intravitreal Injection and Components Thereof, 337-TA-1207</i>	6
<i>Certain Solid State Storage Drives, Stacked Elecs. Components, and Products Containing Same, Inv. No. 337-TA-1097, Comm’n Op. (June 29, 2018)</i>	23
<i>Certain Stringed Musical Instruments, Inv. No. 337-TA-586, Comm’n Op., 2008 WL 2139143 (May 16, 2008)</i>	6
<i>Certain Strontium-Rubidium Radioisotope Infusion Systems, Inv. No. 337-TA-1110, ID (Aug. 1, 2019)</i>	5, 32
<i>Certain Percussive Massage Devices, Inv. No. 337-TA-1206, Comm’n Op. (Jan. 4, 2022)</i>	28
<i>Crown Operations Int’l, Ltd. v. Solutia, Inc., 289 F.3d 1367 (Fed. Cir. 2002)</i>	4
<i>Hyosung TNS Inc. v. ITC, 926 F.3d 1353 (Fed. Cir. 2019)</i>	34
<i>Lashify, Inc. v. Int’l Trade Comm’n, 130 F.4th 948 (Fed. Cir. 2025)</i>	19, 26
<i>Wuhan Healthgen Biotechnology Corp. v. Int’l Trade Comm’n, 127 F.4th 1334 (Fed. Cir. 2025)</i>	25, 29, 30, 31
Statutes	
19 U.S.C. § 1337(a)(2).....	5
19 U.S.C. §1337(a)(3)(B) and (C)	4
Other Authorities	
19 C.F.R. § 210.18(b)	4

LIST OF EXHIBITS CITED

Exhibit No.	Description
1	Certified U.S. Patent No. 11,446,512 to Boyajian et al. [JX-0001]
2	Certified U.S. Patent No. 11,697,028 to Boyajian et al. [JX-0002]
3	Letter from James E. Dillard III, Acting Dir., FDA Div. of Gen. & Restorative Devices, to Samuel D. Swetland, Vice President, DUSA Pharms., (Dec. 3, 1999) [JX-0216C] (CBI)
4	Compl. Ex. 24, SEC Form 10-K for DUSA Pharmaceuticals, Inc. for Fiscal Year Ended December 31, 2008 [CX-0048]
5	Declaration of Zvi Albert [CX-1043C] (CBI)
6	Excerpts from the Deposition Transcript of Zvi Albert
7	Spreadsheet: Building Cost in New Jersey and Massachusetts [JX-0097C] (CBI)
8	Excerpts from the Deposition Transcript of Montserrat Foguet (Dec. 11, 2024)
9	Ex. 39, Biofrontera Inc., <i>Ameluz® Outer Packaging</i> (May 2024) [CX-0058]
10	Excerpts from the Deposition Transcript of Thomas Boyajian
11	Excerpts from the Deposition Transcript of Brian Mazejka 90:24–93:5
12	Sun Pharma’s Special Premarket Notification Submission to the FDA [JX-0215]
13	Declaration of Scott Lundahl (06-25-2024) [JX-0154C] (CBI)
14	Excerpts from the Deposition Transcript of Mark Carota
15	Intentionally Omitted
16	Intentionally Omitted
17	Compl. Ex. 27, Letter from Tanisha Hithe, Assistant Dir., FDA Div. of Gen. Surgery Devices, to Scott Lundahl, Sun Pharm. Indus., Inc. (June 13, 2024)
18	Intentionally Omitted
19	Excerpts from Opening Expert Report of Vander Veen (CBI)
20	FY 2022 Sun Salary spreadsheet [JX-0099C] (CBI)
21	FY 2023 Sun Salary spreadsheet [JX-0100C] (CBI)
22	FY 2024 Sun Salary spreadsheet [JX-0101C] (CBI)
23	FY 2025 Sun Salary spreadsheet [JX-0239C] (CBI)
24	Master Services Agreement entered into between Sun Pharma and [REDACTED] dated September 15, 2016 [JX-0238C] (CBI)
25	Declaration of [REDACTED] Representative [REDACTED] with Attachment A (2024-11-07) [JX-0219C] (CBI)
26	Excerpts from the Deposition Transcript of [REDACTED]
27	Excerpts from the Deposition Transcript of Scott Lundahl
28	SOW For [REDACTED] Support to Sun [CX-1280C] (CBI)
29	SOW to deliver [REDACTED] Project [CX-1295C] (CBI)
30	SOW to Deliver [REDACTED] [CX-1296C] (CBI)

31	SOW to Deliver [REDACTED] [CX-1297C] (CBI)
32	SOW to Deliver [REDACTED] [CX-1298C] (CBI)
33	Intentionally Omitted
34	SOW to Deliver [REDACTED] [CX-1299C] (CBI)
35	SOW to deliver [REDACTED] [CX-1300C] (CBI)
36	[REDACTED] Quote for Compliance Testing of BLU-U, Model 4170E product [CX-1190C] (CBI)
37	[REDACTED] Purchase Order [JX0076C] (CBI)
38	DUSA - [REDACTED] - Development and Contract Manufacturing Agreement Execution Version DUSA stamp (CBI)
39	Receipt of Payment from Scott Lundahl (Sun) to [REDACTED] (03-01-2022) [JX-0092C] (CBI)
40	Declaration of [REDACTED] Inc. Representative [REDACTED] [JX-0114C] (CBI)
41	Sun's Response to Biofrontera's First Set of Interrogatories No. 4 (Aug. 28, 2024) (CBI)
42	United States Contractors FY 22-24 [JX-0113C] (CBI)
43	Contract between Sun Pharma and [REDACTED] [JX-0210C] (CBI)
44	Excerpts from the Deposition Transcript of Thomas Vander Veen
45	Consulting Agreement between Sun Pharma and [REDACTED], LLC [JX-0230C] (CBI)
46	[REDACTED] Proposal for Regulatory Support [JX-0232C] (CBI)
47	[REDACTED] Incorporated Website, [REDACTED] /
48	Vendor Payment Spreadsheet [JX-0240C] (CBI)
49	Excerpts from Opening Expert Report of Nan Jokerst (CBI)
50	Excerpts from Rebuttal Expert Report of Julia Rowe (CBI)
51	Summary of DUSA Profit and Loss Spreadsheet (10-22-2024) [JX-0093C] (CBI)
52	Excerpts from the Deposition Transcript of Frederick Leffler 45:1-12
53	Excerpts from the Deposition Transcript of Hermann Luebbert
54	Biofrontera's Strategy Meeting Presentation (11-10-2020)
55	Excerpts from the Deposition Transcript of Julia Rowe Dep. Tr.
56	Declaration of Zvi Albert in Support of Sun Pharma's Motion for Summary Determination

I. INTRODUCTION

Complainant Sun Pharmaceutical Industries, Inc. (“Sun Pharma” or “Complainant”) is a U.S. corporation organized under the laws of Delaware, with its principal place of business at Independence Way, Princeton, New Jersey 08540. Sun Pharma also maintains a 70,000-square-foot facility located in Billerica, Massachusetts. Both facilities are shown below and house employees that work on the technical domestic industry products at issue:



Fig. 1: Princeton, New Jersey Facility



Fig. 2: Billerica, Massachusetts Facility

Among its diverse product offerings, Sun Pharma designs, markets, and sells products for photodynamic therapy (“PDT”) treatment, including the BLU-U® Blue Light Photodynamic Therapy Illuminator devices (BLU-U® 4170/4170D¹ and BLU-U® 4170E), and pharmaceutical products such as the Levulan® prescription medicine, which is indicated for use in conjunction with the BLU-U® devices. Sun Pharma’s latest PDT product—the BLU-U® Model 4170E—either individually or in combination with the Levulan® Kerastick® prescription medicine (the “Domestic Industry Products”) practices one or more claims of U.S. Patent Nos. 11,446,512 (“the

¹ The BLU-U® 4170 is also referred to as the BLU-U® 4170D. The “D” designates that the BLU-U® 4170 device is shipped fully assembled.

'512 Patent”) and 11,697,028 (“the ’028 Patent”) (collectively, the “Asserted Patents”).² Ex. 1 (’512 Patent); Ex. 2 (’028 Patent).

For more than two decades, Sun Pharma has invested substantial resources in the United States to research, develop, manufacture, and commercialize its PDT treatments. In December 1999, Sun Pharma obtained U.S. Food and Drug Administration (“FDA”) approval for the BLU-U® 4170 illumination device in combination with Levulan to treat non-hyperkeratotic actinic keratosis (“AK”) of the face, scalp, and upper extremities.³ Ex. 3 (Letter from FDA (Dec. 3, 1999)). After approval, Sun Pharma launched Levulan® in combination with its BLU-U® 4170 device in September 2000. Ex. 4 (DUSA 2008 10-K) at CX-0048.6. Sun Pharma continued to innovate to further advance its leadership in PDT. Starting around the 2014–2015 timeframe, Sun Pharma began research and development of the BLU-U® 4170E, its next-generation illumination device. And while the BLU-U® 4170E builds upon the technology and research and development efforts for the predicate BLU-U® 4170 device, the BLU-U® 4170E achieves its efficacy for PDT through novel features which are protected by the ’512 and ’028 Patents—both of which stem from an October 15, 2015 provisional application. Ex. 1 (’512 Patent); Ex. 2 (’028 Patent).

From 2016 through the filing of its Complaint on June 25, 2024, Sun Pharma invested at least [REDACTED] in cognizable U.S. expenditures related to the BLU-U® 4170E. These investments in labor and capital expenses relate to the design, engineering, development, and manufacture of the BLU-U® 4170E. *All* of Sun Pharma’s work related to the BLU-U® 4170E

² The BLU-U® 4170E, alone, practices the system claims of the ’512 and ’028 Patents. The method claims of the ’512 and ’028 Patents require the administration of 5-aminolevulinic acid (ALA)—the active ingredient of Levulan®. Accordingly, the use of the BLU-U® 4170E in combination with Levulan® practices the method claims of the Asserted Patents.

³ Levulan® and the BLU-U® 4170 were originally developed and commercialized by DUSA Pharmaceuticals, Inc., which was acquired by Sun Pharma in 2012.

device takes place in the United States e [REDACTED]
 [REDACTED], Ex. 5 (Albert Decl.) ¶ 11–12—which Sun Pharma acquired in [REDACTED]
 [REDACTED], respectively⁴—or by remote U.S. employees. Ex. 6 (Albert Dep. Tr.)
 at 43:9–45:8. Sun Pharma has hired and incurred [REDACTED] of expenses from 2016–June 25,
 2024 related to U.S. third-party contractors assisting with the design, engineering, development,
 and manufacture of the BLU-U® 4170E. Moreover, Levulan® is exclusively manufactured in
 Sun Pharma’s Massachusetts facility. Ex. 5 (Albert Decl.) ¶ 11.

In stark contrast to Sun Pharma, Biofrontera⁵ exclusively manufactures, assembles,
 packages, and tests its RhodoLED®⁶ XL device outside of the United States [REDACTED]
 [REDACTED]. Ex. 8 (Foguet Dep. Tr.) at 35:3–7, 161:10–16. Similarly, Biofrontera’s Ameluz®
 prescription medicine, which is used in combination with its RhodoLED® XL device, is
 manufactured in Switzerland and imported into the United States. Ex. 9 (Biofrontera Inc.,
Ameluz® Outer Packaging, at 2–3 (May 2024)).

Respondents offer only a cursory and unfounded challenge to the significance of the
 domestic industry by raising flimsy objections regarding the relationship between third-party
 investments and the device; contesting a purchase order that, even if excluded, leaves substantial
 investment in the BLU-U® 4170E; and improperly comparing device-specific research and
 development to the overall research and development and disparate revenue of a diversified
 company. Importantly, Respondents do not offer any corrections to Sun Pharma’s allocations, nor

⁴ Ex. 7 (Facility Acquisition Spreadsheet).

⁵ The Respondents in this Investigation are Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera AG (collectively, “Biofrontera” or “Respondents”).

⁶ RhodoLED® XL, individually and in combination with Ameluz® prescription medicine, are the Accused Products in this Investigation.

do Respondents demonstrate that Sun Pharma's allocations capture expenditures unrelated to the BLU-U® 4170E. Indeed, documents produced by Sun Pharma in this Investigation as well as witness testimony demonstrate that Sun Pharma investments relate only to cognizable expenditures specifically for the BLU-U® 4170E. Thus, there is no genuine dispute of material facts as it relates to Sun Pharma's satisfaction of the economic prong of the domestic industry requirement.

In sum, Sun Pharma has expended at least [REDACTED] in cognizable BLU-U® 4170E research and development, regulatory, and manufacturing expenditures based on activities that take place domestically. These expenditures include [REDACTED] in R&D investments which alone establish an existing domestic industry under each of subsections 19 U.S.C. §1337(a)(3)(B) and (C) because they are qualitatively and quantitatively significant and substantial.

II. LEGAL STANDARDS

Commission Rule 210.18 governs summary determinations and provides, in relevant part, that a summary determination shall be granted "if pleadings and any depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a summary determination as a matter of law." 19 C.F.R. § 210.18(b). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the party opposing the motion. *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1374 (Fed. Cir. 2002). Once the moving party has met its burden, the opposing party must "set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986).

In Section 337 investigations, a complainant must establish that an industry “relating to the articles protected by the patent . . . exists or is in the process of being established” in the United States. 19 U.S.C. § 1337(a)(2). To establish a domestic industry under Section 337, a complainant must satisfy both the “technical prong” and “economic prong” of the domestic industry requirement. *See, e.g., Alloc, Inc. v. Intl Trade Comm’n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). The “economic prong” of the domestic industry requirement requires that, with respect to the products protected by the patent, there must be evidence of either: (a) significant investment in plant and equipment; (b) significant employment of labor or capital; or (c) substantial investment in the patent’s exploitation, including activities such as engineering, research and development, or licensing. *See Certain Child Resistant Closures with Slider Devices Having Actuated Insertable Torpedo for Selectively Opening the Closures and Slider Devices Thereof*, Inv. No. 337-TA-1171, Comm’n Op., 2020 WL 5701025, at *6 (Sept. 18, 2020). Notably, a product need not be commercially available to satisfy the domestic industry requirement. *See, e.g., Certain Strontium-Rubidium Radioisotope Infusion Systems*, Inv. No. 337-TA-1110, ID at 134 (Aug. 1, 2019) (“[C]ommercial availability of a patented article in the United States is not necessary to show either that a domestic industry exists or that an industry in the process of being established”); *Certain Non-Volatile Memory Devices & Prods. Containing the Same*, Inv. No. 337-TA-1046, Comm’n Op. at 41–42 (Oct. 26, 2018) (“The term ‘article’ [as required by § 337] on its own is sufficiently capacious to embrace pre-commercial or noncommercial items.”).

Whether investments are “significant” or “substantial” is assessed on a case-by-case basis, considering the facts of each investigation, the nature of the articles of commerce, and the realities of the marketplace. *See Certain Magnetic Data Storage Tapes and Cartridges Containing the Same*, Inv. No. 337-TA-1012, Comm’n Op., 2018 WL 8648372, at *75 (Apr. 2, 2018). There is

no requirement for a minimum monetary expenditure, nor must a complainant define the domestic industry using rigid mathematical terms. *See Certain Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm’n Op., 2008 WL 2139143, at *14 (May 16, 2008). Under Section 337, summary determination may be granted on the economic prong even when disputes concerning the technical prong remain unresolved. *See, e.g., Certain Pouch-Type Battery Cells, Battery Modules, and Battery Packs, Components Thereof, and Products Containing the Same*, 337-TA-1179, ID at 6 (Dec. 14, 2020) (ALJs “routinely consider[s] these prongs separately and ha[ve], in fact, issued determinations finding that the economic prong is met, even if the technical prong is not”). The Commission routinely grants summary determination on economic prong even when the motion is opposed. *See, e.g., Certain Pre-Filled Syringes for Intravitreal Injection and Components Thereof*, 337-TA-1207, ID (Apr. 2, 2021); *Certain Cartridges for Electronic Nicotine Delivery Systems and Components Thereof*, Inv. No. 337-TA-1141, ID (Aug. 14, 2019).

III. SUN PHARMA’S DOMESTIC INDUSTRY INVESTMENTS SATISY THE ECONOMIC PRONG UNDER EACH OF SUBSECTIONS 337(A)(3)(B) AND(C)

The development of the BLU-U® 4170E device began in [REDACTED]. Ex. 10 (Boyajian Dep. Tr.) at 41:8–42:22; Ex. 11 (Mazejka Dep. Tr.) at 90:24–93:5. The project—[REDACTED]—originated at DUSA Pharmaceuticals, a company later acquired by Sun Pharma in November 2012 for approximately \$230 million. Ex. 12 (Special Premarket Notification to the FDA); Ex. 13 (Lundahl Decl.) at n.1. The DUSA engineers working on the project included the inventors of the Asserted Patents—Mr. Mark Carota, Mr. Thomas Boyajian, and Mr. Brian Mazejka. Ex. 14 (Carota Dep. Tr.) at 41:13–16. While Sun Pharma created the original prototype for the BLU-U® 4170E in-house, Ex. 14 (Carota Dep. Tr.) at 29:6–32:16; Ex. 10 (Boyajian Dep. Tr.) at 162:8–165:9; Ex. 26 (Bacon Dep. Tr.) at 57:9–20, it subsequently retained United States-based contractors, who—at Sun Pharma’s direction—assisted with R&D activities, product

design, and regulatory compliance testing—activities which Sun Pharma continued to concurrently perform in-house. Sun Pharma also engaged third parties to assist with manufacturing the BLU-U® 4170E in anticipation of its commercial launch.⁷

Sun Pharma spent more than eight years researching and developing the BLU-U® 4170E, and on May 13, 2024, submitted a Premarket Notification or “510(k)” Application to the FDA, representing that the BLU-U® 4170E device is substantially equivalent to Sun Pharma’s existing, approved PDT device, BLU-U® 4170D. Ex. 12 (Sun Pharma’s Special Premarket Notification to the FDA). The FDA cleared the BLU-U® 4170E device on June 13, 2024, confirming it is “substantially equivalent” to the BLU-U® 4170. Ex. 17 (Letter from FDA to Sun Pharm. Indus., Inc. (June 13, 2024).)). Subsequently, on February 2, 2025, Sun Pharma submitted its Premarket Approval (“PMA”) application, which is now under real-time review, which is an expedited process. The PMA involves in-depth FDA review of scientific evidence, including clinical trial data, of a device’s safety and effectiveness. Ex. 27 (Lundahl Dep. Tr.) at 93:9–94:10. Having already put manufacturing capabilities in place, Sun Pharma is poised for commercial launch soon after its PMA is approved.

A. Sun Pharma’s U.S. Investments in Labor and Capital Under Section 337(a)(3)(B)

Using documentation and data produced by Sun Pharma and third-party contractors, Dr. Vander Veen determined that between 2016 and the filing of the Complaint on June 25, 2024, Sun

⁷ Because the third-party contractors Sun Pharma engaged provide specialized services, Sun Pharma’s payments to those contractors are cognizable for purposes of domestic industry. *See, e.g., Certain Active Matrix Organic Light-Emitting Diode Display Panels And Modules For Mobile Devices, And Components Thereof*, Inv. No. 337-TA-1351, ID (Nov. 15, 2024) (“A complainant can, however, rely on investments made by third parties if there is evidence to show that the third party’s investments are attributable to the domestic industry products...In contrast to the ‘retailer’ suppliers in *Lelo*, who simply sold ‘off-the-shelf’ components, the evidence shows that the third-party entities here are, in fact, contractors, who provide specialized services, and do not simply sell ‘off-the-shelf’ products.”)

Pharma invested [REDACTED] in cognizable U.S. investments in labor and capital expenditures related to the BLU-U® 4170E. Each of Sun Pharma's internal and external investments related to the research, design, development, testing, and manufacture of the BLU-U® 4170E that Dr. Vander Veen allocated under prong (B) are shown in Table 1 and will be further discussed below.

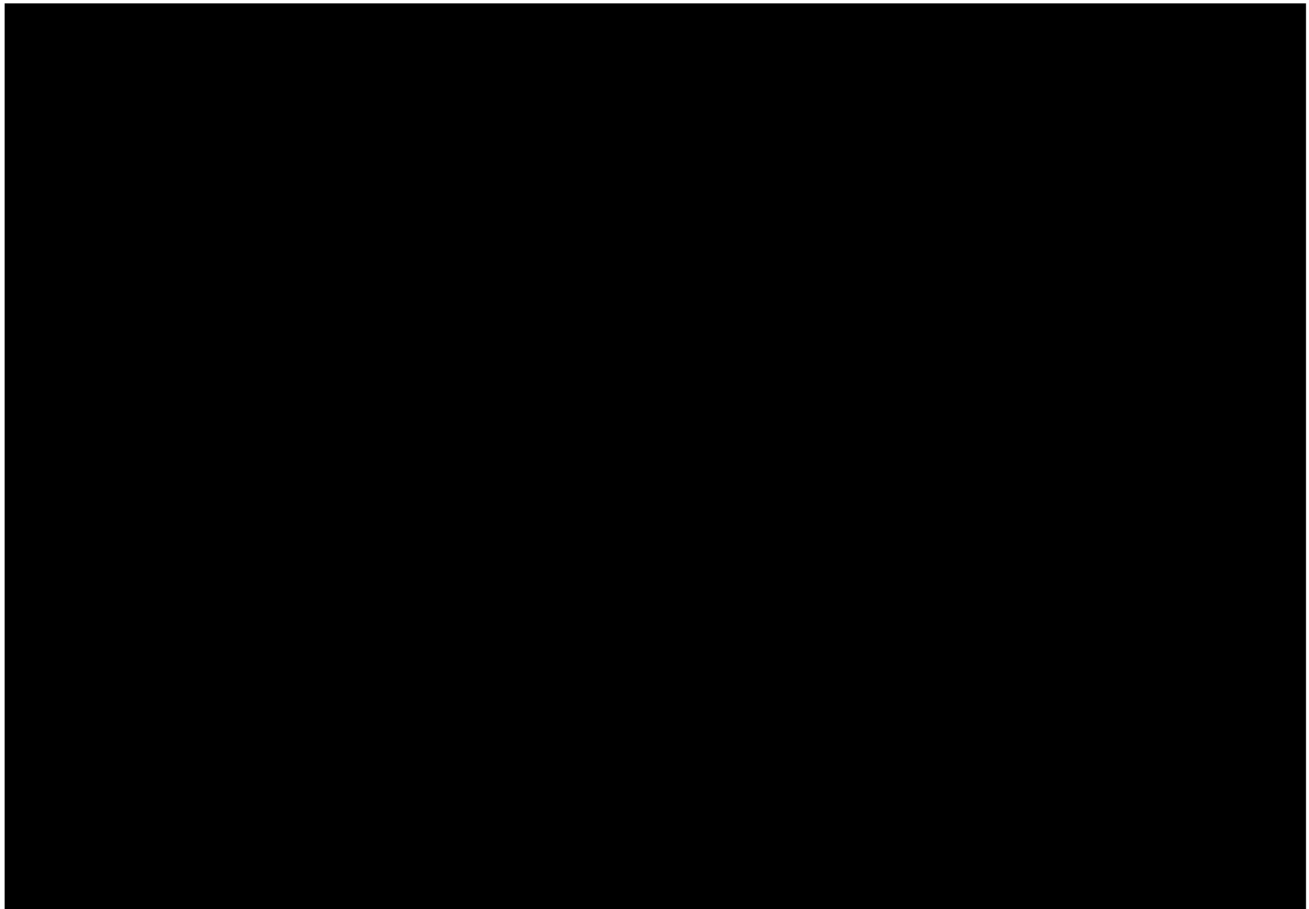


Table 1: Ex. 19 (Vander Veen Rpt.), Tab 4a

1. Sun Pharma's Internal Labor Expenditure

Although Sun Pharma engaged third party contractors, Sun Pharma employees continued to develop the BLU-U® 4170E in-house. And as Dr. Vander Veen quantified, Sun Pharma spent a total of [REDACTED] on cognizable internal labor expenditures, including Regulatory and R&D labor, from 2021 through June 25, 2024.

