UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

Before the Honorable Judge MaryJoan McNamara
Administrative Law Judge

In the Matter of **CERTAIN SKIN REJUVENATION RESURFACING DEVICES, COMPONENTS THEREOF, AND PRODUCTS CONTAINING THE SAME**	**Inv. No. 337-TA-1356**

JEISYS MEDICAL INC.'S AND CYNOSURE, LLC'S RESPONSE TO THE COMPLAINT AND NOTICE OF INVESTIGATION

Pursuant to 19 C.F.R. §§ 210.13, Jeisys Medical Inc. ("Jeisys") and Cynosure, LLC ("Cynosure"); (collectively "Respondents") hereby respond to the Complaint ("Complaint") filed by Serendia, LLC ("Serendia" or "Complainant") on March 1, 2023, under Section 337 of the Tariff Act of 1930 as Amended ("Section 337")[1] and to the Notice of Investigation ("Notice") issued by the U.S. International Trade Commission ("Commission") on March 31, 2023, as published in the Federal Register on April 6, 2023, 88 Fed. Reg. 20551, instituting Investigation No. 337-TA-1356 ("Investigation"). This Response also contains Respondents' preliminary affirmative defenses, prayer for relief, and statements pursuant to 19 C.F.R. § 210.13(b).

RESPONSE TO COMPLAINT

Respondents each deny that they have engaged in unfair competition or a violation of

[1] As used herein, "Complaint" shall include as appropriate any supplements, appendices, exhibits, or attachments to the Complaint that existed as of the date of this Response.

Serendia, LLC
Exhibit 2021
Jeisys v. Serendia
IPR2024-00383
Ex. 2021-001

Section 337 by importing, selling for importation, or selling after importation into the United States any product that infringes (directly, literally, and/or under the doctrine of equivalents, or indirectly, by contribution and/or inducement) any valid and enforceable claim of U.S. Patent Nos. 9,480,836; 10,058,379; 11,406,444; 9,320,536; 9,775,774; 10,869,812 (collectively, the "Asserted Patents").

Jeisys is a medical device company headquartered in Korea that produces high-end products for use by plastic surgeons, dermatologists, physicians, and other healthcare professionals. Jeisys products are sold in over 40 countries worldwide.

Cynosure is a medical device company headquartered in Westford, Massachusetts. Cynosure develops, manufactures, and distributes products for use in numerous medical and aesthetic applications, including hair removal, skin revitalization, scar reduction, gynecological health, body contouring, and more. In the United States, Cynosure has over 405 permanent employees and maintains facilities in two states, Massachusetts and California.

Respondents each deny that they have engaged in unfair or unlawful acts, including violations of Section 337, as alleged by Complainant, by importing, selling for importation, or selling within the United States after importation any products that infringe any valid and enforceable patent rights asserted in this Investigation. Respondents provide the below responses to the numbered paragraphs of the Complaint based on their current knowledge and understanding of Complainant's claims. These responses are presented in numbering that corresponds to the numbering used in the Complaint.

All allegations in the Complaint which are not specifically admitted are hereby denied. Any factual allegation admitted herein is admitted only as to the specific facts, and not as to any

purported conclusions that might follow from the admitted facts. Any speculation, legal conclusions, subjective characterizations, or implications are hereby denied. Nothing stated in this Response shall constitute a construction of any patent claims asserted in this Investigation.

I. INTRODUCTION

1.1. Respondents admit that Complainants purport to have filed the Complaint pursuant to Section 337, which requests that the Commission institute an investigation based on alleged violations of that statute, including allegations of infringement of certain claims (listed in ¶ 1.1 of the Complaint and referred to herein as the "Asserted Claims") of the Asserted Patents. Respondents deny all remaining allegations and characterizations in paragraph 1.1 and specifically deny that they have acted unlawfully, including by infringing any of the Asserted Claims of the Asserted Patents.

1.2. Respondents admit that Exhibits 1-6 of the Complaint appear to be certified copies of the Asserted Patents. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 1.2, and therefore deny them.

1.3. Respondents admit that an article titled "Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes" is purported to have published in Scientific Reports on November 13, 2015, and that article lists "Jongju Na" as an author. Respondents further admit that the article uses the phrase "Na effect." Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 1.3, and therefore deny them.

1.4. Respondents admit that the Complaint identifies, and the Commission subsequently ordered, that Sung Hwan E&B Co., LTD. d/b/a SHEnB Co. LTD ("SHEnB");

Aesthetics Biomedical, Inc. ("AB"); Cartessa Aesthetics, LLC ("Cartessa"); Lutronic Corporation; Lutronic Aesthetics, Inc., also known as Lutronic, Inc.; Lutronic, LLC (the Lutronic entities collectively "Lutronic" or "Lutronic Respondents"); Ilooda Co., Ltd. ("Ilooda"); Cutera, Inc. ("Cutera"); Jeisys Medical Inc. ("Jeisys"); Cynosure, LLC ("Cynosure"); Rohrer Aesthetics, LLC and Rohrer Aesthetics, Inc. (collectively "Rohrer"); EndyMed Medical Ltd. (Israel); EndyMed Medical, Ltd. (New York); and EndyMed Medical, Inc. (collectively "EndyMed" or "EndyMed Respondents") are Respondents in this Investigation. Respondents further admit that Jeisys manufactures Potenza products that are imported and sold by Cynosure. Respondents deny that Jeisys and Cynosure are "affiliated" and otherwise lack sufficient knowledge to admit or deny the remaining allegations of paragraph 1.4, and therefore deny them.

1.5. Respondents admit that Jeisys manufactures the accused Potenza products in South Korea, which are imported into the United States and sold by Cynosure. Respondents deny that they have "used Complainant's patented inventions without payment or permission." Respondents further deny that the accused Potenza products "compete with licensed devices."[2] Respondents further deny that accused Potenza products or their components infringe any valid and enforceable Asserted Claim of the Asserted Patents. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 1.5, and therefore deny them.

1.6. Respondents deny that they have engaged in any "unfair methods of competition [or] unfair acts," including any alleged "importation of articles into the United States, the sale for importation, and sale after importation of articles that infringe the Asserted Patents."

[2] Respondents construe the phrase "licensed devices" as referring to the Sylfirm X product identified as the purported "Domestic Industry Product" in the Complaint and exhibits thereto (*see, e.g.*, Complaint Exhibit 65 at ¶ 1).

Respondents further deny any remaining allegations of paragraph 1.6.

1.7. Respondents deny that a domestic industry as required by 19 U.S.C. § 1337(a)(2) and (3) exists in the United States relating to "Complainant's licensee's exploitation of the Asserted Patents."

1.8. Jeisys admits that it designs and manufactures the accused Potenza products in Korea, which it sells to Cynosure. Cynosure admits that it imports the accused Potenza products into the United States where it distributes, markets, and sells them. Respondents deny that the accused Potenza products infringe any valid and enforceable claim of the Asserted Patents, whether directly, contributorily, or by inducement. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 1.8, and therefore deny them.

1.9. Respondents admit that paragraph 1.9 purports to seek cease and desist orders and the imposition of a bond during the Presidential Review Period. Respondents deny that Complainant is entitled to any relief by or through its Complaint.

II. COMPLAINANT

2.1. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 2.1, and therefore deny them.

III. PROPOSED RESPONDENTS

A. Vivace/Virtue Respondents

3.1. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.1, and therefore deny them.

3.2. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.2, and therefore deny them.

3.3. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.3, and therefore deny them.

3.4. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.4, and therefore deny them.

3.5. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.5, and therefore deny them.

3.6. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.6, and therefore deny them.

B. Lutronic Respondents

3.7. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.7, and therefore deny them.

3.8. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.8, and therefore deny them.

3.9. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.9, and therefore deny them.

3.10. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.10, and therefore deny them..

C. Secret Respondents

3.11. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.11, and therefore deny them.

3.12. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.12, and therefore deny them.

3.13. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.13, and therefore deny them.

3.14. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.14, and therefore deny them.

D. Potenza Respondents

3.15. Respondent Jeisys admits that Jeisys Medical Inc. is a corporation organized and existing under the laws of South Korea, and that Jeisys Medical Inc. maintains its headquarters at Daeryung Techno Town 8th, Gasang-dong, Room 307, 96 Gamasan-ro, Geumcheon-gu, Seoul 08501, Republic of Korea.

3.16. Respondent Cynosure admits that Cynosure, LLC is a limited liability company organized and existing under the laws of the state of Delaware, and that Cynosure, LLC maintains its headquarters at 5 Carlisle Rd., Westford, MA 01886.

3.17. Respondent Jeisys admits that it designs, develops, and manufactures healthcare equipment, including RF microneedling dermatological treatment devices such as the accused Potenza products. Respondent Jeisys further admits that the accused Potenza product is imported into the United States for sale. Except as admitted, Respondents deny all remaining allegations of this paragraph.

3.18. Respondent Cynosure admits that it imports into the United States and subsequently sells the accused Potenza products, and further admits that Cynosure sells other medical aesthetic devices in the United States. Except as admitted, Respondents deny all remaining allegations of this paragraph.

E. Pixel8 Respondent

3.19. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.19, and therefore deny them.

3.20. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.20, and therefore deny them.

F. Intensif Respondents

3.21. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.21, and therefore deny them.

