UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH,
BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG
Petitioner

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner

Case IPR2025-00287

U.S. Patent No. 11,446,512

DECLARATION OF THOMAS D. VANDER VEEN, PH.D.

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I. INTRODUCTION

I, Thomas D. Vander Veen, hereby declare under penalty of perjury under the laws of the United States of America as follows:

1. I am Managing Director at Epsilon Economics, an economic consulting firm. I specialize in the application of economics to intellectual property, international trade, and complex commercial disputes.

2. I have a Ph.D. in economics from Brown University. As a consultant or expert witness, I have performed economic analyses in a variety of commercial litigation engagements, including numerous matters involving patent infringement, as well as breach of contract claims, misappropriation of trade secrets, copyright infringement, and trademark infringement. I have served as an economic expert in matters in the U.S. Courts, before the U.S. International Trade Commission, and before the U.S. Patent Trial and Appeal Board. I have also provided business consulting services related to intellectual property valuation and licensing and to the valuation of intra-company transactions. I co-developed a course and taught advanced courses on intellectual property valuation at the Licensing Executives Society, the leading professional organization for intellectual property valuation and licensing.

3. I served as an economist on the staff of Commissioner Koplan, the former Chairman and Commissioner of the U.S. International Trade Commission. In this role, I analyzed financial, trade, and industry information, and assisted Commissioner Koplan in reaching his determinations in international trade litigation matters before the Commission. Prior to my service at the U.S. International Trade Commission, I was an assistant professor of economics at Skidmore College. I have also served as an Adjunct Professor in the Department of Industrial Engineering and Management Sciences at Northwestern University, where I taught economics and finance. I am a member of the American Economic Association and the Licensing Executives Society, and an associate member of the International Trade Commission Trial Lawyers Association. I also served as a member of the International Trade Commission Committee of the Intellectual Property Owners Association.

4. A copy of my curriculum vitae is attached as Appendix A. Epsilon Economics bills $875 per hour for my work on this matter. No part of any compensation to Epsilon Economics for work in this matter is affected by the results of this matter. I also have been assisted by my team at Epsilon Economics.

II. ASSIGNMENT

5. I have been retained by counsel for Sun Pharmaceutical Industries, Inc. ("Sun Pharma") to provide economic analysis related to certain claims brought by Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and

Biofrontera AG (collectively, "Biofrontera") against Sun Pharma. Specifically, I have been asked to provide analysis and my opinions regarding certain purported secondary considerations of non-obviousness related to claims 1, 3, 5, 8, 17, 18, and 20 of U.S. Patent No. 11,446,512 (Exhibit 1001 or "the '512 Patent"). I have personal knowledge of the facts and opinions set forth in this declaration and believe them to be true. If called upon, I would testify competently thereto. I have been warned that willful false statements and the like are punishable by fine or imprisonment, or both.

6. In the course of conducting my analysis, I have reviewed various documents, including declarations, business documents, sales, advertising and promotional data, as well as publicly available information, and I have spoken with Sun Pharma's technical expert, Dr. Nan Jokerst. For the exhibits that I have introduced, these are the types of documents that experts in my field would reasonably rely upon when forming their opinions. A list of materials that I have considered in forming the opinions set forth in this declaration is attached as Appendix B.

III. SUMMARY OF OPINIONS

7. Based on my analysis of the documents and other information produced in this matter, and on my education and experience, I have reached the conclusion that the commercial success of Biofrontera's products that practice the claims of

the ’512 Patent, including the RhodoLED® XL, is the result of the features claimed in the claims of the ’512 Patent. The economic evidence indicates that the claimed features and benefits enabled by the claims of the ’512 Patent have directly contributed to the commercial success of the RhodoLED® XL embodying the claims of the ’512 Patent.

IV. BASES FOR OPINIONS

A. Background

i. Parties

8. Sun Pharma is a corporation organized under the laws of Delaware, having its principal place of business in Princeton, New Jersey.[1] Sun Pharma is the assignee and sole owner of the ’512 Patent.[2] Sun Pharma designs, markets, and sells photodynamic therapy systems, including the BLU-U® Blue Light Photodynamic Therapy Illuminator device, as well as pharmaceutical products, including the Levulan® prescription medicine, used in combination with the BLU-U® Blue Light Photodynamic Therapy Illuminator device.[3]

9. Founded in 2015, Biofrontera Inc. is a biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy (“PDT”) and

[1] Exhibit 1020 – 6-25-2024 ITC Verified Complaint at ¶ 9.
[2] Exhibit 1020 – 6-25-2024 ITC Verified Complaint at ¶ 10.
[3] Exhibit 1020 – 6-25-2024 ITC Verified Complaint at ¶ 11.

topical antibiotics.[4] Headquartered in Woburn, Massachusetts, Biofrontera Inc. has approximately 85 employees, about 57% of which are focused on marketing and sales activities.[5]

10. I understand that Biofrontera Pharma GmbH ("Biofrontera Pharma") and Biofrontera Bioscience GmbH ("Biofrontera Bioscience") are related entities to Biofrontera Inc.[6] Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH are located in Germany.[7] Biofrontera AG is a stock corporation organized under the laws of Germany, and the parent company of Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, and Biofrontera Inc.[8]

ii. The '512 Patent

11. The '512 Patent, titled "Adjustable Illuminator for Photodynamic Therapy and Diagnosis," was filed on February 14, 2020 and issued on September 20, 2022.[9] I understand that the '512 Patent relates to "[a]n adjustable illuminator for photodynamically diagnosing or treating a surface [that] includes a plurality of first panels and at least one second panel. The plurality of first panels have wider

[4] Exhibit 2070 - Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023, at page 4.
[5] Exhibit 2070 - Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023, at pages 3-4.
[6] Exhibit 2070 - Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023, at pages 3-4.
[7] Exhibit 2065 - "Biofrontera Bioscience GmbH," <www.medicines.ie>; Exhibit 2071 - "Biofrontera Pharma GmbH," <www.medicines.org.uk>.
[8] Exhibit 2070 - Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023, at pages 3-4.
[9] Exhibit 1001 - U.S. Patent No. 11,446,512.

widths and [] at least one second panel has a narrower width. The narrower width is less than the wider widths. The illuminator further includes a plurality of light sources, each mounted to one of the plurality of first panels or the at least one second panel and configured to irradiate the surface with substantially uniform intensity visible light."[10] The '512 Patent states it is an object of the invention to "provide for a more uniform light distribution in an adjustable illuminator designed for PDT" and "to provide an infinitely adjustable illuminator that can effectively deliver a uniformity of light across various areas of a patient's body….Thus, a uniform light may be delivered to a targeted treatment area regardless of the shape and location of the contoured surface of the patient's body."[11]

iii. Industry Overview

a. Products Practicing the '512 Patent

12. I understand that PDT treatment typically consists of a two-step process: 1) application of a "photosensitizer" medication, and 2) activation of the "photosensitizer" medication by controlled exposure to a selective light source.[12]

13. Currently, the available FDA approved devices for PDT treatment include Sun Pharma's BLU-U® device, Sun Pharma's BLU-U® 4170E device,

[10] Exhibit 1001 - U.S. Patent No. 11,446,512, at Abstract.
[11] Exhibit 1001 - U.S. Patent No. 11,446,512, col. 2, lines 50-62.
[12] Exhibit 2018 - "How to Use Levulan® Kerastick® + BLU-U®," <https://www.levulanhcp.com/how-to-use> ; Exhibit 2055 - 3-20-2025 Biofrontera 10K, at page 5; Exhibit 2074 - "Photodynamic Therapy," Mayo Clinic, < https://www.mayoclinic.org/tests-procedures/photodynamic-therapy/about/pac-20385027>.

Biofrontera's RhodoLED® device, and Biofrontera's RhodoLED® XL device.[13] I understand that these PDT devices are used in combination with prescription medications for the treatment of non-hyperkeratotic actinic keratosis ("AK").[14] I understand that Sun Pharma's BLU-U® devices are FDA approved for use with Sun Pharma's photosensitizer prescription medicine, Levulan®, and Biofrontera's RhodoLED® and RhodoLED® XL devices are FDA approved for use with Biofrontera's photosensitizer prescription medicine, Ameluz®.[15] I understand that Biofrontera's RhodoLED XL device and Sun Pharma's BLU-U® 4170E device are FDA-approved PDT treatment devices that practice the '512 Patent.[16]

14. Prior to the launch of Biofrontera's RhodoLED® XL device, the only two FDA approved PDT devices available were the RhodoLED® and BLU-U® devices.[17] Biofrontera's old device, the RhodoLED®, and Sun Pharma's BLU-U®

[13] Exhibit 2018 - "How to Use Levulan® Kerastick® + BLU-U®," <https://www.levulanhcp.com/how-to-use> ; Exhibit 2077 - "FDA-Approved Red-Light LED Lamp Released for Patients With Actinic Keratosis," AJMC, <https://www.ajmc.com/view/fda-approved-red-light-led-lamp-released-for-patients-with-actinic-keratosis>, June 28, 2024; Exhibit 2079 – FDA Letter Regarding BLU-U Model 4170E, dated May 1, 2025.
[14] Exhibit 2076 - "Why Levulan® Kerastick® + BLU-U®," <https://www.levulan.com/why-levulan-kerastick>; Exhibit 2055 - 3-20-2025 Biofrontera 10K Sun-ITC-0185914, at page 5.
[15] Exhibit 2076 - "Why Levulan® Kerastick® + BLU-U®," <https://www.levulan.com/why-levulan-kerastick>; Exhibit 2055 - 3-20-2025 Biofrontera 10K Sun-ITC-0185914, at page 5; Exhibit 2079 – FDA Letter Regarding BLU-U Model 4170E, dated May 1, 2025.
[16] Exhibit 1020 – 6-25-2024 ITC Verified Complaint, at ¶¶ 12, 50, 63-87, and 92; conversation with Dr. Jokerst.
[17] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp; Exhibit 2039 - Redacted Deposition Transcript of Baldyga in ITC, at pages 138-139.

device do not practice the ’512 Patent.[18] An image of the RhodoLED® is pictured below:[19]

15. Biofrontera launched the RhodoLED® XL in June 2024 and Sun Pharma alleges that the RhodoLED® XL practices the ’512 Patent.[20] I understand that the RhodoLED® XL is differentiated from the original RhodoLED® device in

[18] Exhibit 2018 - “How to Use Levulan® Kerastick® + BLU-U®,” <https://www.levulanhcp.com/how-to-use>; conversation with Dr. Jokerst.
[19] Exhibit 2056 - AMELUZ® and BF-RhodoLED® - us.ameluz.com, at page 3.
[20] Exhibit 1020 – 6-25-2024 ITC Verified Complaint, at ¶¶ 50, 63-87.

that it has adjustable panels and practices the patented features and allows for treatment of larger areas.[21] An image of the RhodoLED® XL is pictured below:[22]

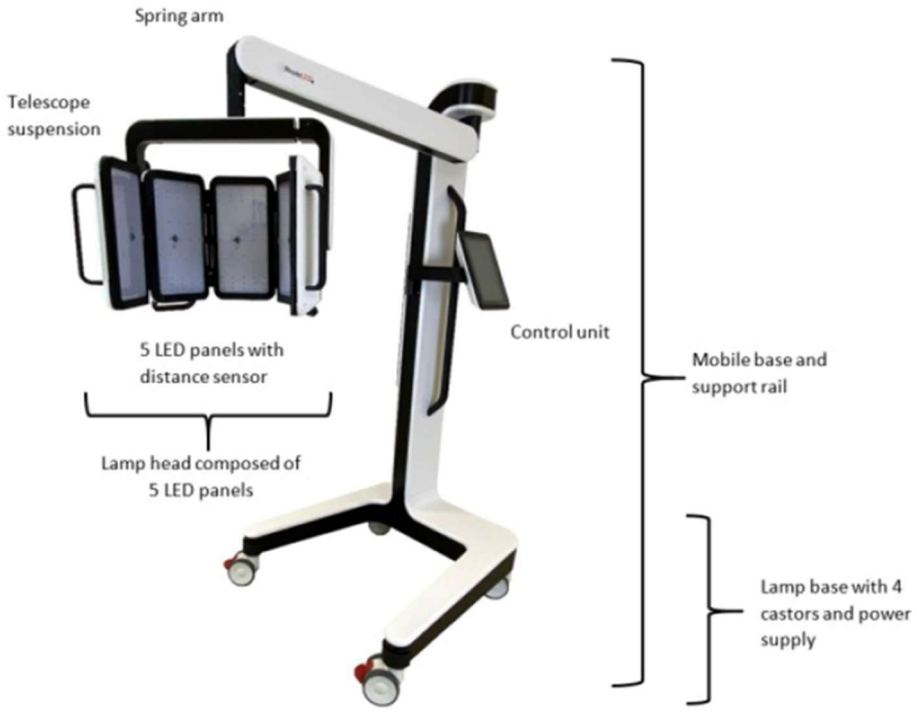

Figure 2: RhodoLED® XL main components

16. I understand that the patented features of the '512 Patent include (1) an adjustable five-panel design, (2) uniform illumination of the treatment surface of a patient, and (3) an LED arrangement that provides for a higher intensity of light emitted proximate the shorter edges of the panels.[23] I understand that the primary differences between the original RhodoLED® and the RhodoLED® XL are the