In its ordinary course of business, Sun Pharma maintains accounting records in an SAP system, from which it produced data in the form of Excel spreadsheets in this Investigation. Ex. 6 (Albert Dep. Tr.) at 23:2–10, 43:20–44:11; Ex. 5 (Albert Decl.) at ¶ 19. Amongst those spreadsheets, Sun Pharma produced four relating to annual employee compensation for United States-based Sun Pharma personnel working on PDT products—*i.e.*, the BLU-U® 4170D device, the BLU-U® 4710E device, and Levulan® Kerastick®. Ex. 20 (FY 2022 Sun Pharma Salary spreadsheet); Ex. 21 (FY 2023 Sun Pharma Salary spreadsheet); Ex. 22 (FY 2024 Sun Pharma Salary spreadsheet); Ex. 23 (FY 2025 Sun Pharma Salary spreadsheet). Employee compensation includes salaries, bonuses, and benefits. Ex. 6 (Albert Dep. Tr.) at 46:1–22. The data is presented on a fiscal year (“FY”) basis, which for Sun Pharma runs from April 1st through March 31st. Ex. 6 (Albert Dep. Tr.) at 20:13–15. For reference, an exemplary excerpt of one of the compensation spreadsheets is shown in the figure below.

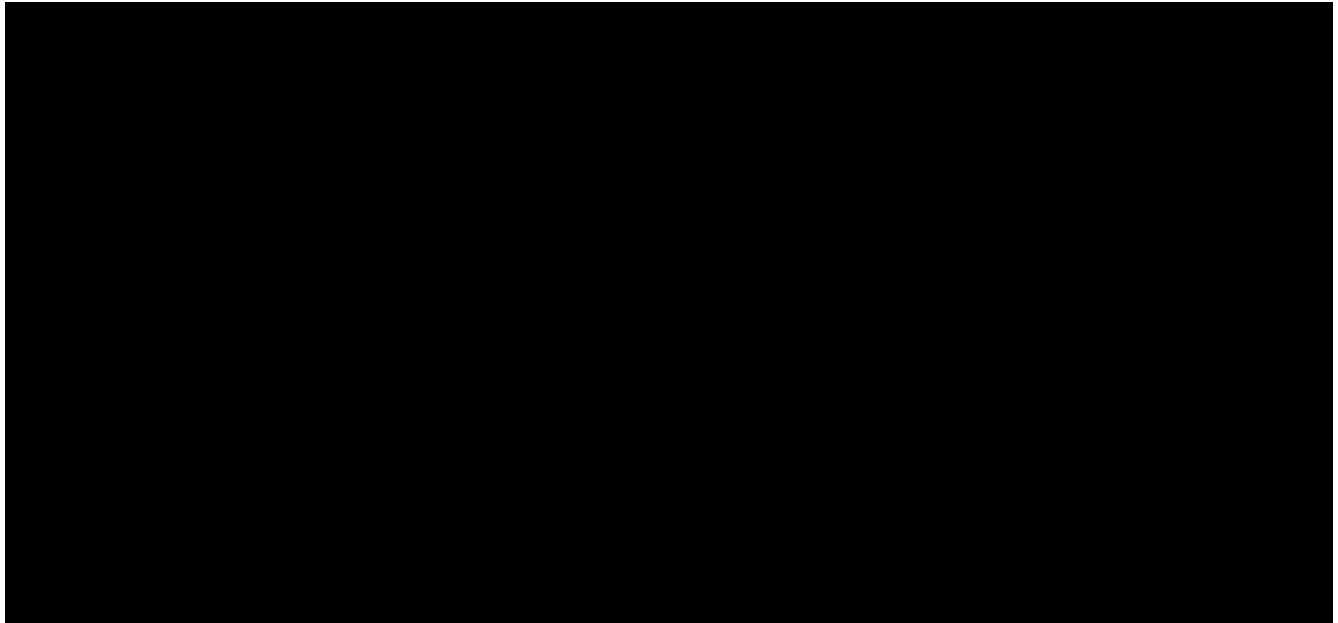


Fig. 3: Ex. 20 (FY 2022 Salary Spreadsheet) (highlighting added)⁸

[REDACTED]

[REDACTED]

[REDACTED] As Mr. Zvi Albert—Sun Pharma’s Chief Financial Officer—testified, Sun Pharma allocated each employee’s time to the PDT business, which includes work related to the BLU-U® 4170, BLU-U® 4170E, and Levulan®. Ex. 6 (Albert Dep. Tr.) at 48:3–19. That percentage was then used to apportion each employee’s compensation to the PDT business. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As Mr. Albert explained, the specific percentage of each employee’s time allocated to a product was determined by Mr. Scott Lundahl, the technical lead

⁸ Certain columns in the spreadsheet showing each employee’s benefits and bonuses have been collapsed for readability.

on the product, for the technical activities, and Mr. Ron Groff, the head of product support, for product support and customer service activities. Ex. 6 (Albert Dep. Tr.) at 24:12–25:15; 46:1–52:4. This allocation methodology is reflected in each of the compensation spreadsheets produced by Sun Pharma. *See* Exs. 20–23. All of the employees listed in these records work in the United States. Ex. 6 (Albert Dep. Tr.) at 45:20–22. No Sun Pharma employee that works on the BLU-U® 4170E is located outside of the United States. Ex. 5 (Albert Decl.) at ¶ 13.

Using these spreadsheets, Dr. Vander Veen allocated Sun Pharma’s internal R&D and Regulatory labor costs to the BLU-U® 4170E. Ex. 19 (Vander Veen Rpt.) ¶ 58. Sun Pharma’s R&D employees do product engineering, electronics technician work, medical science liaison, medical information and medical affairs work, and publications work. Sun Pharma’s Regulatory employees do FDA compliance work, including preparation and submission of documentation to the FDA and facilitating FDA approval for product release. The R&D and Regulatory labor costs for each fiscal year was calculated by totaling each R&D and Regulatory employee’s compensation allocated to the BLU-U® 4170E [REDACTED]

[REDACTED]

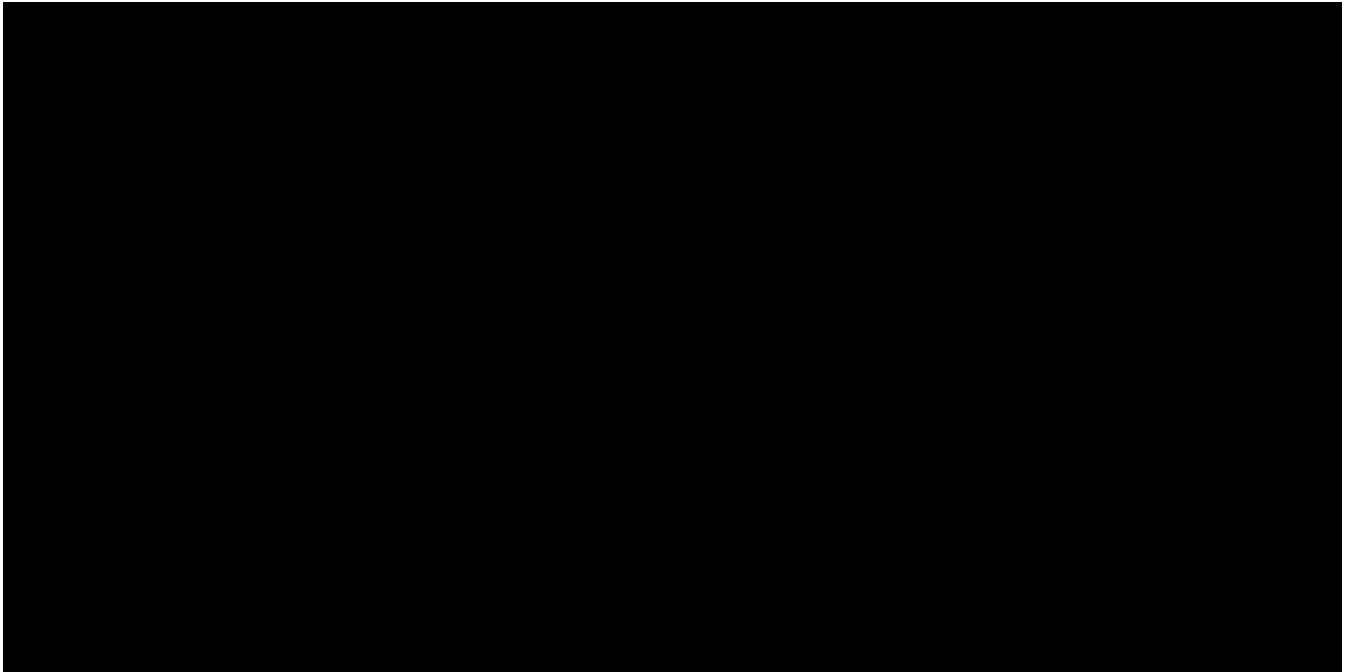


Fig. 4: Ex. 20 (Sun Pharma Salary spreadsheet FY 2022) (highlighting added)

For example, Sun Pharma's FY 2022 spreadsheet (Ex. 20) shows that Sun Pharma spent a total of [REDACTED] on R&D labor compensation and [REDACTED] on regulatory labor compensation specific to the BLU-U® 4170E in FY 2022. Those amounts can be seen in Fig. 4, above. Applying this same methodology, to each spreadsheet, Dr. Vander Veen further calculated that SunPharma spent a total of [REDACTED] on R&D labor and [REDACTED] on Regulatory labor in FY 2023 (*see* Ex. 21); [REDACTED] on R&D labor and [REDACTED] on Regulatory labor in FY 2024 (*see* Ex. 22); and [REDACTED] on R&D labor and [REDACTED] on Regulatory labor in FY 2025 (*see* Ex. 23) for the BLU-U® 4170E device. Because the compensation data was provided on a fiscal year basis (April 1 – March 31), Dr. Vander Veen adjusted the totals to coincide with calendar years. Those adjusted amounts are shown in Table 2, below.

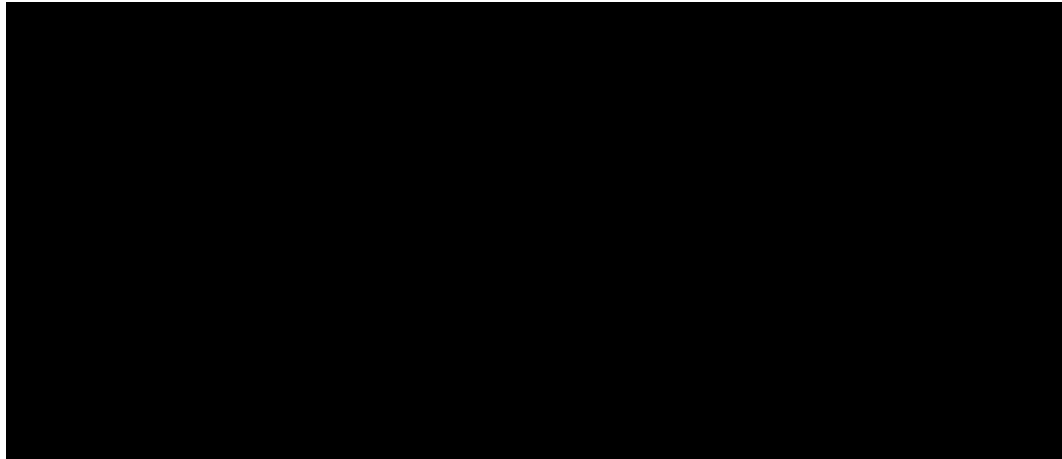


Table 2: Ex. 19 (Vander Veen Rpt.), Tab 4b

These annual R&D and Regulatory labor investments are reflected on lines [A] (for R&D labor) and [B] (Regulatory labor) of Table 1, *supra*.

2. Payments to [REDACTED]

While Sun Pharma continued to internally perform R&D work related to the BLU-U® 4170E, it also retained the services of [REDACTED] to assist in the design and development of the device. In 2016, DUSA (which was acquired by Sun Pharma) entered into a Services Agreement with [REDACTED], which were later acquired by [REDACTED]. Ex. 24 ([REDACTED]-Sun Pharma Services Agreement); Ex. 25 ([REDACTED] Decl.) ¶ 2. Beginning in September 2016, [REDACTED] provided software engineering and industrial design services related to development and testing of the BLU-U® 4170E prototype developed at DUSA, at Sun Pharma's direction. Ex. 5 (Albert Decl.) ¶ 20; Ex. 13 (Lundahl Decl.) ¶ 18; Ex. 6 (Albert Dep. Tr.) at 84:12–85:2. [REDACTED] is based in [REDACTED] and continued to provide industrial design and software support services for the BLU-U® 4170E from 2016–2021 including improvements on additional prototypes. Ex. 25 ([REDACTED] Decl.) ¶ 3. According to [REDACTED]—the Associate Director at [REDACTED], the parent company of [REDACTED] work for Sun Pharma included sizing, spacing, electronic feedback, and the mechanical design of the BLU-U® 4170E

prototype to achieve the desired wavelength with the LED light sources. *See, e.g.*, Ex. 25 ([REDACTED] Decl.) ¶ 4, Ex. 26 ([REDACTED] Dep. Tr.) at 24:1–8, 29:12–30:13, 77:8–79:19 (testifying that [REDACTED] worked on [REDACTED] on the 4170E device at Sun Pharma’s direction); Ex. 27 (Lundahl Dep. Tr.) at 73:5–22 (testifying that [REDACTED] “implement[ed] what the inventors wanted in terms of the light source and the invention” and created “additional prototypes, improvement in certain aspects of the device”); Ex. 14 (Carota Dep. Tr.) at 38:18–39:10, 55:1–11 (testifying that [REDACTED] assisted with “optical spec[s]” and prototype support structures during development of the 4170E).

work for Sun Pharma on the 4170E device is reflected in the Statements of Work (SOWs) and Change Orders submitted by .

[illegible]

██████████ provided a declaration containing a table depicted in Fig. 5, below, showing the amounts Sun Pharma paid ██████████ on a calendar year basis from 2016 through 2024 for ██████████ work related to the BLU-U® 4170E:



Fig. 5: Ex. 25 (██████████ Dec.) at ¶ 5

Sun Pharma's payments went to pay salaries for U.S. based ██████████ employees working on the BLU-U® 4170E (██████████) as well as software and equipment to perform that development work. Ex. 25 (██████████ Dec.) at ¶¶ 6-9. ██████████ has no employees located outside of the United States working on the BLU-U® 4170E. *Id.*

To allocate the ██████████ expenditures, Dr. Vander Veen took the payments from Mr. ██████████ declaration and prorated the 2024 payments to reflect pre-Complaint and post-Complaint numbers, as shown in the Table 3 below:

Table 3: Ex. 19 (Vander Veen Rpt.) at Tab 4c

These payments for 2016–June 25, 2024 are reflected in line [C] of Table 1, *supra*.

3. Payments to ██████████

Sun Pharma retained ██████████
to provide testing, inspection, safety compliance, and certification services related to the BLU-U®

4170E. Ex. 5 (Albert Decl.) ¶ 22. [REDACTED] is a certification company which performed product safety evaluations on the BLU-U® 4170E, including electrical & mechanical construction review and testing, as well as evaluating the device for compliance with recognized industry standards and safety requirements. Ex. 36 ([REDACTED] Quote for Compliance Testing of BLU-U, Model 4170E). This work was carried out at [REDACTED] location. Ex. 13 (Lundahl Decl.) ¶ 20. Sun Pharma produced a [REDACTED] purchase order with [REDACTED] dated May 3, 2024. Ex. 37 ([REDACTED] Purchase Order). Mr. Albert testified that all of the payments made to [REDACTED] related specifically to the 4170E device. Ex. 6 (Albert Dep. Tr.) 92:19–93:8; Ex. 13 (Lundahl Decl.) at ¶ 20; Ex. 5 (Albert Decl.) at ¶ 22. Although Mr. Albert’s declaration shows that Sun Pharma made additional payments to [REDACTED], Ex. 5 (Albert Decl.) at ¶ 22, Dr. Vander Veen conservatively allocated only the [REDACTED] payment, which is reflected in line [D] of Table 1, *supra*.

4. Payments to [REDACTED]

[REDACTED] is an Assurance, Testing, Inspection and Certification (ATIC) company based in [REDACTED]. [REDACTED] provided safety compliance services with various industry standards for the BLU-U® 4170E device at Sun Pharma’s direction. Ex. 13 (Lundahl Decl.) ¶ 21; Ex. 5 (Albert Decl.) ¶ 23; Ex. 10 (Boyajian Dep. Tr.) at 163:4–15 (testifying that [REDACTED] provided testing services). A receipt from March 1, 2022 produced by Sun Pharma shows that [REDACTED] was paid to [REDACTED] in relation to testing services for the BLU-U® 4170E. Ex. 39 (Receipt of Payment to [REDACTED]), *see also* Ex. 34 (“[REDACTED] [REDACTED] for Phase 2 of the [REDACTED] Project). Mr. Albert testified that all of the payments made to [REDACTED] related specifically to the 4170E device. Ex. 6 (Albert Dep. Tr.) at 93:14–94:5. Although Mr. Albert’s declaration showed that Sun Pharma made additional payments to [REDACTED], Ex. 5 (Albert Decl.) at

¶ 23, Dr. Vander Veen conservatively allocated only the [REDACTED] payment, which is reflected in line [E] of Table 1.

5. Payments to [REDACTED]

In 2021, in preparation for the commercial release of the BLU-U® 4170E, Sun Pharma entered into a Development and Contract Manufacturing Agreement with [REDACTED] [REDACTED] the manufacture of BLU-U® 4170E devices. Ex. 38 (DUSA - [REDACTED] - Development and Contract Manufacturing Agreement). [REDACTED] is a manufacturer based in [REDACTED], and provides labor, engineering services, and equipment for manufacturing the BLU-U® 4170E. Ex. 13 (Lundahl Decl.) ¶ 19. According to Mr. [REDACTED] [REDACTED], the General Manager at [REDACTED], the manufacturing engineers that have and will support the engineering builds and other manufacturing activities related to the BLU-U® 4170E are all located in the United States, as are the plants, laboratories, and other technical spaces that will be used to work on manufacturing the BLU-U® 4170E. Ex. 40 ([REDACTED] Decl.) at ¶¶ 7-12. To date, [REDACTED] BLU-U® 4170E devices have been manufactured by [REDACTED] in the United States. Ex. 41 (Sun Pharma's Response to Biofrontera's First Set of Interrogatories Nos. (1-17) (Aug. 28, 2024)) at 17.

Mr. [REDACTED] declaration includes a table showing payments Sun Pharma made for materials and direct and engineering labor costs related to the manufacturing of BLU-U® 4170E units, which is shown in Fig. 6, below.

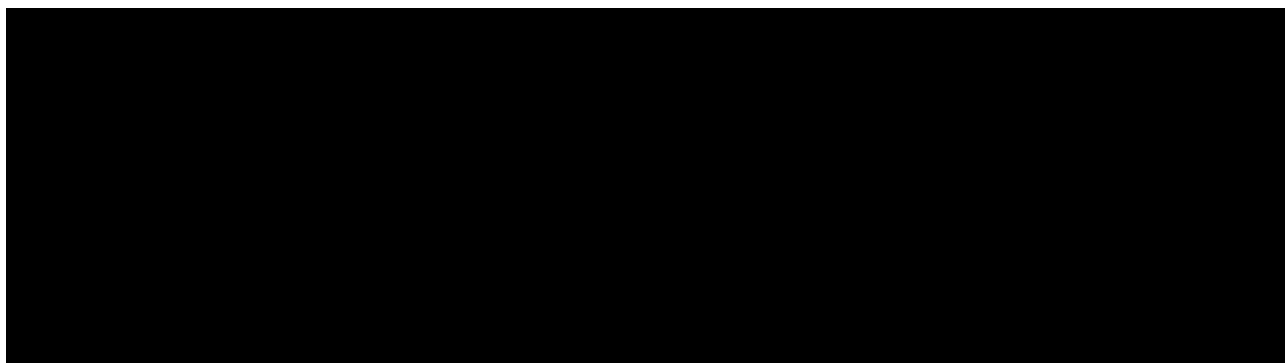


Fig. 6: Ex. 40 ([REDACTED] Decl.) at ¶¶ 5–6

For the purposes of his prong (B) analysis, Dr. Vander Veen conservatively excluded the “Materials” cost paid to [REDACTED] and allocated only the “Direct Labor” and “Engineering Labor” costs from 2021 through June 25, 2024, as shown in Table 4.

Table 4: Ex. 19 (Vander Veen Rpt.) at Tab 4d

To support its commercial launch, Sun Pharma also entered into a purchase order with [REDACTED] for an additional [REDACTED] on May 23, 2024, to manufacture [REDACTED] units of the BLU-

U® 4170E. Ex. 40 (██████ Decl. ¶ 6). Mr. Albert testified that all expenses paid to ██████ were “specifically on the 4170E device.” Ex. 6 (Albert Dep. Tr.) at 92:8–12. Mr. ██████ also explained that ██████ work with Sun Pharma related to the “manufacturing readiness of the BLU-U Blue Light Photodynamic Therapy Illuminator ██████ /4170E device,” and that Sun Pharma paid ██████ in the amounts mentioned above for manufacture of the BLU- U® 4170E device. Ex. 40 (██████ Decl.) ¶ 4–5. The direct and engineering labor expenses shown in Table 4 and the May 2024 purchase order amount are reflected in line [F] of Table 1, *supra*.

6. Payments to Other Contractors

Sun Pharma contracted with three additional contractors for regulatory consulting and pre-launch compliance activities for the BLU-U® 4170E. Sun Pharma’s payments to these contractors are reflected in an accounting spreadsheet produced by Sun Pharma, which is shown in Fig. 7.⁹

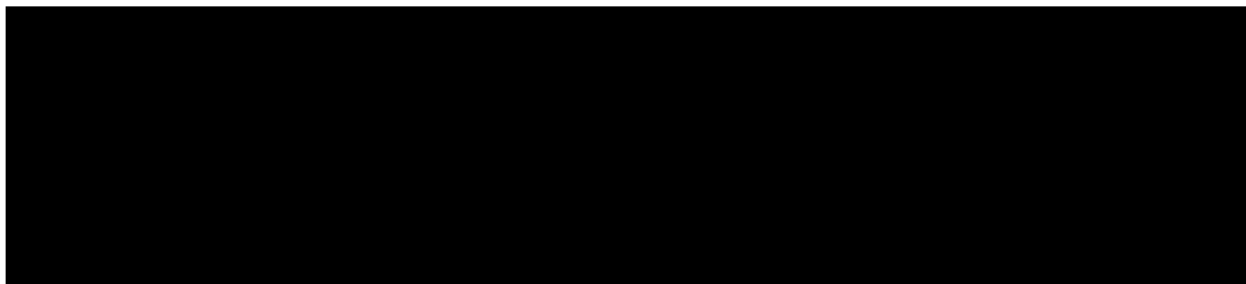


Fig 7: Ex. 42 (U.S. Contractors FY 22-24)

██████

Sun Pharma paid Mr. ██████ to provide Quality Assurance consulting for the BLU-U® 4170E device in the U.S. Ex. 56 (Albert Decl. (May 1, 2025)) ¶ 4; Ex. 43 (Contract with

⁹ Dr. Vander Veen excluded payments made to ██████, a third-party contractor engaged in marketing activities for at least the BLU-U® 4170E, from his calculation of Sun’s domestic industry investments. Ex. 19 (Vander Veen Rpt.) n. 256. Sun Pharma paid Ms. ██████ in FY 2022, ██████ in FY 2023, ██████ in FY 2024, and ██████ from April 1st through September 30, 2024. Ex. 42 (U.S. Contractors FY 22-24). Sales and marketing expenses are cognizable under *Lashify*, and the additional marketing expenses illustrate the conservative approach to Dr. Vander Veen’s estimates. *Lashify Inc.*, 130 F.4th at 959.