3.22. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.22, and therefore deny them.

3.23. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.23, and therefore deny them.

3.24. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 3.24, and therefore deny them.

IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE

4.1. Respondents admit that the Commission's Notice states under the "Scope of Investigation" that "the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is 'RF microneedling dermatological treatment devices and components thereof.'"

4.2. Respondents admit that the Complaint recites the "Vivace," "VirtueRF," "Genius," "Secret RF and Secret Pro," "Potenza," "Pixel8 RF and Pixel Pro" and "Intensif" as purported "Accused Products." *See* Complaint at, *e.g.*, ¶4.2. Respondents further respond as follows to the subparts of paragraph 4.2:

a) Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 4.2, subpart (a), and therefore deny them.

b) Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 4.2, subpart (b), and therefore deny them.

c) Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 4.2, subpart (c), and therefore deny them.

d) Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 4.2, subpart (d), and therefore deny them.

e) Respondents admit that the accused Potenza products are manufactured in South Korea by Respondent Jeisys and are imported, sold, and distributed in the United States by Respondent Cynosure.

f) Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 4.2, subpart (f), and therefore deny them.

g) Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 4.2, subpart (g), and therefore deny them.

4.3. Respondents admit that the accused Potenza products are manufactured in South Korea and imported into the United States. The remaining allegations of paragraph 4.3 are not factual assertions and do not require a response; however, to the extent a response is required, Respondents deny them.

V. THE ASSERTED PATENTS AND NON-TECHNICAL DESCRIPTION OF THE INVENTIONS

A. Patent Family One

1. U.S. Patent No. 9,480,836

a. Identification of the Patent and Ownership by Complainant

5.1. Respondents admit that Exhibit 1 to the Complaint appears to be a copy of U.S. Patent No. 9,480,836, bears the title "Skin Treatment Apparatus and Method," identifies Jongju Na as a purported inventor, and identifies "Appl. No.: 14/006,930" and "PCT Filed Jun. 14, 2012." Respondents deny that the '836 Patent was validly issued or that a full and fair examination occurred. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.1 and therefore deny them.

5.2. Respondents admit that Exhibit 1 contains 29 claims, 2 of which are independent and 27 of which are dependent. Respondents further admit that the Complaint purports to identify claims 1, 2, 5, 6, 9-14, 16, 17, 19, and 22 of the '836 Patent as Asserted Claims. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.2 and therefore deny them.

5.3. Respondents deny that the claims of the '836 Patent are valid and enforceable. Respondents lack sufficient knowledge to admit or deny the "rights, title and interest" allegations of paragraph 5.3 and therefore deny them. Respondents deny the remaining allegations of paragraph 5.3.

5.4. Respondents admit that Appendix A appears to comprise a certified copy of the file history for the '836 Patent. Respondents further admit that Appendix G appears to consist of references. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.4 and therefore deny them.

b. Non-Technical Description of the Patent

5.5. Respondents deny Complainant's characterization of the '836 Patent and refer to the '836 Patent for its content.

c. Foreign Counterparts to the Patent

5.6. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 5.6 and therefore deny them.

d. Licenses

5.7. Respondents admit that Confidential Exhibit 14 purports to identify licensed entities. Respondents deny that the listing in Confidential Exhibit 14 is complete. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.7 and therefore deny them.

2. U.S. Patent No. 10,058,379

a. Identification of Patent and Ownership by Complainant

5.8. Respondents admit that Exhibit 2 to the Complaint appears to be a copy of U.S. Patent No. 10,058,379, which bears the title "Electrically Based Medical Treatment Device and Method," identifies Jongju Na as a purported inventor, identifies "Appl. No.: 15/202,511," states that it was "Filed: Jul. 5, 2012," and states that the "Date of Patent" is Aug. 28, 2018. Respondents further admit that the face of the '379 Patent indicates that it is a "[c]ontinuation of application No. 14/006,930," which issued as the '836 Patent. Respondents deny that the '379 Patent was validly issued or that a full and fair examination occurred. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.8 and therefore deny them.

5.9. Respondents admit that Exhibit 2 appears to contain 18 claims, 2 of which are

independent and 16 of which are dependent. Respondent further admits that the Complaint lists claims 1-5, 7-10, and 15 of the ’379 Patent as “Asserted Claims.” Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.9 and therefore deny them.

5.10. Respondents deny that the claims of the ’379 Patent are valid and enforceable. Respondents lack sufficient knowledge to admit or deny the “rights, title and interest” allegations of paragraph 5.10 and therefore deny them. Respondents deny the remaining allegations of paragraph 5.10.

5.11. Respondents admit that Appendix B appears to comprise a certified copy of the file history for the ’379 Patent. Respondents further admit that Appendix H appears to consist of references. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.11 and therefore deny them.

b. Non-Technical Description of the Patent

5.12. Respondents deny Complainant’s characterization of the ’379 Patent and refer to the ’379 Patent for its content.

c. Foreign Counterparts to the Patent

5.13. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 5.13 and therefore deny them.

d. Licenses

1.1. Respondents admit that Confidential Exhibit 14 purports to identify entities. Respondents deny that the listing in Confidential Exhibit 14 is complete. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 1.1[3] and therefore

[3] A paragraph numbering error present in the Complaint has been reproduced here in order to preserve

deny them.

3. U.S. Patent No. 11,406,444

a. Identification of the Patent and Ownership by Complainant

5.14. Respondents admit that Exhibit 3 to the Complaint appears to be a copy of U.S. Patent No. 11,406,444, which bears the title "Electrically Based Medical Treatment Device and Method," identifies Jongju Na as a purported inventor, identifies "Appl. No.: 17/061,523," states that it was "Filed: Oct. 1, 2020," and states that the "Date of Patent" is Aug. 9, 2022. Respondents further admit that the face of the '444 Patent states that it is a "[c]ontinuation of application No. 16/111,616, filed on Aug. 24, 2018, now Pat. No. 10,799,286, which is a continuation of application No. 15/202,511, filed on Jul. 5, 2016, now Pat. No. 10,058,379, which is a continuation of application No. 14/006,930, filed as application No. PCT/KR2012/004695 on Jun. 14, 2012, now Pat. No. 9,480,836." Respondents deny that the '444 Patent was validly issued or that a full and fair examination occurred. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.14 and therefore deny them.

5.15. Respondents admit that the '444 Patent appears to contain 18 claims, 2 of which are independent and 16 of which are dependent. Respondent further admits that the Complaint lists claims 1-10 of the '444 Patent as "Asserted Claims." Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.15 and therefore deny them.

5.16. Respondents deny that the claims of the '444 Patent are valid and enforceable. Respondents lack sufficient knowledge to admit or deny the "rights, title and interest" allegations

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subsequent paragraph numbering.

of paragraph 5.16 and therefore deny them. Respondents deny the remaining allegations of paragraph 5.16.

5.17. Respondents admit that Appendix C appears to comprise a certified copy of the file history for the ’444 Patent. Respondents further admit that Appendix I appears to consist of references. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.17 and therefore deny them.

b. Non-Technical Description of the Patent

5.18. Respondents deny Complainant’s characterization of the ’444 Patent and refer to the ’444 Patent for its content.

c. Foreign Counterparts to the Patent

5.19. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 5.19 and therefore deny them.

d. Licenses

5.20. Respondents admit that Confidential Exhibit 14 purports to identify entities. Respondents deny that the listing in Confidential Exhibit 14 is complete. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.20 and therefore deny them.

B. Patent Family Two

1. U.S. Patent No. 9,320,536

a. Identification of the Patent and Ownership by Complainant

5.21. Respondents admit that Exhibit 4 to the Complaint appears to be a copy of U.S. Patent No. 9,320,536, which bears the title “Method, System, and Apparatus for Dermatological Treatment,” identifies Jongju Na as a purported inventor, identifies “Appl. No.: 13/825,083,”

states that it was "PCT Filed: Feb. 22, 2012," and states that the "Date of Patent" is Apr. 26, 2016. Respondents deny that the '536 Patent was validly issued or that a full and fair examination occurred. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.21 and therefore deny them.

5.22. Respondents admit that the '536 Patent appears to contain 20 claims, 2 of which are independent and 18 of which are dependent. Respondent further admits that the Complaint lists claims 1, 2, 4, 5, 8, 9, 11-13, 16, and 17 of the '536 Patent as "Asserted Claims." Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.22 and therefore deny them.

5.23. Respondents deny that the claims of the '536 Patent are valid and enforceable. Respondents lack sufficient knowledge to admit or deny the "rights, title and interest" allegations of paragraph 5.23 and therefore deny them. Respondents deny the remaining allegations of paragraph 5.23.

5.24. Respondents admit that Appendix D appears to comprise a certified copy of the file history for the '536 Patent. Respondents further admit that Appendix J appears to consist of references. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.24 and therefore deny them.

b. Non-Technical Description of the Patent

5.25. Respondents deny Complainant's characterization of the '536 Patent and refer to the '536 Patent for its content.

c. Foreign Counterparts to the Patent

5.26. Respondents lack sufficient knowledge to admit or deny the allegations of

paragraph 5.26 and therefore deny them.

d. Licenses

5.27. Respondents admit that Confidential Exhibit 14 purports to identify entities. Respondents deny that the listing in Confidential Exhibit 14 is complete. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.27 and therefore deny them.