[21] Exhibit 1020 – 6-25-2024 ITC Verified Complaint, at ¶¶ 50, 63-87; conversation with Dr. Jokerst.
[22] Exhibit 2043 – RhodoLED User Manual Version 1.7 SW_G2, at page 8.
[23] Conversation with Dr. Jokerst.

claimed combination of these patented features.[24] I understand that these features enable the benefit of illumination over a larger treatment area.[25] Specifically, Biofrontera touts this combination of patented features and the benefits enabled by these features in the marketing and sale of its RhodoLED® XL, as discussed below.

b. Overview of PDT Market

17. According to the Cleveland Clinic, approximately 58 million Americans have one or more spots of AK, and it is the most common type of skin precancer.[26] AK can be treated with chemical peels, cryotherapy, excision, or PDT.[27] Patients who are treated with PDT are first provided with a solution applied to the affected areas then treated with light therapy.[28] According to Biofrontera's annual report for the fiscal year ended December 31, 2023, the market size for AK treatment including cryotherapy, topical medications, and PDT totaled approximately $4 billion.[29] Of this, PDT treatment comprised approximately "11% or $500 million of

[24] Conversation with Dr. Jokerst; Exhibit 2046 - 12/23/2024 Article – Biofrontera Announces 100 RhodoLED XL Machines Now Placed in the US Market; Exhibit 2040 – Exhibit 6 to Baldyga Deposition Transcript in ITC, at pages 6-7.
[25] Conversation with Dr. Jokerst.
[26] Exhibit 2062 - "Actinic Keratosis," Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/14148-actinickeratosis, at page 2; Exhibit 2070 - Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023, at page 5.
[27] Exhibit 2062 - "Actinic Keratosis," Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/14148-actinickeratosis, at pages 4-5; Exhibit 2063 - "Actinic Keratosis: Diagnosis and Treatment," American Academy of Dermatology Association, https://www.aad.org/public/diseases/skin-cancer/actinic-keratosistreatment, at pages 2-3.
[28] Exhibit 2062 - "Actinic Keratosis," Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/14148-actinickeratosis, at page 3; Exhibit 2063 - "Actinic Keratosis: Diagnosis and Treatment," American Academy of Dermatology Association, https://www.aad.org/public/diseases/skin-cancer/actinic-keratosistreatment, at page 3.
[29] Exhibit 2070 - Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023, at page 5.

the total AK market" on a revenue basis.[30] However, of AK treatments on a quantity basis, PDT comprises approximately 2%.[31]

18. Other estimates indicate that the overall PDT market size is estimated to reach $4.9 billion in 2025, and could expand to approximately $9.0 billion by 2034.[32] In the U.S., the PDT market size is expected to reach $1.52 billion in 2025 and grow at a compound annual growth rate ("CAGR") of 7.18% over the next ten years.[33] Similar estimates indicate consistent growth trends in the market for PDT due to increasing cancer prevalence.[34] Estimates specific to AK treatment in the U.S., indicate a market size of approximately $2.9 billion in 2023 that is projected to increase to $4.0 billion by 2033.[35]

[30] Exhibit 2070 - Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023, at page 5.
[31] Exhibit 2070 - Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023, at page 5.
[32] Exhibit 2072 - "Photodynamic Therapy Market Size, Share, and Trends 2025 to 2034," Precedence Research, https://www.precedenceresearch.com/photodynamic-therapy-market, at page 1.
[33] Exhibit 2072 - "Photodynamic Therapy Market Size, Share, and Trends 2025 to 2034," Precedence Research, https://www.precedenceresearch.com/photodynamic-therapy-market, at page 2.
[34] Exhibit 2073 - "Photodynamic Therapy Market to Grow by USD 2.35 Billion (2024-2028), Driven by Rising Cancer Prevalence, AI-Powered Report Highlights Market Trends – Technavio," PR Newswire, <https://www.prnewswire.com/news-releases/photodynamic-therapy-market-to-grow-by-usd-2-35-billion-2024-2028-driven-by-rising-cancer-prevalence-ai-powered-report-highlights-market-trends---technavio-302305410.html>, November 14, 2024.
[35] Exhibit 2075 - "U.S. Actinic Keratosis Treatment Market Size Industry Analysis 2033," BioSpace, <https://www.biospace.com/u-s-actinic-keratosis-treatment-market-size-industry-analysis-2033>, April 25, 2024, at page 1.

V. COMMERCIAL SUCCESS

A. Economic Indicia of Commercial Success

19. I understand that when determining whether the claims of a patent are obvious or non-obvious, the following factors are considered:

- the level of ordinary skill in the pertinent art;
- the scope and content of the prior art;
- the differences between the prior art and the claims at issue; and
- secondary considerations such as commercial success, long felt but unsolved needs, and failure of others.[36]

20. With respect to secondary considerations, economists analyze a number of factors to determine whether a product is commercially successful. The essential element of a commercial success analysis in the context of the secondary considerations of non-obviousness is a *nexus* between the claims of the '512 Patent and the success of the product embodying the claims.[37] I understand that when a product is coextensive with the patented invention, nexus is presumed.[38]

21. In the evaluation of any nexus between the commercial performance of a product and the claimed patented features, economists consider a number of factors including sales and market share, advertising and promotion, and price. A

[36] *Graham v. John Deere*, 383 U.S. 1, 17 (1966).
[37] *Ormco Corp. v. Align Techs.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006).
[38] *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019).

commercially successful product is generally differentiated in the marketplace *as a result of* its claimed patented product features.

22. Markets react to innovative products and such market reaction is generally reflected in significant sales and market share. Innovative products also tend to expand the market demand for such products. However, measures of sales, market share, and market expansion must be evaluated within the context of the product and the marketplace, including evaluation of product differentiation, pricing, and marketing and promotion, to assess whether the sales, market share, and/or expansion of the market are a result of the claimed patented features. Without context, it is not possible to determine whether a particular product has had significant sales or any nexus to the claimed patented features of the product.

23. A product that is commercially successful as a result of its claimed patented features also typically commands a price premium as a result of those features. Prices for products generally reflect the economic value added to the consumer. Products that deliver higher functionality compared to existing alternatives in the marketplace—all else being equal—should support a higher price.

24. An analysis of commercial success in the context of non-obviousness should consider the extent to which sales of the product are attributable to advertising and promotion unrelated to the claimed patented features of the product. Economists recognize that producers promote and advertise their products to inform consumers

of the products' features and to differentiate the products in the marketplace. A key issue for an analysis of commercial success is whether advertising and marketing (or other factors)—rather than product differentiation resulting from the claimed patented features—are key drivers of sales. Thus, economists consider the nature of advertising and promotion and the impact on sales in the analysis of commercial success as a result of the claimed patented features.

25. In analyzing the extent to which the patented features contribute to the marketplace success of Biofrontera's RhodoLED® XL, and a nexus between the claims of the '512 Patent and the alleged success of the product, I consider a variety of evidence regarding the importance of these features in driving demand for the product at issue. As described below, the evidence indicates that the features enabled by the patented technology are important drivers of demand for the RhodoLED® XL.

26. In this case, as stated above, I understand from Sun Pharma's technical expert that the features enabled by the '512 Patent include: (1) an adjustable five-panel design, (2) uniform illumination of the treatment surface of a patient, and (3) an LED arrangement that provides for a higher intensity of light emitted proximate the shorter edges of the panels.[39] I understand that these features allow for

[39] Conversation with Dr. Jokerst.

illumination over a larger treatment area and enhanced adjustability of the device.[40] The commercial success of the RhodoLED® XL has a direct nexus to these features.

B. A Nexus Exists Between the '512 Patent Claims and the Commercial Success of the RhodoLED® XL Products

i. Sales of the RhodoLED® XL

27. Biofrontera's sales of the RhodoLED® XL evidence the commercial success of the product as a result of the patented features. Biofrontera began selling RhodoLED® XL in the U.S. in June 2024.[41] In the first week of its launch, Biofrontera placed three devices, and in the first three months, Biofrontera placed approximately 39 devices.[42] In the press release announcing its launch, Biofrontera highlighted the device's "innovative" features, including its five panels, adjustability, and larger treatment area.[43] Specifically, Biofrontera stated in its press release: [44]

> This innovative device represents a significant advancement in the treatment of PDT with state-of-the-art engineering, robust but sleek construction and an intuitive user interface. It is designed to be simple to maneuver and able to accommodate various patient treatment positions

[40] Conversation with Dr. Jokerst.
[41] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp.
[42] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp, at page 1; Exhibit 2069 - "Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial Results and Provides Business Update," <https://www.biospace.com/press-releases/biofrontera-inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update>, November 14, 2024, at page 4.
[43] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp, at page 1.
[44] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lam, at page 1.

> in order to optimize ease of use.... The introduction of the RhodoLED XL provides the option to illuminate a larger area in a single on-label Ameluz PDT treatment…. In comparison to Biofrontera's existing lamp, the RhodoLED XL offers a larger illumination area with five panels compared to one, and additional features such as positioning sensors to ensure the patient receives the optimal energy delivery from the LED array.

28. In this press release, Dr. Luebbert (CEO of Biofrontera, Inc.) stated:[45]

> This new device underscores our commitment to innovation and excellence, providing dermatologists with a powerful tool to deliver superior patient care. The XL lamp's advanced features and user-friendly design will undoubtedly set a new standard in photodynamic therapy…. I'm pleased to say we have already shipped three of these new devices to customers in our first week of launch and the response from dermatology organizations across the US has been very encouraging.

29. Similarly, less than three months after its launch, Biofrontera had sold 39 units of the RhodoLED® XL, whereas it had sold 66 units of the original RhodoLED® in the previous three quarters.[46] In this press release, Biofrontera stated that its Q3 revenues compared to the same period of the prior year increased due to "a higher unit sales price for Ameluz® and a revenue increase in device sales due to the commercial launch of the RhodoLED XL."[47]

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[45] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp, at page 1.
[46] Exhibit 2069 - "Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial Results and Provides Business Update," <https://www.biospace.com/press-releases/biofrontera-inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update>, November 14, 2024, at page 1.
[47] Exhibit 2069 - "Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial Results and Provides Business Update," <https://www.biospace.com/press-releases/biofrontera-inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update>, November 14, 2024, at page 2.

30. By the end of 2024, Biofrontera had sold 100 units of the RhodoLED® XL and 72 units of the RhodoLED®.[48] Biofrontera attributed its nearly 10% revenue increase in 2024 compared to 2023 to "increases in Ameluz® sales volume and unit price, and the successful launch of our RhodoLED® XL Lamp."[49] Biofrontera also stated that it had placed 52 RhodoLED® XL lamps in Q4 2024.[50] Dr. Luebbert stated in this press release, "We are encouraged by the sales of the RhodoLED® XL lamp which is a considerable advance over previous FDA-approved Photodynamic Therapy devices."[51] Biofrontera's 10-K for the fiscal year 2024 also states that the RhodoLED® XL lamp "enables the illumination of larger areas, thus allowing the simultaneous treatment of several actinic keratoses distant from each other."[52] In its 10-K, Biofrontera stated that it sold $1.1 million of the RhodoLED® XL in 2024.[53]

31. Biofrontera's sales of 100 units in less than 6 months evidences the commercial success of the RhodoLED® XL in the context of Biofrontera's sales of the original RhodoLED device, which is not asserted to practice the '512 Patent. As stated above, prior to the launch of Biofrontera's RhodoLED® XL device, the only two FDA approved PDT devices available were the RhodoLED® and BLU-U®

[48] Exhibit 2047 - 3-21-2025 Biofrontera Inc. Reports Record Fiscal Year 2024, at page 1.
[49] Exhibit 2047 - 3-21-2025 Biofrontera Inc. Reports Record Fiscal Year 2024, at page 1.
[50] Exhibit 2047 - 3-21-2025 Biofrontera Inc. Reports Record Fiscal Year 2024, at page 1.
[51] Exhibit 2047 - 3-21-2025 Biofrontera Inc. Reports Record Fiscal Year 2024, at page 2.
[52] Exhibit 2055 - 3-20-2025 Biofrontera 10K Sun-ITC-0185914, at page 6.
[53] Exhibit 2055 - 3-20-2025 Biofrontera 10K Sun-ITC-0185914, at page 51.

devices.[54] Biofrontera launched the original RhodoLED® in 2016 and has been selling it in the U.S. since that time.[55] After Biofrontera launched the RhodoLED® XL in June of 2024, its sales of this product increased rapidly, surpassing quarterly sales of the older, established, RhodoLED® device by six months after its launch:[56] In particular, by the beginning of 2024, the RhodoLED® had been available for sale for more than 7 years. Sales of the RhodoLED® device in 2024 totaled 29 units through Q1 2024, 57 units through Q2, 66 units through Q3, and 72 units through Q4.[57] In contrast, the RhodoLED® XL achieved total sales of between 39 and 48

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[54] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp; Exhibit 2039 - Redacted Deposition Transcript of Baldyga in ITC, at pages 138-139.