[REDACTED], LLC); Ex. 44 (Vander Veen Dep. Tr.) at 109:18-110:4; Ex. 19 (Vander Veen Rpt.) at ¶ 69 (citing conversation with Mr. Albert and Mr. Lundahl). The payments to Mr. [REDACTED], who performed this work as a consultant for [REDACTED] LLC, are shown in Fig. 7. Ex. 42 (U.S. Contractors FY 22-24).

[REDACTED]

For additional regulatory support, Sun Pharma paid Mr. [REDACTED] [REDACTED] in FY 2024 through September 30, 2024, as shown in Fig. 7. Ex. 56 (Albert Decl. (May 1, 2025)) ¶ 6; Ex. 42 (United States Contractors FY 22-24). Mr. [REDACTED] does business as [REDACTED] [REDACTED], LLC, and provided Sun Pharma with expert opinion on regulatory consulting services for the BLU-U® 4170E. Ex. 45 (Consulting Agreement between Sun Pharma and [REDACTED], LLC Sun-ITC-0163993); Ex. 44 (Vander Veen Dep. Tr.) at 110:5-11; Ex. 19 (Vander Veen Rpt.) at ¶ 69 (citing conversation with Mr. Albert and Mr. Lundahl).

[REDACTED]

Sun Pharma also retained Mr. [REDACTED], who does business as [REDACTED] [REDACTED], LLC. (“[REDACTED]”), to provide regulatory support for preparation and submission of the 510(k) application to the FDA as well as the Premarket Approval Application, including review of the applications for submission. Ex. 56 (Albert Decl. (May 1, 2025)) ¶ 5; Ex. 46 ([REDACTED] Proposal for Regulatory Support); Ex. 44 (Vander Veen Dep. Tr.) at 110:12-17; Ex. 19 (Vander Veen Rpt.) at ¶ 69 (citing conversation with Mr. Albert and Mr. Lundahl). Sun Pharma payments to Mr. [REDACTED] are shown in Fig. 7.

Because the payments to the foregoing third party contractors are reported from Sun Pharma’s SAP system on a fiscal year basis, Dr. Vander Veen adjusted those payments to reflect calendar years as shown in Table 5.

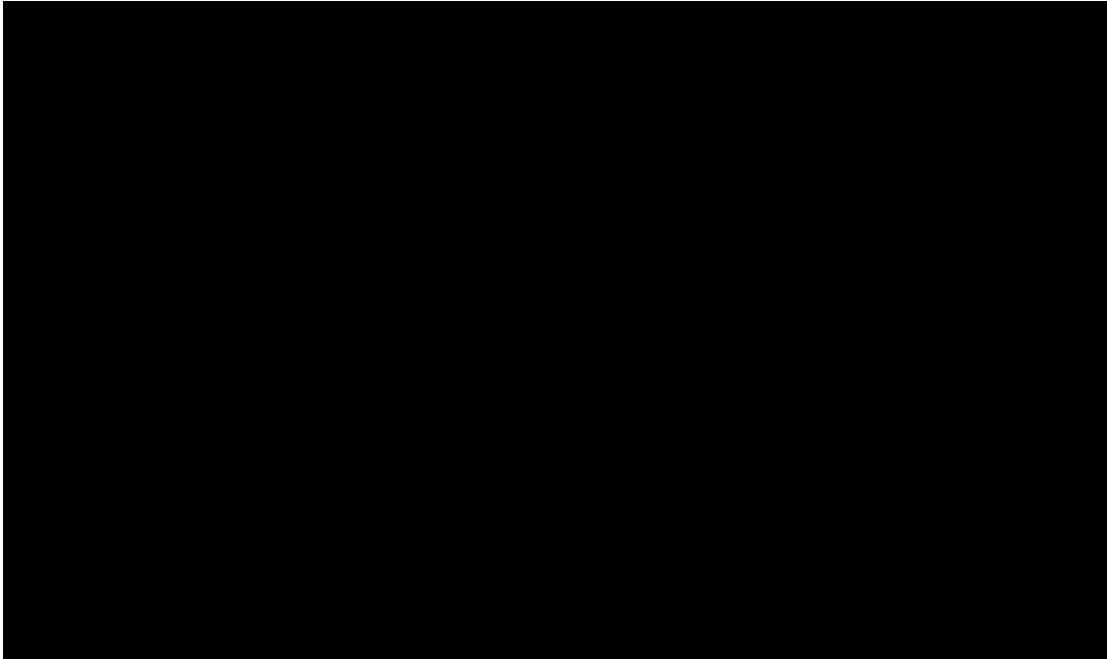


Table 5: Ex. 19 (Vander Veen Rpt.) at Tab 4e

The totals in Table 5 are reflected in line [G] of Table 1, *supra*.

7. Payments to [REDACTED]

Sun Pharma contracted with [REDACTED], a custom plastic injection molding company based in [REDACTED], to manufacture certain parts for the BLU-U® 4170E device. Ex. 47 (“About Us” [REDACTED]); Ex. 44 (Vander Veen Dep. Tr.) at 104:15-107:10 (discussing conversation with Mr. Albert and Mr. Lundahl regarding custom parts provided by [REDACTED]); Ex. 19 (Vander Veen Rpt.) at ¶ 68 (citing conversation with Mr. Albert and Mr. Lundahl). According to accounting records produced by Sun Pharma in this investigation, Sun Pharma paid [REDACTED] from April to September 2024 for its manufacturing activities related specifically to producing BLU-U® 4170E parts. Ex. 56 (Albert Decl. (May 1, 2025)) ¶ 3; Ex. 48 (Vendor Payment Spreadsheet). Dr. Vander Veen prorated this amount to reflect pre-Complaint and post-Complaint expenses and allocated [REDACTED], which is reflected in line [H] of Table 1, *supra*.

B. Sun Pharma’s U.S. Investments in R&D Under Section 337(a)(3)(C)

In addition to calculating Sun Pharma’s labor and capital expenditures related to the BLU-U® 4170E under prong (B), (*see* Table 1, *supra*) Dr. Vander Veen allocated [REDACTED] in pure R&D investments under prong (C), as shown in Table 6.

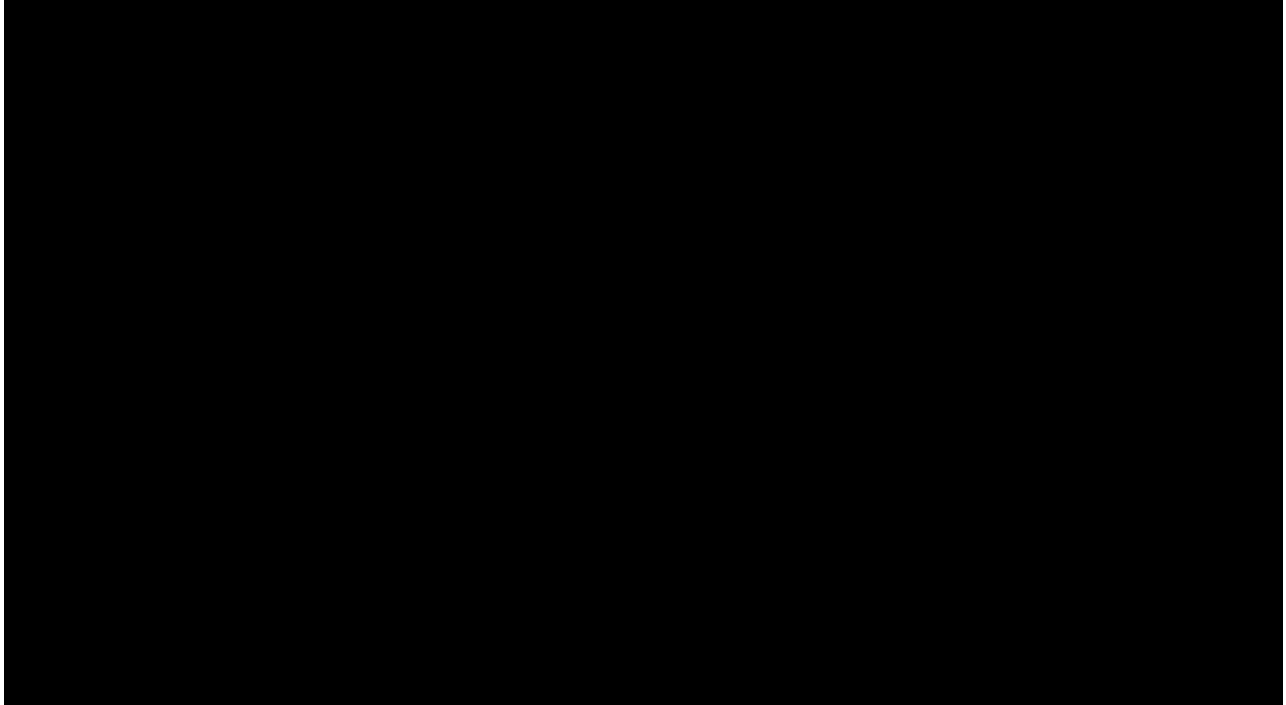


Table 6: Ex. 19 (Vander Veen Rpt.) at Tab 3b

To calculate investments under prong (C), Dr. Vander Veen excluded the manufacturing expenses to [REDACTED] from his labor and capital investments shown in Table 1, *supra*. These remaining expenditures relate to the design, development, engineering, and regulatory activities necessary for the launch of the BLU-U® 4170E. As Sun Pharma’s technical expert Dr. Nan Jokerst has shown, the BLU-U® practices and embodies the claims of the Asserted Patents. *See* Ex. 49 (Jokerst Opening Rpt.) at ¶¶ 140-207; 368-422. Biofrontera does not genuinely dispute that the BLU-U® 4170E practices the Asserted Patents. Rather, Ms. Rowe claims that “Dr. Vander Veen did not identify the nature of the work that was specific to the asserted patents.” Ex. 50 (Rowe Rebuttal Rpt.) at ¶ 102. Ms. Rowe’s criticism is baseless and

ignores Dr. Vander Veen’s robust analysis and explanation of how all the R&D expenditures that he allocated under prong (C) are in furtherance of the development and commercialization of the BLU-U® 4170E. As such, there is a nexus between the R&D activities and the exploitation of the Asserted Patents. *Certain Gas Spring Nailer Prods. and Components Thereof*, Inv. No. 337-TA-1082, Comm’n Op. at 80 (Apr, 28, 2020) (“The requisite nexus between [complainant’s] exploitation activities and [the asserted patent] is met here because the activities here go towards developing DI products that embody and practice the asserted claims.”). Nevertheless, all of the R&D activities are investments in labor and capital and therefore, are separately cognizable under prong (B). *See Certain Solid State Storage Drives, Stacked Elecs. Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm’n Op. at 8 (June 29, 2018).

C. Sun Pharma’s U.S. Investments Specific to the BLU-U® 4170E Are Significant and Substantial

As discussed above, Dr. Vander Veen determined that between 2016 and the filing of the Complaint on June 25, 2024, Sun Pharma invested [REDACTED] in labor and capital related to the research, design, development, and manufacture of the BLU-U® 4170E under prong (B). *See* Table 1, *supra*. And even if one were to exclude Sun Pharma’s May 2024 purchase order with [REDACTED] for [REDACTED], that would still leave [REDACTED] in expenses related to the BLU-U® 4170E that Sun Pharma already incurred. Dr. Vander Veen further calculated that if Sun Pharma’s expenditures specific to the BLU-U® 4170E were limited to pure R&D expenses—*i.e.*, excluding any manufacturing expenses paid to [REDACTED] or [REDACTED]—that would result in [REDACTED] cognizable under either prong (B) or (C). *See*, Table 6, *supra*. Moreover, allocating Sun Pharma’s internal R&D and Regulatory labor investments alone still demonstrates a domestic investment of [REDACTED] in the three-and-half years leading up to the filing of the complaint. *See*, Table 1, lines [A] + [B], *supra*.

There is no genuine dispute that anyone of those investment amounts is significant and substantial in the context of the product, the facts of this case, and realities of the marketplace are because: (1) all of Sun Pharma's investments in the research, design, and manufacture of the BLU-U® 4170E take place in the United States; (2) Sun Pharma's investments in R&D labor and capital have generally been increasing over time; (3) Sun Pharma's R&D investments in labor and capital represent an [REDACTED] reinvestment of revenues from the current BLU-U® 4170 device into R&D for the next generation BLU-U® 4170E device; and (4) Sun Pharma's R&D expenditures to develop the BLU-U® 4170E are in line with and comparable to Biofrontera's development expenditure related to its RhodoLED® XL illumination device. While anyone of these factors is sufficient to demonstrate significance and substantiality, when considered together, there is no genuine dispute that the domestic industry requirement has been satisfied.

1. 100% Of Sun Pharma's R&D And Manufacturing For The BLU-U® 4170E Takes Place In The United States

Investments are considered significant when they occur exclusively within the United States. For example, in *Certain Plant-Derived Recombinant Human Serum Albumins ("rHSA") and Products Containing Same*, the ALJ found that the complainant's investments in labor and capital and R&D were significant and substantial because all of the investments occurred in the United States. Inv. No. 337-TA-1238, ID at 106 (April 7, 2022) ("In contrast, all of [complainant's] investments in its DI Products occurred in the U.S. and thus, the significance and substantiality of its domestic expenditures is apparent when viewed in comparison to its nonexistent foreign expenditures."). The ALJ further found that "because all of [complainant's] investments in the DI Products were made in the United States, all the value for the DI Products is derived from U.S. activities and investments." *Id.*; see also *Certain Bone Cements Components Thereof and Products Containing the Same*, Inv. No. 337-TA-1153, Comm'n Op. at 26-27 (Jan.

25, 2021) (noting that another approach to determining significance is to consider “the value added to the article in the United States by the domestic activities.”) (citation omitted). The Commission affirmed the ALJ’s finding that the domestic industry requirement had been satisfied based on at least one DI product. *Plant Derived rHSA*, Comm’n Op. at 52-53 (Oct. 11, 2022). The Commission’s decision was appealed to the Federal Circuit, which affirmed the Commission earlier this year stating: “Though the dollar amounts of [complainant’s] investments are small, the Commission found all of the investments are domestic, all market activities occur within the United States, and the high investment-to-revenue ratios indicate this is a valuable market.” *Wuhan Healthgen Biotechnology Corp. v. Int’l Trade Comm’n*, 127 F.4th 1334, 1339 (Fed. Cir. 2025). In reaching its decision, the Federal Circuit further noted that “[c]omparing the cost of foreign to domestic manufacturing to determine the percentage of additional value created by domestic ... operations in the final product yields a value added of 100%.” *Id.*

Here, there is no genuine dispute that all of Sun Pharma’s investments related to the BLU-U® 4170E are made in the United States. First, all of Sun Pharma’s employees working on R&D and regulatory functions related to the BLU-U® 4170E device are located in the United States. Ex. 6 (Albert Dep. Tr.) at 43:9–45:8. Second, all of the R&D, testing, and regulatory activities undertaken by third party contractors that Sun Pharma paid for occurs in the United States. Ex. 5 (Albert Decl.) ¶ 10; Ex. 25 (██████ Decl.) ¶ 7–8. Third, all of the manufacturing services Sun Pharma paid for, and will pay for, occurs in the United States. Ex. 56 (Albert Decl. (May 1, 2025)) ¶ 3; Ex. 13 (Lundahl Decl.) ¶ 19; Ex. 40 (██████ Decl.) ¶ 7–9. As such, 100% of the value added to the BLU-U® 4170E is created by Sun Pharma’s domestic investments. Thus, whether one considers the ████████ in labor and capital expenditures related to the BLU-U 4170E that Dr. Vander Veen calculated, or the ████████ in expenditures when the ████████ purchase order for

█ units is excluded, or the █ when Sun Pharma's investments are purely limited to R&D, or even simply the █ in Sun Pharma's internal R&D labor costs (see Table 1, lines [A] + [B], *supra*), Sun Pharma's investments related to the BLU-U® 4170E are significant and substantial.

2. Sun Pharma's Domestic Investments Related to the BLU-U® 4170E Have Been Increasing Over Time

In *Lelo Inc. v. Int'l Trade Comm'n*, the Federal Circuit determined that the terms "significant" and "substantial" refer to an "increase in quantity, or to a benchmark in numbers." 786 F.3d 879, 883 (May 15, 2015). Recently, the Federal Circuit reiterated this definition in *Lashify, Inc. v. Int'l Trade Comm'n*, 130 F.4th 948, 959 (Fed. Cir. 2025).

Here, the domestic investments related to the BLU-U® 4170E are generally increasing over time. First, as discussed above, Dr. Vander Veen determined that from 2016 – June 25, 2024, Sun Pharma invested █ in labor and capital under prong (B) related to the research, design, development, regulatory, and manufacture of the BLU-U® 4170E, which is shown in Table 7, below.

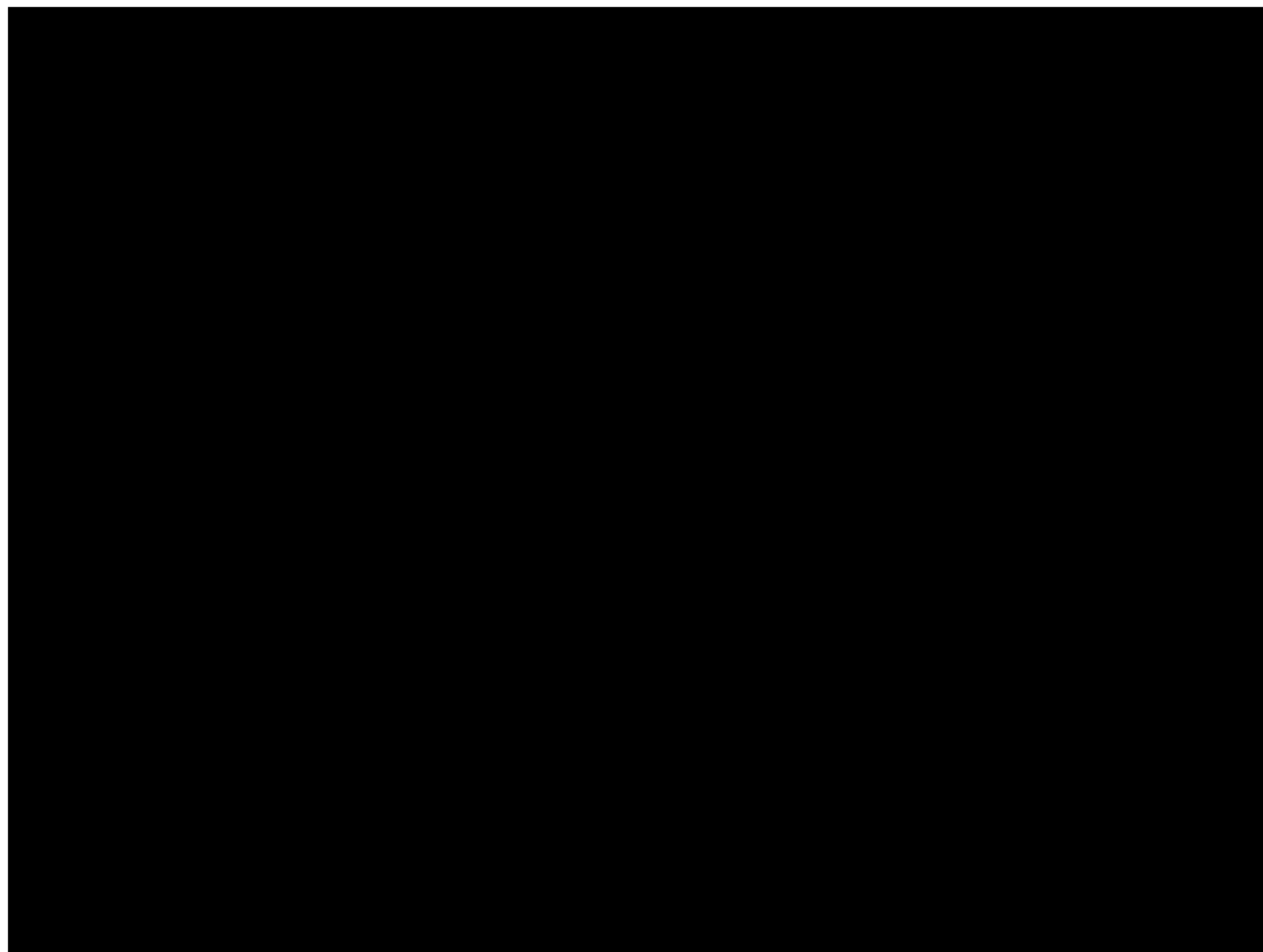


Table 7: Ex. 19 (Vander Veen Rpt.), Tab 4a

As can be seen in Table 7, Sun Pharma's overall investments in labor and capital related to the BLU-U® 4170E device increased from [REDACTED] in 2016 to [REDACTED] in 2023—the last full calendar year prior to the filing of the Complaint. Additionally, Sun Pharma's overall investments in labor and capital increased year-over-year from [REDACTED] in 2020 to [REDACTED] in 2023. If the [REDACTED] purchase order placed with [REDACTED] is excluded Sun Pharma's expenditures slightly decrease to [REDACTED]¹⁰ in 2024—the year Sun Pharma filed its Complaint. That modest decrease

¹⁰ Subtracting the May 2024 [REDACTED] purchase order from the [REDACTED] total labor and capital expenditures from January 1, 2024 – June 25, 2024, leaves [REDACTED] in investments in that period. Adding the [REDACTED] in additional expenses incurred for the remainder of the year brings Sun Pharma's total 2024 investments in labor and capital to [REDACTED].

does not preclude a finding that Sun Pharma's investments are substantial. *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Products Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op. at 63 (Jan. 6, 2016) ("Nothing in that discussion or elsewhere in *Lelo* requires, as the ID and [respondent] suggest, that the complainant's domestic industry investment *at the time of the filing of the complaint* be increasing compared to past years.") (emphasis in original). In fact, in *Certain Percussive Massage Devices*, the Commission found a complainant's investments in labor and capital significant under *Lelo*'s test where the complainant's investments increased from 2018-2019 even though the complainant's allocated investment period ran from 2018-2020. Inv. No. 337-TA-1206, Comm'n Op. at 13 (Jan. 4, 2022). Nevertheless, as shown in Table 7, line [A], above, Sun Pharma's internal R&D labor expenditures for the BLU-U® 4170E increased year-over-year from [REDACTED] in 2021 to [REDACTED] through 2024 [REDACTED]). Thus, Sun Pharma's labor and capital investments are significant under *Lelo*.

Additionally, when Sun Pharma's investments in the BLU® 4170E are restricted to R&D—*i.e.*, when all manufacturing expenses are excluded—those investments are also substantial under *Lelo*.