2. U.S. Patent No. 9,775,774

a. Identification of the Patent and Ownership by Complainant

5.28. Respondents admit that Exhibit 5 to the Complaint appears to be a copy of U.S. Patent No. 9,775,774, which bears the title "Method, System, and Apparatus for Dermatological Treatment," identifies Jongju Na as a purported inventor, identifies "Appl. No.: 15/096,686," states that it was "Filed: Apr. 12, 2016," and states that the "Date of Patent" is Oct. 3, 2017. While not stated on the face of the '774 Patent, Respondents admit that the '774 Patent recites that it is a "continuation of U.S. Application Ser. No. 13/825,083." Complaint Ex. 5, col. 1, lines 7-8. Respondents deny that the '774 Patent was validly issued or that a full and fair examination occurred. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.28 and therefore deny them.

5.29. Respondents admit that the '774 Patent appears to recite 20 claims, 2 of which are independent and 18 of which are dependent. Respondent further admits that the Complaint lists claims 1, 6-11, and 12-15 of the '774 Patent as "Asserted Claims." Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.29 and therefore deny them.

5.30. Respondents deny that the claims of the ’774 Patent are valid and enforceable. Respondents lack sufficient knowledge to admit or deny the “rights, title and interest” allegations of paragraph 5.30 and therefore deny them. Respondents deny the remaining allegations of paragraph 5.30.

5.31. Respondents admit that Appendix E appears to comprise a certified copy of the file history for the ’774 Patent. Respondents further admit that Appendix K appears to consist of references. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.31 and therefore deny them.

b. Non-Technical Description of the Patent

5.32. Respondents deny Complainant’s characterization of the ’774 Patent and refer to the ’744 Patent for its content.

c. Foreign Counterparts to the Patent

5.33. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 5.33 and therefore deny them.

d. Licenses

5.34. Respondents admit that Confidential Exhibit 14 purports to identify entities. Respondents deny that the listing in Confidential Exhibit 14 is complete. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.34 and therefore deny them.

3. U.S. Patent No. 10,869,812

a. Identification of the Patent and Ownership by Complainant

5.35. Respondents admit that Exhibit 6 to the Complaint appears to be a copy of U.S.

Patent No. 10,869,812, which bears the title "Method, System, and Apparatus for Dermatological Treatment," identifies Jongju Na as a purported inventor, identifies "Appl. No.: 15/724,261," states that it was "Filed: Oct. 3, 2017," and states that the "Date of Patent" is Dec. 22, 2020. Respondents further admit that the '812 Patent recites that it is a "[c]ontinuation of application No. 15/096,686, filed on Apr. 12, 2016, now U.S. Pat. No. 9,775,774, which is a continuation of application No. 13/825,083, filed as application No. PCT/KR2012/001335 on Feb. 22, 2012, now Pat. No. 9,320,536." Respondents deny that the '812 Patent was validly issued or that a full and fair examination occurred. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.35 and therefore deny them.

5.36. Respondents admit that the '812 Patent appears to recite 20 claims, 2 of which are independent and 18 of which are dependent. Respondent further admits that the Complaint lists claims 1, 5-7, 9, 10, and 12-19 of the '812 Patent as "Asserted Claims." Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.36 and therefore deny them.

5.37. Respondents deny that the claims of the '812 Patent are valid and enforceable. Respondents lack sufficient knowledge to admit or deny the "rights, title and interest" allegations of paragraph 5.37 and therefore deny them. Respondents deny the remaining allegations of paragraph 5.37.

5.38. Respondents admit that Appendix F appears to comprise a certified copy of the file history for the '812 Patent. Respondents further admit that Appendix I appears to consist of references. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.38 and therefore deny them.

b. Non-Technical Description of the Patent

5.39. Respondents deny Complainant's characterization of the '812 Patent and refer to the '812 Patent for its content. Respondents deny the remaining allegations of paragraph 5.39.

c. Foreign Counterparts to the Patent

5.40. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 5.40 and therefore deny them.

d. Licenses

5.41. Respondents admit that Confidential Exhibit 14 purports to identify entities. Respondents deny that the listing in Confidential Exhibit 14 is complete. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 5.41 and therefore deny them.

VI. UNLAWFUL AND UNFAIR ACTS OF RESPONDENTS

A. Vivace

6.1. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.1 and therefore deny them.

6.2. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.2 and therefore deny them.

6.3. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.3 and therefore deny them.

6.4. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.4 and therefore deny them.

6.5. Respondents lack sufficient knowledge to admit or deny the allegations of

paragraph 6.5 and therefore deny them.

6.6. Respondents admit that Exhibits 70-75 to the Complaint appear to be claim charts. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 6.6 and therefore deny them.

B. VirtueRF

6.7. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.7 and therefore deny them.

6.8. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.8 and therefore deny them.

6.9. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.9 and therefore deny them.

6.10. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.10 and therefore deny them.

6.11. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.11 and therefore deny them.

6.12. Respondents admit that Exhibits 76-81 to the Complaint appear to be claim charts. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 6.12 and therefore deny them.

C. Genius

6.13. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.13 and therefore deny them.

6.14. Respondents lack sufficient knowledge to admit or deny the allegations of

paragraph 6.14 and therefore deny them.

6.15. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.15 and therefore deny them.

6.16. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.16 and therefore deny them.

6.17. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.17 and therefore deny them.

6.18. Respondents admit that Exhibits 82-87 to the Complaint appear to be claim charts. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 6.18 and therefore deny them.

D. Secret RF and Secret Pro

6.19. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.19 and therefore deny them.

6.20. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.20 and therefore deny them.

6.21. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.21 and therefore deny them.

6.22. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.22 and therefore deny them.

6.23. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.23 and therefore deny them.

6.24. Respondents admit that Exhibits 88-99 to the Complaint appear to be claim

charts. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 6.24 and therefore deny them.

E. Potenza

6.25. Respondents admit that Respondent Jeisys manufactures and sells, in South Korea, the accused Potenza products. Respondents further admit that Respondent Cynosure imports and sells the accused Potenza products in the United States. Respondents deny that the accused Potenza products, or the import or sale thereof, infringe any valid or enforceable Asserted Claim of the Asserted Patents, either directly, contributorily, or by inducement.

6.26. Respondents admit that Respondent Jeisys manufactures and sells, in South Korea, the accused Potenza products. Respondents further admit that Respondent Cynosure imports and sells the accused Potenza products in the United States. Respondents deny that the accused Potenza products, or the import or sale thereof, infringe, either literally or under the doctrine of equivalents, any valid or enforceable Asserted Claim of the Asserted Patents, either directly, contributorily, or by inducement.

6.27. Respondents admit that they became aware of the Asserted Patents at least as of the date of the filing of this Complaint. Respondents deny the remaining allegations of paragraph 6.27. Particularly, Respondents deny that they, or the accused Potenza device, induce infringement of any valid and enforceable Asserted Claim of any Asserted Patent.

6.28. Respondents deny that they, or the accused Potenza device, contribute to infringement of any valid and enforceable Asserted Claim of any Asserted Patent. Respondents further deny the remaining allegations of paragraph 6.28.

6.29. Respondents deny the allegations of paragraph 6.29 to the extent they suggest

that the scope of discovery in this Investigation should extend beyond the accused Potenza products. To the extent Complainant seeks discovery from Respondents that is beyond the scope of this Investigation, Respondents will provide their objections in response to such discovery requests as appropriate. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 6.29 and therefore deny them.

6.30. Respondents admit that Exhibits 100-105 to the Complaint appear to be claim charts. Respondents deny that these claim charts show that the accused Potenza products infringe, under any theory, any valid and enforceable Asserted Claim of the Asserted Patents.

F. Pixel8 RF and Pixel8 Pro

6.31. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.31 and therefore deny them.

6.32. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.32 and therefore deny them.

6.33. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.33 and therefore deny them.

6.34. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.34 and therefore deny them.

6.35. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.35 and therefore deny them.

6.36. Respondents admit that Exhibits 106-111 to the Complaint appear to be claim charts. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 6.36 and therefore deny them.

G. Intensif

6.37. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.37 and therefore deny them.

6.38. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.38 and therefore deny them.

6.39. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.39 and therefore deny them.

6.40. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.40 and therefore deny them.

6.41. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 6.41 and therefore deny them.

6.42. Respondents admit that Exhibits 112-117 to the Complaint appear to be claim charts. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 6.42 and therefore deny them.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

7.1. Respondents admit that the accused Potenza product is manufactured in South Korea and subsequently offered for importation by Respondent Jeisys. Respondents further admit that Respondent Cynosure imports and subsequently sells the accused Potenza products in the United States. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 7.1 and therefore deny them.

B. Vivace[4]

7.2. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.2 and therefore deny them.

7.3. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.3 and therefore deny them.

7.4. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.4 and therefore deny them.

7.5. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.5 and therefore deny them.

7.6. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.6 and therefore deny them.

C. VirtueRF

7.7. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.7 and therefore deny them.

7.8. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.8 and therefore deny them.

7.9. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.9 and therefore deny them.

7.10. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.10 and therefore deny them.

[4] Heading "A" is skipped in this section, as it was in the Complaint.

D. Genius

7.11. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.11 and therefore deny them.