[55] Exhibit 2064 - "Biofrontera Announces U.S. FDA Approval of Ameluz® and Activating BF-RhodoLED® Device for Treatment of Actinic Keratosis," Biofrontera News Release, <https://www.biofrontera.com/fileadmin/files/PDFs/Corporate_news/2016/EN/20160511>, May 11, 2016, at pages 1-2.

[56] RhodoLED® cumulative unit sales in 2024 were 29 in Q1, 57 in Q2, 66 in Q3, and 72 in Q4. RhodoLED® XL cumulative unit sales in 2024 were between 39 and 48 in Q3 and 100 in Q4, and total sales in Q4 were 52. From this information, I was able to derive cumulative and quarterly sales for the RhodoLED® and RhodoLED® XL in each quarter of 2024. (Biofrontera sold 3 RhodoLED® XL devices in the first week of its launch in June 2024. Based on information that it sold 100 devices in 2024 and 52 devices in Q4 2024, then it sold 48 devices in Q2 and Q3. Biofrontera's Q3 2024 earnings call states that it sold at least 39 RhodoLED® XL devices in Q3, indicating that it sold up to 9 devices in Q2.) See Exhibit 2047 - 3-21-2025 Biofrontera Inc. Reports Record Fiscal Year 2024, at page 1; Exhibit 2057 - "Biofrontera Inc. (BFRI) Q4 2024 Earnings Call Transcript," <https://seekingalpha.com/article/4769506-biofrontera-inc-bfri-q4-2024-earnings-call-transcript>, March 21, 2025, at page 3 (this document indicates that Biofrontera sold 52 RhodoLED® XL units in Q4 2024 and 100 units in total in 2024. Thus, its cumulative RhodoLED® XL unit sales in Q3 were likely 48) ; Exhibit 2069 - "Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial Results and Provides Business Update," <https://www.biospace.com/press-releases/biofrontera-inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update>, November 14, 2024, at page 1; Exhibit 2066 - "Biofrontera Inc. (BFRI) Q2 2024 Earnings Call Transcript," <https://seekingalpha.com/article/4714932-biofrontera-inc-bfri-q2-2024-earnings-call-transcript>, August 15, 2024, at page 3; Exhibit 2068 - "Biofrontera Inc. Reports First Quarter 2024 Financial Results and Provides a Business Update," <https://www.biospace.com/biofrontera-inc-reports-first-quarter-2024-financial-results-and-provides-a-business-update>, May 15, 2024, at page 2; Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp, at page 1.

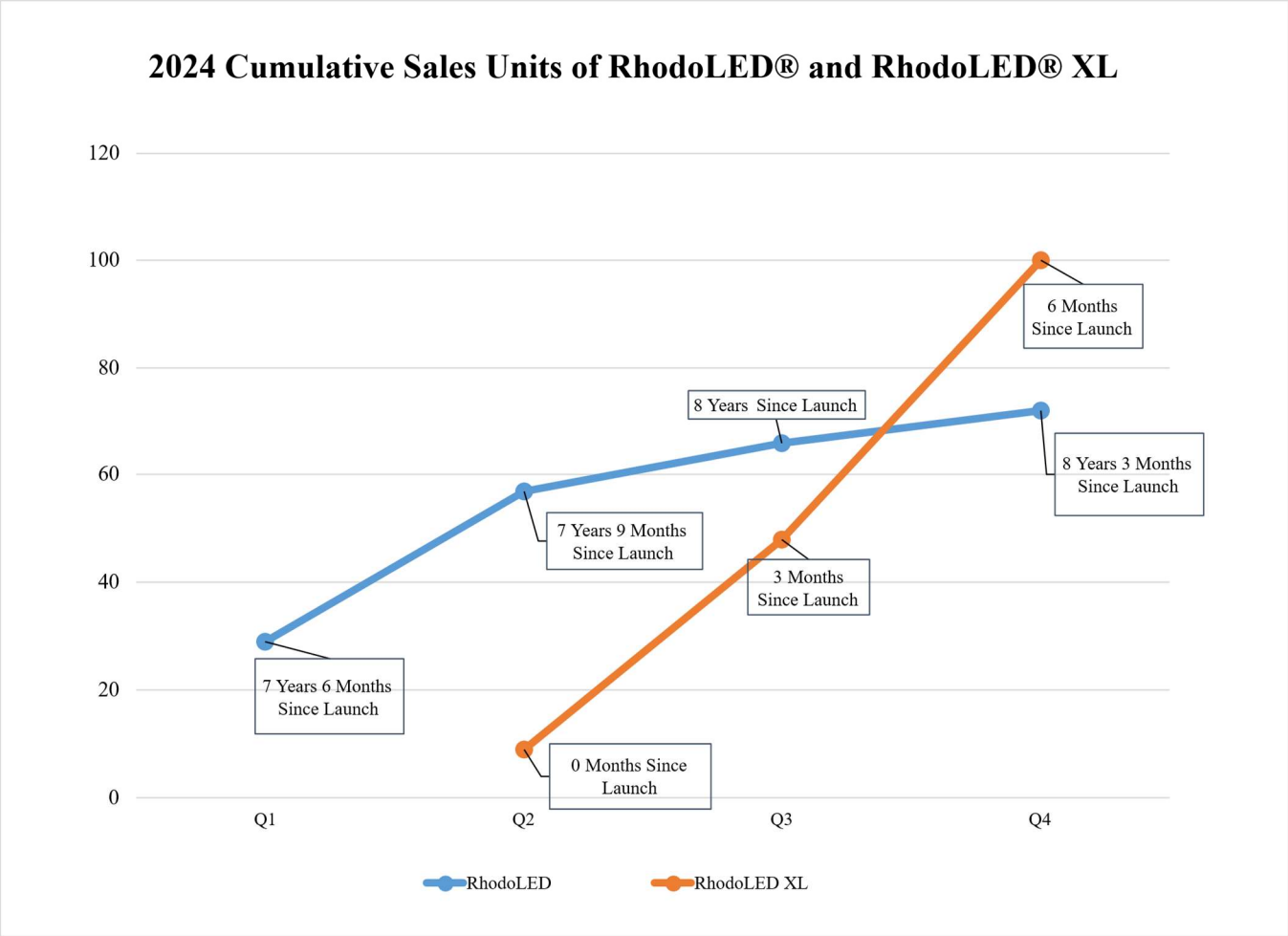
[57] Exhibit 2057 - "Biofrontera Inc. (BFRI) Q4 2024 Earnings Call Transcript," <https://seekingalpha.com/article/4769506-biofrontera-inc-bfri-q4-2024-earnings-call-transcript>, March 21, 2025, at page 3 (this document indicates that Biofrontera sold 52 RhodoLED® XL units in Q4 2024 and 100 units in total in

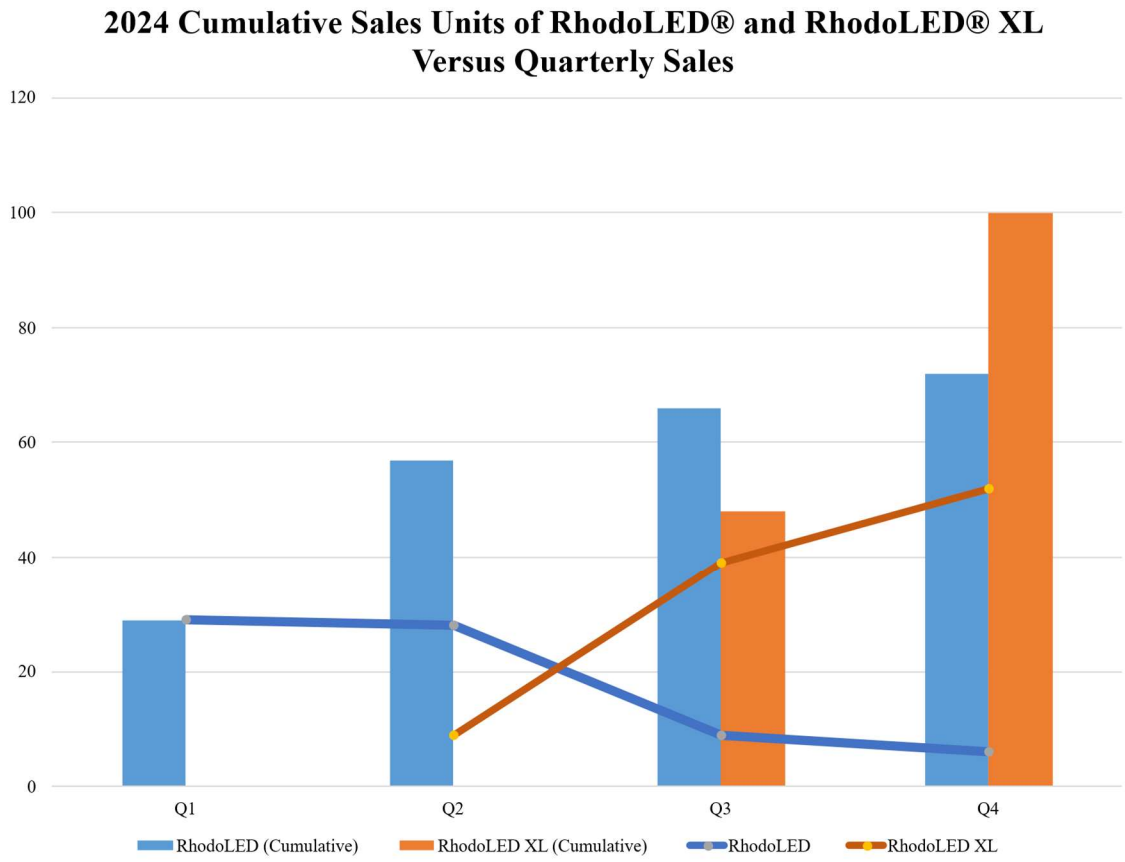
units after its first full quarter of sales, and 100 units by the end of 2024.[58] In other words, the RhodoLED® XL achieved far higher sales in six months than the RhodoLED® achieved in all of 2024. Moreover, in the time period in which both products were on the market, unit sales of the RhodoLED® XL were more than 6 times the unit sales of the RhodoLED® (compare sales of 100 units of the RhodoLED® XL between Q2 2024 and Q4 2024 with total sales of 15 units of the RhodoLED® in that same time period).[59]

2024. Thus, its cumulative RhodoLED® XL unit sales in Q3 were likely 48); Exhibit 2047 - 3-21-2025 Biofrontera Inc. Reports Record Fiscal Year 2024, at page 1; Exhibit 2069 - "Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial results and Provides Business Update," <https://www.biospace.com/press-releases/biofrontera-inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update>, November 14, 2024, at page 1; Exhibit 2066 - "Biofrontera Inc. (BFRI) Q2 2024 Earnings Call Transcript," <https://seekingalpha.com/article/4714932-biofrontera-inc-bfri-q2-2024-earnings-call-transcript>, August 15, 2024, at page 3; Exhibit 2068 - "Biofrontera Inc. Reports First Quarter 2024 Financial Results and Provides a Business Update," <https://www.biospace.com/biofrontera-inc-reports-first-quarter-2024-financial-results-and-provides-a-business-update>, May 15, 2024, at page 2.

[58] Exhibit 2057 - "Biofrontera Inc. (BFRI) Q4 2024 Earnings Call Transcript," <https://seekingalpha.com/article/4769506-biofrontera-inc-bfri-q4-2024-earnings-call-transcript>, March 21, 2025, at page 3 (this document indicates that Biofrontera sold 52 RhodoLED® XL units in Q4 2024 and 100 units in total in 2024. Thus, its cumulative RhodoLED® XL unit sales in Q3 were likely 48); Exhibit 2069 - "Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial Results and Provides Business Update," <https://www.biospace.com/press-releases/biofrontera-inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update>, November 14, 2024, at page 1.