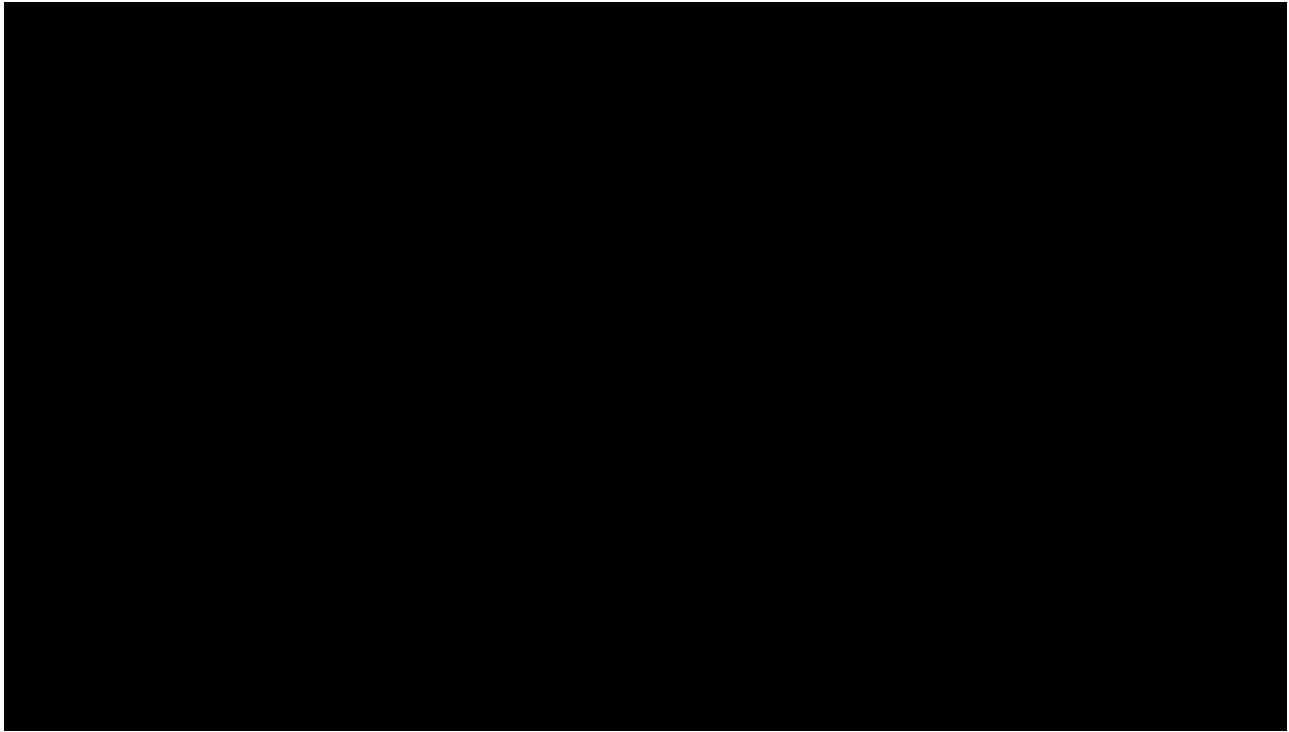


Table 7: Ex. 19 (Vander Veen Rpt.), Tab 3b

Specifically, as shown in Table 7, Sun Pharma’s R&D specific investments in the BLU-U® 4170E increased from [REDACTED] in 2016 to [REDACTED] in 2023, and year-over-year from [REDACTED] in 2020 to [REDACTED] in 2023. Thus, Sun Pharma’s domestic investments related to the BLU-U® 4170E are significant and substantial.

3. Sun Pharma’s Investments Represent a Substantial Reinvestment of Revenue Into the Development of the BLU-U® 4170E

As the Federal Circuit recently stated in *Wuhan Healthgen*, an “investment-to-revenue ratio can indicate whether an investment is significant and substantial.” 127 F.4th at 1339. The Federal Circuit went on to explain that “[a] high ratio signals the company is investing heavily in the industry despite comparatively low revenue, highlighting the industry’s importance and value to the company, which can be predictive of a significant market.” *Id.* As noted above, the court ultimately found that the domestic industry requirement was satisfied, despite complainant’s

investments being small, because all of the investments were based in the United States and represented a high investment-to-revenue ratio. *Id.*

Here, Sun Pharma’s purely domestic investments in R&D related to the BLU-4170E have a high investment-to-revenue ratio when compared to the revenues being generated by its current PDT illuminator—the BLU-U® 4170. Because the BLU-U® 4170E is not currently being sold, Dr. Vander Veen set out to determine what percentage of the revenues generated by the current BLU-U® 4170 illuminator is being reinvested by Sun Pharma into the research and development of its next generation BLU-U® 4170E device. Sun Pharma produced a “business P/L”, Ex. 51 (Summary of DUSA Profit and Loss), that “includes all of the sales and costs that are attributed to run the Levulan 4170D and 4170E business,” Ex. 6 (Albert Dep. Tr.) at 36:5–12. Using that spreadsheet, Dr. Vander Veen calculated Sun Pharma’s BLU-U® 4170 sales revenues for fiscal years 2020 – 2024, which are shown in Table 8 below.

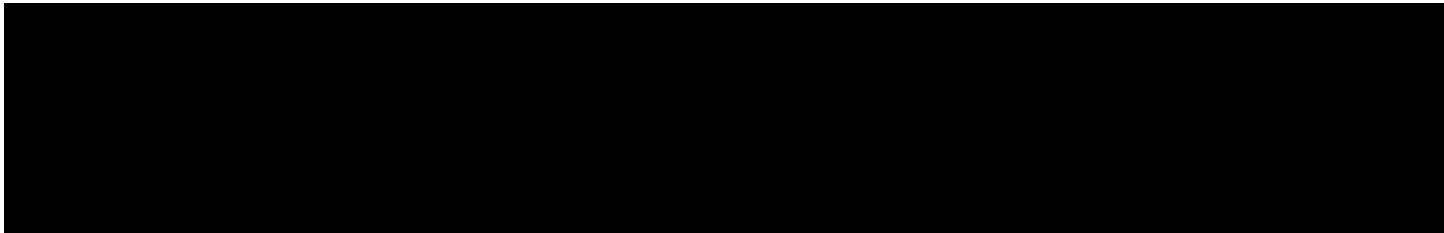


Table 8: See Ex. 19 (Vander Veen Rpt.), Tab 11

Dr. Vander Veen then took Sun Pharma’s calendar year R&D specific investments shown in Table 6, *supra*, which exclude any manufacturing costs, and converted them to corresponding fiscal years to match the BLU-U® 4170 revenue data. Those values are also shown in Table 8. Dr. Vander Veen then divided Sun Pharma’s R&D investments in the BLU-U® 4170E from FY2020-2024 by BLU-U® 4170 revenues for the same period and found that Sun Pharma spent [REDACTED] of its revenues from the BLU-U® 4170 on R&D for the BLU-U® 4170E, representing a substantial reinvestment of revenues in its next-generation device. [REDACTED]

These high investment-to-revenue ratios demonstrate that Sun Pharma's investments are significant and substantial.

4. Sun Pharma's Investments in The Development Of The 4170E Are Greater Than or In Line With Industry Standards

As the Federal Circuit has stated, the significance analysis considers, among other things, investments in the context of the marketplace. *Wuhan Healthgen Biotechnology Corp. v. Int'l Trade Comm'n*, 127 F.4th 1334, 1339 (Fed. Cir. 2025) (“[W]hether investment activities are significant or substantial ‘is not evaluated according to any rigid mathematical formula,’ but rather requires ‘an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace’”). One way to assess significance in the context of the marketplace is a comparison between a complaint's investments and investments made by other market participants. For example, in *Plant-Derived rHSA*, the complainant compared its investment-to-revenue ratio to the investment-to-revenue ratios for two other market participants. Inv. No. 337-TA-1238, ID at 107. In finding that the domestic industry requirement had been satisfied, the ALJ stated: “While this is not a direct comparison to a competitor in the same market, it nonetheless provides context for the significance and substantiality of [complainant's] investments.” *Id.*

Here, Sun Pharma and Biofrontera currently manufacture the only FDA-approved PDT products for treatment of actinic keratosis in combination with a pharmaceutical in the United States. Ex. 52 (Leffler Dep. Tr.) at 45:1–12; Ex. 53 (Luebbert Dep. Tr.) at 49:1–8. And unlike in *Plant-Derived rHSA*, Sun Pharma and Biofrontera are direct competitors. Ex. 53 (Luebbert Dep. Tr.) at 49:1–3. Thus, a comparison between Sun Pharma's BLU-U® 4170E development costs and Biofrontera's development costs for its second generation RhodoLED® XL illuminator is a relevant indicator of significance.

Like Sun Pharma, Biofrontera employed third party contractors to develop the RhodoLED® XL and continues to do so to manufacture the device. Ex. 53 (Luebbert Dep. Tr.) at 43:19–44:1. Internal Biofrontera documents and witness testimony demonstrate that Biofrontera’s total budget for the development of RhodoLED® XL was [REDACTED]. Ex. 8 (Foguet Dep. Tr.) at 68:20–69:7, Ex. 54 (Biofrontera’s [REDACTED]). As shown in Table 6, above, Sun Pharma invested [REDACTED] in research and development (exclusive of manufacturing costs) for the BLU-U® 4170E. Thus, Sun Pharma spent approximately [REDACTED] times¹¹ as much on the development of its next-generation lamp as Biofrontera. Even if only Sun Pharma’s internal R&D and Regulatory Labor (Table 1, lines [A] + [B], [REDACTED]) are considered, comparing that expense to Biofrontera’s development budget shows that Sun Pharma’s expenses are [REDACTED] with its only direct competitor in the market. As such, Sun Pharma’s investments are significant and substantial in the context of the marketplace.

D. Sun Pharma Has Demonstrated a Domestic Industry In The Process Of Being Established

While there is no requirement that a complainant have a commercially available product to show an existing domestic industry, *Strontium-Rubidium Radioisotope Infusion Systems*, Inv.No. 337-TA-1110, ID at 134, to the extent there is any doubt that Sun Pharma’s domestic industry exists because the BLU-U® 4170E is not yet available, Sun Pharma’s investments alternatively establish a domestic industry in the process of being established. To show a domestic industry in the process of being established, a complainant has to show that it is “taking the necessary tangible steps to establish such an industry in the United States” and there is a “significant likelihood that the industry requirement will be satisfied in the future.” *Certain Non-Volatile Memory Devices And Prods. Containing The Same*, Inv. No. 337-TA-1046, Comm’n Op. at 29 (Oct. 9, 2018)

¹¹ Currently, [REDACTED].

(noting that “the owner of the intellectual property right must be actively engaged in steps leading to the exploitation of the intellectual property, including application engineering, design work, or other such activities.”) As explained above, Sun Pharma has made significant investments in labor and capital for the development and manufacture of its BLU-U® 4170E device. Since 2016, Sun Pharma has invested [REDACTED] in researching, designing, developing, testing the BLU-U® 4170E and seeking regulatory approval for the device. Sun Pharma has additionally spent [REDACTED] manufacturing the device, Table 4, *supra*, and is poised to spend another [REDACTED] under the purchase order it placed with [REDACTED] in anticipation of FDA approval. Each of these are necessary and tangible steps needed to commercialize its device and establish a domestic industry for the BLU-U® 4170E—to the extent one does not already exist. Indeed, Ms. Rowe admits that in order to commercialize a medical device, like the BLU-U® 4170E, development, testing, seeking regulatory approval, and manufacturing are all necessary steps to commercialization. *See* Ex. 55 (Rowe Dep. Tr.) at 160:1–161:11.

Moreover, Sun Pharma’s investment into the BLU-U® 4170E is expected to increase in the future. For example, once the PMA for the BLU-U® 4170E is approved, Sun Pharma will begin to incur increasing manufacturing expenses as it takes deliveries of the BLU-U® 4170E devices under its May 2024 purchase order with [REDACTED]. Moreover, Sun Pharma is in discussions with [REDACTED] for the next purchase order. Ex. 44 (Vander Veen Dep. Tr.) 129:18–130:4. Additionally, after launch, Sun Pharma will incur customer service expenses in order to support the BLU-U® 4170E. Indeed, Dr. Vander Veen calculated that from April 2021 through June 25, 2024, Sun Pharma invested over [REDACTED] in customer service support for the current BLU-U® 4170 device, *see* Ex. 19 (Vander Veen Rpt.) at ¶ 71, and over [REDACTED] in customer service support for Levulan®, *see* Ex. 19 (Vander Veen Rpt.) at ¶ 78, which will also be used with

the BLU-U® 4170E. There is no reason to believe that Sun Pharma will invest any less to support its next-generation PDT offering. Thus, while Sun Pharma contends that it has an existing domestic industry, it certainly has a domestic industry in the process of being established for the foregoing reasons.

E. Biofrontera’s Arguments Lack Merit

Biofrontera criticizes Dr. Vander Veen’s calculations but does not offer any corrected numbers or evidence for disputing the validity of his calculations. Thus, Biofrontera’s anticipated arguments will not raise any genuine disputes of material fact that need to be resolved at the evidentiary hearing.

First, Biofrontera will likely argue that Dr. Vander Veen failed to demonstrate that investments made ten years prior to the filing of the complaint are indicative of a domestic industry at the time of filing. However, as the Federal Circuit has stated, “[t]here is nothing in the statutory language that support . . . a bright line rule research expenditures made more than five years earlier.” *Hyosung TNS Inc. v. ITC*, 926 F.3d 1353, 1362 (Fed. Cir. 2019). Rather past expenditures can be counted so long as those investments pertain to articles protected by the asserted patents and “the complainant is continuing to make qualifying investments at the time the complaint is filed.” *Id.* at 1361 (*quoting Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, 2015 WL 6755093, at *36 (Oct. 30, 2015)). Here, all of Sun Pharma’s investments dating back to 2016 were made in order to develop the BLU-U® 4170E that as of February 2025 simply needs regulatory approval to be commercialized. Indeed, in the six months leading up to the Complaint, Sun Pharma invested over [REDACTED] to get the BLU-U® 4170E to this final stage before commercial release. As such, Sun Pharma was making qualified investments at the time of the Complaint.

Second, Biofrontera will likely argue that Dr. Vander Veen has not reliably demonstrated that the [REDACTED] purchase order with [REDACTED] should be included in his calculations because [REDACTED]. This argument lacks merit. Sun Pharma is [REDACTED] to [REDACTED] upon delivery of the [REDACTED] BLU-U® 4170E devices in accordance with the payment schedule. Ex. 6 (Albert Dep. Tr.) 110:2–22. Regardless, even if the purchase order price is excluded, the remaining [REDACTED] in labor and capital expenditures is significant as shown above.

Third, Biofrontera will likely argue that Sun Pharma’s third-party contractor payments are not sufficiently tied to the BLU-U® 4170E; these unsubstantiated objections do not pass scrutiny. Regardless, even if Biofrontera’s argument is countenanced, it does not change the fact that Sun Pharma has an existing domestic industry because if Sun Pharma’s internal R&D and Regulatory labor costs are the only ones considered, those are still significant and substantial. Sun Pharma’s internal R&D and Regulatory costs were [REDACTED] for 2021, [REDACTED] for 2022, [REDACTED] for 2023, and [REDACTED] from January 1 – June 25, 2024. *See*, Table 1, lines [A] + [B], *supra*. All of these investments related to the BLU-U® 4170E were made in the United States. The total investment of [REDACTED] is [REDACTED] to Biofrontera’s development budget for the RhodoLED® XL. And Sun Pharma’s internal R&D and Regulatory investments generally increase over time. While Biofrontera may argue that Sun Pharma’s R&D investments began decreasing in 2024, that argument is inconsequential under Commission precedent. *Marine Sonar Imaging Devices*, Inv. No. 337-TA-921, Comm’n Op. at 63. Indeed, the decrease in R&D investments is expected as the BLU-U® 4170E moves from the R&D phase to the manufacturing phase in the product life-cycle as it approaches market readiness. Finally, even if Sun Pharma’s

internal R&D and Regulatory labor investments alone are compared to revenues from the BLU-U® 4170, there is still a high investment-to-revenue ratio as shown in Table 9, below.

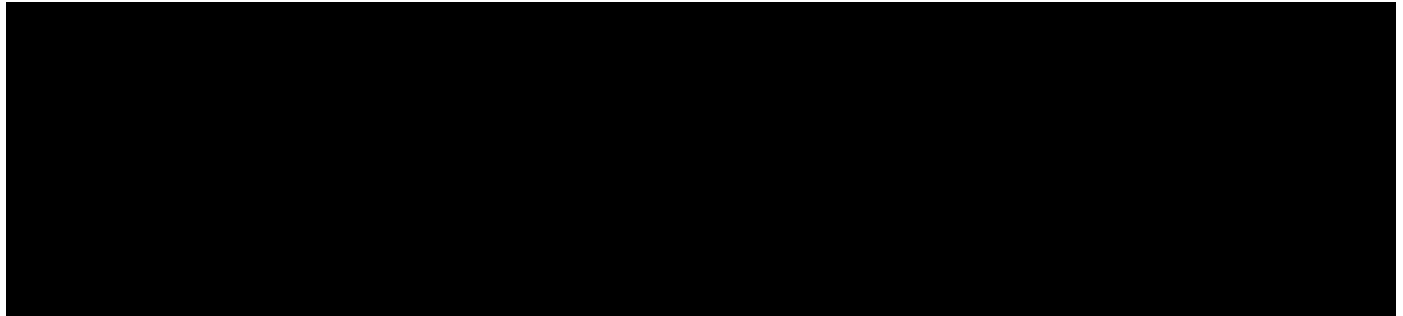


Table 9: Internal R&D and Regulatory Labor Reinvestment

Fourth, Biofrontera’s remaining arguments will likely focus on making apples to oranges comparisons to undermine the significance of Sun Pharma’s R&D investments, Biofrontera will likely attempt to compare Sun Pharma’s BLU-U® 4170E investments to Sun Pharma’s overall R&D expenses. However, such a comparison is not appropriate where a company has a diversified product portfolio such as Sun Pharma. *See* Ex. 19 (Vander Veen Opening Rpt.) at Tab 9 (showing different products offered by Sun Pharma); *Certain Mobile Electronic Devices*, Inv. No.337-TA-794, Initial Determination at 604–05 (Oct. 3, 2012) (rejecting a comparison of claimed investments to overall operations because “such an analysis is not a requirement” and “such a comparison would hurt large, diversified companies that produce a wide range of products”). Similarly, Biofrontera may attempt to compare Sun Pharma’s R&D investments in the BLU-U® 4170E to Levulan® R&D investments or revenue. However, such a comparison is inapposite. While Levulan® can be used with the BLU-U® lamps, they are different types of products—one is a pharmaceutical while the other is a medical device. As such, Levulan® and the BLU-U® lamps have different revenue structures (recurring v. one-time cost) and development costs. Here, the salient comparison to determine whether the market for PDT illuminators is significant to Sun

Pharma is to determine how much of the revenue from the older lamp Sun Pharma is reinvesting in its next generation lamp, as Dr. Vander Veen analyzed.

IV. CONCLUSION

The technology claimed in the Asserted Patents was developed in the United States by U.S. engineers working at Sun Pharma. This technology is embodied by the domestic industry Products which have been engineered, designed, developed and manufactured in the United States. As such, a domestic industry exists or, in the alternative, is in the process of being established by virtue of Sun Pharma's significant, substantial, cognizable investments under Subsections (B) and (C) of Section 1337(a)(3).

WORD COUNT CERTIFICATION

Sun Pharmaceutical Industries, Inc. certifies that the foregoing contains 9,656 words excluding words in the tables of contents, exhibits, table of authorities, figures, signature blocks, certification of word count and certificate of service. In preparing the certification, the undersigned relied on the word count of the word processing software used to prepare this brief.

Dated: May 2, 2025

Respectfully submitted,

/s/ Betty Chen

Betty Chen

Gabrielle Higgins

Maximillian McDonald

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
Paul Macri
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.*

CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2025, copies of the foregoing were filed and served upon the following as indicated:

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. INTERNATIONAL TRADE COMMISSION
500 E Street, SW, Room 112
Washington, DC 20436

VIA ELECTRONIC FILING

The Honorable Bryan F. Moore
Administrative Law Judge
U.S. INTERNATIONAL TRADE COMMISSION
500 E. Street, S.W., Room 317
Washington, DC 20436
Email: Moore1411@usitc.gov

VIA ELECTRONIC MAIL & BOX

COUNSEL FOR RESPONDENTS BIOFRONTERA INC., BIOFRONTERA PHARMA GMBH, BIOFRONTERA BIOSCIENCE GMBH, AND BIOFRONTERA AG:

Deanna Tanner Okun
POLSINELLI P.C.
1401 Eye Street, N.W., Suite 800
Washington, D.C. 20005
Telephone: (202) 626-8320
Email: biofrontera-itc@polsinelli.com

VIA ELECTRONIC MAIL

COUNSEL FOR RESPONDENT BIOFRONTERA INC.:

Tyler T. VanHoutan
McGUIRE WOODS LLP
Texas Tower
845 Texas Avenue, 24th Floor
Houston, TX 77002
Telephone: (713) 571-9191
Facsimile: (713) 571-9652
Email: mw-biofronteraitc@mcguirewoods.com

VIA ELECTRONIC MAIL

/s/ Kiichi Take
Kiichi Take, Senior IP Paralegal
DESMARAIS LLP
1899 Pennsylvania Avenue, NW
Suite 400
Washington, DC 20001
Phone: (202) 451-4925
Email: KTake@desmaraisllp.com

**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

**DECLARATION OF TUHIN GANGULY JUSTIFYING THE
CONFIDENTIALITY OF EXHIBITS**

Pursuant to Ground Rule 1.5 in this Investigation, I, Tuhin Ganguly, hereby declare and state as follows:

1. I am a partner at the firm of Desmarais LLP representing Complainant Sun Pharmaceuticals Industries, Inc. ("Sun Pharma" or "Complainant") in this investigation. I am over the age of 18 and competent to submit this declaration.
2. I respectfully submit this declaration justifying the confidentiality of exhibits that contain confidential business information. For the reasons set forth below, Sun Pharma requests that these exhibits be maintained as confidential and not be disclosed except to the extent permitted by the Protective Order in this Investigation, Order No. 1.
3. Sun Pharma's confidential designation of exhibits is justified because these exhibits contain or disclose: confidential business information, as such term is defined in Commission Rule 201.6(a); proprietary information that is maintained as confidential by Sun Pharma in the ordinary course of business; information marked by Sun Pharma or by Respondents Biofrontera

Inc., Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Bioscience GmbH as containing confidential business information; or discovery responses.

4. The designation of these exhibits as confidential ensures that confidential business information is protected from disclosure to parties and entities not subscribed to the Protective Order in this investigation. These exhibits are either documents produced by the Parties and marked “Confidential Business Information” or include excerpts from such. To the best of my knowledge, the confidential business information within these exhibits has not been disclosed to the public in form or in substance, is not readily ascertainable by others through public sources, has significant current commercial value, and would give rivals in the marketplace a competitive advantage if disclosed.

5. Exhibits 5, 13, 25 and 40, attached hereto, contain declarations signed by Sun Pharma corporate representatives and non-party representatives, all of who are witnesses in this Investigation. The declarations discuss sensitive, confidential and proprietary information that is not publicly available, including information related to Complainant’s and its non-party contractors’ finances, investments, facilities, regulatory affairs, and the development, design, engineering, and manufacturing of the products at issue in this Investigation. The subject declarations were filed or produced in this Investigation under the confidential business information designation and are not capable of redaction.

6. Exhibits 7, 20 through 23, and 51 attached hereto, contain Sun Pharma’s confidential financial information including salary information across years 2022 through 2025, financial data related to domestic building costs, and Profit-Loss data. As this sensitive financial information is not publicly available and cannot be disclosed without revealing party confidential business information, these exhibits are not capable of redaction.

7. Exhibits 8, 44, 52, 53, and 55, attached hereto, contain excerpts from the confidential deposition transcripts of Respondents' fact witnesses Montserrat Foguet, Frederick Leffler, and Hermann Luebbert, as well as the parties' Domestic Industry expert witnesses Thomas Vander Veen and Julia Rowe. The excerpts of these deposition transcripts discuss the parties' confidential business information and confidential expert opinions substantively throughout and are not capable of meaningful redactions.

8. Exhibits 19, 49, and 50, attached hereto, contain excerpts from confidential Expert Reports served in this Investigation under the CBI designation (Opening Expert Report of Thomas Vander Veen, Opening Expert Report of Nan Jokerst, and Rebuttal Expert Report of Julia Rowe, respectively). These reports contain confidential and proprietary information that is not publicly available, including information related to Complainant's and its non-party contractors' finances, investments, facilities, regulatory affairs, and the development, design, engineering, and manufacturing of the products at issue in this Investigation. These excerpts of the expert reports are therefore not capable of redaction.

9. Exhibit 24, Exhibits 28 through 32, Exhibits 34 through 39, and Exhibits 42 through 46, and Exhibit 48 attached hereto, are Sun Pharma production documents related to non-party vendors/contractors which disclose both Sun Pharma and non-party CBI. These documents include service and manufacturing agreements, purchase orders and payment information, scope of work (SOW's) materials that include design and engineering schematics related to the domestic industry products and regulatory consulting documents. These materials are not capable of redaction.

10. Exhibit 41, attached hereto, are Complainant's Responses and Objections to Respondents' First Set of Interrogatories (Nos. 1-17), which contains Sun Pharma Confidential Business Information. Specifically, Exhibit 41 discloses and substantively discusses Sun Pharma's sales, revenue, inventory and pricing information, and investments and expenditures for the domestic industry products. Therefore, this exhibit is not capable of redaction.