7.12. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.12 and therefore deny them.

7.13. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.13 and therefore deny them.

7.14. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.14 and therefore deny them.

E. Secret RF

7.15. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.15 and therefore deny them.

7.16. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.16 and therefore deny them.

7.17. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.17 and therefore deny them.

7.18. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.18 and therefore deny them.

F. Secret Pro

7.19. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.19 and therefore deny them.

7.20. Respondents lack sufficient knowledge to admit or deny the allegations of

paragraph 7.20 and therefore deny them.

7.21. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.21 and therefore deny them.

7.22. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.22 and therefore deny them.

G. Potenza

7.23. Respondents admit that the accused Potenza products are manufactured in South Korea. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 7.23 and therefore deny them.

7.24. Respondents admit that Exhibit 47 to the Complaint appears to contain images of a Potenza device, but Respondents lack information sufficient to admit or deny the authenticity or content of Exhibit 47. Respondents further admit that Respondent Jeisys filed 510(k) premarket notifications with the U.S. Food and Drug Administration. Respondents further admit that Potenza products were imported from Respondent Jeisys in South Korea to Respondent Cynosure in the United States in 2021-2022. Respondents admit that Exhibit 50 appears to list purportedly imported items, but Respondents lack information sufficient to admit or deny the authenticity or content of Exhibit 50. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 7.24 and therefore deny them.

7.25. Respondents admit that Respondent Jeisys sells the accused Potenza products for importation into the United States. Respondents further admit that Cynosure imports the accused Potenza products to, and sells the accused Potenza products in, the United States. Respondents deny the remaining allegations of paragraph 7.25.

7.26. Respondents admit that Respondent Jeisys sells the accused Potenza devices to Respondent Cynosure, which are then imported into the United States and sold by Respondent Cynosure. Respondents further admit that the accused Potenza products are electrically suitable for use in the United States. Respondents deny the remaining allegations of paragraph 7.26.

7.27. Respondents admit that Respondent Cynosure is the U.S. distributor for the accused Potenza products. Respondents further admit that the accused Potenza products are in use in various locations in the United States. Respondents admit that Exhibits 52 and 53 to the Complaint appear to be advertisements that refer to the Potenza product, but lack information sufficient to admit or deny their authenticity or their content. Respondents deny the remaining allegations of paragraph 7.27.

H. Pixel8 RF

7.28. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.28 and therefore deny them.

7.29. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.29 and therefore deny them.

7.30. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.30 and therefore deny them.

7.31. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.31 and therefore deny them.

I. Pixel 8 Pro

7.32. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.32 and therefore deny them.

7.33. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.33 and therefore deny them.

7.34. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.34 and therefore deny them.

J. Intensif

7.35. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.35 and therefore deny them.

7.36. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.36 and therefore deny them.

7.37. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.37 and therefore deny them.

7.38. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 7.38 and therefore deny them.

VIII. HARMONIZED TARIFF SCHEDULE ITEM NUMBERS

8.1. Respondents admit that the accused Potenza products are imported under HTSUS code 9018.90.6000. Respondents deny the remaining allegations of paragraph 8.1.

IX. THE DOMESTIC INDUSTRY

9.1. Respondents deny that a domestic industry exists in the United States in this case as required and defined by Section 337(a)(2) and (a)(3). Respondents deny that Complainant or its licensee have made "significant investments in plant and equipment and significant employment of labor and capital in the United States in products that practice the Asserted Patents." Respondents further deny that the Asserted Patents are practiced by the "Domestic

Industry Product." Respondents further deny that the "Domestic Industry Product" is protected by the Asserted Patents.

A. The Economic Prong of the Domestic Industry Requirement is Satisfied

9.2. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 9.2 and therefore deny them.

9.3. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 9.3 and therefore deny them.

9.4. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 9.4 and therefore deny them.

9.5. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 9.5 and therefore deny them.

9.6. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 9.6 and therefore deny them.

B. The Technical Prong of the Domestic Industry Requirement Is Satisfied

9.7. Respondents deny that a domestic industry within the United States exists in connection with the Asserted Patents.

9.8. Respondents admit that Exhibits 118-123 appear to be claim charts. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 9.8 and therefore deny them.

9.9. Respondents admit that Exhibit 118 appears to be a claim chart. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 9.9 and therefore deny them.

9.10. Respondents admit that Exhibit 119 appears to be a claim chart. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 9.10 and therefore deny them.

9.11. Respondents admit that Exhibit 120 appears to be a claim chart. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 9.11 and therefore deny them.

9.12. Respondents admit that Exhibits 121 appears to be a claim chart. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 9.12 and therefore deny them.

9.13. Respondents admit that Exhibits 122 appears to be a claim chart. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 9.13 and therefore deny them.

9.14. Respondents admit that Exhibits 123 appears to be a claim chart. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 9.14 and therefore deny them.

X. RELATED LITIGATION

10.1. Respondents admit that they are aware of a lawsuit bearing the caption *SynKloud Technologies, LLC, et al. v. Sung Hwan E&B Co., LTD.*, 6:21-cv-811, in the Western District of Texas which identifies Respondent SHEnB as a defendant. Respondents further admit that the complaint in that action purports to assert the ’536, ’836, ’379, and ’812 Patents. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 10.1 and therefore deny them.

10.2. Respondents admit that they are aware of a lawsuit bearing the caption *SynKloud Technologies, LLC, et al. v. Cartessa Aesthetics, LLC,* 21-cv-44, in the Eastern District of New York which identifies Respondent Cartessa as a defendant. Respondents further admit that the complaint in that action purports to assert the ’536, ’836, ’774, ’379, and ’812 Patents. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 10.2 and therefore deny them.

10.3. Respondents admit that they are aware of a lawsuit bearing the caption *SynKloud Technologies, LLC, et al. v. Aesthetics Biomedical, Inc.,* 2:22-cv-15, in the District of Arizona which identifies Respondent AB as a defendant. Respondents further admit that the complaint in that action purports to assert the ’536, ’836, ’379, and ’812 Patents. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 10.3 and therefore deny them.

10.4. Respondents admit that they are aware of a lawsuit bearing the caption *Serendia, LLC v. Lutronic Aesthetics, Inc.*, 1:23-cv-00225, in the District of Delaware and filed on March 1, 2023, which identifies the Lutronic Respondents as defendants. Respondents further admit that the complaint in that action purports to assert the ’536, ’836, ’774, ’379, ’812, and ’444 Patents. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 10.4 and therefore deny them.

10.5. Respondents admit that they are aware of a lawsuit bearing the caption *Serendia, LLC v. Cutera, Inc.*, 1:23-cv-00222, in the District of Delaware and filed on March 1, 2023, which identifies Respondent Cutera as a defendant. Respondents further admit that the complaint in that action purports to assert the ’536, ’836, ’774, ’379, ’812, and ’444 Patents. Respondents

lack sufficient knowledge to admit or deny the remaining allegations of paragraph 10.5 and therefore deny them.

10.6. Respondents admit that they are aware of a lawsuit bearing the caption *Serendia, LLC v. Cynosure, LLC*, 1:23-cv-00223, in the District of Delaware and filed on March 1, 2023, which identifies Respondent Cynosure as a defendant. Respondents further admit that the complaint in that action purports to assert the ’536, ’836, ’774, ’379, ’812, and ’444 Patents.

10.7. Respondents admit that they are aware of a lawsuit bearing the caption *Serendia, LLC v. Rohrer Aesthetics, Inc.*, 1:23-cv-00226, in the District of Delaware and filed on March 1, 2023, which identifies Respondent Rohrer as a defendant. Respondents further admit that the complaint in that action purports to assert the ’536, ’836, ’774, ’379, ’812, and ’444 Patents. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 10.7 and therefore deny them.

10.8. Respondents admit that they are aware of a lawsuit bearing the caption *Serendia, LLC v. EndyMed Medical, Inc.*, 1:23-cv-00224, in the District of Delaware and filed on March 1, 2023, which identifies Respondent EndyMed as a defendant. Respondents further admit that the complaint in that action purports to assert the ’536, ’836, ’774, ’379, ’812, and ’444 Patents. Respondents lack sufficient knowledge to admit or deny the remaining allegations of paragraph 10.8 and therefore deny them.

10.9. Respondents admit that they are aware that an *inter partes* review (“IPR”) petition having the caption *Cartessa Aesthetics, LLC v. Serendia, LLC*, PTAB-IPR2022-00378 challenging certain claims of the ’536 Patent was filed with the Patent Trial and Appeal Board (“PTAB”) on December 28, 2021, and that institution was denied by the PTAB.

10.10. Respondents admit that they are aware that an IPR petition having the caption *Cartessa Aesthetics, LLC v. Serendia, LLC*, PTAB-IPR2022-00594 challenging certain claims of the ’836 Patent was filed with the PTAB on February 10, 2022, and that institution was denied by the PTAB.

10.11. Respondents admit that they are aware that an IPR petition having the caption *Cartessa Aesthetics, LLC v. Serendia*, *LLC*, PTAB-IPR2022-00376 challenging certain claims of the ’774 Patent was filed with the PTAB on December 28, 2021, and that institution was denied by the PTAB.