[59] Exhibit 2057 - "Biofrontera Inc. (BFRI) Q4 2024 Earnings Call Transcript," <https://seekingalpha.com/article/4769506-biofrontera-inc-bfri-q4-2024-earnings-call-transcript>, March 21, 2025, at page 3 (this document indicates that Biofrontera sold 52 RhodoLED® XL units in Q4 2024 and 100 units in total in 2024. Thus, its cumulative RhodoLED® XL unit sales in Q3 were likely 48) ; Exhibit 2069 - "Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial Results and Provides Business Update," <https://www.biospace.com/press-releases/biofrontera-inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update>, November 14, 2024, at page 1; Exhibit 2066 - "Biofrontera Inc. (BFRI) Q2 2024 Earnings Call Transcript," <https://seekingalpha.com/article/4714932-biofrontera-inc-bfri-q2-2024-earnings-call-transcript>, August 15, 2024,at page 3; Exhibit 2068 - "Biofrontera Inc. Reports First Quarter 2024 Financial Results and Provides a Business Update," <https://www.biospace.com/biofrontera-inc-reports-first-quarter-2024-financial-results-and-provides-a-business-update>, May 15, 2024, at page 2.


2024 Cumulative Sales Units of RhodoLED® and RhodoLED® XL
120
100
80
60
40
20
0
Q1
Q2
Q3
Q4
7 Years 6 Months Since Launch
7 Years 9 Months Since Launch
8 Years Since Launch
8 Years 3 Months Since Launch
0 Months Since Launch
3 Months Since Launch
6 Months Since Launch
RhodoLED
RhodoLED XL



32. Even further underscoring the significance of the RhodoLED® XL sales in the first 6 months of launch, Biofrontera sold 66 units of the RhodoLED® device in the full year 2022 and 123 units in the full year 2023.[60] Thus, Biofrontera's sales of 100 units of the RhodoLED® XL device from June 10 to December 31, 2024 (approximately 178 units annualized) are significant in the context of its total annual sales of the prior device for the previous two years.[61]

[60] Exhibit 2067 - "Biofrontera Inc. (NASDAQ: BFRI) Q4 2023 Earnings Call Transcript," <https://finance.yahoo.com/news/biofrontera-inc-nasdaq-bfri-q4- 132209594.html>, March 19, 2024, at pages 2-3.
[61] Exhibit 2057 - "Biofrontera Inc. (BFRI) Q4 2024 Earnings Call Transcript," <https://seekingalpha.com/article/4769506-biofrontera-inc-bfri-q4-2024-earnings-call-transcript>, March 21, 2025, at page 3.

33. Additionally, one analyst report indicates that the commercial launch of RhodoLED® XL is, in part, responsible for growing success of the Ameluz® drug.[62] As stated by Dr. Jonathan Aschoff, "revenue growth should continue to benefit from an improved competitive position for Ameluz, which is partly due to the commercial launch of the larger RhodoLED® XL lamp last quarter.…"[63] Moreover, this analyst report describes a "favorable shift towards larger lamp sales" for Biofrontera from the first half of 2024 to the third quarter of 2024.[64] I understand that Ameluz® is used with either the RhodoLED® or the RhodoLED® XL.[65] Since sales of RhodoLED® XL have exceeded RhodoLED®, as discussed above, this incrementally higher level of sales of RhodoLED® XL compared to RhodoLED® must be the result of the novel features of the RhodoLED® XL compared to the RhodoLED®. Since both products are used with Ameluz, the increase in sales of the RhodoLED® XL compared to the RhodoLED® cannot be the result of Ameluz®.

ii. Price Premium

34. As further evidence of the RhodoLED® XL's commercial success as a result of the patented features, this device holds a significant price premium over the

[62] Exhibit 2078 - ROTH MKM, Biofrontera, Inc, "BFRI 3Q24: Hurricane Milton Impacted 3Q Revs, But 4Q Is Already Compensating," Jonathan Aschoff, Ph.D., November 14, 2024, at page 1.
[63] Exhibit 2078 - ROTH MKM, Biofrontera, Inc, "BFRI 3Q24: Hurricane Milton Impacted 3Q Revs, But 4Q Is Already Compensating," Jonathan Aschoff, Ph.D., November 14, 2024, at page 1.
[64] Exhibit 2078 - ROTH MKM, Biofrontera, Inc, "BFRI 3Q24: Hurricane Milton Impacted 3Q Revs, But 4Q Is Already Compensating," Jonathan Aschoff, Ph.D., November 14, 2024, at page 1.
[65] Conversation with Dr. Jokerst; Exhibit 2056 - AMELUZ® and BF-RhodoLED® - us.ameluz.com.

non-patented RhodoLED® device. For example, Mr. Baldyga testified that "part of the justification for the higher price of the" RhodoLED® XL over the original RhodoLED® is "that the difference between the XL and the original lamp is the XL has five panels, the original lamp has one panel."[66] He also testified that the original RhodoLED® device sells for approximately $7,500, while the current "market price" of the new RhodoLED® XL is $18,500.[67] Even accounting for potential discounts or other factors impacting the price of the RhodoLED® XL, it still commands a significant price premium over the non-patented device. According to Biofrontera's 10-K for fiscal year 2024, its revenues for the RhodoLED® XL totaled $1.1 million in 2024.[68] Similarly, Biofrontera sold approximately 100 units of the RhodoLED® XL in 2024, implying an average selling price of approximately $11,000 per device.[69] Biofrontera's significant quantity sales increase of the RhodoLED® XL compared to the RhodoLED®, despite the patented device being nearly 2.5 times the price of the non-patented device, underscores the commercial success of the RhodoLED® XL as a result of the patented features.[70]

35. The price premium for the RhodoLED® XL device is largely due to these patented features. As stated above, I understand that the primary differences

[66] Exhibit 2039 - Redacted Deposition Transcript of Baldyga in ITC, at pages 56-57.
[67] Exhibit 2039 - Redacted Deposition Transcript of Baldyga in ITC, at pages 91 and 114.
[68] Exhibit 2055 - 3-20-2025 Biofrontera 10K Sun-ITC-0185914, at page 51.
[69] Exhibit 2055 - 3-20-2025 Biofrontera 10K Sun-ITC-0185914, at page 51; Exhibit 2047 - 3-21-2025 Biofrontera Inc. Reports Record Fiscal Year 2024, at page 1.
[70] 2.47 = $18,500 / $7,500.

between the original RhodoLED® and the RhodoLED® XL are the features enabled by the '512 Patent, including (1) an adjustable five-panel design, (2) uniform illumination of the treatment surface of a patient, and (3) an LED arrangement that provides for a higher intensity of light emitted proximate the shorter edges of the panels.[71] I understand that these features enable the benefit of illumination over a larger treatment area.[72] Biofrontera's continued sales of the RhodoLED® XL at a higher price point than its RhodoLED® device is indicative of the patented features driving the RhodoLED® XL's commercial success.

36. I also understand from Dr. Heather Roberts that devices like the RhodoLED® XL are considered large capital expenditures for dermatology practices.[73] An interested practice would not make the decision to purchase a significantly more expensive PDT lamp unless the benefits of that lamp over the older devices were significant.[74]

iii. Deposition Testimony and Marketing Materials

37. As stated above, I understand that the primary differences between the original RhodoLED® and the RhodoLED® XL are the features enabled by the '512 Patent, including (1) an adjustable five-panel design, (2) uniform illumination of the

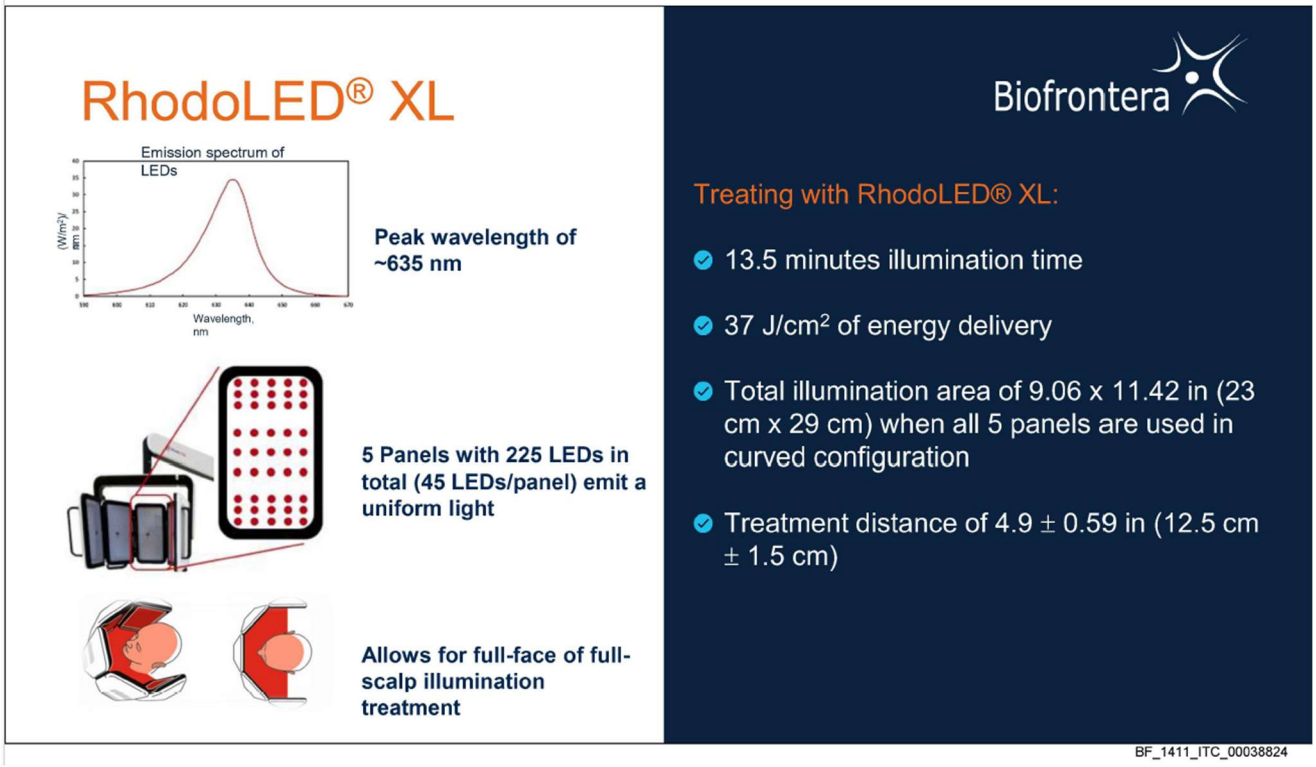
[71] Conversation with Dr. Jokerst; Exhibit 2046 - 12/23/2024 Article – Biofrontera Announces 100 RhodoLED XL Machines Now Placed in the US Market; Exhibit 2040 – Exhibit 6 to Baldyga Deposition Transcript in ITC case, at page 7.
[72] Conversation with Dr. Jokerst.
[73] Exhibit 2015 – Declaration of Heather J. Roberts, M.D., FAAD, at ⁋42.
[74] Exhibit 2015 – Declaration of Heather J. Roberts, M.D., FAAD, at ⁋42.

treatment surface of a patient, and (3) an LED arrangement that provides for a higher intensity of light emitted proximate the shorter edges of the panels.[75] I understand that these features enable the benefit of illumination over a larger treatment area.[76] The commercial success of the RhodoLED® XL has a direct nexus to the cumulative effect of these features.[77] In fact, I understand that the RhodoLED® XL device is coextensive with the claims of the '512 Patent.[78] Evidence from marketing documents and deposition testimony provided by Biofrontera witnesses indicates the commercial success of the patented features of the RhodoLED® XL.

38. For example, according to Mr. Baldyga, the five panels of the RhodoLED® XL are different from the original RhodoLED® device and allow for a larger illumination area.[79] Mr. Baldyga testified that he has received feedback from healthcare providers that "they like having the five panels versus the one panel" because "you can treat a patient's full face with one treatment. On our original lamp, you cannot do that."[80] Mr. Baldyga further testified that the marketing materials for the RhodoLED® XL advertise the particular LED arrangement used on the device: "another one of the features that was advertised with the customer was that the

[75] Conversation with Dr. Jokerst; Exhibit 2046 - 12/23/2024 Article – Biofrontera Announces 100 RhodoLED XL Machines Now Placed in the US Market; Exhibit 2040 – Exhibit 6 to Baldyga Deposition Transcript in ITC, at page 7.
[76] Conversation with Dr. Jokerst.
[77] Conversation with Dr. Jokerst.
[78] Conversation with Dr. Jokerst.
[79] Exhibit 2039 - Redacted Deposition Transcript of Baldyga in ITC, at pages 48-49.
[80] Exhibit 2039 - Redacted Deposition Transcript of Baldyga in ITC, at pages 58-59.