11. Exhibit 54, attached hereto, is a Strategy Meeting Presentation containing Biofrontera's Confidential Business Information and produced by Respondents during discovery under the CBI designation. This exhibit discusses Biofrontera's internal strategies related to the accused products and other products in its medical devices division. Complainant's counsel conferred with Respondents' counsel, who agreed this exhibit should be redacted in entirety as it is not capable of redaction.

12. Sun Pharma reserves the right to amend this declaration and identification of confidential exhibits to the extent a party adds an exhibit or has inadvertently failed to identify the correct confidentiality designation on the exhibit list for an exhibit that is ultimately admitted into evidence at the forthcoming evidentiary hearing.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: June 12, 2025

Respectfully submitted,

/s/ Tuhin Ganguly

Tuhin Ganguly

DESMARAIS LLP

1899 Pennsylvania Avenue, NW, Suite 400

Washington, DC 20006

Telephone: (202) 451-4900

Facsimile: (202) 451-4901

Email: Sun-

BiofronteraITCService@desmaraisllp.com

*Counsel for Complainant Sun Pharmaceutical
Industries, Inc.*

EXHIBIT 5 IS REDACTED IN ENTIRETY

EXHIBIT 6



Planet Depos®
We Make It *Happen™*

Transcript of Zvi Albert, Corporate Designee & Individually

Date: December 17, 2024

Case: Certain Photodynamic Therapy Systems & Pharmaceutical Products (337-TA-1411)

Planet Depos

Phone: 888.433.3767 | **Email:** transcripts@planetdepos.com

www.planetdepos.com

Michigan #8598 | Nevada #089F | New Mexico #566

7 1 A. No. 2 Q. So you've been the CFO since you 3 started there in 2015? 4 A. Yes. 5 Q. And is it correct that your 6 undergraduate degree is a BS in engineering 7 from Purdue? 8 A. Yes. 9 Q. What major was that? 10 A. Industrial engineering. 11 Q. And then you completed an MBA in 12 finance at Rutgers? 13 A. Yes. 14 Q. Do you hold any other degrees? 15 A. No. 16 Q. You mentioned speaking with some 17 members of your team. 18 How many people are on your team 19 that you mentioned? 20 A. I just want to clarify. 21 Domestic, international, or – 22 Q. We'll take domestic.	9 1 A. Yes. 2 Q. So does DUSA still exist at all? 3 A. DUSA is not a standalone entity 4 as it was prior to March 2023. It's merged 5 into SPII, Sun Pharmaceuticals. 6 Q. So DUSA doesn't exist at all as a 7 legal entity? 8 A. No. 9 Q. It's entirely subsumed within Sun 10 Pharma? 11 A. Yes. 12 Q. Mr. Albert, you filed a 13 declaration that accompanied the complaint 14 filed in this investigation, correct? 15 A. Yes. 16 Q. I'd like to mark what will be 17 Exhibit 4. 18 (Albert Exhibit 4, Declaration of 19 Zvi Albert, marked for identification, 20 as of this date.) 21 BY MS. PETERSON: 22 Q. Mr. Albert, do you know when you
8 1 [REDACTED] 2 [REDACTED] 3 Q. And, sorry, I should have 4 clarified. What would you call that team? 5 A. The accounting and finance team. 6 Q. And you were the head of the 7 accounting and finance team? 8 A. Yes. 9 Q. For North America, correct? 10 A. For North America, yes. 11 Q. Okay. And your employer is Sun 12 Pharmaceutical Industries. 13 Are you familiar with the 14 corporation DUSA Pharmaceuticals? 15 A. Yes. 16 Q. What is the relationship between 17 Sun and DUSA? 18 A. Currently, DUSA is Sun 19 Pharmaceuticals. It was merged into Sun 20 Pharmaceuticals approximately seven, eight 21 months ago. 22 Q. Was that in March of 2024?	20 1 drafted this declaration? 2 A. Approximately June 2024. 3 Q. I see the date at the end is June 4 25th? 5 A. Yes. 6 Q. So the financials in this 7 declaration would have been current as of 8 June 25th? 9 A. Yes. 10 Q. And in several instances in this 11 declaration, you list amounts by fiscal 12 year. 13 What is Sun's fiscal year? 14 A. April 1st through to the 15 following March 31st. 16 Q. Okay. You can set that aside for 17 now. 18 I'd like to mark Exhibit 5. 19 (Albert Exhibit 5, Complainant 20 Sun Pharmaceutical Industries, Inc.'s 21 Fourth Supplemental Objections and 22 Responses to Respondents' First Set of

2 1 Interrogatories (Nos. 1-17), marked for 2 identification, as of this date.) 3 BY MS. PETERSON: 4 Q. And Exhibit 5 is a document 5 entitled "Complainant Sun Pharmaceuticals 6 Industries Inc. s Fourth Supplemental 7 Objections and Responses to Respondent s 8 First Set of Interrogatories." 9 And I will represent this is an 10 excerpt. This is not the entire document. 11 But you can take a moment to review and let 12 me know if you have seen this document 13 before. 14 (Document review.) 15 A. No. 16 Q. Okay. So you -- I will -- I will 17 state that this is a set of interrogatories 18 responses that your counsel served in this 19 investigation. 20 So you are not prepared -- sorry. 21 Strike that. 22 You were not involved in	23 1 A. Yes. 2 Q. Okay. Where would these numbers 3 have come from? 4 A. From our financial statements, 5 from our general ledger where we hold our 6 official accounting records and documents. 7 Q. And then turning back to page 4 8 -- actually, I should ask, what system does 9 Sun use for accounting records? 10 A. SAP. 11 Q. So these numbers would have been 12 pulled out of the SAP system? 13 A. Yes. 14 Q. If you go back to page 4 of your 15 declaration in paragraph 14, the numbers 16 listed here reflect Sun's spend on labor 17 expenses related to Levulan? 18 A. Yes. 19 Q. And would those numbers also have 20 come out of Sun's SAP system? 21 A. Yes. 22 Q. And if you turn to page 30 of the
22 1 preparing this interrogatory response? 2 A. I've spoken about some of the 3 things here. So the information I've 4 discussed and talked about might be used, 5 but I wasn't -- I didn't write this 6 document. 7 Q. Okay. Looking at -- going back 8 to Exhibit 4 on paragraph 24, there is a 9 chart for Levulan revenues. 10 A. Can you say that again? 11 Q. Yes. Exhibit 4, your 12 declaration, paragraph 24. 13 A. Perfect. Okay. Thank you. 14 (Document review.) 15 BY MS. PETERSON: 16 Q. Do you see the chart there says 17 "Revenues for fiscal year '22, '23, and 18 '24"? 19 A. Yes. 20 Q. Okay. So -- and that would be, 21 as you said, based on an April 1st fiscal 22 year?	24 1 contentions, Exhibit 5, the chart at the 2 top of page 30 of Exhibit 5 matches the 3 chart on page 4 of your declaration, 4 correct? 5 A. Yes. 6 Q. So you didn't have involvement in 7 putting together the contentions -- sorry, 8 the interrogatory responses, but you did 9 prepare the numbers in your declaration? 10 A. The declaration, yes, I prepared 11 the numbers. 12 Q. Okay. And also on page 4 of your 13 declaration there is a chart at the bottom 14 for labor spend on the 4170 device. 15 How were the numbers in the chart 16 in paragraph 16 generated? 17 A. These numbers were taken with 18 consultation with Scott and -- Scott, the 19 technical manager, technical lead on the 20 product, getting his input on his research 21 and development team, and also Ron, the 22 head of product support, getting his input

25 1 on how his team is utilized across the 2 business unit, and taking the people who 3 are dedicated to the business and 4 allocating their costs. 5 Q. Okay. And on page 5 of your 6 declaration in paragraph 19, there is a 7 chart for labor expenses attributable to 8 the 4170E device. 9 Same question, how did you 10 calculate the numbers in the chart in 11 paragraph 19? 12 A. This was done in consultation 13 with Scott and it's quite a conservative 14 estimate on the resources on his team that 15 are working on the 4170E. 16 Q. Mr. Albert, are you familiar with 17 the two patents that are asserted in this 18 investigation? 19 A. No. 20 Q. Okay. Is it your understanding 21 that the asserted patents in this 22 investigation cover the 4170E?	27 1 MS. CHEN: Objection. Outside 2 the scope. 3 A. I would rely on Scott to tell me 4 the exact date. 5 Q. Okay. As the CFO, you obviously 6 are familiar with the financials of Sun 7 Pharma. 8 Do you recall a time when you 9 started seeing spend related to the 4170E? 10 MS. CHEN: Objection. Outside 11 the scope. 12 A. No. 13 Q. Is it your understanding that the 14 4170E design is finalized? 15 MS. CHEN: Objection. Outside 16 the scope. 17 A. I am not aware of the stages or 18 process of that device. 19 Q. Okay. I'd like to mark Exhibit 20 6. 21 (Albert Exhibit 6, Document 22 titled "G2 Device US Launch Strategy,"
26 1 A. Yes. 2 Q. And when -- 3 A. But I think it's 4170 and the 4 system Levulan and 4170E, I believe, as 5 well. 6 Q. Okay. Thinking about the device 7 itself, the 4170E, when did Sun decide to 8 pursue commercial development of that 9 device? 10 MS. CHEN: Objection. Outside 11 the scope. 12 A. That's -- I would rely on Scott 13 to tell me the exact timing for that 14 question. 15 Q. Do you know whose idea it was to 16 -- who first had the idea to develop what 17 is now the 4170E? 18 MS. CHEN: Objection. Outside 19 the scope. 20 A. No. 21 Q. Do you know when the development 22 work began?	28 1 Bates-stamped SunITC0168467, marked for 2 identification, as of this date.) 3 BY MS. PETERSON: 4 Q. And for the record, this is a 5 document bearing the Bates number 6 SunITC0168467. 7 Mr. Albert, are you familiar with 8 this document now marked as Exhibit 6? 9 A. No. 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 MS. CHEN: Objection. Outside 17 the scope. 18 [REDACTED] 19 [REDACTED] 20 Q. In the -- well, let me back up a 21 bit. 22 Is it your understanding --

4 1 this spreadsheet? 2 MS. CHEN: Objection. Outside 3 the scope. 4 A. No, I am not familiar with this 5 spreadsheet. 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 MS. CHEN: Objection. Lacks 17 foundation. Outside the scope. 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]	43 1 Sun Pharma to license either of those 2 patents? 3 A. I am not aware of any efforts to 4 license the patents. 5 Q. Are you aware of any plans to try 6 to license either of the asserted patents? 7 A. I am not aware of any plans to 8 license these two patents. 9 Q. I'm going to mark what will be 10 Exhibit 9. It's another native Excel file. 11 The Bates number is SunITC0163567. 12 (Albert Exhibit 9, Electronic 13 Document Bates-stamped SunITC0163567, 14 marked for identification, as of this 15 date.) 16 BY MS. PETERSON: 17 Q. Mr. Albert, do you recognize this 18 spreadsheet? 19 A. Yes. 20 Q. And what is this? 21 A. This is a spreadsheet of the 22 individuals we have identified that support
42 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 MS. CHEN: Objection. Outside 5 the scope. Lacks foundation. 6 [REDACTED] 7 [REDACTED] 8 Q. Okay. And just to confirm, do 9 you have any understanding of what the 10 second tab, NREs, is? 11 A. I do not know what the second 12 tab, NREs, is. 13 Q. Mr. Albert, are you aware of the 14 two patents that are at issue in this 15 litigation? 16 A. I am aware that there are two 17 patents-at-issue. I am not aware of the 18 details of the patents. 19 Q. And for the record, those are 20 U.S. Patent Number 11,446,512 and 21 11,697,028. 22 Are you aware of any efforts by	44 1 and work on the Levulan BLU-U business and 2 their costs, their personnel costs 3 associated with that. 4 Q. And I will represent that the 5 file name of this document was "2022 6 Salaries." 7 Is this a report that you would 8 prepare in the normal course of your 9 business? 10 A. The salary costs of individuals 11 by department, yes. 12 Q. Okay. And these are all Sun 13 employees? 14 A. These are Sun employees, yes. 15 Q. And where are the Sun employees 16 located? 17 A. They could be in Billerica, 18 Massachusetts; Princeton, New Jersey; or in 19 various states. 20 Q. When you say "various states," 21 what do you mean? 22 A. Various states across the United

45 1 States of America. 2 Q. Meaning -- 3 A. Different states, different 4 locations. 5 Q. Are those employees working 6 remotely? 7 A. Those are remote -- yeah, remote 8 field, slash, employees. 9 Q. So the only two Sun facilities 10 where these employees would work would be 11 in -- I didn't remember the pronunciation 12 of the first one. 13 A. Billerica. 14 Q. Billerica. Okay. 15 A. And Princeton. 16 Q. In my head, that's not how I was 17 saying it. 18 A. Yeah. But people in 19 Massachusetts say it differently. 20 Q. Okay. Are any of these employees 21 located outside of the United States? 22 A. No.	47 1 Q. And in column D, the column is 2 entitled "Annual." I assume that's annual 3 salary? 4 A. Yes. 5 Q. Okay. If someone started or left 6 in the middle of the year, how would that 7 be reflected in this document? 8 A. Yeah, I don't think we've taken 9 the date, the person started or finished 10 unless we knew beforehand. These are 11 people who are on the payroll, you know, at 12 a certain time of the year, usually 13 November/December time frame. So it's 14 assumed that they're there for the full 15 year. 16 Q. Okay. So the total column in 17 column N assumes they were there for the 18 entire year and does not reflect the amount 19 that person actually received, if they were 20 not there the whole year? 21 A. Yes. Conversely, if someone 22 left, we don't reflect that person's
46 1 Q. In the column -- let me see. 2 Where is that? If you could scroll back to 3 the top, please. In the column for -- 4 column F for -- actually, column J, how are 5 benefits determined? 6 A. Benefits are determined based on 7 how much we spend on medical/vision costs, 8 payroll tax, which are FICA, Social 9 Security, 401-K company match, and all the 10 short-term disability, the unemployment 11 benefits. 12 We then take a percentage based 13 on the person's salary. So we would -- if 14 the person's salary is around 50, we have a 15 percentage. If their salary is around 100, 16 we have percentage. If their salary is 17 around 150, we have a percentage. If their 18 salary is 200, we have a percentage. 19 So we take that percentage, 20 multiply it by their salary to estimate 21 what the benefit will be, cost to the 22 company.	48 1 contribution or amount we've paid if 2 they've left. 3 Q. Okay. In the column P, 4 allocation to PDT, what does that mean? 5 A. That's what we believe that 6 employee's time centered on the Levulan 7 BLU-U 4170E, how much time they're 8 dedicating to that business unit. For the 9 more technical areas, that was done with 10 Scott. For the customer service product 11 support, a lot of that was done through 12 Ron, who is head of product support. 13 And for some of the corporate 14 functions, I would have -- you know, people 15 on my team, I would have been making that 16 estimate or, you know, I might have had to 17 ask someone from regulatory how much they 18 were spending or for medical affairs on the 19 product. 20 Q. Okay. And just to clarify, you 21 said that you believe that's employee's 22 time centered on Levulan, BLU-U, 4170E.

69 1 functions, if we were more aggressive, we 2 could probably assign some corporate 3 functions to 4170E, but we did not. 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 Q. So just to go back to clarify one 22 thing, because I don't know that I was 70 1 entirely appreciating this. 2 So you signed this declaration on 3 June 25th, but the majority of these 4 figures are through fiscal year 2024, 5 meaning, that they are accurate as of March 6 31st? 7 A. 2024. 8 Q. Have you run any reports for 9 updated -- for any updates that are more 10 recent in time than March 31st for any of 11 these? 12 A. In this format? 13 Q. In any format. 14 A. Well, we monitor our financials 15 and track our spending and track our 16 businesses monthly and quarterly. So, yes, 17 we do monitor our expenses and our 18 spending. 19 Q. But have you generated any 20 updated versions of these? 21 A. We have not updated this for the 22 first -- you know, for the April onward	7 1 time frame. 2 Q. And going back to paragraph 19 of 3 your declaration, the first line item in 4 that chart is, "Research and Development." 5 Do you have a sense of what 6 activities were encompassed in the research 7 and development line item? 8 A. The specifics I would confer or 9 talk to Scott about exactly what activity 10 he's doing, him and his team are doing. 11 MS. PETERSON: I would like to 12 mark the next exhibit, which will be 13 Exhibit 12. 14 (Albert Exhibit 12, Document 15 titled "2022 Mfg. Labor Expenses," 16 Bates-stamped SunITC0163570, marked for 17 identification, as of this date.) 18 BY MS. PETERSON: 19 Q. I will state for the record that 20 there's not a Bates number in here because 21 it's a printout of a cell file, but this 22 was produced with Bates number 72 1 SunITC0163570. And it had a file name, 2 "Manufacturing Salaries, 2022 to 2024." 3 Mr. Albert, are you familiar with 4 this document? 5 A. Yes. 6 Q. And what is this document? 7 A. This is the projected estimated 8 costs of production for Levulan at the 9 Billerica facility. 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 Q. So to back up, are all of these 19 employees located in the Billerica 20 facility? 21 A. Yes. 22 Q. And all of these employees are
---	--

73 1 working on Levulan exclusively? 2 A. I'm not -- I'm not 100 percent 3 sure if they're exclusive. I don't know 4 how they run the facility, if they have 5 dual -- other activities. But this is the 6 resource equivalent required to produce 7 Levulan. 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 Q. Okay. But the figures in this 16 chart are specific to Levulan? 17 A. Yes. 18 Q. And for these four categories of 19 individuals, inspection, manufacturing, 20 facility engineer, and quality, did they 21 have any counterparts outside the United 22 States?	75 1 on page 3, in paragraph 11, you state that 2 "Sun Pharma has a factory in campus -- 3 campus in Billerica, Massachusetts." 4 And "Sun Pharma owns a building 5 consisting of approximately 70,000 square 6 feet acquired in 2015 [REDACTED] 7 [REDACTED] 8 Do you know where that dollar 9 figure comes from? 10 A. I believe it's from the 11 acquisition cost of when we bought the 12 business and the building. 13 MS. PETERSON: Okay. I'd like to 14 mark Exhibit 13. 15 (Albert Exhibit 13, Document 16 titled "Building Cost," Bates-stamped 17 SunITC0163560, marked for 18 identification, as of this date.) 19 BY MS. PETERSON: 20 Q. And this is a printout of a 21 native Excel file that was produced with 22 the Bates number SunITC0163560. And it had
74 1 A. Could you -- I'm not 100 percent 2 sure I understand the question. 3 Q. Sure. I can rephrase that. 4 Is all of the inspection of 5 Levulan completed in the United States? 6 A. Yes. 7 Q. Are there any employees who work 8 on Levulan based outside of the United 9 States? 10 A. Production employees? 11 Q. Yes. 12 A. No. 13 Q. Okay. Are there any other types 14 of employees other than production 15 employees who work on Levulan who are based 16 outside of the United States? 17 A. Not that I am aware of. Maybe 18 there is a very, very small study done on 19 Levulan. One is a very small minor study. 20 But generally, no, Levulan is a Billerica, 21 Massachusetts, based business and run. 22 Q. Going back to your declaration,	76 1 a file name of "BLDG Cost." 2 Mr. Albert, are you familiar with 3 this document? 4 A. Yes. 5 Q. It looks like the -- some of the 6 columns printed on the second page, I don't 7 know why, but there are only the two dollar 8 figures. So I imagine we can figure it 9 out. 10 What is this document we are 11 looking at as Exhibit 13? 12 A. This is a list of our two 13 buildings, you know, what we classified 14 them as and how much our initial cost was 15 to purchase them. It doesn't take into 16 account all the money we have spent 17 upgrading or investing in them. 18 Q. So it's just the cost of the 19 building? 20 A. Just the cost of acquisition, 21 yes. 22 Q. And did you prepare this

8	1 Florida, the following amounts for 2 manufacturing BLU-U 4170 device in the 3 United States." 4 And, Mr. Albert, where did you 5 obtain the numbers for the chart in 6 paragraph 18? 7 A. From our financial system in SAP. 8 MS. PETERSON: I'll mark Exhibit 9 15. This is a printout of the native 10 Excel file. This one is SunITC0163542. 11 (Albert Exhibit 15, Document 12 titled "Payments to [REDACTED] 13 (Odessa, Florida)," Bates-stamped 14 SunITC0163542, marked for 15 identification, as of this date.) 16 BY MS. PETERSON: 17 Q. Mr. Albert, are you familiar with 18 Exhibit 15? 19 A. Yes. 20 Q. And did you create this document? 21 A. Yes. 22 Q. And is this chart in Exhibit 15	83	1 has a signature page. I am guessing 2 you don't have a signature page and his 3 just has the first page. So I think if 4 we combine all three, we have one file. 5 MS. PETERSON: Well, everyone can 6 do a little arts and craft project. 7 I have pages 3 and 4. 8 A. I have 1, 8, 2. 9 MS. PETERSON: Clearly someone in 10 the office services does not know how 11 to collate copies. 12 (Hanging.) 13 THE WITNESS: You want to just 14 give them all to me. 15 (Hanging.) 16 MS. PETERSON: Good thing I 17 didn't have too many multiple-page 18 documents. 19 MS. CHEN: This is one complete 20 copy. 21 BY MS. PETERSON: 22 Q. All right. This is
82	1 where you got the dollar amounts for 2 paragraph 18 of your declaration? 3 A. Yes. 4 Q. And to confirm, [REDACTED] 5 [REDACTED] al only did manufacturing work for Sun 6 relating to the 4170D, correct? 7 A. Yes. 8 Q. They haven't done any work on the 9 4170E? 10 A. Not that I'm aware of. 11 MS. PETERSON: Next I'm going to 12 mark Exhibit 16. 13 (Albert Exhibit 16, Document 14 titled "Statement of Work," 15 Bates-stamped SunITC0163403 through 16 01643411, marked for identification, as 17 of this date.) 18 BY MS. PETERSON: 19 Q. And this is a document produced 20 as SunITC -- 21 MS. CHEN: I think this is 22 stapled incorrectly. The one I have	84	1 SunITC0163403. 2 Mr. Albert, are you familiar with 3 this document? 4 A. No. 5 Q. In the first paragraph, it states 6 this is a statement of work between Sun 7 Pharmaceuticals and [REDACTED]. 8 Do you know who [REDACTED] is? 9 MS. CHEN: Objection. Outside 10 the scope. 11 A. No, I don't. 12 Q. Do you know who [REDACTED], 13 [REDACTED] is? 14 A. Yes. So I think these are 15 vendors in relation to the PDT work I'm 16 familiar with, but I don't know the 17 specifics of what they do on each project 18 or assignment, but I do know that they are 19 vendors related to the PDT business unit. 20 Q. Okay. Do you know whether 21 Continuum or [REDACTED] has done work 22 for Sun on the 4170E?