10.12. Respondents admit that they are aware that an IPR petition having the caption *Cartessa Aesthetics, LLC v. Serendia, LLC,* PTAB-IPR2022-00593 challenging certain claims of the ’379 Patent was filed with the PTAB on February 10, 2022, and that institution was denied by the PTAB.

10.13. Respondents admit that they are aware that an IPR petition having the caption *Cartessa Aesthetics, LLC v. Serendia, LLC,* PTAB-IPR2022-00377 challenging certain claims of the ’812 Patent was filed with the PTAB on February 10, 2022, and that institution was denied by the PTAB.

10.14. Respondents lack sufficient knowledge to admit or deny the allegations of paragraph 10.14 and therefore deny them.

XI. RELIEF REQUESTED

11.1. Respondents deny that Complainant is entitled to any relief in this Investigation, including without limitation any and all relief requested in paragraph 11.1 and all of its subparts. Respondents deny that they or the accused Potenza products violate or give rise to any violation

of Section 337, and further deny that the accused Potenza products violate any valid and enforceable claim of the Asserted Patents under any theory of infringement. To the extent any allegations or statements in paragraph 11.1 are directed to respondents other than Jeisys or Cynosure, or to products other than the accused Potenza products, Respondents deny them.

AFFIRMATIVE DEFENSES

1. Respondents assert the following affirmative and other defenses. Respondents presentation of these defenses is not, and shall not be construed as, a concession that Respondents bear the burden of proof with respect to any of these defenses. These defenses are based on Respondents' current knowledge and information, and because discovery has just begun, Respondents are still collecting and reviewing all of the information that may be relevant to these defenses. Respondents reserve the right, pursuant to 19 C.F.R. §§ 210.14(b) and 210.14(c), to seek amendment of and/or to expand or modify these defenses, and to assert further defenses and positions as discovery proceeds. Respondents further reserve the right to amend this Response if Complainants amend or supplement the Complaint.

2. Respondents also reserve the right to rely on, and hereby incorporate to the extent necessary to so rely, on defenses pled by other respondents named in this Investigation in their respective Answers to the Complaint and Notice of Investigation.

FIRST AFFIRMATIVE DEFENSE
(Non-Infringement)

3. Respondents do not, individually or collectively, directly infringe, indirectly infringe, contribute to infringement, or induce infringement of any valid and enforceable Asserted Claim of the Asserted Patents under any theory, whether literally or under the doctrine

of equivalents, and have not committed any acts in violation of 19 U.S.C. § 1337 or 35 U.S.C. § 271.

SECOND AFFIRMATIVE DEFENSE
(Invalidity)

4. The Asserted Claims of the Asserted Patents are each invalid for failure to meet the requirements of patentability set forth in Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256.

5. The Asserted Claims of the Asserted Patents are invalid as anticipated under 35 U.S.C. § 102 or as obvious under 35 U.S.C. § 103 in view of at least the prior art references identified in Appendix A to this Response, either alone or in combination. Respondents reserve the right to identify and rely on additional prior art as discovery continues.

THIRD AFFIRMATIVE DEFENSE
(Domestic Industry Requirement Not Met)

6. On information and belief, no protectable domestic industry exists or is being established in the United States as required by Section 337 with respect to any of Asserted Claims or Asserted Patents.

FOURTH AFFIRMATIVE DEFENSE
(No Unfair Act)

7. Respondents have not engaged in any unfair act or acts of unfair competition within the scope and meaning of 19 U.S.C. § 1337.

FIFTH AFFIRMATIVE DEFENSE
(Inequitable Conduct and Unclean Hands)

8. Serendia's enforcement of the '836, '379, '444, '536, '774, and '812 Patents is barred by the doctrines of inequitable conduct and unclean hands.

Inequitable Conduct Claim 1 ('836, '379, and '444 Patents)

9. The '536, '774, and '812 Patents claim priority to Korean Patent Application No. 10-2008-0076993 ("Korean '993 Application") filed by Jongju Na ("Na"). On August 22, 2008, Na and Merle Richman ("Richman"), prosecuting attorney and co-inventor, filed a PCT application (PCT/US2008/074131; "'131 Application"), which claims priority to the Korean '993 Application. On March 3, 2011, Applicants, Na and Richman, subsequently filed a national stage application in Korea (Korea Patent Application No. 10-2011-7005052; "'052 Application"), which claims priority to the '131 application. Applicants newly added three paragraphs in the '052 Application, which among other things, explained that "the high-frequency, such as radio waves, are basically alternating current." ('052 Application at [0016]).

10. On September 23, 2013, Na filed U.S. Application No. 14/006,930 ("'930 Application") which ultimately issued as the '836 Patent. Na was the sole inventor, and Richman was the prosecuting attorney for the '930 Application. Early in the prosecution of the '930 Application, Na and Richman amended the claims to recite "a signal generation module . . . coupled to the set of electrodes and providing high frequency signals to the bipolar electrodes." Complaint, Appendix A ('836 FH), Response Under 37 CFR 1.111 (July 7, 2015) at 3.

11. The United States Patent and Trademark Office ("USPTO"), among other things, rejected the claims under § 102(b) as being anticipated by U.S. Patent Publication No. 2005/0222565 ("Manstein"), citing Manstein's disclosure of needles operating "in bipolar mode . . . delivering RF." (Manstein at [0043]); Complaint, Appendix A ('836 FH), Detailed Action (Aug. 4, 2015) at 4.

12. Manstein describes an energy source 320 as supplying power to bipolar electrodes. Manstein at [0041-0042]. Manstein also describes this energy source 320 as "a radio frequency (RF) device capable of outputing signals having frequencies in a desired range." Manstein at [0032]. As Na admitted in his own publication, it was well-known in the art that radiofrequency (also called as high frequency) energy is generated from alternating current (AC). Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes, Na, J. et al, Scientific Reports (2015) 5:16735 at 1 ("[R]adiofrequency (RF) refers to high frequency alternating electrical current at the frequency range traditionally used for radio-wave communication."); see also Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias, Manolis, A.S., et al., Ann Intern Med. (1994) 121:452-461 at 452 ("Radiofrequency energy is a form of electrical energy, generated from low-power (15 to 60 V), high-frequency (30 KHz to 300 MHz) alternating current."). Manstein therefore described, in a single embodiment, application of radio frequency alternating current signals to bipolar electrodes.

13. In responding to the USPTO's rejections, Na and Richman amended the claims to specify that the claimed "signal generation module" provides "a high frequency Alternating Current (AC) . . . to . . . the . . . electrodes." Id., Response Under 37 CFR 1.111 (Oct. 18, 2015) at 2. In an attempt to overcome the USPTO's rejections, Na and Richman further falsely stated that "the Manstein reference does not teach applying a high frequency Alternating Current signal to bipolar electrodes." Id., Response Under 37 CFR 1.111 (Oct. 18, 2015) at 9.

14. After the USPTO then rejected the claims again based on Manstein, Na and Richman again falsely stated that Manstein does not disclose the claimed "a radio frequency

(RF) generation module . . . configured to provide an Alternating Current RF signal to the plurality of electrodes" because "Manstein clearly does not teach or suggest providing a high frequency AC signal to bipolar electrodes." *Id*., Response Under 37 CFR 1.111 (Mar. 1, 2016) at 2, 8. In their remarks, Na and Richman falsely distinguished between RF "in one embodiment" and AC in "another embodiment" even though RF signals are high frequency AC signals and that they had stated in a prior Korean applications that "the high-frequency, such as radio waves, are basically alternating current." ('052 Application at [0016]).

15. The factual representations made to the USPTO by Na and Richman to distinguish Manstein from the then-pending claims were false. Despite Na and Richman's statements to the contrary, Manstein in fact teaches, suggests, and describes, in a single embodiment, the application of high frequency AC signals to a plurality of electrodes operating in a bipolar mode.

16. At all times material to the prosecution of the '836 patent, Na and Richman knew of the falsity of the statements identified above. Specifically, Na and Richman knew that, in a single embodiment of Manstein, the radio frequency signals applied to electrodes operating in a bipolar mode were high frequency alternating current signals. They demonstrated this knowledge in their own '052 application: "the high-frequency, such as radio waves, are basically alternating current." ('052 Application at [0016]).

17. On information and belief, Na and Richman had a specific intent to deceive the USPTO when they repeatedly falsely stated that the "RF" and "AC" clearly disclosed by Manstein is not a disclosure of the claimed "high frequency signals" (June 22, 2015), is not a disclosure of the claimed "high frequency Alternating Current (AC)" (Oct. 18, 2015), and is not

a disclosure of the claimed "Alternating Current (AC) RF signal" (Mar. 1, 2016). The statements repeatedly made by Na and Richman to the USPTO clearly contradict Na and Richman's prior disclosure to the Korean Patent Office that a high-frequency signal, such as an RF signal, is "basically alternating current." And, it was well known in the art that radiofrequency energy is generated from alternating current. Both Na and Richman had been aware of this fact at least since 2008 when they submitted the '052 Application to the Korean Patent Office. Consistent with the misrepresentation made by Na and Richman, Na and Richman had also omitted from the '930 Application the disclosure they had made to the Korean Patent Office that high-frequency signal, such as RF signal, is "basically alternating current."