RhodoLED XL includes five panels with this particular LED arrangement that we see here."[81] The same marketing materials explain that the RhodoLED® XL includes "5 Panels" that "emit a uniform light" and "allows for full-face o[r] full-scalp illumination treatment."[82]



39. Those benefits are also stressed in Biofrontera's documents. For example, the User Manual for the RhodoLED® XL explains how the RhodoLED® XL emits a "uniform, visible red light."[83] The User Manual includes Figure 1, which shows the "LED panels with LED distribution."[84] The User Manual stresses the

[81] Exhibit 2039 - Redacted Deposition Transcript of Baldyga in ITC, at pages 44-45 (discussing Exhibit 2040 – Exhibit 6 to Baldyga Deposition Transcript in ITC, at page 7).
[82] Exhibit 2040 – Exhibit 6 to Baldyga Deposition Transcript in ITC, at page 7.
[83] Exhibit 2043 - RhodoLED User Manual Version 1.7 SW_G2, at page 7.
[84] Exhibit 2043 - RhodoLED User Manual Version 1.7 SW_G2, at page 7.

importance of that LED distribution: "The LEDS are distributed on each panel in a specific way (see Figure 1), such that they are more densely packed towards the upper and lower edges than in the center region of each panel. This distribution optimizes the homogeneity of illumination over the treated skin."[85] The User Manual further explains how the illumination area of the RhodoLED® XL "usually allows for a full-face illumination" and includes a graphic showing all five panels illuminating a full face.[86]

40. Biofrontera's marketing documentation, press releases, public announcements, and other public information also evidence the commercial success of the RhodoLED® XL device as a result of the patented features, including (1) an adjustable five-panel design, (2) uniform illumination of the treatment surface of a patient, and (3) an LED arrangement that provides for a higher intensity of light emitted proximate the shorter edges of the panels. For example, as stated above, when Biofrontera launched the RhodoLED® XL in the United States, it highlighted the device's "innovative" features, including its five panels, adjustability, and larger treatment area.[87]

[85] Exhibit 2043 - RhodoLED User Manual Version 1.7 SW_G2, at page 7.
[86] Exhibit 2043 - RhodoLED User Manual Version 1.7 SW_G2, at page 17.
[87] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp; Exhibit 2040 – Exhibit 6 to Baldyga Deposition Transcript in ITC, at page 7.

41. Specifically, Biofrontera stated in a press release: [88]

> This innovative device represents a significant advancement in the treatment of PDT with state-of-the-art engineering, robust but sleek construction and an intuitive user interface. It is designed to be simple to maneuver and able to accommodate various patient treatment positions in order to optimize ease of use.... The introduction of the RhodoLED XL provides the option to illuminate a larger area in a single on-label Ameluz PDT treatment…. In comparison to Biofrontera's existing lamp, the RhodoLED XL offers a larger illumination area with five panels compared to one, and additional features such as positioning sensors to ensure the patient receives the optimal energy delivery from the LED array.

42. Biofrontera's first customers of RhodoLED® XL in the U.S. claimed that "[t]he advanced features and versatility of this device represent a considerable upgrade on what has been available until now and will allow us to provide our patients with the highest standard of care."[89]

43. More recently, Biofrontera has publicly discussed the commercial success of the RhodoLED® XL device as result of the patented features. According to a statement from December 2024, "Biofrontera started commercial distribution of the RhodoLED XL in June 2024 and has seen rapid uptake in the US market since launch."[90] Biofrontera announced that it had placed the 100th commercial

[88] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp, at page 1.
[89] Exhibit 2045 - 6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp, at page 2.
[90] Exhibit 2046 - 12/23/2024 Article – Biofrontera Inc. Announces 100 RhodoLED XL Machines Now Placed in the US Market, at page 1.

RhodoLED® XL device in the United States market.[91] This announcement further highlighted the patented features, specifically the five paneled design:[92]

> The RhodoLED XL was approved by the FDA for use in combination with Ameluz® in 2022 and was launched in June of this year. Since then, it has seen rapid adoption by offices who had previously used Ameluz and those who are new to the product, with 100 now being installed since launch. The main difference between the company's existing BF-RhodoLED lamp and the new RhodoLED XL is the number of LED panels which allows a larger surface area to be illuminated during a single PDT treatment with Ameluz®.

44. In this announcement, Biofrontera customers also mentioned the benefits attainable as a result of the patented features. One customer stated, "We were thoroughly impressed by the lamp's robust yet elegant design, as well as its exceptional maneuverability and adjustability, which made it ideal for Photodynamic Therapy (PDT) treatments in our offices…. The larger illumination area has significantly increased our patient throughput while also enhancing the overall quality of care and patient experience."[93] Additionally, the announcement notes, "'We are delighted that the RhodoLED XL Lamp has had such an enthusiastic reaction from dermatologists who perform PDT, with more than 10% of offices

[91] Exhibit 2046 -12/23/2024 Article – Biofrontera Inc. Announces 100 RhodoLED XL Machines Now Placed in the US Market, at page 1.
[92] Exhibit 2046 -12/23/2024 Article – Biofrontera Inc. Announces 100 RhodoLED XL Machines Now Placed in the US Market, at page 1.
[93] Exhibit 2046 - 12/23/2024 Article – Biofrontera Inc. Announces 100 RhodoLED XL Machines Now Placed in the US Market, at page 1.

using Ameluz already installing one' said Dr Hermann Luebbert, CEO and Chairman of Biofrontera Inc. 'It is remarkable to have placed this many in such a short span of time post launch, and our customers have been very complimentary about the level of service we have delivered both in the lead up to installation, and with the training and support afterwards.'"[94]

45. Certain of Biofrontera's marketing materials also illustrate and call out the RhodoLED® XL "Lamp head composed of 5 LED panels."[95] Among other features, Biofrontera marketing materials state that "5 Panels with 225 LEDs in total (45 LEDs/panel) emit a uniform light…. Allows for full-face of [sic] full-scalp illumination treatment."[96]

VI. CONCLUSION

46. Based on my analysis of the documents and other information produced in this matter, and on my education and experience, I have reached the conclusion that the commercial success of Biofrontera's products that practice the claims of the '512 Patent, including the RhodoLED® XL, is the result of the features claimed in the claims of the '512 Patent. The economic evidence indicates that the claimed features and benefits enabled by the claims of the '512 Patent have directly

[94] Exhibit 2046 -12/23/2024 Article – Biofrontera Inc. Announces 100 RhodoLED XL Machines Now Placed in the US Market, at page 1.
[95] Exhibit 2040 – Exhibit 6 to Baldyga Deposition Transcript in ITC, at page 6; Exhibit 2039 - Redacted Deposition Transcript of Baldyga in ITC, at pages 45-46.
[96] Exhibit 2040 – Exhibit 6 to Baldyga Deposition Transcript in ITC, at page 7; Exhibit 2039 - Redacted Deposition Transcript of Baldyga in ITC, at pages 45-46.

contributed to the commercial success of the RhodoLED® XL embodying the claims of the ’512 Patent.

47. I reserve the right to supplement my opinions in the future to respond to any arguments that Patent Owner or its expert(s) may raise and to take into account new information as it becomes available to me.

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

5/9/2025
Date

Thomas D. Vander Veen, Ph.D.

APPENDIX A

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Summary

Thomas Vander Veen specializes in the application of economics to intellectual property, international trade, and complex commercial disputes. Dr. Vander Veen has served as an economic expert in U.S. Courts, state courts and before the U.S. International Trade Commission.

His expertise includes valuation of intellectual property; evaluation of economic damages related to patent, copyright and trademark infringement, false advertising, breach of contract, and theft of trade secrets; and economic analysis in section 337 intellectual property matters before the U.S. International Trade Commission. Dr. Vander Veen's analysis of economic damages has included the development and analysis of consumer surveys. His intellectual property experience also includes the evaluation of commercial success of patented products, including in ANDA actions. He has studied market structure, competition, and performance of numerous pharmaceutical products, including pricing, marketing and promotion, and regulatory approval. He has performed economic analysis in numerous industries, including medical devices, pharmaceuticals, consumer retail products, consumer electronic devices, semiconductors, software and automotive products.

Dr. Vander Veen served as the principal economic advisor to a Commissioner, and subsequently the Chairman, of the U.S. International Trade Commission. He has taught economics and finance at Northwestern University and economics at Skidmore College. He served as the Chairman of the Board of Directors of the Chicago Youth Centers. He serves as a Governing Member of the Chicago Symphony Orchestra Association, as a Director of the American Association of Professional Baseball and on the boards of several academic and non-profit institutions.

Education

- Ph.D. (Economics), Brown University, 1998
- M.A. (Economics), Brown University, 1992
- B.A. (Economics and Mathematics), Calvin College, 1990

Professional and Academic Experience

- Epsilon Economics
  Managing Director and Vice Chairman, 2022 – present
  Managing Director and President, 2015 – 2022
- REV Entertainment
  Senior Advisor, 2023 – present
- Northwestern University – McCormick School of Engineering and Applied Science
  Adjunct Lecturer, 2016
- Navigant Economics
  Managing Director and Principal, 2013 – 2015
  Director and Principal, 2010 – 2013
- LECG, LLC
  Senior Managing Economist, 2006 – 2010
- Wheaton College
  Adjunct Instructor of Economics – 2009
- Charles River Associates, Inc. / CRA International, Inc. / InteCap, Inc.
  Associate Principal, 2005 – 2006
  Associate, 2003 – 2005
- U.S. International Trade Commission
  Economist and Advisor to Commissioner Stephen Koplan, 1999 – 2003
- Skidmore College
  Assistant Professor of Economics, 1997 – 1999

Professional Affiliations

- American Economic Association
- Licensing Executives Society
- International Trade Commission Trial Lawyers Association (Associate Member)

Expert Testimony

1. Tesla, Inc. v. **Samsung SDI Co. LTD**
   ICC International Court of Arbitration
   ICC Case No. 27852/PDP

2. *Certain Pre-Stretched Synthetic Braiding Hair and Packaging Therefore*
   JBS Hair, Inc. v. **Mayde Beauty Inc., Shake N Go Fashion, Inc., et al.**
   U.S. International Trade Commission
   Investigation No. 337-TA-1415
   Patent Infringement

3. *Certain Photodynamic Therapy Systems, Components Thereof, and Pharmaceutical Products Used in Combination with The Same*
   Sun Pharmaceutical Industries, Inc. v. Biofrontera Inc., et al.
   U.S. International Trade Commission
   Investigation No. 337-TA-1411
   Patent Infringement

4. *Certain Cameras, Camera Systems, and Accessories Used Therewith*
   GoPro, Inc. v. **Arashi Vision, Inc. and Arashi Vision (U.S.), LLC**
   U.S. International Trade Commission
   Investigation No. 337-TA-1400
   Patent Infringement

5. *Certain Vehicle Telematics, Fleet Management, and Video-Based Safety Systems, Devices, and Components Thereof*
   Samsara Inc. v. **Motive Technologies, Inc.**
   U.S. International Trade Commission
   Investigation No. 337-TA-1393
   Patent Infringement

6. *Certain Computing Devices Utilizing Indexed Search Systems and Components Thereof*
   X1 Discovery, Inc. v. **ASUSTeK Computer Inc., Dell Technologies Inc., et al.**
   U.S. International Trade Commission
   Investigation No. 337-TA-1389
   Patent Infringement

7. *Certain Products Containing Tirzepatide and Products Purporting to Contain Tirzepatide*
   Eli Lilly and Company v. Audrey Beauty Co., et al.
   U.S. International Trade Commission
   Investigation No. 337-TA-1377 (Declaration)
   Trademark Infringement, False Advertising

8. *Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof*
   NJOY LLC v. JUUL Labs, Inc.
   U.S. International Trade Commission
   Investigation No. 337-TA-1372
   Patent Infringement

9. *Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof*
   JUUL Labs, Inc., et al. v. **NJOY LLC, et al.**
   U.S. International Trade Commission
   Investigation No. 337-TA-1368
   Patent Infringement

10. *Certain Semiconductor Devices, and Methods of Manufacturing Same and Products Containing the Same*
    Efficient Power Conversion Corporation v. Innoscience America, Inc., et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1366
    Patent Infringement

11. *Certain Active Matrix Organic Light-Emitting Diode Display Panels and Modules for Mobile Devises, and Components Thereof*
    Samsung Display Co., Ltd. v. Apt-Ability, LLC, Mobile Defenders, LLC, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1351
    Patent Infringement

12. *Certain Dermatological Treatment Devices and Components Thereof*
    Serendia, LLC v. **Lutronic Corporation, et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1356
    Patent Infringement

13. *Certain Video Processing Devices and Products Containing the Same*
    VideoLabs, Inc. v. **HP Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1341
    Patent Infringement

14. Janssen Pharmaceuticals, Inc., et al. v. **Tolmar, Inc.**
    U.S. District Court – District of Delaware
    Case No. 1:21-cv-01784
    Patent Infringement

15. *Certain Bio-Layer Interferometers and Components Thereof*
    Sartorius BioAnalytical Systems, Inc. v. **Gator Bio, Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1344
    Patent Infringement

16. Epistar Corporation v. **Lowe's Companies, Inc. and Lowe's Home Centers, LLC**
    U.S. District Court – Central District of California
    Case No. 2:17-cv-03219 (Damages Retrial)
    Patent Infringement