85 1 A. So the 4170E, yes, [REDACTED] 2 has done work. Yeah, they have done work. 3 Q. But you don't -- you don't have 4 any understanding as to whether this is the 5 agreement for that work? 6 A. I would need to spend some time 7 to review it. I don't know offhand. 8 Q. So is it correct to say that you 9 wouldn't know one way or the other whether 10 Continuum had been executing the activities 11 listed starting on page 1? 12 A. That's a Scott question. 13 Q. And similar question, on page 8 14 of the document, there is a paragraph for 15 Sun responsibility numbered 4. 16 You personally wouldn't know one 17 way or the other whether Sun has worked on 18 or completed the responsibilities listed in 19 this paragraph? 20 MS. CHEN: Objection. Outside 21 the scope. Lacks foundation. 22 A. I don't know offhand, no. I	87 1 native Excel file that was produced with 2 Bates number SunITC0163540. 3 Mr. Albert, are you familiar with 4 Exhibit 17? 5 A. Yes. 6 Q. And what is Exhibit 17? 7 A. That's the numbers that we got 8 out of the system to detail how much we had 9 paid to this vendor, [REDACTED] over 10 the course of those years. 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 A. Yes. I think that's fiscal year. 22 So I have to look offhand. I can't
86 1 would have to verify and research it. 2 Q. In your declaration, looking at 3 page 5, paragraph 20, it states, "Sun 4 Pharma has paid [REDACTED] based in 5 [REDACTED], the following amounts 6 for developing and testing the BLU-U 4170E 7 device in the United States." 8 Same question as with the other 9 tables, where did you obtain the dollar 10 amounts listed in the chart in paragraph 11 20? 12 A. Yeah, in our financial ledger 13 system in SAP. 14 MS. PETERSON: I'd like to mark 15 Exhibit 17. 16 (Albert Exhibit 17, Document 17 titled "Payments to [REDACTED] 18 (Newton, Pennsylvania)," Bates-stamped 19 SunITC0163540, marked for 20 identification, as of this date.) 21 BY MS. PETERSON: 22 Q. And this is a printout of a	88 1 recall -- 2 Q. Sorry. 3 A. -- if it's fiscal year or not. 4 Q. Right. So in paragraph 20 of 5 your declaration, it does say, "fiscal 6 year." 7 A. Yeah. So then it would be more 8 than March. It would be from the prior 9 April 1st. 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 Q. Do you know if [REDACTED] 14 work for Sun has been ongoing since March 15 31st of this year? 16 A. I'm not sure. That's something I 17 would verify with Scott. 18 MS. PETERSON: I will mark 19 Exhibit 18. 20 (Albert Exhibit 18, Change Order 21 No. 1 to Statement of Work No. 1, 22 Bates-stamped SunITC0168450, marked for

89	1 identification, as of this date.) 2 BY MS. PETERSON: 3 Q. And this is a document bearing 4 Bates number SunITC0168450. 5 Mr. Albert, are you familiar with 6 this document? 7 A. No. 8 Q. At the top, it states that this 9 is a change order and that it is amendment 10 to the parties' Statement of Work Number 1 11 dated June 20th, 2024. 12 And in the change order 13 description, it says, "Revision of term 14 expiry date to December 31st, 2024." 15 Does this change your 16 understanding as to whether Sun has had an 17 ongoing relationship with [REDACTED]? 18 A. I mean, it appears that there is 19 a relationship. But once again, I would 20 defer to Scott. He's actually the 21 signatory on the page. 22 Q. Right.	9	1 has paid [REDACTED] based in 2 [REDACTED], the following 3 amounts for manufacturing BLU-U 4170E 4 device in the United States." 5 And then it lists dollar amounts 6 for three years in the chart. 7 Where did you obtain the numbers 8 listed in the chart in paragraph 21? 9 A. From the SAP financial ledger 10 system. 11 MS. PETERSON: I'm going to mark 12 Exhibit 19. 13 (Albert Exhibit 19, Document 14 titled "Payments to [REDACTED] 15 [REDACTED]," Bates-stamped 16 SunITC0163540, marked for 17 identification, as of this date.) 18 BY MS. PETERSON: 19 Q. Okay. And this is a printout of 20 a native Excel file produced as 21 SunITC0163540. 22 Mr. Albert, are you familiar with
90	1 So would it also be correct to 2 say that you're not aware whether the 3 project will be extended, again, past 4 December 31st of this year? 5 MS. CHEN: Objection. Outside 6 the scope. 7 A. I am not aware. Once again, I 8 would defer to Scott. 9 MS. CHEN: Do you want to take a 10 really quick break and then another 11 hour before lunch? 12 MS. PETERSON: Sure. That's 13 fine. 14 (Recess is taken.) 15 BY MS. PETERSON: 16 Q. Welcome back. 17 Did you discuss the substance of 18 your testimony with your counsel during the 19 break? 20 A. No. 21 Q. All right. Going to paragraph 21 22 of your declaration, it says, "Sun Pharma	92	1 the document marked Exhibit 19? 2 A. Yes. 3 Q. And what is this? 4 A. This is the backup information 5 that we have from the Excel system, the 6 summary from how much we've paid the 7 vendor. 8 Q. And the vendor being [REDACTED]? 9 A. Yes. 10 Q. And all of these expenses were 11 specifically on the 4170E device? 12 A. Yes. 13 Q. And you prepared this document? 14 A. Yes. 15 Q. Do you know if Sun has made 16 additional payments to [REDACTED] since March 17 31st of this year? 18 A. I don't know offhand. 19 Q. And then in paragraph 22 of your 20 declaration, you state, "Sun Pharma has 21 paid [REDACTED] based 22 in Buffalo, New York, the following amounts

93 1 for testing, inspection, and certification 2 of the BLU-U 4170E in the United States." 3 Mr. Albert, where did you obtain 4 the numbers for the chart in paragraph 22? 5 A. In the SAP financial system. 6 Q. And all of these numbers relate 7 specifically to the 4170E? 8 A. Yes. 9 Q. And do you know if Sun has made 10 additional payments to [REDACTED] in 11 conjunction with the 4170E since March 31st 12 of this year? 13 A. I'm not aware offhand. 14 Q. And in paragraph 23 of your 15 declaration, you state, "Sun Pharma has 16 paid [REDACTED] 17 [REDACTED] based in [REDACTED], 18 the following amounts for testing, 19 inspection, and certification of the BLU-U 20 4170E device in the United States." 21 Same question, where did you 22 obtain the dollar amounts listed in the	95 1 Q. Has Sun generated any forecasts 2 for the sales of the 4170E? 3 A. Not that I'm aware of. 4 Q. Would that be something your 5 department would be responsible for? 6 A. We would not generate the 7 forecast. We would review it and validate 8 it, but the general forecast would come 9 from the product support team. 10 Q. Is there a specific person in the 11 product support team who does forecasting? 12 A. I would initially talk to Ron. 13 Q. Sorry, I know you mentioned him a 14 few times. 15 A. Ron Groff, G-r-o-f-f. 16 Q. Do you have -- have you heard 17 anything from Ron or anyone else within Sun 18 approximately how many 4170E devices Sun 19 plans to sell in 2025? 20 MS. CHEN: Objection. Outside 21 the scope. 22 A. I think there has been one or two
94 1 chart in paragraph 23? 2 A. From the SAP financial system. 3 Q. And these amounts all relate 4 specifically to the 4170E? 5 A. Yes. 6 Q. And do you know if Sun has made 7 any additional payments to Intertek -- 8 sorry, [REDACTED] since March 31st of this 9 year? 10 A. I would need to research it 11 further. 12 Q. We discussed earlier that the 13 4170E is scheduled to be on sale at some 14 point in 2025, correct? 15 A. Yes. 16 Q. Who is the target customer for 17 the 4170E? 18 MS. CHEN: Objection. Outside 19 the scope. 20 A. Yeah, that's something I would 21 consult with the product support head or 22 even Scott.	96 1 conversations, but I don't recall the 2 specific amount of how many BLU-U's he will 3 have to sell this year. There's been some 4 general discussion. 5 Q. But you don't -- aren't aware of 6 a number? 7 A. I do not know a specific number. 8 Q. How does Sun define the market in 9 which the 4170E will compete? 10 MS. CHEN: Objection. Outside 11 the scope. 12 A. Well, I'm not sure. Could you 13 maybe explain the question a little? 14 Q. Sure. 15 What products or other forms of 16 dermatological treatment does Sun think 17 that the 4170E will compete with? 18 MS. CHEN: Objection. Outside 19 the scope. Vague and ambiguous. Calls 20 for a legal conclusion. 21 A. Yeah. I mean, that's really a 22 commercial question. I think, you know,

09

1 date.)
2 BY MS. PETERSON:
3 Q. Mr. Albert, are you familiar with
4 this document?
5 A. I am not.
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 Do you have any understanding one
14 way or the other if this would be the
15 purchase order for the sale referenced in
16 your declaration?
17 A. I would need to look at it a
18 little more carefully. Can you scroll
19 down?
20 Q. Sure. I'm happy to.
21 A. Yeah, that should be it. I
22 haven't seen it before, but I believe that

0

1 would be it, yeah.
2 Q. Okay. And earlier I asked you
3 some questions about when -- whether the
4 payment had been made or if it would be
5 made upon delivery, and you said that it
6 would depend on the terms of the purchase
7 order.
8 And here in this purchase order,
9 it states, "Payment terms. Payment 30 days
10 from invoice date."
11 Does that affect your
12 understanding of the payment terms?
13 A. So, I mean, the PO is just what
14 we give to the vendor that they can bill us
15 on.
16 The question is, if there is
17 another contract that has terms in
18 something, that would stipulate a little
19 more detail exactly. This is just a
20 standard 30 days from invoice. So I would
21 need to see if there is a contract with
22 that.

1 Q. Okay. And sitting here right
2 now, you're not aware if Sun has a contract
3 with [REDACTED]?
4 A. I'm not aware if there is a
5 statement of work or an additional
6 documented agreement between us. No, I'm
7 not aware.
8 MS. PETERSON: Next I'm going to
9 mark Exhibit 22 and this is going to be
10 a native Excel file. The Bates number
11 is SunITC0163912.
12 (Albert Exhibit 22, Electronic
13 Document Bates-stamped SunITC0163912,
14 marked for identification, as of this
15 date.)
16 BY MS. PETERSON:
17 Q. Mr. Albert, do you recognize this
18 document marked as Exhibit 22?
19 A. No, I do not.
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

2

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 Have you been involved in any
19 discussions with [REDACTED] about the price
20 of the 4170E?
21 A. No.
22 Q. Or what about the Sun's cost for

Transcript of Zvi Albert, Corporate Designee & Individually
Conducted on December 17, 2024

33 (129 to 132)

29

3

1 to find a schedule like that.

2 MS. PETERSON: Okay. I have no
3 further questions, but I am going to
4 leave this deposition open in light of
5 the six financial documents that were
6 produced last night after I had been
7 requesting them for some time.

8 So I pass the witness.

9 MS. CHEN: And I'll object to
10 leaving it open.

11 And no further questions.

12 And can we designate the
13 transcript as confidential business
14 information.

15
16
17 ZVI ALBERT

18
19 Subscribed and sworn to before me
20 this day of 2025.

21
22

1

** ERRATA SHEET **

2

On Assignment No 563519

3

Case Captioned In re CERTAIN PHOTODYNAMIC

4

* DECLARATION UNDER PENALTY OF PERJURY *

5

I declare under penalty of perjury

6

that I have read the entire transcript of
my deposition taken on the above-captioned

7

case, and the same is true and accurate,

8

save and except for changes and/or

9

corrections, if any, as indicated by me on

10

the ERRATA SHEET hereto, with the

11

undersigned has offered these

12

changes as follows:

13

Signed on the _____ day of

14

_____ 2025

15

16

ZVI ALBERT

17

18

Subscribed and sworn to on the

19

_____ day of _____ 2025 before me

20

21

22

No a y Pub c, n and fo he S a e of

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60

61

62

63

64

65

66

67

68

69

70

71

72

73

74

75

76

77

78

79

80

81

82

83

84

85

86

87

88

89

90

91

92

93

94

95

96

97

98

99

100

101

102

103

104

105

106

107

108

109

110

111

112

113

114

115

116

117

118

119

120

121

122

123

124

125

126

127

128

129

130

131

132

133

134

135

136

137

138

139

140

141

142

143

144

145

146

147

148

149

150

151

152

153

154

155

156

157

158

159

160

161

162

163

164

165

166

167

168

169

170

171

172

173

174

175

176

177

178

179

180

181

182

183

184

185

186

187

188

189

190

191

192

193

194

195

196

197

198

199

200

201

202

203

204

205

206

207

208

209

210

211

212

213

214

215

216

217

218

219

220

221

222

223

224

225

226

227

228

229

230

231

232

233

234

235

236

237

238

239

240

241

242

243

244

245

246

247

248

249

250

251

252

253

254

255

256

257

258

259

260

261

262

263

264

265

266

267

268

269

270

271

272

273

274

275

276

277

278

279

280

281

282

283

284

285

286

287

288

289

290

291

292

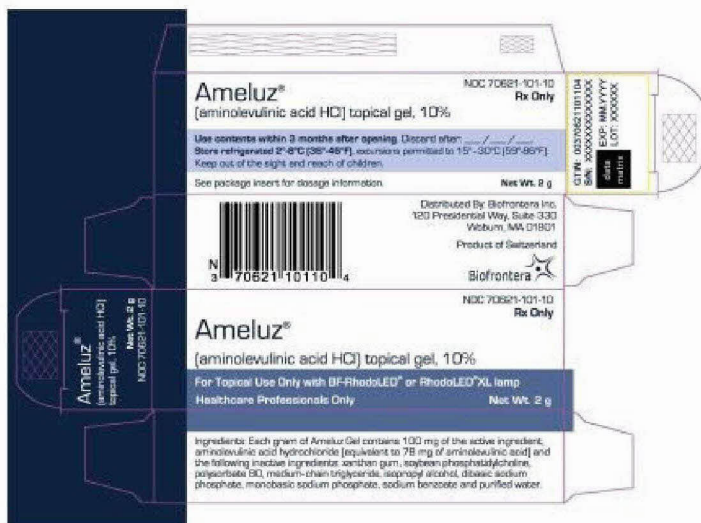
293

294

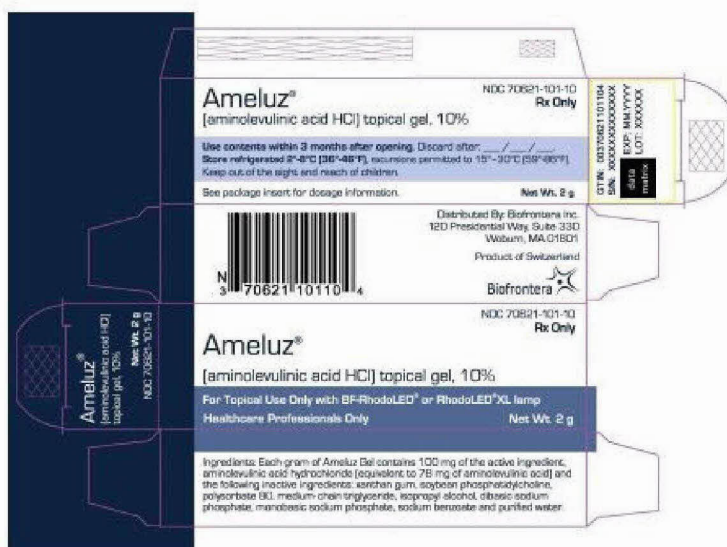
EXHIBIT 9

EXHIBIT 39

Outer Packaging, single Carton



Outer Packaging, Physician's Sample



Outer Packaging, Multipack

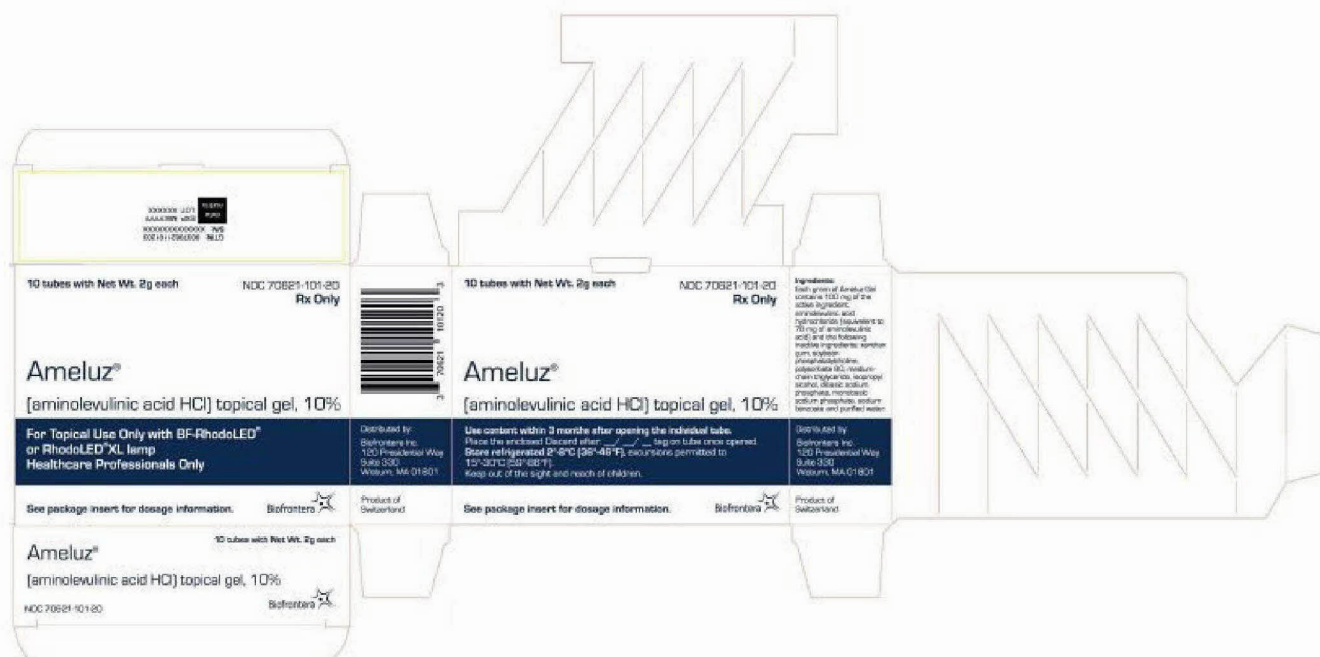


EXHIBIT 10



Planet Depos®
We Make It *Happen*™

Transcript of Thomas Boyajian

Date: December 10, 2024

Case: Certain Photodynamic Therapy Systems & Pharmaceutical Products (337-TA-1411)

Planet Depos

Phone: 888.433.3767 | **Email:** transcripts@planetdepos.com

www.planetdepos.com

Michigan #8598 | Nevada #089F | New Mexico #566

[REDACTED]

Transcript of Thomas Boyajian
Conducted on December 10, 2024

11 (41 to 44)

4 1 limitation. 2 A We, me, my team. 3 Q Who was on your team? 4 A At the time, Brian Mazejka. Geez, 5 I – I think when we were looking at possibly 6 updating, I think it was just him and I, when it 7 initially started. 8 Q I'm going to hand you what's been 9 marked as Exhibit 7. 10 (Boyajian Exhibit 7 marked for 11 identification and attached to the transcript.) 12 Q So Exhibit 7 looks like a series of 13 memos or a series of documents. 14 A This is a lot. 15 Q Did you review these in preparation 16 for your deposition today? 17 A I may have seen pieces of these. I 18 don't recall seeing all of this. 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]	43 1 Q [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]
42 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]	44 1 MS. CHEN: Objection. Vague. 2 A Yeah, I don't know how to answer that. 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 Q And if you turn with me to the page

6

63

Q So why don't we turn to slide 11. It is labeled 16130 at the bottom.

A Yep.

1 discussing the patent or are you discussing
2 concepts from the patent or are you discussing
3 what we wanted to make for commercial?

Q So I think you mentioned them having
input. Did you say power input or power source?
You used some word with "power."

A Yeah, they had input to, you know,
what – we considered them, again, gun for hire.
So we could ask a specific question like, what
power supply would you use that could provide
20 volts at 15 amps that you believe would pass
Intertek testing? So just simple – what
component would you use that could provide this
voltage and this power? And they would tell us,
use this one.

Q And did they --

A No – no relation at all to the
patent. They had no input to the patent.

Q And did they assist with any of the
determinations as to light uniformity?

A Determinations of light uniformity?
Not that I recall. Can you repeat the

62

64

question, though. I want to get it right.

Q Did they assist -- and I probably used
the wrong word because I used "determinations,"
and you, I think, correctly kind of were puzzled
over that, and I guess so am I, but did they
assist you at all with dealing with issues of
light uniformity?

A One more time, just so I --

Q Did they assist you with dealing with
issues of light uniformity?

A Not with respect to the patent.

Q So in what ways did they help with
light uniformity?

A When we gave -- we had a prototype, as
I mentioned, that was our concept, looking to
make that better, turn it into something
commercial

18 [REDACTED]
19 [REDACTED]

If they wanted to try maybe a
different component, different power supply or
something like that, we did give them the

(Boyajian Exhibit 14 marked for
identification and attached to the transcript.)

Q I'm going to hand you what's been
marked as Exhibit 14. You mentioned before
working with [REDACTED]?

A Yes.

Q How did [REDACTED] contribute to the design?

MS. CHEN: Objection. Assumes facts
not in evidence.

A When you say "design," again, are you

65

67

1 ability to test uniformity so that we could see
2 that it was doing what we wanted it to do
3 instead of having them get a new power supply,
4 then we have to bring it in, we test it, bring
5 it back to them. They weren't five minutes
6 away. They were — I don't remember exactly how
7 far away, but it was a car drive.

8 So they could do that testing just as
9 an extension of us.

10 Q And were they doing that testing on
11 complete panels, an array of panels? What were
12 they doing on the uniformity testing?

13 A I can't really remember. I remember
14 them having the ability to test uniformity.
15 Aside from that, I can't remember.

16 Q Did they assist with determining how
17 many LED bulbs to use on a panel?

18 A I don't believe so. This was post the
19 prototype. So once we locked into something we
20 were happy with, we wanted to stay there.

21 Q Did they assist with determining the
22 arrangement of the LEDs within a panel?

66

1 A I don't believe so. That wasn't what
2 we asked them to do. That wasn't — we didn't
3 need it.

4 Q And did they assist with coming up
5 with a power output for any of the LED bulbs?

6 A Can you be more specific?

7 Q In what way?

8 A Well, repeat the question.

9 Q Yeah. Did they assist with coming up
10 with the power output for any of the LED bulbs?

11 A I don't believe so.

12 Q If we can turn back to the '512
13 patent. This is Exhibit 5.

14 A Yes. Got it.

15 Q And if you turn with me to claim 17.

16 A Is that column 11?

17 Q Column 11, yeah, bottom of column 11.

18 Claim 17 says, "The method of claim 8,
19 wherein at least one panel includes a recess
20 configured to receive a flange of one of the
21 nested hinges."

22 Do you see that?

1 A I do.

2 Q What is a recess?

3 MS. CHEN: Objection. Calls for a
4 legal conclusion.

5 A In this context, I'm not sure.

6 Q If you turn to the '028 patent, and
7 let's go back to claim 1 that I know we talked a
8 lot about before, but I think I skipped over
9 this limitation. So it's like the fourth clause
10 down, but it says, "wherein the five panels are
11 positioned to allow treatment within
12 approximately 4 inches of the treatment
13 surface."

14 Do you see that?

15 A Yep.

16 Q And we talked a lot earlier, not
17 necessarily with the patent in front of us, but
18 about the distance that you were considering.
19 Does "within 4 inches" mean -- sorry, does
20 "within approximately 4 inches of the treatment
21 surface" mean less than or equal to 4 inches?

22 MS. CHEN: Objection.

68

1 A No.

2 MS. CHEN: Objection. Calls for a
3 legal conclusion.

4 THE WITNESS: Sorry.

5 Q What does it mean?

6 A So, again, didn't write it, not a
7 lawyer, that disclaimer there. That seems
8 pretty clear. "Within approximately 4 inches."
9 Approximately is not 4 inches, so plus or minus.