18. The USPTO relied upon intentional false factual representations made by Na and Richman. In its Notice of Allowability, the USPTO stated "[t]he examiner agrees that with the applicant's argument that the AC signal and RF signal are applied in different embodiments in the prior art (e.g. see [0032] of Manstein) and that there would be no motivation to combine the embodiments. [0052] of the applicant's specification is where the applicant discloses the RF AC signal being implemented in one embodiment." Complaint, Appendix A ('836 FH), Notice of Allowability (May 18, 2016) at 2.

19. The misrepresentations made by Na and Richman during the prosecution of the '930 Application were material. But for the false statements identified above, the '836 Patent would not have been issued.

20. Therefore, both Applicant Na and prosecuting attorney Richman breached the duty of candor and good faith during the prosecution of the '836 Patent by misrepresenting the

facts concerning Manstein's disclosure of the claimed limitations with the specific intent to deceive the USPTO. Accordingly, the '836 Patent is unenforceable under the doctrine of inequitable conduct.

21. The '379 and '444 Patents are also unenforceable for inequitable conduct. The '379 Patent is a continuation of the '836 Patent, and the '444 Patent is a continuation that traces of its lineage back to the '836 Patent. Na filed applications that issued as the '379 and '444 Patents as the sole inventor and applicant. Richman was the prosecuting attorney for both applications.

22. The inequitable conduct by Na and Richman during prosecution of the '836 patent, which was not cured, renders each of the '379 and '444 Patents also unenforceable.

23. Moreover, similar to the '836 Patent, the '379 Patent would not have been issued but for Na and Richman's misrepresentation. In the "Reasons for Allowance," the Examiner concluded that "applying an RF signal with an oscillating current at an extremely high frequency which causes each needle to change polarity many times per second" and "[t]his results in the current or energy forming around each needle rather than between needles as is disclosed in the prior art." Complaint, Appendix B ('379 FH), Notice of Allowability (June 18, 2018) at 2.

24. Similar to the '379 Patent, the '444 Patent would not have been issued but for Na and Richman's misrepresentation. In the "Reasons for Allowance," the Examiner specifically stated that "the allowable subject matter [was] requiring the RF signal to be oscillating current. . . . This produces the effect . . . where the RF energy flows around individual needles rather than between needles as each individual needle is completing the positive/negative flow path

itself." Complaint, Appendix C ('444 FH), Notice of Allowability (March 23, 2022) at 2.

25. On information and belief, Applicant had a specific intent to deceive the USPTO when he omitted the information that the RF current, which is an alternating current, is an oscillating current by nature. See, e.g., Catheter Ablation Using Radiofrequency Energy, Borggrefe, M., et al., Clin. Cardiol. (1990) 13: 127-131 at 128, Fig. 1 (showing oscilloscopic recordings of current wave forms of radiofrequency current). Both Na and Richman had been aware of the fact that an RF signal is an oscillating current at least since 2008 when they submitted to the Korean Patent Office the '052 Application, which disclosed that "the high-frequency, such as radio waves, are basically alternating current."

26. Therefore, both Applicant Na and prosecuting attorney Richman breached the duty of candor and good faith during the prosecution of the '836, '379 and '444 Patents ("the Family One patnets") and had a specific intent to deceive the USPTO. Accordingly, the '836,'379 and '444 Patents are unenforceable under the doctrine of inequitable conduct.

Inequitable Conduct Claim 2 ('536, '774, and '812 Patents)

27. Serendia's enforcement of the '536, '774 and '812 Patents ("the Family Two patents") is barred by the doctrines of unclean hands and inequitable conduct. Richman also prosecuted each of these patents, and during prosecution, repeatedly misrepresented the priority date of these applications, which resulted in the USPTO erroneously allowing the patents to issue. *See, e.g.*, Complaint, Appendix E ('774 FH), ADS (Apr. 12, 2016) at 2, 6 (falsely characterizing PCTKR2012001335 (the application leading to the '536 patent) as a "Continuation of" the '274 Application):

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	13825083	2013-03-19
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13825083	a 371 of international	PCTKR2012001335	2012-02-22
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCTKR2012001335	non provisional of	61449080	2011-03-03
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
PCTKR201200133	Continuation of	13060274	2011-02-22	8979912	2015-03-17

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13060274	a 371 of international	PCTUS2008074131	2008-08-22

Signature: Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Signature	/mwresq/			Date (YYYY-MM-DD)	2016-04-12
First Name	Merle	Last Name	Richman	Registration Number	38282

28. *See also* '774 FH, Request for Certificate of Correction dated March 6, 2023 (not included in Appendix E); Complaint, Appendix F ('812 FH), ADS (Oct. 3, 2017) at 2; Complaint, Appendix D ('536 FH), Request for Expedited Issuance of Certificate of Correction (Feb. 8, 2021).

29. The Family Two patents have a common specification. Figures 1 through 8 (and associated description) describe a dermatology device that includes needles extending a fixed amount past an acupuncture plate or roller. Figures 9 through 12 (and associated description) also describe a dermatology device, but the embodiments of these figures have extendable needles. In the latter embodiments, a motor drives the needles to a desired position beyond the

device surface.

30. Each of the Family Two patents claims priority to earlier applications filed in the United States, Korea, and under the Patent Cooperation Treaty (PCT). Relying on a chain of prior applications, for each of the Family Two patents, the applicant attempted to claim a priority date of August 6, 2008, which was the filing date of the Korean ’993 Application. Each of the Family Two patents also claims priority to a second chain of applications beginning with U.S. Provisional Application 61/449,080 (“the US ’080 Application”), which was filed on March 3, 2011.

31. The Korean ’993 Application described did not include Figures 9 through 12 and the corresponding description of the Family Two patents, and thus does not include any discussion or depiction of extendable needles. The US ’080 Application, in contrast, includes an extensive discussion and depiction of extendable needles, all of which is new matter relative to the Korean ’933 Application and the ’274 Application claiming priority to the Korean ’933 Application. For example, comparing the disclosure of the ’536 Patent relative to the disclosure of U.S. Patent No. 8,979,912 (issued from the ’274 Application), it can be seen that at least 14 figures (Figs. 9A-9D, 10A-10F, 11A-11C and 12) and 5 columns of text (cols. 9:18-14:4) have been added as new matter relative to the ’274 Application.

32. Every claim in the Family Two patents recites extendable needles. Because this concept was first described in the US ’080 Application, the earliest possible filing date for the Family Two patents is the March 3, 2011, filing date of that application. The claims of the Family Two patents are not entitled to any date earlier than March 3, 2011, because none of the relevant applications in the priority chain filed prior to March 3, 2011 describe the claimed

“extendable” needles.

33. On February 11, 2010, the applicant’s own PCT application (International Application No. PCT/US2008/074131) claiming priority to the Korean ‘993 Application had been published as WO 2010/016848 A1 (“the ’848 publication”) and was therefore available as prior art to any of the applicant’s claims having a priority date later than February 11, 2011 (which applies to all claims of the Family Two patents). However, by representing to the USPTO that the Family Two patents were continuation applications of U.S. Application No. 13/060,274 (“the ’274 Application”), which was filed February 22, 2011 and which claimed priority to the Korean ’993 Application filed August 6, 2008, the applicant misled the Examiner to believe that the ’848 publication could not be considered as prior art to the Family Two patents.

34. On information and belief, the priority claims made by the applicant were known by Richman to be false, and Richman intentionally made these false priority claims to mislead the Examiner as to the availability of the ‘848 publication as invalidating prior art. As a named inventor and prosecuting attorney of the ’274 Application, and as the original prosecuting attorney of each of the Family Two patents, Richman would have known that each of the Family Two patents included substantial new matter relative to the ’274 Application, including the new figures and description directed to the “extendable” needle embodiments. Richman also would have known that none of the Family Two patents were actually continuations, as opposed to continuations-in-part, of the ’274 Application and that none of the claims of the Family Two patents (all of which recite extendable needles) were actually entitled to the priority date of the Korean ’993 Application (which does not describe extendable needles).

35. Richman's repeated claims that the Family Two patents were continuations of the '274 Application, and therefore entitled to the priority date of the Korean '993 Application, conveyed to the USPTO false information that no new matter was included in the specifications of the Family Two patents relative to the '274 Application. However, given the actual significant new matter in the Family Two patents, there was no good faith basis for these priority claims. To comply with his duty of candor, Richman was required to inform the USPTO that the Family Two patents included subject matter that was not in the '274 Application or the prior Korean '993 Application. For example, and at the very least, Richman should have properly identified the '536 Patent as being a continuation-in-part of the '274 Application in each of the Family Two patents. Had Richman complied with his duty of candor, the USPTO would have known that the '848 publication was available as prior art to each of the Family Two patents.

36. Instead, Richman's misrepresentations with respect to these priority claims concealed the status of the '848 publication as prior art. The USPTO's lack of knowledge of the '848 publication as being available as prior art is evident, for example, based on the issuance of claims 1 and 11 of the '774 Patent. Each of these claims recites in the alternative needles that are either "extending or extendable." Because these claims cover the "extendable" embodiment, the earliest possible priority date for them is March 3, 2011, and because the claims simultaneously cover the alternative "extending" embodiment, the '848 publication is invalidating prior art to these claims. The '848 publication exactly describes all limitations of the claimed "extending" embodiment. But for the false priority claim, the USPTO would not have issued these claims of the '774 Patent over the '848 publication.