17. *Certain Video Processing Devices and Products Containing the Same*
    VideoLabs, Inc. v. **ASUSTeK Computer Inc. and ASUS Computer International**
    U.S. International Trade Commission
    Investigation No. 337-TA-1323
    Patent Infringement

18. *Certain Movable Barrier Operator Systems and Components Thereof*
    Overhead Door Corporation and GMI Holdings, Inc v. **The Chamberlain Group, Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1209 (Enforcement Proceeding)
    Patent Infringement

19. *Certain Cellular Base Station Communication Equipment*
    Apple Inc. v. Ericsson Inc., et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1302
    Patent Infringement

20. *Core Orientation Systems*
    Australian Mud Co. Pty Ltd., Reflex USA LLC v. Boart Longyear Group Ltd., et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1309
    Patent Infringement

21. *Certain Playards and Strollers*
    Graco Children's Products Inc., et al. v. Baby Trend, Inc., et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1288
    Patent Infringement

22. *Certain High-Performance Gravity-Fed Water Filters and Products Containing Same*
    Brita LP v. **Zero Technologies LLC and Culligan International Co.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1294
    Patent Infringement

23. *Certain Oil-Vaping Cartridges, Components Thereof, and Products Containing*
    Shenzhen Smoore Technology Limited v. Blinc Group Holdings, LLC, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1286
    Patent Infringement

24. *Certain Flocked Swabs, Products Containing Flocked Swabs, and Methods of Using*
    Copan Industries, Inc., et al. v. **NEST Scientific Inc., et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1279
    Patent Infringement

25. *Certain Video Security Equipment and Systems, Related Software, Components Thereof, and Products Containing Same*
    Avigilon Corporation, Motorola Solutions, Inc., et al. v. Verkada Inc.
    U.S. International Trade Commission
    Investigation No. 337-TA-1281
    Patent Infringement

26. *Certain Replacement Automotive Lamps*
    Kia Corporation and Kia America, Inc. v. **TYC Brother Industrial Co., Ltd.; Genera Corporation; LKQ Corporation; Keystone Automotive Industries, Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1291
    Patent Infringement

27. *Certain Replacement Automotive Lamps*
    Hyundai Motor Company, et al. v. **TYC Brother Industrial Co., Ltd.; Genera Corporation; LKQ Corporation; Keystone Automotive Industries, Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1292
    Patent Infringement

28. *Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*
    AliveCor, Inc. v. **Apple Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1266
    Patent Infringement

29. *Certain Radio Frequency Transmission Devices and Components Thereof*
    Zebra Technologies v. OnAsset Intelligence, Inc.
    U.S. International Trade Commission
    Investigation No. 337-TA-1278
    Patent Infringement

30. *Certain Fitness Devices, Streaming Components Thereof and Systems*
    DISH DBS Corporation, et al. v. iFIT, Inc.; Peloton Interactive, Inc.; et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1265
    Patent Infringement

31. *Certain Portable Battery Jump Starters and Components Thereof*
    The NOCO Company v. **Schumacher Electric Corporation; et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1256
    Patent Infringement

32. *Certain IP Camera Systems Including Video Doorbells and Components Thereof*
    SkyBell Technologies, Inc. et al. v. Vivint Smart Home, Inc.; SimpliSafe, Inc.; et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1242
    Patent Infringement

33. *Certain UMTS and LTE Cellular Communications Modules*
    Koninklijke Philips N.V, et al. v. **Thales DIS AIS USA, LLC, Thales DIA AIS Deutschland GmbH,** et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1240
    Patent Infringement

34. *Certain Radio Frequency Identification Products, Components Therefore, and Products Containing the Same*
    Amtech Systems, LLC v. Kapsch TrafficCom AG, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1234
    Patent Infringement

35. *Certain Shingled Solar Modules, Components Thereof, and Methods for Manufacturing*
    The Solaria Corporation v. **Canadian Solar Inc. and Canadian Solar (USA) Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1223
    Patent Infringement

36. *Certain Artificial Eyelash Extension Systems, Products, and Components Thereof*
    Lashify, Inc. v. **KISS Nail Products, Inc., Ulta Salon, Cosmetics & Fragrance, Inc., Walmart, Inc. and CVS Pharmacy, Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1226
    Patent Infringement

37. Zimmer, Inc., et al. v. **Heraeus Medical LLC, et al.**
    Kosciusko County Superior Court, State of Indiana, Marshall County
    Cause No. 43D01-1802-PL-000021
    Trade Secret Misappropriation, Breach of Contract, Tortious Interference

38. *Certain Variable Speed Wind Turbine Generators and Components Thereof*
    General Electric Company v. **Siemens Gamesa Renewable Energy Inc., et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1218
    Patent Infringement

39. **Shure Incorporated, et al.** v. ClearOne, Inc.
    U.S. District Court – District of Delaware
    Civil Action No. 19-1343-RGA-CJB
    Patent Infringement, False Advertising, Tortious Interference, Unfair Competition

40. Micro Focus (US), Inc., et al. v. **Insurance Services Office, Inc.**
    U.S. District Court – District of Delaware
    Case No. 15-252-RGA
    Breach of Contract, Copyright Infringement

41. *Certain Movable Barrier Operator Systems and Components Thereof*
    Overhead Door Corporation and GMI Holdings, Inc v. **The Chamberlain Group, Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1209
    Patent Infringement

42. **Medline Industries, Inc.** v. C.R. Bard, Inc.
    U.S. District Court – Northern District of Illinois, Eastern Division
    Civil Action No. 1:17-cv-07216
    Patent Infringement

43. Arendi S.A.R.L. v. **LG Electronics, Inc., et al.**
    U.S. District Court – District of Delaware
    Case No. 1:12-cv-01595 (LPS)
    Patent Infringement

44. *Certain Electronic Devices, Including Streaming Players, Televisions, Set Top Boxes, Remote Controllers, and Components Thereof*
    Universal Electronics, Inc. v. **Roku, Inc., et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1200
    Patent Infringement

45. *Certain Chemical Mechanical Planarization Slurries and Components Thereof*
    CMC Materials, Inc. v. DuPont de Nemours, Inc., et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1204
    Patent Infringement

46. *Certain Portable Gaming Console Systems with Attachable Handheld Controllers*
    Gamevice, Inc. v. **Nintendo Co., Ltd. and Nintendo of America, Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1197
    Patent Infringement

47. *Certain Lithium-Ion Battery Cells, Battery Modules, Battery Packs*
    LG Chem, Ltd. and LG Chem Michigan Inc., et al. v. SK Innovation Co., Ltd, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1181
    Patent Infringement

48. *Certain Pouch-Type Battery Cells, Battery Modules, and Battery Packs*
    SK Innovation Co., Ltd, et al. v. **LG Chem, Ltd. and LG Chem Michigan Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1179
    Patent Infringement

49. *Certain Bone Cements and Bone Cement Accessories*
    Zimmer, Inc., et al. v. **Heraeus Medical GmbH and Heraeus Medical LLC**
    U.S. International Trade Commission
    Investigation No. 337-TA-1175
    Trade Secret Misappropriation, False Advertising, Tortious Interference

50. **Medline Industries, Inc.** v. C.R. Bard, Inc.
    U.S. District Court – Northern District of Illinois, Eastern Division
    Civil Action No. 1:16-cv-03529
    Patent Infringement

51. *Certain Wireless Communication Devices and Related Components Thereof*
    Innovation Sciences LLC v. **Resideo Technologies, Inc, HTC Corporation, et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1180
    Patent Infringement

52. ClearOne, Inc. v. **Shure Incorporated**
    U.S. District Court – Northern District of Illinois, Eastern Division
    Civil Action No. 1:17-cv-03078
    Patent Infringement

53. *Certain Laparoscopic Surgical Staplers, Reload Cartridges, and Components Thereof*
    Ethicon LLC, et al. v. **Intuitive Surgical, Inc., et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1167
    Patent Infringement

54. *Certain Foodservice Equipment and Components Thereof*
    Illinois Tool Works Inc., et al. v. **Guangzhou Rebenet Catering Equipment Manufacturing Co., Ltd., et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1166
    Patent Infringement

55. *Certain Vehicle Security and Remote Convenience Systems and Components Thereof*
    DEI Holdings, Inc., Directed, LLC and Directed Electronics Canada Inc. v. Automotive Data Solutions, Inc. and Firstech, LLC
    U.S. International Trade Commission
    Investigation No. 337-TA-1152
    Patent Infringement

56. *Certain Multi-Stage Fuel Vapor Canister Systems and Activated Carbon Components Thereof*
    Ingevity Corp. and Ingevity South Carolina, LLC v. MAHLE Filter Systems North America, Inc., et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1140
    Patent Infringement

57. Automotive Data Solutions, Inc. v. **Directed Electronics Canada Inc., DEI Holdings, Inc. and Directed, LLC**
    U.S. District Court – Central District of California
    No. 2:18-cv-01560-GW
    Patent Infringement, Copyright Infringement, Trade Secret Misappropriation

58. **Medline Industries, Inc.** v. C.R. Bard, Inc.
    U.S. District Court – Northern District of Illinois, Eastern Division
    Civil Action No. 1:14-cv-03618
    Patent Infringement

59. *Certain Unmanned Aerial Vehicles and Components Thereof*
    Autel Robotics USA LLC v. SZ DJI Technology Co. Ltd., DJI Technology Inc., et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1133
    Patent Infringement

60. *Certain Wireless Mesh Networking Products and Related Components Thereof*
    SIPCO LLC v. **Emerson Electric Co.**, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1131
    Patent Infringement

61. *Certain Motorized Vehicles and Components Thereof*
    FCA US LLC v. Mahindra & Mahindra Ltd.; Mahindra Automotive North America, Inc.
    U.S. International Trade Commission
    Investigation No. 337-TA-1132
    Trademark and Trade Dress Infringement

62. *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same*
    Fujifilm Corporation, et al v. Sony Corporation, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1012 (Enforcement Proceeding)
    Patent Infringement

63. Core Wireless Licensing S.A.R.L. v. **LG Electronics, Inc. and LG Electronics Mobilecomm U.S.A., Inc.**
    U.S. District Court – Eastern District of Texas, Marshall Division
    Case No. 2:14-cv-912-JRG-RSP (Damages Retrial)
    Patent Infringement

64. *Certain Microfluidic Systems and Components Thereof and Products Containing Same*
    10X Genomics, Inc. v. Bio-Rad Laboratories, Inc.
    U.S. International Trade Commission
    Investigation No. 337-TA-1100
    Patent Infringement

65. *Certain Memory Modules and Components Thereof, and Products Containing Same*
    Netlist Inc. v. **SK hynix Inc., SK hynix America, Inc. et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1089
    Patent Infringement

66. *Certain Strontium-Rubidium Radioisotope Infusion Systems and Components Thereof Including Generators*
    Bracco Diagnostics Inc. v. **Jubilant DraxImage Inc. et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1110
    Patent Infringement

67. Rick C. Sasso, M.D. v. **Warsaw Orthopedic, Inc., Medtronic, Inc., et al.**
    Plymouth Circuit Court, State of Indiana, Marshall County
    Cause No. 50C01-1806-PL-000027
    Breach of Contract

68. **VIZIO, Inc.** v. Nichia Corporation
    The United States Patent and Trademark Office, Patent Trial and Appeal Board
    Case Nos. IPR2017-01608 and IPR2017-01623
    Patent Review

69. Epistar Corporation v. **Lowe's Companies, Inc. and Lowe's Home Centers, LLC**
    U.S. District Court – Central District of California
    Case No. 2:17-cv-03219
    Patent Infringement

70. *Certain Gas Spring Nailer Products and Components Thereof*
    Kyocera Senco Brands Inc. v. **Hitachi Koki U.S.A., Ltd.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1082
    Patent Infringement

71. *Certain Clidinium Bromide and Products Containing Same*
    Valeant Pharmaceuticals North America LLC et al. v. ECI Pharmaceuticals, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1109
    False Advertising, Unfair Competition

72. Nuance Communications, Inc. et al. v. **Pindrop Security, Inc.**
    U.S. District Court – Eastern District of Virginia, Alexandria Division
    Civil Action No. 1:17cv1193 (CMH/IDD)
    Breach of Contract, Copyright Infringement, Unfair Competition

73. *Certain Batteries and Electrochemical Devices Containing Composite Separators, Components Thereof, and Products Containing the Same*
    LG Chem, Ltd., et al v. Amperex Technology Limited, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1087
    Patent Infringement

74. *Certain Automated Teller Machines, ATM Modules, Components Thereof, and Products Containing the Same*
    Nautilus Hyosung, Inc., et al. v. Diebold Nixdorf, Incorporated, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-989 (Enforcement Proceeding)
    Patent Infringement

75. *Certain Electrochemical Glucose Monitoring Systems and Components Thereof*
    Dexcom, Inc. v. **AgaMatrix, Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1075
    Patent Infringement