10 Q Plus or minus how much?

11 A Again — if it wanted to specify, it
12 would have.

13 Q Well, it is your patent.

14 A Uh-huh.

15 Q Did you specify plus or minus how
16 much?

17 A Clearly not.

18 MS. CHEN: Objection. Calls for a
19 legal conclusion.

20 Q And the distance is important --

21 MR. LANDMON: Sorry, strike that.

22 Q If you change the distance, it may

Transcript of Thomas Boyajian
Conducted on December 10, 2024

45 (177 to 180)

77

1 A I don't know that product well.
2 Q What products on the market do you
3 consider to be competitive with the Sun product?
4 MS. CHEN: Objection. Outside the
5 scope. Lacks foundation.
6 A I don't consider any of the products
7 to be competitive.
8 Q Why not?
9 A I'm not aware of any product that's
10 similar.
11 Q Including the Biofrontera product?
12 MS. CHEN: Objection. Lacks
13 foundation.
14 A Again, I don't know their product. I
15 don't know if it is similar or not similar. It
16 might be, but I wouldn't consider them a
17 competitor to that product. I should be
18 specific.
19 MR. LANDMON: Why don't we go off the
20 record and take a break.
21 (A recess was taken.)
22 MR. LANDMON: Subject to any questions

78

1 your counsel has, I have no further questions.
2 MS. CHEN: I have no questions.
3 MR. LANDMON: Thank you for your time.
4 THE WITNESS: Thank you.
5 MR. LANDMON: Off the record.
6 (Time noted: 3:17 p.m.)
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

79

1 ACKNOWLEDGMENT OF DEPONENT
2
3 I, THOMAS BOYAJIAN, do hereby
4 acknowledge that I have read and examined the
5 foregoing testimony, and the same is a true,
6 correct and complete transcription of the
7 testimony given by me and any corrections appear
8 on the attached Errata sheet signed by me.
9
10
11 (Date) (Signature)
12
13
14
15
16
17
18
19
20
21
22

80

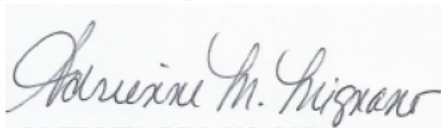
1 CERTIFICATE OF REPORTER - NOTARY PUBLIC
2 I, ADRIENNE MIGNANO, the officer before
3 whom the foregoing deposition was taken, do hereby
4 certify that the foregoing transcript is a true
5 and correct record of the testimony given; that
6 said testimony was taken by me and thereafter
7 reduced to typewriting under my direction; that
8 reading and signing was requested; and that I am
9 neither counsel for, related to, nor employed by
10 any of the parties to this case and have no
11 interest, financial or otherwise, in its outcome.
12 IN WITNESS WHEREOF, I have hereunto set my
13 hand and affixed my notarial seal this 20th day of
14 December, 2024.
15 My Commission Expires: June 2026.
16
17 
18
19 ADRIENNE MIGNANO, RPR
20
21
22

EXHIBIT 11



Planet Depos®
We Make It *Happen™*

Transcript of Brian M. Mazejka

Date: December 16, 2024

Case: Certain Photodynamic Therapy Systems & Pharmaceutical Products (337-TA-1411)

Planet Depos

Phone: 888.433.3767 | **Email:** transcripts@planetdepos.com

www.planetdepos.com

Michigan #8598 | Nevada #089F | New Mexico #566

89 1 Q. Okay. For now let's set that aside. 2 MR. HABBAZ: Like the other one, I'm going 3 to put this over here. 4 MR. LARIVÉE: Yeah. Let's take a quick 5 break and see whether our lunch is here. 6 (Whereupon the deposition recessed at 7 12:05 p.m.) 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	9 1 [REDACTED]-0012578-12584.) 2 MR. LARIVÉE: Before I -- I think I've 3 established a foundation, if you've got an 4 objection... 5 MR. HABBAZ: You're good. 6 Q. Sir, you've been handed a document bearing 7 Bates No. [REDACTED] 0012578. 8 Do you have that document in front of you? 9 A. I do. 10 MR. HABBAZ: Sorry. I'm just going to 11 clarify for the record because I want to make sure 12 -- reserve the right to have an objection to 13 foundation. I'm assuming what you were referring 14 to was the protective order issue. And I'm not 15 objecting as a violation of the protective order 16 for this deposition. 17 MR. LARIVÉE: Yes, I was concerned about 18 the protective order and I'm sure you won't object. 19 MR. HABBAZ: I understand. 20 Q. Sir, at the very top right-hand corner 21 there's a date. 22 Do you see that? 23 A. I see two dates. 24 Q. And what are those dates? 25 A. One is July 20th, 2014, and the other is
90 1 AFTERNOON SESSION (1:07 PM). 2 MR. LARIVÉE: I guess we're back on the 3 record at 1:07. I don't know why I thought to say 4 that because there's no video recording here. 5 We've just concluded a lunch break. 6 Q. Sir, did you talk to your attorney about 7 the substance of your deposition during the break? 8 A. No. 9 Q. Okay. This morning during your testimony 10 we discussed a company called [REDACTED]; correct? 11 A. Yes. 12 Q. [REDACTED]. 13 And is it your understanding that [REDACTED] was 14 working on certain electrical aspects of the 15 investigational blue light? 16 A. Yes. 17 Q. And did you receive or review any of their 18 work product? 19 A. Yes, we have -- or yes, we did. 20 Q. And would that have included circuit 21 diagrams? 22 A. I believe so. 23 Q. Okay. 24 MR. LARIVÉE: Could we mark... 25 (Exhibit 11, Layout Notes,	92 1 March 6th, 2015. 2 Q. I'm impressed with your eyesight. 3 What is -- what is being shown on this -- 4 on this front page here? 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 [REDACTED] 25 [REDACTED]

93 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 Q. And did the investigational blue light 11 have four LED strings? 12 A. I don't recall. 13 Q. [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 Q. And are you familiar with circuit 18 diagrams? 19 A. I know they exist. I can't read them. 20 Q. Did [REDACTED] design the layout of the LED 21 strings on the panels? 22 MR. HABBAZ: Sorry. Objection. Vague. 23 A. I don't know. 24 Q. Did you make any inventions -- did you 25 personally make any contribution -- contributions	95 1 Q. 8876. 2 A. Oh. 3 Q. Has figure -- yes. 4 A. Oh, 76, yes. 5 Q. And in your words what is being shown in 6 this figure? 7 A. This is the top view of the 8 investigational head. 9 Q. Did you, yourself, prepare this drawing? 10 A. This looks like a facsimile of -- of my 11 drawing, yes. It's not as accurate as my drawing. 12 Q. And do we see five panels here? 13 A. Yes. 14 Q. And are they labeled with "10a, 10b, 10c," 15 and so on? 16 A. Yes. 17 Q. Do you recall what 40 is pointing to? 18 This isn't a memory test. Just a question. 19 A. I think it's where all the wires were -- 20 were joined into -- I can't remember the technical 21 term, but it was where all the wires were -- were 22 being joined together. 23 Q. Turning to figures 2A and 2B on the next 24 page, what is being shown here? 25 A. An isometric view of the IBL.
94 1 to the invention around configuring the intensity 2 of the LEDs? 3 A. I don't believe so. 4 Q. Who -- do you know who would have 5 contributed to the ideas around configuring the 6 intensity of the LEDs? 7 A. I -- I don't know. 8 Q. Did [REDACTED] develop the ability to control 9 the power output of the individual LEDs? 10 MR. HABBAZ: Objection. Vague. Form. 11 A. I couldn't tell you. 12 Q. Okay. We can set that document aside. 13 And would you mind pulling out from your file 14 Exhibit 6, which is US Patent 11,446,512. 15 Do you have that in front of you, sir? 16 A. Yes. 17 Q. And just so the record is clear, what is 18 it? 19 A. It appears to be a patent. 20 Q. Are you a named inventor on this patent? 21 A. I am. 22 Q. Okay. And could you please turn to Bates 23 ending 876 that has figure 1A and 1B on that. 24 Do you see that? 25 A. 886?	96 1 Q. Okay. Did you make a contribution to this 2 figure? 3 A. Yes, this is based off of mechanical 4 drawings. 5 Q. Did you prepare those mechanical drawings? 6 A. I did, yes. 7 Q. Looking at the top figure, 2B, and 8 directing your attention to the panel labeled 10C, 9 do you see that? 10 A. That's a -- yes. 11 Q. And do you see the rows of LEDs there? 12 A. Yes. 13 Q. Okay. If you count the rows of LEDs from 14 10c down towards the bottom, do you come to -- up 15 with 11 rows? 16 A. There are 9 appearing on -- I'm sorry. 17 There are 11 appearing on the draw -- on the 18 sketch, yes. 19 Q. Okay. And so 11 rows. That means one row 20 in the middle, five above, and five below? 21 A. Yes. 22 Q. How can you tell which rows are arranged 23 close to the top or the bottom of the panel 24 respectively? 25 MR. HABBAZ: Objection. Incomplete

Transcript of Brian M. Mazejka
Conducted on December 16, 2024

40 (157 to 160)

57	59
1 COURT REPORTER: Rough transcripts?	SUBSCRIPTION OF DEPONENT
2 MR. LARIVEE: Yes, please.	2 State of _____
3 MR. HABBAZ: Sure.	3 County of _____
4 (Whereupon the deposition ended at	4
5 3:48 p.m.)	5
6	6 I, Brian M Mazejka, do hereby certify
7	7 that I have read the foregoing transcript of my
8	8 testimony and further certify that said transcript
9	9 (with/without) suggested corrections on the Errata
10	0 Sheet is a true and accurate record of said
11	testimony taken at the time and place designated
12	2
13	3
14	4
15	5
16	6 _____
17	7 Brian M Mazejka
18	8
19	9 Date _____
20	20 Subscribed and sworn to
21	Before me this _____
22	2 day of _____, 20____
23	22
24	23 Notary Public
25	State of New Hampshire
	24 Commission expires:
	25 _____

58	60
1 ERRATA SHEET	1 CERTIFICATE
2	2
3 A review of the transcript was not	3 I, Patricia Jod Onneus, a Licensed
4 requested	Shorthand Reporter for the State of New Hampshire,
5 Brian M Mazejka wish to document	4 do hereby certify that the foregoing statement and
6 the following corrections	5 accurate transcription of the proceedings of the
7	6 proceeding taken at the place and on the date
8	7 heenbefore said for the best of my skill and
9	8 ability under the conditions presented to me
10	9 I further certify that I am not
11	10 a oney or counsel for, nor employed by
12	11 by any of the parties to the action in which this
13	12 proceeding was taken, and further that I am not a
14	13 employee of any attorney or counsel
15	14 employed in this case, nor an interested party
16	15 needed in this action
17	16 The foregoing certificate of the
18	17 transcription does not apply to any reproduction of
19	18 the same by any means unless under the direct
20	19 control and/or direction of the certifying
21	20 reporter
22	21
23	22
24	23
25	24

**EXHIBIT 13 IS REDACTED IN
ENTIRETY**

EXHIBIT 14



Planet Depos[®]
We Make It *Happen*[™]



Transcript of Mark Carota

Date: December 5, 2024

Case: Certain Photodynamic Therapy Systems & Pharmaceutical Products (337-TA-1411)

Planet Depos

Phone: 888.433.3767 | **Email:** transcripts@planetdepos.com

www.planetdepos.com

Michigan #8598 | Nevada #089F | New Mexico #566

29	1 oversee the projects and the development and the 2 concepts for the same types of reasons I mentioned 3 before, which was to make sure the technology and 4 the approaches were the best for the product line 5 and its ability to get approval with FDA. 6 Q So, the outsourcing, what sorts of 7 projects did you need to outsource? 8 A Can you be a little bit more specific? 9 Q Yeah. I guess I'm trying to figure out 10 what the company did internally on the product 11 development versus what aspects you outsourced to 12 others? 13 A It depended on the projects at hand. You 14 know, whatever we were working on. You know, 15 again, it's over a 19-year period, so... 16 Q Yeah. Sorry. Yeah. So, let's focus on 17 the coming up with the five-panel device. 18 A Um-hmm. 19 Q Can you recall what projects were 20 outsourced for that project? 21 A Yeah. We outsourced the electronics, and 22 we outsourced some of the mechanical development,	3	1 A Well, we understood the premise of the 2 approval and that how that tied back into clinical 3 trials in and order to, again, minimize the time 4 component, questions, potential impact on supply, 5 we tried to match up as close as we could, in 6 order to give us the most probability, highest 7 probability of success. 8 Q And the -- so, I guess, let's focus first, 9 on the outsourcing of the LED portion. Were you 10 just putting a general question to these 11 third parties that -- maybe I should back up. 12 I'm asking too much at once, and I 13 apologize if this takes a little longer to get all 14 the information out. 15 But do you remember who you outsourced the 16 LED issues to? 17 A I don't. 18 Q Does a company called [REDACTED] 19 [REDACTED]? 20 MR. WAGNER: [REDACTED]. 21 Q [REDACTED]? 22 A Yeah, [REDACTED] was one that we used. I
30	1 so that we could generate some -- what we would 2 "alpha drawings" concepts, so that the marketing 3 in upper management could take a look at them for 4 feedback on whether they thought they were 5 suitable or not. 6 Q What sort of electronic issues were 7 outsourced? 8 A We were, you know, mainly, looking at the 9 electronic driver of the LEDs that we were using 10 as the fluorescent technology, had been 11 essentially outlawed, and so, we were looking for 12 replacements in the same wavelength and power 13 areas. 14 So, we worked with companies in order to 15 see what the best options were to match up with 16 the optical specs that had been approved by FDA. 17 Q So is the goal always to achieve the same 18 wavelength and power with the LED bulbs as with 19 the fluorescent bulbs? 20 A That was certainly my goal. 21 Q And you said that was to meet FDA's 22 requirements?	32	1 don't know what [REDACTED] is. 2 Q And how about a company [REDACTED]? 3 A Yes, [REDACTED]. 4 Q Were both of those of those used on the 5 LED side? 6 A Yes, in different ways. 7 Q Which ways were they used? 8 A Well, early on, [REDACTED] got us to the point 9 where we had -- and this is my recollection -- 10 that we got -- we had achieved optical equivalence 11 in a breadboard design. 12 Q A breadboard design? 13 A Yeah, so, it's not a design. It's just a 14 breadboard. 15 Q Sorry I'm not -- 16 A Very early prototype. 17 Q Okay. Understood. 18 Do you know about when that was? 19 A No, I -- I couldn't recall when that was. 20 Q Totally fine. It's been a long time, and 21 that's -- 22 A Yeah, it has.

37 1 fluorescent lamp would. 2 Q And were there problems with a rigid, 3 curved device? 4 A It was limiting. 5 Q In what way? 6 A It was rigid. 7 Q And did that cause problems getting around 8 different shapes or sizes of body parts in terms 9 of the treatment surface? 10 A In general, no. When you design, you 11 design around human factors, and that was done 12 with the lamp, so the size was designed with that 13 in mind. 14 Q The size of the original or the new one? 15 A We were talking about the original, 16 correct? 17 Q Yes. Yeah. Okay. So, I guess, you 18 mentioned that the LEDs give you more flexibility, 19 but why then make it other changes? Like, why go 20 to the five-panel hinge design? 21 A I don't recall exactly how we ended up 22 there.	39 1 A I mean, everything you would normally deal 2 with in any brand new design from basically 3 starting with a blank piece of paper. 4 Q What -- what were they given in terms of 5 design instructions, do you know? 6 A I think there might have been some general 7 instructions, but mainly around the optical spec. 8 And they certainly were given a BLUE-U, so that 9 they kind of understood what was currently fielded 10 and in use. 11 Q Did they come up with the idea of using 12 five panels? 13 A Again, I don't -- I'm not really sure who 14 came up with it or how it ended up there. 15 Q Did you come up with the idea of using 16 five panels? 17 A I just said I don't know how we came up 18 with that. 19 Q Okay. Do you know that it wasn't an idea 20 of yours, though, I guess is the -- 21 A I don't believe it was, no. 22 Q Okay. So I know we generally talked
38 1 Q With the static design, was there a 2 realization that -- you know, the fixed, static 3 design, was there a realization that there could 4 be, you know, issues getting around other surface 5 areas other than a human head? 6 A Well, that was the target, you know. It 7 was it was for the face and scalp, and that's what 8 it was designed around, and that was the target 9 market at the time. 10 Q Was there a recognized issue that people 11 had different sized, you know, faces, scalps, 12 heads, and it would be better to have a design 13 that was more flexible to adjust to those sizes? 14 A No. 15 Q You mentioned earlier outsourcing of 16 electronics, but also outsourcing of mechanicals? 17 A Yeah. 18 Q Do you know who you outsourced those 19 issues to? 20 A That was with Continuum. 21 Q That was with -- okay. And what sorts of 22 issues did they deal with?	40 1 about, kind of, your role with the company. 2 A Yeah. 3 Q But maybe let's focus on your role with 4 the development of the five-panel device. 5 What was your role there? 6 A Well, as I stated before, it was more -- 7 probably a little bit more strategic, where I was 8 looking for something that would meet the optical 9 spec, be as effective as possible in the 10 marketplace with what I knew over the years that I 11 worked there. 12 Maybe fill in for some shortcomings that 13 we may have experienced or over time with the 14 BLUE-U. And keep an eye on costs and the ability 15 to supply it and ability to manufacture it. 16 Q What were some of the shortcomings of the 17 older device? 18 A It was rigid. And when you have a rigid 19 device, it was like shipping eggs. So you have 20 got a rigid device with glass lamps in it, so you 21 could get breakage. If the derms were rolling 22 around their office place, they can bang it

37 1 fluorescent lamp would. 2 Q And were there problems with a rigid, 3 curved device? 4 A It was limiting. 5 Q In what way? 6 A It was rigid. 7 Q And did that cause problems getting around 8 different shapes or sizes of body parts in terms 9 of the treatment surface? 10 A In general, no. When you design, you 11 design around human factors, and that was done 12 with the lamp, so the size was designed with that 13 in mind. 14 Q The size of the original or the new one? 15 A We were talking about the original, 16 correct? 17 Q Yes. Yeah. Okay. So, I guess, you 18 mentioned that the LEDs give you more flexibility, 19 but why then make it other changes? Like, why go 20 to the five-panel hinge design? 21 A I don't recall exactly how we ended up 22 there.	39 1 A I mean, everything you would normally deal 2 with in any brand new design from basically 3 starting with a blank piece of paper. 4 Q What -- what were they given in terms of 5 design instructions, do you know? 6 A I think there might have been some general 7 instructions, but mainly around the optical spec. 8 And they certainly were given a BLUE-U, so that 9 they kind of understood what was currently fielded 10 and in use. 11 Q Did they come up with the idea of using 12 five panels? 13 A Again, I don't -- I'm not really sure who 14 came up with it or how it ended up there. 15 Q Did you come up with the idea of using 16 five panels? 17 A I just said I don't know how we came up 18 with that. 19 Q Okay. Do you know that it wasn't an idea 20 of yours, though, I guess is the -- 21 A I don't believe it was, no. 22 Q Okay. So I know we generally talked
38 1 Q With the static design, was there a 2 realization that -- you know, the fixed, static 3 design, was there a realization that there could 4 be, you know, issues getting around other surface 5 areas other than a human head? 6 A Well, that was the target, you know. It 7 was it was for the face and scalp, and that's what 8 it was designed around, and that was the target 9 market at the time. 10 Q Was there a recognized issue that people 11 had different sized, you know, faces, scalps, 12 heads, and it would be better to have a design 13 that was more flexible to adjust to those sizes? 14 A No. 15 Q You mentioned earlier outsourcing of 16 electronics, but also outsourcing of mechanicals? 17 A Yeah. 18 Q Do you know who you outsourced those 19 issues to? 20 A That was with [REDACTED]. 21 Q That was with -- okay. And what sorts of 22 issues did they deal with?	40 1 about, kind of, your role with the company. 2 A Yeah. 3 Q But maybe let's focus on your role with 4 the development of the five-panel device. 5 What was your role there? 6 A Well, as I stated before, it was more -- 7 probably a little bit more strategic, where I was 8 looking for something that would meet the optical 9 spec, be as effective as possible in the 10 marketplace with what I knew over the years that I 11 worked there. 12 Maybe fill in for some shortcomings that 13 we may have experienced or over time with the 14 BLUE-U. And keep an eye on costs and the ability 15 to supply it and ability to manufacture it. 16 Q What were some of the shortcomings of the 17 older device? 18 A It was rigid. And when you have a rigid 19 device, it was like shipping eggs. So you have 20 got a rigid device with glass lamps in it, so you 21 could get breakage. If the derms were rolling 22 around their office place, they can bang it

4	1 against the wall, because it was heavy, and it 2 would break the lamps. 3 So those kinds of things were definitely 4 the main shortcomings that I can recall. 5 Q And those issues would have been 6 communicated to you by someone outside of the 7 company? 8 A Sure. I mean, I was involved enough that 9 I became quite aware of what was going on 10 through -- either through returns, service, 11 working with our contract manufacturer, working 12 with marketing and sales. 13 Q And so, we, kind of, went through what 14 your role was with the design. Who else worked on 15 the design? 16 A Tom Boyajian, Brian Mazejka. 17 Q Anyone else? 18 A Yeah. There may have been a couple of 19 other people internal. I think we had a 20 contractor at one time that was in. He may have 21 actually became -- bless you. He may have 22 actually became a permanent employee, but I don't	43	1 A They knew the goals that we had, some of 2 the, you know, time frames, cost supply issues and 3 so forth. So, yeah, from time to time, we would 4 have project reviews. They'd show us where they 5 were. We'd drill into it during meetings, kind 6 of, if it needed to be, you know, redirected, it 7 might be slightly redirected, tweaked. We might 8 have to dig into something deeper on things that 9 they weren't aware of, and so forth. 10 So there was a good give and take. 11 Q And I think you said it already, you don't 12 recall any ideas or suggestions that you had about 13 the design, right? 14 A Oh, I'm sure I had ideas and suggestions 15 about the design. 16 Q Do you recall any? 17 A Off the top -- no, I don't recall. 18 Q And I think I asked you this. You don't 19 recall who had the idea of having the five panels? 20 A No, I don't. 21 Q Do you recall any -- who had the ideas 22 about using hinges between the panels?
42	1 really recall because it was done over a period of 2 time, so... 3 Q Do you remember that person's name? 4 A I don't. 5 Q Okay. And I guess let's focus first on 6 Mr. Boyajian. 7 A Boyajian. 8 Q I'll get it right by the end. 9 What was his role with respect to the 10 design? 11 A Well, he was the lead, you know, engineer, 12 if you will, over that project. 13 Q Do you know what ideas he came up with? 14 A God, I couldn't -- countless ideas that go 15 into any kind of design, so I couldn't -- I 16 couldn't really dissect any of them, tell you what 17 he did or he didn't do because, again, I wasn't in 18 the lab. I wasn't at every meeting. I wasn't 19 working at that detail of a level. 20 Q So was it generally that he and 21 Mr. Mazejka would bring ideas to you about the 22 design?	44	1 A Well, I would imagine -- no, I don't 2 recall. I think it's just -- it's a byproduct of 3 having five panels. You've got to have hinges. 4 Q It's obvious that you need hinges to 5 connect panels? 6 A Yeah, you don't start with a hinge and 7 say, oh, I'll put a panel on it. It's, if you're 8 going to panels and you are trying to get a curve, 9 then you got to put hinges in it in order to get a 10 curve to match up with the BLUE-U head. 11 And so, again, back to FDA, so that we 12 were kind of beating the same profile or optical 13 output as the original device. 14 Q And there is nothing special about the 15 hinges that you guys used on the panels? 16 MS. CHEN: Objection. Misstates witness 17 testimony. 18 MR. DICKISON: You can answer. 19 THE WITNESS: What's that? 20 Q You can still answer. Part of the 21 deposition is -- 22 A Okay.

53 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]	55 1 Q So, when you were still there, did you 2 have a prototype? 3 A Yeah. We had -- we -- I don't know if I 4 would call it a prototype or an alpha, you know, 5 prototype but we definitely had some mechanical 6 ideas on, you know, some concepts that we could 7 potentially commercialize. 8 Most of those concepts were around the 9 support structure for the head because [REDACTED], 10 you know, I mean, that was their main focus, was 11 around the support structure. 12 Q To provide enough structure to hold the 13 head? 14 A Yeah, different approaches to -- so that 15 it could be used in several different treatment 16 environments. That was kind of their thing. 17 Q And going back to Exhibit 6, the statement 18 of work, do you know why -- 19 A Statement 6. What page? 20 Q It's Exhibit 6. I'm still on the third 21 page. 22 A Okay. Statement 6.
54 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 Q Was the design complete when you were 11 still with SUN? 12 A No. 13 Q Okay. Do you know -- 14 A No. 15 Q Do you know -- so what stage was the 16 design at when you were still at SUN? 17 A That's a great question. I don't 18 really -- I don't recall exactly where it was. 19 Q Have you seen the final design? 20 A No. Is there one? 21 Q I believe there is. 22 A Okay.	56 1 Q No, no. I'm sorry. This document is 2 called Exhibit 6. 3 A Okay. 4 Q Right. It was marked with Exhibit 6. 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 Q Sorry if I asked this already, but do you 21 recall any input that [REDACTED] made about the 22 patent?