37. The claims of the ’536 and ’812 Patents likewise would not have issued but for the false priority claims. Every claim of these patents requires movable or extendable needles, and the earliest possible priority date for them is the March 3, 2011, filing date of the ’080 application. There are no patentable differences between the claimed subject matter of the ’536 and ’812 Patents and the prior art ’848 publication, and the USPTO would not have allowed at least the asserted independent claims of the '536 and '812 Patents to issue because they would have been obvious based on the '848 publication alone or when combined with any number of references that teach an extendable needle module or assembly (e.g., WO 2010/098784 A1 to Mehta, and U.S. Patent No. 8,666,487 to Kang). But for the false priority claim, the USPTO would not have issued at least the asserted independent claims of the '536 and '812 Patents over the ‘848 publication.

38. On information and belief, Richman intended to deceive the USPTO through his false claims of priority. Richman was the prosecuting attorney for the Family Two patents, and, on information and belief, he knew that the claims of these patents could not have issued if the USPTO was aware that the ‘848 publication was available as prior art. On information and belief, Richman therefore intentionally and falsely characterized the Family Two patents as being continuations and deceptively claimed priority to the Korean ’993 application, filed in 2008, in a scheme to defraud the USPTO and obtain the Family Two patents.

39. The USPTO issued the Family Two patents only due to the misconduct and lack of candor by Richman. The Family Two patents are therefore unenforceable due to unclean hands and inequitable conduct.

Inequitable Conduct Claim 3 (’836, ’379, ’444, ’536, ’774, ’812 Patents)

40. At least the ’836, ’379, ’444, ’536, ’774, and ’812 Patents are unenforceable as a result of the failure of at least the named inventor, Dr. Jongju Na, to cite the article Hantash, B., et al, “Pilot Clinical Study of a Novel Minimally Invasive Bipolar Microneedle Radiofrequency Device,” Lasers in Surgery and Medicine, 41:87-95 (2009) (“Hantash – Lasers in Surgery”), and/or the article Berube et al., “A Predictive Model of Minimally Invasive Bipolar Fractional Radiofrequency Skin Treatment,” Lasers in Surgery and Medicine, 41:473-478 (2009) (“Berube”), during prosecution of those patents.

41. The named inventor, Jongju Na, was aware of Hantash-Lasers in Surgery and Berube at least as early as the publication of his article “[a] bipolar 2-MHz RF device equipped with non-insulated microneedle electrodes” on November 13, 2015. Na et al., Sci. Rep. 5:16735 at 8 (Nov. 13, 2015) (the “Na article”). The Na article cites Hantash-Lasers in Surgery and Berube. Each of the applications that resulted in the ’836, ’379, ’444, ’536, ’774, and ’812 Patents were either still pending or had not yet been filed as of the date of publication of the Na article.

42. Hantash-Lasers in Surgery and Berube each anticipate, and/or the combination of them renders obvious, at least one granted claim of each of the Asserted Patents, and therefore those references are each material to the issue of patentability and should have been disclosed to the USPTO during prosecution.

43. Upon information and belief, Jongju Na knew of the Hantash-Lasers in Surgery and Berube references, because he had cited them in the 2015 Na article and knew of their materiality to the patent applications on which he was the named inventor, but deliberately failed to disclose these material references to the USPTO with the specific intent to mislead or

deceive the USPTO.

Inequitable Conduct Claim 4 (At Least '836 Patent)

44. At least the '836 Patent is unenforceable because it introduced new matter into the specification. As a U.S. national phase of PCT/KR2012/004695 ("the '695 PCT application"), no new matter was permitted to be added to the specification, but a substitute specification was presented on September 23, 2013. Contrary to merely "correcting grammatical and language issues," as stated in the supplemental preliminary amendment filed on September 24, 2013, the substitute specification contains deletions, substitutions, additions, and recharacterizations of the invention and the prior art.

45. An accurate translation of the '695 PCT specification would have been material to the patentability of the '836 patent, but upon information and belief, the named inventor Dr. Jongju Na and/or the prosecuting attorney Merle Richman ("Richman") made a deliberate decision to withhold an accurate translation and instead submit to the USPTO a substitute specification that improperly introduced new matter for the purpose of omitting the reference to the Na effect and broadening the scope of the claims. But for Na and/or Richman's material misrepresentations and/or omission, the USPTO either would not have granted the '836 patent, and/or the '836 patent would have issued with a materially different specification.

Inequitable Conduct Claim 5 (At Least '812 Patent)

46. At least the '812 Patent is unenforceable as a result of the failure to cite an April 8, 2011 INTRAcel video that was cited and relied upon by the Patent Trial and Appeal Board of the Korean Patent Office in invalidating the claims in a corresponding Korean patent. *See* "Evaluation of the wound healing response post-deep dermal heating by fractional RF:

INTRAcel" by Yeo, 12th Symposium of the Association of Korean Dermatologists (2009).

47. On November 30, 2018, the Patent Trial and Appeal Board of the Korean Patent Office issued a decision invalidating KR101181870B1 ("the Korean '870 Patent") (one of the priority documents to the '444 Patent) over, inter alia, a video showing operation of the INTRAcel device. The invalidated claims of the Korean '870 Patent, which also lists Na as an inventor, were similar to claims of and the '812 Patents. As provided in M.P.E.P. 2001.06, "[t]he inference that such prior art or other information is material is especially strong where it has been used in rejecting the same or similar claims in the foreign application or where it has been identified in some manner as particularly relevant."

48. Notwithstanding that the Korean Patent Trial and Appeal Board decision includes stills of the INTRAcel video, Mr. Na did not cite the Korean Patent Trial and Appeal Board decision, the INTRAcel video or any of the stills from that video during the prosecution of the'812 Patents. Na omitted citing the video despite being listed as the sole inventor on both the '444 and the '812 patents and having cited both the '836 patent and the search report of the corresponding PCT application in the '812 patent. Claim 11 of '812 Patent is directed to an apparatus for treating dermatological tissue which requires: "a user holdable device including a proximal end", a "releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles"; and a movable needle assembly "to extend the plurality of needles from the releasably couplable deployable needle assembly" into tissue "while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end." These features are shown in the video captures below

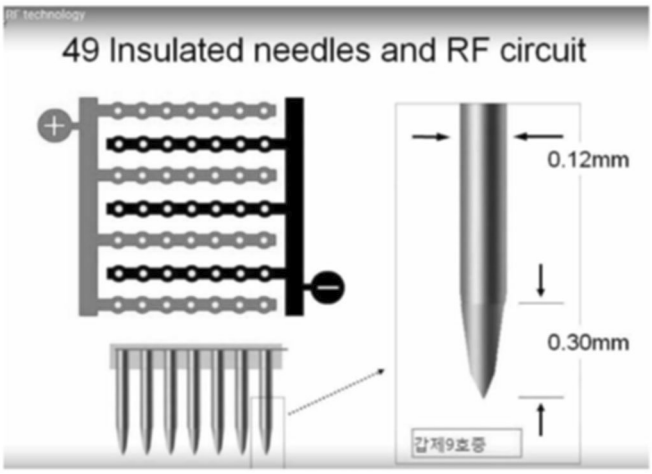
from the Korean invalidation decision.

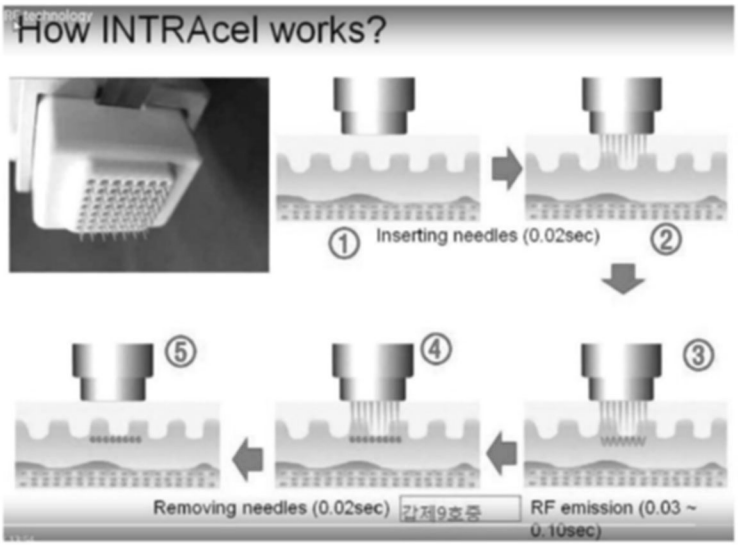
RF technology

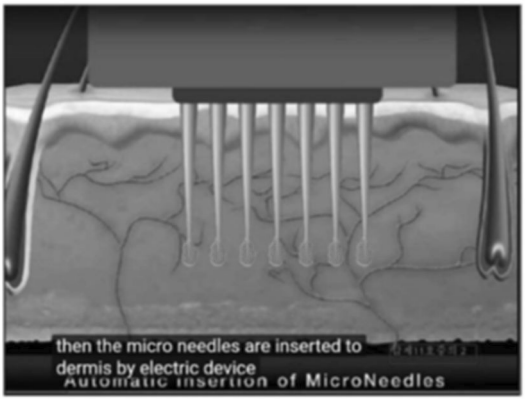
Specification

Applied Energy	RF (Radio Frequency)-1Mhz
Output Power	Mono-polar : up to 700W (Peak power & 200Ω)
	Bi-polar : up to 700W (Peak power & 200Ω)
Spot Size (Treated Area)	1cm X 1cm / 0.2cm X 0.2cm
Disposable tip matrix	49 electrode needles 4 electrode needles 7 electrode needles

갑제9호증


RF technology
49 Insulated needles and RF circuit
0.12mm
0.30mm
갑제9호증


RF technology
How INTRAcel works?
① Inserting needles (0.02sec) ②
③
④
⑤
Removing needles (0.02sec)
갑제9호증
RF emission (0.03 ~ 0.10sec)


then the micro needles are inserted to dermis by electric device
Automatic insertion of MicroNeedles

49. Furthermore, while the invalidation decision issued in 2018, the invalidation trial was requested on October 11, 2016. To the extent that Mr. Na was aware of the INTRAcel video before the October 3, 2017, issue date of the '774 patent, Mr. Na should have also submitted INTRAcel video or any of the stills from that video during the prosecution of the '774 patent. The claims of the '774 patent also require features that are disclosed in submitted INTRAcel video or any of the stills from that video.