76. *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same*
    Fujifilm Corporation, et al v. Sony Corporation, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1076
    Patent Infringement

77. *Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same*
    BiTMICRO, LLC v. **SK hynix Inc., Samsung Semiconductor, Inc. et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1097
    Patent Infringement

78. *Certain Robotic Vacuum Cleaning Devices and Components Thereof*
    iRobot Corporation v. Bissell Homecare, Inc., Hoover, Inc., et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1057
    Patent Infringement

79. *Certain Magnetic Tape Cartridges and Components Thereof*
    Sony Corporation, et al. v. **Fujifilm Corporation, et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1058
    Patent Infringement

80. *Certain Semiconductor Devices and Consumer Audiovisual Products Containing Same*
    Broadcom Corporation v. **MediaTek Inc., MediaTek USA Inc. and MStar Semiconductor Inc.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1047
    Patent Infringement

81. *Certain Digital Cable and Satellite Products, Set-Top Boxes, Gateways, and Components Thereof*
    Sony Corporation, et al. v. **ARRIS International plc, Pace Americas LLC, et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1049
    Patent Infringement

82. *Certain Graphics Systems, Components Thereof, and Consumer Products Containing the Same*
    ATI Technologies ULC, et al. v. **VIZIO, MediaTek Inc., Sigma Designs, Inc., et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1044
    Patent Infringement

83. *Certain Magnetic Tape Cartridges and Components Thereof*
    Sony Corporation, et al. v. **Fujifilm Corporation, et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1036
    Patent Infringement

84. **Huawei Technologies Co. Ltd.** v. T-Mobile US, Inc. and T-Mobile USA, Inc.
    U.S. District Court – Eastern District of Texas, Marshall Division
    Case Nos. 2:16-cv-00052-JRG-RSP, 2:16-cv-00055-JRG-RSP, 2:16-cv-00056-JRG-RSP, and 2:16-cv-00057-JRG-RSP
    Patent Infringement

85. **Amneal Pharmaceuticals, LLC** v. Purdue Pharma L.P., et al.
    The United States Patent and Trademark Office, Patent Trial and Appeal Board
    Case Nos. IPR2016-01027 and IPR2016-01028
    Patent Review

86. *Certain Audio Processing Hardware, Software, and Products Containing the Same*
    Andrea Electronics Corporation v. **Apple Inc., Samsung Electronics Co., Ltd. et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1026
    Patent Infringement

87. *Certain Sleep-Disordered Breathing Treatment Mask Systems*
    ResMed Corp.; ResMed Inc.; et al. v. Fisher & Paykel Healthcare, Inc. et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1022
    Patent Infringement

88. *Certain Memory Modules and Components Thereof*
    Netlist Inc. v. **SK hynix Inc., SK hynix America, Inc. et al.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1023
    Patent Infringement

89. Audio MPEG, Inc. et al. v. **Dell, Inc.**
    U.S. District Court – District of Virginia
    Case No. 2:15-cv-73 (HCM/RJK)
    Patent Infringement

90. *Certain Mobile Electronic Devices Incorporating Haptics*
    Immersion Corporation v. **Apple Inc. and AT&T Mobility LLC**
    U.S. International Trade Commission
    Investigation No. 337-TA-1004/990
    Patent Infringement

91. Nokia Technologies LTD v. **LG Electronics Inc.**
    ICC International Court of Arbitration
    ICC Case No. 22326/EMT/GR

92. *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same*
    Fujifilm Corporation, et al v. Sony Corporation, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-1012
    Patent Infringement

93. *Certain Silicon-On-Insulator Wafers*
    Silicon Genesis Corporation v. **Soitec S.A.**
    U.S. International Trade Commission
    Investigation No. 337-TA-1025
    Patent Infringement

94. *Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*
    ResMed Corp.; ResMed Inc.; and ResMed Ltd. v. BMC Medical Co., Ltd. et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-997
    Patent Infringement

95. *Certain Automated Teller Machines, ATM Modules, Components Thereof, and Products Containing the Same*
    Nautilus Hyosung, Inc., et al. v. Diebold, Incorporated, et al.
    U.S. International Trade Commission
    Investigation No. 337-TA-989
    Patent Infringement

96. Core Wireless Licensing S.A.R.L. v. **LG Electronics, Inc. and LG Electronics Mobilecomm U.S.A., Inc.**
U.S. District Court – Eastern District of Texas, Marshall Division
Case No. 2:14-cv-912-JRG-RSP
Patent Infringement

97. *Certain RF Capable Integrated Circuits and Products Containing the Same*
ParkerVision, Inc. v. **Qualcomm Incorporated; Apple Inc.; LG Electronics, Inc.; Samsung Electronics Co., Ltd.; et al.**
U.S. International Trade Commission
Investigation No. 337-TA-982
Patent Infringement

98. *Certain Automated Teller Machines, ATM Modules, Components Thereof, and Products Containing Same*
Diebold, Incorporated, et al. v. **Nautilus Hyosung, Inc., et al.**
U.S. International Trade Commission
Investigation No. 337-TA-972
Patent Infringement

99. *Certain Wearable Activity Tracking Devices, Systems, and Components Thereof*
Fitbit, Inc. v. **AliphCom, Inc. d/b/a/ Jawbone and BodyMedia, Inc.**
U.S. International Trade Commission
Investigation No. 337-TA-973
Patent Infringement

100. Oracle USA, Inc. et al. v. **Rimini Street, Inc. and Seth Ravin**
U.S. District Court – District of Nevada
Case No. 2:10-cv-0106-LRH-PAL
Copyright Infringement

101. Core Wireless Licensing S.A.R.L. v. **LG Electronics, Inc. and LG Electronics Mobilecomm U.S.A., Inc.**
U.S. District Court – Eastern District of Texas, Marshall Division
Case No. 2:14-cv-911-JRG-RSP
Patent Infringement

102. *Certain Variable Valve Actuation Devices and Automobiles Containing the Same*
Jacobs Vehicle Systems, Inc. v. **Fiat Chrysler Automobiles N.V.; FCA US LLC, et al.**
U.S. International Trade Commission
Investigation No. 337-TA-954
Patent Infringement

103. Zimmer, Inc. v. **Stryker Corporation; Howmedica Osteonics Corp.; et al.**
U.S. District Court – Northern District of Indiana
Case No. 3:14-cv-00152-JD-CAN
Breach of Contract, Breach of Fiduciary Duty, Unfair Competition, Tortious Interference

104. *Certain Electronic Devices, Including Wireless Communication Devices, Computers, Tablet Computers, Digital Media Players, and Cameras*
Ericsson Inc. and Telefonaktiebolaget LM Ericsson v. **Apple Inc.**
U.S. International Trade Commission
Investigation No. 337-TA-952
Patent Infringement

105. *Certain Lithium Metal Oxide Cathode Materials, Lithium-Ion Batteries for Power Tool Products Containing Same, and Power Tool Products with Lithium-Ion Batteries Containing Same*
BASF Corporation and UChicago Argonne, LLC v. **Umicore S.A.; Umicore USA, Inc.**; et al.
U.S. International Trade Commission
Investigation No. 337-TA-951
Patent Infringement

106. *Certain Network Devices, Related Software and Components Thereof (II)*
Cisco Systems, Inc. v. **Arista Networks, Inc.**
U.S. International Trade Commission
Investigation No. 337-TA-945
Patent Infringement

107. *Certain Light-Emitting Diode Products and Components Thereof*
Cree, Inc. v. **Feit Electric Co. Inc.; Unity Opto Technology, Co. Ltd.; et al.**
U.S. International Trade Commission
Investigation No. 337-TA-947
Patent Infringement, False Advertising

108. *Certain Three-Dimensional Cinema Systems and Components Thereof*
RealD, Inc. v. **MasterImage 3D, Inc. and MasterImage 3D Asia, LLC**
U.S. International Trade Commission
Investigation No. 337-TA-939
Patent Infringement

109. *Certain Network Devices, Related Software and Components Thereof (I)*
Cisco Systems, Inc. v. **Arista Networks, Inc.**
U.S. International Trade Commission
Investigation No. 337-TA-944
Patent Infringement

110. **LG Chem, LTD.** v. Celgard, LLC
The United States Patent and Trademark Office, Patent Trial and Appeal Board
Case No. IPR2014-00692
Patent Review

111. Pfizer Inc. and UCB Pharma GMBH v. **Alkem Pharmaceuticals, Inc. et al.**
U.S. District Court – District of Delaware
Case No. 1:13-cv-01110-GMS
Patent Infringement

112. *Certain Consumer Electronics and Display Devices with Graphics Processing and Graphics Processing Units Therein*
NVIDIA Corporation v. **Qualcomm Inc.;** Samsung Electronics Co., Ltd.; et al.
U.S. International Trade Commission
Investigation No. 337-TA-932
Patent Infringement

113. **Heckler & Koch, Inc., Heckler & Koch GmbH, et al.** v. German Sport Guns GmbH and American Tactical Imports, Inc.
U.S. District Court – Southern District of Indiana
Case No. 1:11-CV-1108 SEB-TAB
Breach of Contract, Tortious Interference

114. *Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*
Cresta Technology Corporation v. **Silicon Laboratories Inc.; MaxLinear, Inc.; et al.**
U.S. International Trade Commission
Investigation No. 337-TA-910
Patent Infringement

115. *Certain Non-Volatile Memory Devices and Products Containing Same*
Macronix International Co., Ltd. et al. v. **Spansion, Inc. et al.**
U.S. International Trade Commission
Investigation No. 337-TA-909
Patent Infringement

116. *Certain Soft-Edged Trampolines and Components Thereof*
Springfree Trampoline, Inc. et al. v. Vuly Trampolines Pty. Ltd.
U.S. International Trade Commission
Investigation No. 337-TA-908
Patent Infringement

117. *Certain Optical Disc Drives, Components Thereof and Products Containing Same*
Optical Devices, LLC v. **Lenovo Group Ltd.; LG Electronics, Inc.; et al.**
U.S. International Trade Commission
Investigation No. 337-TA-897
Patent Infringement

118. *Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*
ResMed Corp.; ResMed Inc.; and ResMed Ltd. v. BMC Medical Co., Ltd. et al.
U.S. International Trade Commission
Investigation No. 337-TA-890
Patent Infringement

119. United Therapeutics Corporation v. **Sandoz, Inc.**
U.S. District Court – District of New Jersey
Civil Action No. 12-1617
Patent Infringement

120. *Certain Microelectromechanical Systems ("MEMS Devices") and Products Containing the Same*
STMicroelectronics, Inc. v. **InvenSense, Inc.; Roku, Inc.; and Black & Decker, Inc.**
U.S. International Trade Commission
Investigation No. 337-TA-876
Patent Infringement

121. *Certain Wireless Communications Equipment and Articles Therein*
Samsung Electronics Co. Ltd., et al. v. Ericsson Inc. et al.
U.S. International Trade Commission
Investigation No. 337-TA-866
Patent Infringement

122. *Certain Wireless Devices with 3G and/or 4G Capabilities and Components Thereof*
InterDigital Communications, Inc. et al. v. **Huawei Technologies Co., Ltd., et al.**
U.S. International Trade Commission
Investigation No. 337-TA-868
Patent Infringement

123. *Certain Electronic Devices, Including Wireless Communication Devices, Tablet Computers, Media Players, and Televisions, and Components Thereof*
Ericsson Inc. et al. v. **Samsung Electronics Co. Ltd., et al.**
U.S. International Trade Commission
Investigation No. 337-TA-862
Patent Infringement

124. *Reduced Folate Nutraceutical Products and L-methylfolate Raw Ingredients*
Merck & Cie, Pamlab, LLC, et al. v. Macoven Pharmaceuticals, Inc. et al.
U.S. International Trade Commission
Investigation No. 337-TA-857
Patent Infringement

125. *Certain Wireless Consumer Electronics Devices and Components Thereof*
Technology Properties Limited LLC et al. v. **Acer Inc.; Amazon.com; et al.**
U.S. International Trade Commission
Investigation No. 337-TA-853
Patent Infringement

126. *Certain Audiovisual Components and Products Containing the Same*
LSI Corporation and Agere Systems, Inc. v. **Funai Electric Co., Ltd., et al.**
U.S. International Trade Commission
Investigation No. 337-TA-837
Patent Infringement

127. *Certain Electronic Imaging Devices*
FlashPoint Technology, Inc. v. **ZTE Corporation,** et al.
U.S International Trade Commission
Investigation No. 337-TA-850
Patent Infringement

128. *Certain Consumer Electronics and Display Devices and Products Containing Same*
Graphics Properties Holdings, Inc. v. **Research in Motion Corp.** et al.
U.S International Trade Commission
Investigation No. 337-TA-836
Patent Infringement