33

1 size-wise and spot-wise, and so forth.
2 So we were kind of working around the
3 commercial form that it might take, which again,
4 it hadn't gotten there yet when I left.
5 But – so we had looked at quite a few of
6 those ideas and come up with what we thought was
7 the best way to approach meeting the optical
8 specification that we were trying to meet.
9 So I think at that point, that was when
10 they decided that, you know, the IP side of this
11 whole thing went off the and did their, and I just
12 continued to work our – more towards continued
13 development and commercialization.
14 Q So you had a lot of "we" in your answer.
15 A Yes.
16 Q I'm asking specifically you individually.
17 A I don't recall specifically which things I
18 sat down in the lab and, you know, and worked on
19 or did, or – or, you know, during meetings, made
20 changes and – you know, that ended up being the
21 novel piece.
22 Q But as you sit here today, you can't

34

1 recall any --
2 A No, I don't -- I can't really recall. It
3 was almost ten years ago.
4 MR. LANDMON: I don't have any further
5 questions. Thank you.
6 MS. CHEN: We can go off the record.
7 (Deposition concluded at 2:30 p.m. EST.
8 Signature of the witness was requested.)
9
10
11
12
13
14
15
16
17
18
19
20
21
22

35

1 VERIFICATION OF DEPONENT
2
3 I, MARK CAROTA, having read the foregoing
4 deposition consisting of my testimony at the
5 aforementioned time and place, do hereby attest to
6 the correctness and truthfulness of the
7 transcript.
8
9

10 NAME: MARK CAROTA
11 DATED:
12
13
14
15
16
17
18
19
20
21
22

36

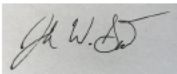
1 CERTIFICATE OF NOTARY PUBLIC
2 I, John Gugarty, Notary Public,
3 do hereby certify that the aforementioned witness
4 was sworn before me at the aforementioned location,
5 and that I am neither counsel for, related to, nor
6 employed by any of the parties to this case and
7 have no interest, financial or otherwise, in its
8 outcome.
9 IN WITNESS WHEREOF, I have hereunto set
10 my hand and affixed my notarial seal this 5th day,
11 of December, 2024.
12
13
14
15
16 
17
18 John Gugarty, Notary Public
19 for the State of Massachusetts
20
21
22

EXHIBIT 26



Planet Depos[®]
We Make It *Happen*[™]

Transcript of Neil Bacon

Date: January 15, 2025

Case: Certain Photodynamic Therapy Systems & Pharmaceutical Products (337-TA-1411)

Planet Depos

Phone: 888.433.3767 | **Email:** transcripts@planetdepos.com

www.planetdepos.com

Michigan #8598 | Nevada #089F | New Mexico #566

2
1 Q. By the way, have you seen the '512 patent
2 before?
3 A. I have not.
4 Q. When I refer to U.S. Patent No. 11,697,028, I
5 may use the phrase "'028 patent." Will you understand
6 that?
7 A. Yes.
8 Q. Do you understand that these two patents, the
9 '512 and the '028 patent, have been asserted by Sun
10 Pharma against Biofrontera?
11 A. I do now.
12 Q. Have you seen the '028 patent before?
13 A. No.
14 Q. Have you seen any issued or granted patents
15 related to the Blu-U 4170E?
16 A. No.
17 (Exhibit 3 marked for identification.)
18 (Discussion off the record.)
19 Q. Just as we went off the record, we marked for
20 identification [REDACTED] 3. It is titled Declaration of
21 Neil Bacon, and it bears Bates number [REDACTED]-0018466.
22 Mr. Bacon, do you have that document in

22
1 front of you?
2 A. Yes.
3 Q. Mr. Bacon, turning to Bates ending 468 --
4 that's Page 3 of the declaration -- do you see your
5 signature there?
6 A. Yes.
7 Q. Did you sign this document on November 7,
8 2024?
9 A. Yes.
10 Q. Without revealing any of the contents of
11 attorney-client communications, can you tell me how
12 you prepared this declaration?
13 A. Yeah. So Ms. Chen provided a shell for me to
14 fill out, and then I wrote in the specific sections.
15 In the instances where there was information that
16 needed to be pulled out, I did contact our financial
17 team or other team members to help pull that
18 information together.
19 Q. Okay. Turning your attention to Paragraph 1
20 of your declaration: It includes your title and the
21 length of time that you have been working with [REDACTED].
22 Could you tell me when, approximately, you were hired

23
1 to work with [REDACTED]?
2 A. So, again, [REDACTED] -- I was hired by
3 [REDACTED] and then [REDACTED] was acquired by [REDACTED] in
4 2018. I started with [REDACTED] in December of 2016.
5 Q. So is December 2016 when you started with
6 [REDACTED]?
7 A. With [REDACTED].
8 Q. With [REDACTED]. When you were hired, what
9 was your title?
10 A. My title with [REDACTED] was senior mechanical
11 engineer II.
12 Q. And what titles have you held with [REDACTED]
13 over the course of your time there?
14 A. So it was senior mechanical engineer II was
15 the original title with [REDACTED], and then after the
16 acquisition and assimilation, then I was given the
17 most recent title of associate director, innovation
18 consulting.
19 Q. And about how long have you held that title?
20 A. So it would be about six years, I'd say --
21 probably closer to five. It probably took me a year
22 or two to figure how to map everything out.

24
1 Q. Turning to Bates ending 467, and directing
2 your attention to Paragraph 4, which states, "[REDACTED]
3 [REDACTED] began working with Sun Pharmaceutical
4 Industries, Inc. ('Sun Pharma') on developing and
5 testing the Blu-U Blue Light Photodynamic Therapy
6 Illuminator [REDACTED] device (also known as the 4170E
7 device) since Q3 2016." Do you see that?
8 A. Yes.
9 Q. Is that accurate, to your knowledge?
10 A. Yes.
11 Q. And so you started in December 2016; correct?
12 A. That's correct.
13 Q. And so after -- that is after Q3 2016;
14 correct?
15 A. That's correct.
16 Q. And so who did you talk to to understand that
17 you started -- that [REDACTED] started working with Sun in
18 Q3 2016?
19 A. So from two sources. One, as I joined the
20 company, I was aware of the project at the time with
21 Sun, and I was not on the project at the inception of
22 the project. So I talk with Doug Kroncke, as I

29 1 know what that relates to? 2 A. So this would have been -- actually... 3 So this was actually an expense. We had 4 likely shipped material to DUSA. So this was not -- 5 this was a project expense. 6 Q. Mr. Bacon, when you answered that question, I 7 saw you looking towards Exhibit A. Could you just 8 state for the record what Exhibit A is? 9 A. Yes. So Exhibit A is the actual reported 10 hours by employee by month. This would be used by our 11 finance team to prepare monthly invoices. 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]	3 1 A. I don't recall. 2 Q. Paragraph 7 contains a list of employees. 3 Can you tell me about who these employees are and why 4 they were included -- pardon me. 5 Can you tell me how these employees became 6 included on this list? 7 A. Yes. So everybody that's on this list had a 8 role in in the project at some point. Generally 9 speaking, they are -- with the exception of Doug 10 Kroncke, everyone else on the list has a technical 11 background, either mechanical engineering, electrical 12 engineering, software or software/firmware 13 engineering. 14 Also, we have team members listed here 15 that are -- that work within [REDACTED]'s 16 made-real lab, which is a prototyping -- in-house 17 prototyping shop that we have. 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]
30 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 Q. Why does one do final verification testing? 7 A. It's required as part of any kind of -- 8 generally speaking, any kind of product development. 9 You want to verify that you're -- that the performance 10 of the device is meeting the specification and 11 requirements that you've identified earlier in the 12 program. And in a medical device product, the 13 verification is a requirement for submission. 14 Q. Is [REDACTED] manufacturing any commercial products 15 for Sun Pharma related to the Blu-U device? 16 A. We -- so no, we are not manufacturing any 17 products for them, and we are not a manufacturer of 18 products. 19 Q. Are you aware of who is manufacturing the 20 Blu-U for Sun Pharma? 21 A. I am aware, yes. 22 Q. And who is that?	32 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 Q. When you say "signal within the system," can 15 you clarify on what kind of signal that is? 16 A. I really can't beyond that. There's -- 17 Anything I would say would just be speculating at this 18 point, because it's not my background. 19 Q. Is it an electrical spectrum or light 20 spectrum? 21 A. This would be an electrical spectrum. 22 Q. Do you know where it's hooked up within the

57 1 A. I do not know how frequently he communicated. 2 Q. And do you have a reason to believe that it 3 would be more or less than the weekly meetings you 4 described earlier? 5 A. I think it would be typical of most project 6 engagements, where he was probably engaged weekly, and 7 there might have been followup phone calls similar to 8 what I described with Mr. Lundahl and myself. 9 Q. To your knowledge, did Mr. Carota provide 10 direction on [REDACTED] work? 11 A. Yes, to my knowledge, he provided the 12 direction for the inputs into the design. 13 Q. And what kind of inputs did he provide 14 direction on? 15 A. So, generally speaking, DUSA provided the 16 direction for the design of the Flexlight system and 17 had provided the inputs. They had created a prototype 18 of the system that was provided to [REDACTED], and that 19 served as the basis for our development. And I'd 20 speculate that was Mark that provided that. 21 Q. By the time you joined the project in 2018, 22 you were no longer -- the [REDACTED] team was no longer	59 1 A. Yes. Similar to Mr. Lundahl, it would have 2 been feedback on the design. It would have been any 3 tasks or schedule-related item, as well as the 4 feedback on the prototypes that we had created. 5 Q. To your recollection, did Mr. Boyajian ever 6 provide input on the hinges used to connect the panels 7 on the lamp head? 8 A. So the -- so the hinge design was -- that was 9 done prior to my engagement. However, I do know that 10 Sun provided the hinge arrangement to [REDACTED]. 11 Q. What do you know about the hinge arrangement 12 that Sun provided to [REDACTED]? 13 A. So I do know that the hinge arrangement, they 14 had specified the panel arrangement and the way they 15 wanted to deploy the panels, and articulated those 16 panels through the use of a hinge. 17 Q. Was there any particular type of hinge that 18 was specified? 19 A. So the hinge itself -- there were attributes 20 that we were working with: primarily the location of 21 the hinges and the proximity of the panels. There's 22 many ways to make a hinge, but it was really about the
58 1 working with Mr. Carota; correct? 2 A. He had left the company at that time. 3 Q. Do you recognize the name Tom Boyajian? 4 A. Yes. 5 Q. Who, to your understanding, is Mr. Boyajian? 6 A. So Mr. Boyajian was the -- he was the project 7 manager that took over for Mark Carota. 8 Q. And did you personally interact with Mr. 9 Boyajian at all? 10 A. I did. 11 Q. And do you remember when you first 12 communicated with Mr. Boyajian? 13 A. Yes. That would have been July 2018. 14 Q. By then was Mr. Boyajian already running the 15 project from Sun's side? 16 A. Yes. 17 Q. And again, was Mr. Boyajian providing 18 direction to [REDACTED] regarding the project? 19 A. Yes. 20 Q. Do you recall the types of directions that 21 Mr. Boyajian would provide to you and the team during 22 the time you worked with him?	60 1 location and the positioning of those. 2 Q. Did Mr. Boyajian provide input as to the 3 arrangement of the LEDs on the panel? 4 A. So that would be before my engagement, so I 5 wouldn't know. 6 Q. Did Mr. Boyajian ever provide direction as to 7 the widths of the panel within the Blu-U? 8 A. So I'd like to just clarify my previous 9 comment. I do not know who from Sun provided the 10 guidance. I do know that Sun provided the guidance 11 for the panel size and LED arrangement. 12 Q. And do you recognize the name Brian Mazejka? 13 A. Yes. 14 Q. And who, to your knowledge, is Mr. Mazejka? 15 A. So Mr. Mazejka was a mechanical engineer at 16 DUSA. 17 Q. And have you personally ever communicated 18 with Mr. Mazejka? 19 A. I did. 20 Q. And what were those communications in regard 21 to? 22 A. They would have been in regard to the

77 1 any records of. 2 Q. Did Mr. Kroncke share anything else about the 3 provisional patent? 4 A. No. He -- in our discussion for preparation, 5 he just indicated that more than likely DUSA -- kind 6 of shared a general understanding on the specific 7 areas that would be pertinent for us to follow. 8 Q. And do you know what those specific areas 9 that would be pertinent for [REDACTED] to follow were? 10 A. It would be items that are related to the 11 functionality of the light, the previous items that we 12 mentioned -- the spectral, the uniformity, the 13 intensity -- and arrangement of the panels would be 14 important. 15 Q. Can I direct your attention to Bates ending 16 136, Page 17 of the presentation. And my question's 17 going to be about those second and third bullet points 18 in red. Do you see those? 19 A. I do. 20 Q. And do you have an understanding of what is 21 being discussed in those red bullet points? 22 [REDACTED] e	79 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 Q. And do you know what the inputs were that Sun 14 provided? 15 A. It would have been the -- I don't know all 16 the inputs. The inputs could be things like the 17 selected LED, the wavelength that it's operating at, 18 the power, the location, the layout of those LEDs. 19 Those would have all been inputs into that model. 20 Q. And regarding the layout of the LEDs, what 21 work did [REDACTED] conduct related to the layout of the 22 LEDs?
78 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 Q. And so what is breadboarding? 14 A. So "breadboarding" is a term that we use for 15 looking at small components of a system and ensuring 16 that they are working properly. So an example of 17 this: In an electrical breadboard we might do, where 18 the item actually comes from, you can actually lay out 19 a circuit that you can place resistors or capacitors 20 onto to ensure that the circuit is working properly. 21 We also do mechanical breadboarding, [REDACTED] 22 [REDACTED]	80 1 A. So the work that we did -- so we were not 2 responsible for the position or the location of the 3 LEDs or the quantity of LEDs. That was all inputs 4 that were provided by Sun based on their work. 5 So we were -- we provided -- that 6 information was provide to the optics engineer, and 7 then he provided a report from that. But we were not 8 involved in changing locations or sizes of panels. 9 Q. And did the report that came back from [REDACTED] 10 or whoever this vendor was -- 11 And by the way, do you know whether the 12 vendor was [REDACTED] or [REDACTED]? 13 A. I know it wasn't [REDACTED]. [REDACTED] is -- I 14 believe those are the -- that's the software tool 15 that's used. So because we do not have optics -- we 16 don't have optical engineering in house at [REDACTED] and we 17 are not optics experts, so we worked with a consultant 18 to utilize a program to provide the report. So I 19 don't know if he used -- he may have used [REDACTED] but I 20 don't know off the top of my head which program he 21 used. 22 Q. And as a result of the report from the

Transcript of Neil Bacon
Conducted on January 15, 2025

38 (149 to 152)

49

CERTIFICATE OF COURT REPORTER

I, Alan H. Brock, Registered Diplomat

Reporter and Notary Public, the officer before whom
the foregoing deposition was taken, do hereby certify
that the foregoing transcript is a true and correct
record of the testimony given; that said testimony was
taken by me stenographically and thereafter reduced to
typewriting under my supervision; that reading and
signing was not requested; and that I am neither
counsel for nor related to nor employed by any of the
parties to this case and have no interest, financial
or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my
hand and affixed my notarial seal this 15th day of
January, 2025.

My commission expires March 25, 2027.

Alan H. Brock

Alan H. Brock, RDR, CRR

EXHIBIT 27



Planet Depos®
We Make It *Happen™*

Transcript of Scott Lundahl

Date: December 13, 2024

Case: Certain Photodynamic Therapy Systems & Pharmaceutical Products (337-TA-1411)

Planet Depos

Phone: 888.433.3767 | **Email:** transcripts@planetdepos.com

www.planetdepos.com

Michigan #8598 | Nevada #089F | New Mexico #566

[REDACTED]

Transcript of Scott Lundahl
Conducted on December 13, 2024

19 (73 to 76)

73 1 Q Do you know anything about the role that 2 ODIC played? 3 A I don't. I don't, other than the fact 4 that they existed. 5 Q And was another consultant that was 6 involved a company called [REDACTED]? 7 A Yes. 8 Q And that company is -- is that company 9 now known as [REDACTED]? 10 A Yes. Yes. 11 Q And did you work directly with [REDACTED]? 12 A Yes, they were involved in the project 13 when I took over. 14 Q And what role did they play? 15 A Their job was to implement what the 16 inventors wanted in terms of the light source and 17 the invention. And as I mentioned, they had 18 already created a prototype. Their job continued 19 to be, you know, additional prototypes, 20 improvement in certain aspects of the device 21 relative to things like, you know, wheel motion 22 and, you know, things like that.	75 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 Q If you could turn to Slide 10. It's 9 labeled 16129 at the bottom. 10 A Yes. 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]
74 1 Q Did they provide any input on the 2 patent -- patents? 3 A I don't know. 4 Q So why don't I turn you to Tab 23 in your 5 binder. 6 MR. LANDMON: And I would ask that that 7 be marked as Exhibit 7. 8 (Lundahl Deposition Exhibit 7 marked for 9 identification and is attached to the transcript.) 10 A Okay, Tab 23. Just for reference, that's 11 0016120 starting? 12 Q Great. 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 Q Correct. If you turn to slide -- it's 18 Slide Number 6. At the bottom it's labeled 16125. 19 A Yes. 20 [REDACTED] 21 [REDACTED] 22 [REDACTED]	76 1 [REDACTED] 2 [REDACTED] 3 MS. CHEN: Objection. Lacks foundation. 4 Lacks personal knowledge. Calls for speculation. 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 Q Do you recall ever receiving anything 19 from Continuum relating to the patents? 20 A I don't recall receiving anything related 21 to that. 22 Q If you had, would that have been

93

1 **that, but ...**
2 Q Do you have any definition of that?
3 A **My personal definition of that would be**
4 **also a dermatologist who does a lot of cosmetic**
5 **work as well.**
6 Q And for the new device -- well, when do
7 you plan to have it out on the market?
8 A **Our planned launch date is April of '25.**
9 Q And you say "planned launch date." What
10 needs to happen to ensure that it's launched in
11 April '25?
12 A **At this point in time we have to submit**
13 **the final PMA application with FDA.**
14 Q What's a PMA application?
15 A **Premarket approval.**
16 Q And then what does FDA need to do with
17 that?
18 A **In our particular situation FDA granted**
19 **us what is known as a real-time review. And so**
20 **that's basically a technical summary of all the**
21 **optical equivalence data that we have on the model**
22 **4170E, the new light, which FDA will review**

94

1 **rapidly and call a meeting and give us feedback as**
2 **to whether they're going to approve it or not.**
3 Q And what is FDA looking for when they
4 look at that data?
5 A **They're looking for optical equivalence,**
6 **do we meet the same optical performance**
7 **specifications as the current light.**
8 Q Have you submitted any of that data yet
9 to FDA?
10 A **Some of that data was submitted, yes.**
11 Q Can we turn to Tab 62 in your binder.
12 MR. LANDMON: And I am going to ask that
13 Tab 62 be marked Exhibit 11.
14 (Lundahl Deposition Exhibit 11 marked for
15 identification and is attached to the transcript.)
16 Q This document is labeled at the bottom
17 168467.
18 A **Yes, I have it.**
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

95

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 Q And it's possible that FDA doesn't
22 approve it. Correct?

96

1 A **That is possible.**
2 Q Is all of the data ready to be submitted,
3 or are you still collecting data?
4 A **We have all the data at this point.**
5 Q Why hasn't the PMA been filed?
6 A **Resource limitations, primarily me.**
7 **So, you know, there are numerous portions**
8 **to a PMA supplement like this, many of which don't**
9 **have anything to do with data, more regulatory**
10 **oriented. And I just have not had time to**
11 **assemble the document into the proper electronic**
12 **format that FDA requires for submission.**
13 Q Have you reviewed all of the data that's
14 going into it?
15 A **I have.**
16 Q And do you believe that it will meet all
17 of FDA's requirements?
18 A **I do.**
19 Q Other than just assembling it -- and I
20 don't want to use the word "just" to diminish the
21 amount of work that has to go into it. But other
22 than assembling the information, is there any

Transcript of Scott Lundahl
Conducted on December 13, 2024

46 (181 to 184)

8

CERTIFICATE OF SHORTHAND REPORTER NOTARY PUBLIC

2 I, Debra Ann Whitehead, E Notary Public in and for
3 the Commonwealth of Virginia, the officer before
4 whom the foregoing proceedings were taken, do hereby
5 certify that the foregoing transcript is a true and
6 correct record of the proceedings; that said
7 proceedings were taken by me stenographically and
8 thereafter reduced to typewriting under my
9 supervision; that reading and signing was not
0 discussed; and that I am neither counsel for,
related to, nor employed by any of the parties to
2 this case and have no interest, financial or
3 otherwise, in its outcome

4 IN WITNESS WHEREOF, I have hereunto set my hand and
5 affixed my notarial seal this 26th day of December,
6 2024

7 My commission expires:

8 October 3 , 2027

9 *Debra Ann Whitehead*
20

2 E NOTARY PUBLIC IN AND FOR THE
22 COMMONWEALTH OF VIRGINIA

EXHIBIT 56

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

**DECLARATION OF ZVI ALBERT IN SUPPORT OF COMPLAINANT'S MOTION
FOR SUMMARY DETERMINATION ON SATISFACTION OF THE ECONOMIC
PRONG OF DOMESTIC INDUSTRY**

I, Zvi Albert, hereby declare, in accordance with 19 C.F.R. §§ 210.4 and 210.12(a) as follows:

1. I am the Chief Financial Officer (CFO) at Complainant Sun Pharmaceutical Industries, Inc. ("Sun Pharma"). I have been employed by Sun Pharma in my current position since August 2015. As CFO, I have knowledge regarding the financial information related to certain products designed and sold by Sun Pharma in the United States.
2. I submit this declaration in support of Sun Pharma's Motion for Summary Determination on Satisfaction of the Economic Prong of Domestic Industry. The information stated herein is either within my personal knowledge or has been assembled at my direction by authorized employees of Sun Pharma.

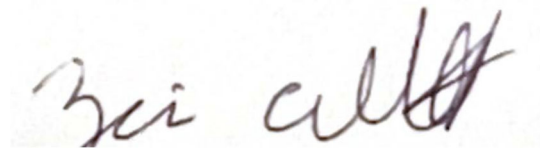
3. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
4. Sun Pharma has paid [REDACTED], for quality assurance work for the BLU-U® 4170E device. [REDACTED] is located in Beverly, Massachusetts, and all the work performed by [REDACTED] was carried out in the United States. [REDACTED]

- [REDACTED]
5. Sun Pharma paid [REDACTED], who does business as [REDACTED] and [REDACTED], for regulatory support for preparation and submission of the 510(k) and Pre-Market Approval applications to the Food and Drug Administration (“FDA”), in the following amounts:

- [REDACTED]
6. Sun Pharma paid [REDACTED], who does business as [REDACTED], for regulatory consulting services for the BLU-U® 4170E, the following amounts:

I declare, under penalty of perjury, under the laws of the United States of America, that the foregoing is true and correct.

Executed on May 1, 2025 in Princeton, NJ.

A handwritten signature in dark ink, appearing to read "Zvi Albert", with a stylized, cursive script.

Zvi Albert
Chief Financial Officer
Sun Pharmaceutical Industries, Inc.

**EXHIBITS 7 THROUGH 8
ARE REDACTED IN
ENTIRETY**

**EXHIBITS 19 THROUGH 25 ARE
REDACTED IN ENTIRETY**

**EXHIBITS 28 THROUGH 32 ARE
REDACTED IN ENTIRETY**

**EXHIBITS 34 THROUGH 46 ARE
REDACTED IN ENTIRETY**

**EXHIBITS 48 THROUGH 55
ARE REDACTED IN ENTIRETY**