Inequitable Conduct Claim 6 ('444 Patent)

50. The '444 Patent is unenforceable due to the submission of a false and fraudulent assertion of unintentional abandonment. The application that resulted in the '444 Patent was allowed on March 23, 2022, with the issue fee payment due June 23, 2022. The issue fee on the '444 Patent was not timely paid and, instead, the issue fee was paid on July 8, 2022, along with a petition asserting that the patent was unintentionally abandoned.

51. At the time of the allowance of the patent application that became the '444 Patent, there were inter partes review (IPR) requests pending in connection with the '536, and '812 Patents. The Patent Trial and Appeal Board (PTAB) denied institution of the IPR on the '812 Patent on June 28, 2022. The PTAB denied institution of the IPR on the '536 Patent on June 30, 2022.

52. It was only after the institution denials on the IPRs relating to the '812 and '536 Patents that the issue fee was paid for the '444 Patent, along with a claim that the failure to timely pay the issue fee had been unintentional. Upon information and belief, the failure to timely pay the issue fee for the '444 Patent was not unintentional as asserted in the petition to revive the application that led to the '444 Patent. Upon information and belief, Jongju Na and/or

prosecuting attorney Merle Richman made this false statement to the USPTO with the intent to deceive or mislead the USPTO, and such false statement was material to the issuance of the '444 Patent.

Inequitable Conduct Claim 7 (Infection Unenforceability)

53. The '836, '379, '444, '536, '774, and '812 Patents are directed to respective features of the same dermatological devices, share the same inventors and prosecuting attorney, have been licensed together (*see, e.g.*, Complaint, Ex. 69), and are asserted together in the present ITC proceeding and related district court litigations. To the extent that any of the '836, '379, '444, '536, '774, and '812 Patents is found to be unenforceable due to inequitable conduct, all of the '836, '379, '444, '536, '774, and '812 Patents would be unenforceable due to the interrelatedness of these patents. *See Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245-47 (1933); *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 803-04 (Fed. Cir. 1990); *Mathis v. Hydro Air Industries, Inc.*, 1 U.S.P.Q.2d 1513, 1529, 1986 WL 84360, at *14 (C.D. Cal. 1986), *aff'd*, 818 F.2d 874 (Fed. Cir. 1987) (unpublished), *cert. denied*, 484 U.S. 826 (1987).

SIXTH AFFIRMATIVE DEFENSE
(Express or Implied License)

54. Complainant is barred from asserting at least

55. In view of this Complainant is further barred from against Respondent Cynosure.

SEVENTH AFFIRMATIVE DEFENSE
(Patent Exhaustion and/or First Sale Doctrine)

56. At least as a result of Dr. Na's license of Asserted Patent Nos. 9,320,536; 9,775,774; and 10,869,812 to Respondent Jeisys, Complainant may not seek further relief against Respondents with respect to at least those patents.

EIGHTH AFFIRMATIVE DEFENSE
(Prosecution History Estoppel)

57. On information and belief, as a result of Applicant's statements, representations, admissions, positions, elections, concessions, and any other communication or filing made to the USPTO during prosecution of the applications that issued as the Asserted Patents and/or any related patents or related applications, Complainant is estopped from construing an otherwise valid and enforceable claim, if any, of the Asserted Patents as infringed by Respondents or by the Accused Potenza products, either literally or under the doctrine of equivalents.

NINTH AFFIRMATIVE DEFENSE
(Prosecution Laches)

58. On information and belief, Complainant's claims for relief based on the Asserted Patents are barred under the doctrine of prosecution laches.

TENTH AFFIRMATIVE DEFENSE
(Inventorship)

59. The Asserted Patents are unenforceable to the extent that they fail to name as an inventor any one or more actual inventors of the purportedly inventive subject matter of the Asserted Patents.

ELEVENTH AFFIRMATIVE DEFENSE
(Waiver and/or Estoppel)

60. On information and belief, Complainant is barred from seeking relief based on

the claims presented in this Investigation because Complainant or its predecessors-in-interest have long been aware of the basis for the allegations it now asserts against Respondents, but unreasonably delayed in seeking relief.

TWELFTH AFFIRMATIVE DEFENSE
(Lack of Standing or Ownership in Asserted Patents)

61. To the extent that Complainant does not have all or substantially all the rights to the Asserted Patents, or to the extent the purported assignments pertaining to the Asserted Patents are incorrect or defective, Complainant lacks standing to bring its claims in this Investigation.

THIRTEENTH AFFIRMATIVE DEFENSE
(Relief Sought Not In The Public Interest)

62. The relief sought by Complainant, including an exclusion order, cease and desist orders, etc., is not in the public interest because they would adversely affect the public health and welfare. The relief Complainant seeks would impair the production of similar or competitive articles in the United States, damage competition in the United States, and harm United States consumers.

FOURTEENTH AFFIRMATIVE DEFENSE
(Ensnarement of Prior Art)

63. Complainant is legally, factually, and/or equitably barred from asserting infringement under the doctrine of equivalents to the extent the alleged equivalents would encompass or ensnare the prior art.

FIFTEENTH AFFIRMATIVE DEFENSE
(Other Defenses)

64. Respondents expressly reserve the right to assert any and all defenses that are or

may become available to Respondents as a result of information developed during discovery, at the final hearing, or otherwise throughout this Investigation.

REQUEST FOR RELIEF

65. WHEREFORE, Respondents respectfully request that the Commission:

a. Find that Respondents, individually and collectively, have not violated Section 337 of the Tariff Act of 1930, as amended;

b. find that Respondents have not infringed any claim of the Asserted Patents;

c. find that the Asserted Claims of the Asserted Patents are invalid or unenforceable;

d. find that no domestic industry exists or is being established within the United States that is related to the Asserted Patents;

e. find, in the alternative, even if an unfair act or unfair competition by Respondents is established, that the relief requested by Complainant should be denied in view of the negative effects on the public interest;

f. dismiss the Complaint and deny all relief requested therein;

g. award Respondents any such relief as the Commission may deem appropriate.

RESPONSE TO THE NOTICE OF INVESTIGATION

i. Pursuant to Commission Rule 210.13(b), Respondents Jeisys and Cynosure hereby respond to the Notice of Investigation issued by the Commission on March 31, 2023 and published in the Federal Register at Vol. 88, No. 66, pages 20551-20552 on April 6, 2023. Respondents acknowledge that the Commission has instituted an investigation as set forth in the Notice. Respondents deny that they are in violation of 19 U.S.C. § 1337, or that they have engaged in unlawful importation into the United States, sale for importation, or sale within the United States after importation of certain dermatological devices and components thereof. Respondents further deny that the Asserted Claims of the Asserted Patents are valid or infringed.

ii. Respondents admit that, as set forth in the Notice "Summary," Complainant filed a Complaint on March 1, 2023 under section 337 of the Tariff Act of 1930, as amended, with supplements thereto filed on March 2, 13, and 14, 2023. Respondents further admit that the Complaint alleges infringement of the Asserted Patents, but Respondents dispute that the Asserted Patents are infringed by Potenza and therefore deny these allegations. Respondents further admit that the Complaint alleges that an industry in the United States exists, but Respondents dispute Complainant's allegation regarding the existence of an industry in the United States, and therefore deny it.

iii. Respondents deny that Complainant is entitled to, or that the Commission should issue, any of the relief sought by the Complaint, including any kind of exclusion order, cease and desist order, or any other form of relief based on the allegations set forth in the Complaint.

ADDITIONAL INFORMATION PURSUANT TO 19 C.F.R. § 210.13(b)

i. Confidential Exhibit A to this Response sets forth the information required by to 19 C.F.R. § 210.13(b). The Potenza Respondents provide this information solely for the purpose of supplying data required by that rule. Respondents deny that any of the information or other data provided as required by the rule is relevant to or supportive of Complainant's allegations of infringement or any other allegedly unlawful act under Section 337 or otherwise.

Date: May 1, 2023

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I hereby certify that on May 1, 2023, copies of the foregoing were filed with and served upon the following as indicated:

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