129. *Certain Food Waste Disposers and Components and Packaging Thereof*
Emerson Electric Co. v. **Anaheim Manufacturing Co. et al.**
U.S. International Trade Commission
Investigation No. 337-TA-838
Patent Infringement, Trade Dress Infringement

130. *Certain Electronic Digital Media Devices and Components Thereof*
Apple, Inc. v. **Samsung Electronics Co., Ltd. et al.**
U.S. International Trade Commission
Investigation No. 337-TA-796
Patent Infringement

131. **Del Monte International GmbH** v. Del Monte Philippines, Inc. and GTL Limited
American Arbitration Association
Breach of Contract

132. Galderma Laboratories, L.P. et al. v. **Tolmar, Inc. and Actavis Mid Atlantic LLC**
U.S. District Court – District of Delaware
C.A. No. 10-cv-45 (LPS)
Patent Infringement

133. *Certain Semiconductor Chips and Products Containing Same*
Rambus, Inc. v. **Freescale Semiconductor, Inc. et al.**
U.S. International Trade Commission
Investigation No. 337-TA-753
Patent Infringement

134. *Certain Printing and Imaging Devices and Components Thereof*
Ricoh Company, Ltd. et al. v. Oki Data Corporation et al.
U.S. International Trade Commission
Investigation No. 337-TA-690
Patent Infringement

135. *MEMS Devices and Products Containing the Same*
Analog Devices, Inc. v. **Knowles Electronics LLC,** et al.
U.S. International Trade Commission
Investigation No. 337-TA-700
Patent Infringement

136. **Software Tree, LLC** v. Red Hat, Inc., et al.
U.S. District Court – Eastern District of Texas
6:09-cv-00097-LED
Patent Infringement

137. *Certain MLC Flash Memory Devices and Products Containing Same*
BTG International Inc. v. Samsung Electronics Co., Ltd. et al.
U.S. International Trade Commission
Investigation No. 337-TA-683
Patent Infringement

138. *Certain Silicon Microphone Packages, and Products Containing The Same*
Knowles Electronics, LLC v. Analog Devices, Inc.
U.S. International Trade Commission
Investigation No. 337-TA-695
Patent Infringement

139. *Certain Automotive Multimedia Display and Navigation Systems, Components Thereof, and Products Containing Same*
Honeywell International, Inc. v. **Alpine Electronics, Inc.; Pioneer Corporation**
U.S. International Trade Commission
Investigation No. 337-TA-657
Patent Infringement

140. O'Gara—Hess & Eisenhardt Armoring Company LLC v. **Ibis Tek, LLC et al.**
Common Pleas Court of Butler County, Ohio
CV 2006 04 1157
Misappropriation of Confidential and Trade Secret Information

141. Multimatic, Inc. v. **Faurecia Interior Systems USA, Inc**.
U.S. District Court – Eastern District of Michigan
05-60120
Breach of Contract

142. Eaton Corporation v. **ZF Meritor LLC, et al.**
U.S. District Court – Eastern District of Michigan
03-74844
Patent Infringement

143. *Certain Automated Mechanical Transmission Systems for Medium-Duty and Heavy-Duty Trucks, and Components Thereof*
Eaton Corporation v. **ZF Meritor LLC, et al.**
U.S. International Trade Commission
Investigation No. 337-TA-503
Patent infringement

144. *Certain Shirts with Pucker Free Seams and Methods of Producing Same*
TALTECH Limited, et al. v. **Esquel Apparel, Inc. et al.**
U.S. International Trade Commission
Investigation No. 337-TA-517
Patent infringement

145. *Certain Universal Transmitters for Garage Door Openers*
The Chamberlain Group, Inc. v. Skylink Technologies, Inc. et al.
U.S. International Trade Commission
Investigation No. 337-TA-497
Patent Infringement, Digital Millennium Copyright Act

Publications and Presentations

1. "Forum: Valuation and damages in IP disputes," *Financier Worldwide*, January 2017.

2. Speaker, *The Uncertain Future of At-Risk Launches: A Study of Injunctive Relief, Damages and the Impact of Protonix,* American Conference Institute's Second Annual Paragraph VI Disputes Master Symposium, Chicago, IL. October 1, 2014.

3. Speaker, *Valuation of Innovation Product and Intellectual Property Based Assets,* Institute of Food Technologists Pre-Annual Meeting Short Course: Commercializing Innovation in Food Products, New Orleans, LA. June 21, 2014.

4. Speaker, *Valuation of Innovation Product and Intellectual Property Based Assets,* Institute of Food Technologists Annual Meeting: Food Expo Forum, Chicago, IL. July 16, 2013.

5. Speaker, *Uniloc USA, Inc. v. Microsoft Corp.: The End of the 25% Rule,* Licensing Executives Society Aerospace and Transportation Committee Webinar, August 1, 2012.

6. "Can We 'Spot' Price-Fixing from Price Patterns?" The *Economics Committee Newsletter*, American Bar Association Section of Antitrust Law, Vol. 12, No. 1, pages 3-6 (Summer 2012).

7. Speaker, *Valuation of Innovation Product and Intellectual Property Based Assets,* Institute of Food Technologists Pre-Annual Meeting Short Course: Commercializing Innovation in Food Products, Las Vegas, NV. June 25, 2012.

8. Guest Lecturer, Patent Litigation, Chicago-Kent College of Law. March 6, 2012.

9. Panel Speaker, *Damages*, 12th Annual Silicon Valley Advanced Patent Law Institute, Palo Alto, CA. December 9, 2011.

10. Speaker, *Technical Session: Intellectual Property Perspective, Patents & Valuation,* Chicago Section – Institute of Food Technologists, River Forest, IL. June 22, 2011.

11. Guest Lecturer, IP Litigation, John Marshall Law School. March 2, 2011.

12. Speaker, *Recent Developments at the U.S. International Trade Commission*, AIPPI-US Annual Meeting and International IP Forum, Chicago, IL. November 8, 2010.

13. Instructor, *Intellectual Asset Management: Valuation*, Licensing Executives Society Professional Development Series: Intermediate, Chicago, IL. July 14, 2010.

14. Instructor, *Intellectual Asset Management: Valuation*, Licensing Executives Society Professional Development Series: Intermediate, Toronto, ON. July 16, 2008.

15. Instructor, *Intellectual Asset Management: Valuation*, Licensing Executives Society Professional Development Series: Intermediate, San Francisco, CA. March 5, 2008.

16. Panel Speaker, *Potential Impact of the Proposed Legislative Changes to Infringement Remedies and Patent Practice*, Los Angeles Intellectual Property Law Association: Washington in the West Conference, Los Angeles, CA. January 30, 2008.

17. Instructor, *Valuation of Intellectual Property*, Practicing Law Institute: Annual Patent Law Institute, San Francisco, CA. January 29, 2008.

18. Instructor, *Advanced Valuation Skills*, Licensing Executives Society Professional Development Series: Intellectual Asset Management Advanced Series, Philadelphia, PA. June 13-14, 2007.

19. Instructor, *Advanced Valuation Skills*, Licensing Executives Society Professional Development Series: Intellectual Asset Management Advanced Series, San Francisco, CA. November 1-2, 2006.

20. Guest Lecturer, *Financial Issues for Engineers*, Master of Engineering Management Program, Northwestern University. March 2006.

21. "AFDC and Births to Unwed Women." With Kurt C. Schaefer and Sarah E. Hamersma. *Labour Economics*. 9, pages 801-813 (2002).

22. "Optimal Contracts for Teams: A Note on the Results of McAfee and McMillan." *International Economic Review*. 36(4), pages 1051-6 (November 1995).

APPENDIX B

Appendix B – Materials Considered

Document	Description
Paper 2	Petition for *Inter Partes* Review in U.S. Patent No. 11,446,512 in IPR2025-00287
Ex. 1001	U.S. Patent No. 11,446,512
Ex. 1015	Expert Declaration of Robert E. Grove, Ph.D. in IPR2025-00287
Ex. 1016	Expert Declaration Of Michael Ehrenreich, MD, in IPR2025-00287
Ex. 1020	6-25-2024 ITC Verified Complaint
Ex. 2015	Declaration of Heather J Roberts, MD, FAAD
Ex. 2018	How to Use Levulan® Kerastick® + BLU-U®," <https://www.levulanhcp.com/how- to-use>;
Ex. 2039	Redacted Deposition Transcript of Mark Baldyga in ITC Inv. No. 337-TA-1411, taken December 19, 2024
Ex. 2040	Exhibit. 6 to Baldyga Deposition Transcript in ITC
Ex. 2043	RhodoLED® XL User Manual, Version 1.7SW_G2
Ex. 2045	6-24-2024 BioSpace Article - Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp
Ex. 2046	12/23/2024 Article - Biofrontera Announces 100 RhodoLED XL Machines Now Placed in the US Market;
Ex. 2047	3-21-2025 Biofrontera's Reports Records Fiscal Year 2024
Ex. 2055	3-20-2025 Biofrontera l0K Sun-ITC-0185914
Ex. 2056	Picture of original RhodoLED®.
Ex. 2057	"Biofrontera Inc. (BFRI) Q4 2024 Earnings Call Transcript," <https://seekingalpha.com/article/4769506-biofrontera-inc-bfri-q4-2024-earnings-call-transcript>, March 21, 2025
Ex. 2062	"Actinic Keratosis," Cleveland Clinic, <https://my.clevelandclinic.org/health/diseases /14148-actinickeratosis>
Ex. 2063	"Actinic Keratosis: Diagnosis and Treatment," American Academy of Dermatology Association, <https://www.aad.org/public/diseases/skin-cancer/actinic- keratosistreatment>
Ex. 2064	Biofrontera Announces U.S. FDA Approval of Ameluz® and Activating BF-RhodoLED® Device for Treatment of Actinic Keratosis," Biofrontera News

Document	Description
	Release, <https://www.biofrontera.com/fileadmin/files/PDFs/Corporate_news/2016/EN/20160511>, May 11, 2016
Ex. 2065	“Biofrontera Bioscience GmbH,” <www.medicines.ie>; Exhibit 2071 - “Biofrontera Pharma GmbH,” <www.medicines.org.uk>.
Ex. 2066	"Biofrontera Inc. (BFRI) Q2 2024 Earnings Call Transcript," <https://seekingalpha.com /article/4714932-biofrontera-inc-bfri-q2 -2024 -earnings-call-transcript>, August 15, 2024
Ex. 2067	"Biofrontera Inc. (BFRI) Q2 2024 Earnings Call Transcript," <https://seekingalpha.corn/article/4714932-biofrontera-inc-bfri-q2-2024-earnings- call-transcript>, August 15, 2024
Ex. 2068	Biofrontera Inc. Reports First Quarter 2024 Financial Results and Provides a Business Update," <https://www.biospace.com/biofrontera-inc-reports-first-quarter- 2024-financial-results-and-provides-a-business-update> , May 15, 2024
Ex. 2069	"Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial results and Provides Business Update," <https://www.biospace.com/press-releases /biofrontera- inc-reports-third-quarter-and-nine-month-2024-financial-results-and-provides-business-update>, November 14, 2024
Ex. 2070	Biofrontera Inc., Annual Report Pursuant to Section 13 or 15(0) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2023
Ex. 2071	"Biofrontera Pharma GmbH," <www.medicines.org.uk>.
Ex. 2072	"PhotodynamicTherapy Market Size, Share, and Trends 2025 to 2034," Precedence Research, <https://www.precedenceresearch.com/photodynamic-therapy-market>.
Ex. 2073	U.S. Actinic Keratosis Treatment Market Size Industry Analysis 2033," BioSpace, <https://www.biospace.corn/u-s-actinic-keratosis-treatment-market-size-industry- analysis-2033 >, April 25, 2024
Ex. 2074	"Photodynamic Therapy," Mayo Clinic,< https://www.mayoclinic.org/tests-procedures/photodynamic-therapy/about/pac-203 85027> .
Ex. 2075	" U.S. Actinic Keratosis Treatment Market Size Industry Analysis 2033," BioSpace, <https://www.biospace.corn/u-s-actinic-keratosis-treatmen t-market-size-industry-analysis-2033>, April 25, 2024
Ex. 2076	Why Levulan® Kerastick® + BLU-U®," <https://www.levulan.com/why-levulan- kerastick>;
Ex. 2077	Tim Smith, "FDA-Approved Red-Light LED Lamp Released for Patients With Actinic Keratosis," AJMC, <https://www.ajmc.com/view/fda-approved-red-light-led-lamp-released-for-patients-with -actinic-keratosis>,June 28, 2024

Document	Description
Ex. 2078	ROTH MKM, Biofrontera, Inc, "BFRI 3Q24: Hurricane Milton Impacted 3Q Revs, But 4Q Is Already Compensating," Jonathan Aschoff, Ph.D., November 14, 2024.
Ex. 2079	FDA letter regarding BLU-U Model 4170E, dated May 1, 2025