

Filed on behalf of: Serendia, LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ENDYMED MEDICAL LTD. AND ENDYMED MEDICAL, INC.,  
Petitioner,

v.

SERENDIA, LLC,  
Patent Owner.

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Case IPR2024-00842  
Patent 9,480,836

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**DECLARATION OF DAVID J. GOLDBERG  
IN SUPPORT OF  
PATENT OWNER'S PRELIMINARY RESPONSE**

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**I. INTRODUCTION AND QUALIFICATIONS**

1. I have been retained by counsel for Serendia, LLC (“Serendia” or “Patent Owner”) to provide my opinion concerning U.S. Patent Publication No. 2007/0208340A1 (“Ganz”), particularly as it relates to U.S. Patent No. 9,480,836 (Ex. 1001). I have also been asked to provide an opinion concerning objective indica of non-obviousness relating to the '836 Patent.

2. This declaration is based on information available to me to date. If called as an expert witness, I expect to testify on my background, qualifications and experience relevant to the issues in this litigation, how RF microneedling devices affect tissue during treatment, Ganz, and objective indica of non-obviousness as to the '836 Patent. Any testimony I give may include appropriate demonstratives to support or summarize my opinions.

**II. BACKGROUND, EXPERIENCE, AND COMPENSATION**

3. I earned my medical degree from Yale University School of Medicine and completed my dermatology residency and dermatologic surgical fellowship at New York University Medical Center. Since then, I have served as President as well as Chairman of both the Ethics and International Committees of the American Society for Laser Medicine and Surgery (ASLMS). I was the first ever recipient of the ASLMS Leon Goldman award named after the founder of laser medicine. I have further been a member of the Board of Directors of the American Society for

Dermatologic Surgery (ASDS), American Academy of Dermatology (AAD) and the American Society for Lasers in Medicine and Surgery. I also served as Chair of the Ethics Committees of the American Academy of Dermatology, the American Society of Dermatologic Surgery and the American Society for Lasers in Medicine and Surgery.

4. I am also a Clinical Professor of Dermatology and former Director of Laser Research and Mohs Surgery at NY's Mount Sinai School of Medicine. In addition, I am a Clinical Professor of Dermatology and Chief of Dermatologic Surgery at UMDNJ-New Jersey Medical School. I have published over 190 peer-reviewed manuscripts and have been the author and/or editor of 15 books on non-invasive aesthetic treatments. I am currently on the editorial boards of the Lasers in Surgery and Medicine and Dermatologic Surgery, and the Journal of Cosmetic Dermatology. I am the former Chief Editor of the Journal of Cosmetic and Laser Therapy. I have trained physicians on the use of energy-based device treatments (including radiofrequency) for over 25 years, have performed pivotal trials on many of the currently used energy-based devices and have lectured on these technologies throughout the world. Additionally, I am an attorney, having graduated from NY's Fordham University School of Law, where I currently serve as an Adjunct Professor of Law and have taught a course entitled "Advances in Health Care Law" for 20 years.

5. I have served as a Key Opinion Leader for a number of RF microneedling products and taught others how to use these products, including the Sylfirm X, Secret Pro, and EndyMed Intensif devices. I have also personally used the Sylfirm X, Secret Pro, and EndyMed Intensif as part of my practice.

6. I am being compensated for my work on this matter, but my opinions are based on my own views of the documents and test results cited herein. In connection with this matter, I am being compensated at the rate of \$1,000 per hour for my work performed. I further served as an expert in the 1356 ITC Investigation and was compensated the same for my work in that matter. My compensation is not dependent on and in no way affects the substance of my statements, opinions, or conclusions in this declaration, nor is it dependent on the outcome of these or any other proceedings. A copy of my C.V. is attached to this declaration as **Ex. 2055**.

### **III. SUMMARY OF MATERIALS REVIEWED AND CONSIDERED**

7. All of the opinions contained in this declaration are based on the documents I reviewed and my knowledge and professional judgment. In forming the opinions expressed in this declaration, while drawing on my experience in the field of dermatology, I reviewed the following documents:

| <b>Ex.</b> | <b>Description</b>                                       |
|------------|----------------------------------------------------------|
| 2055       | <i>Curriculum Vitae</i> of David J. Goldberg, M.D., J.D. |

| Ex.  | Description                                                                                                                                                                                                                                              |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2056 | Hee Kyung Kim et al., <i>Immediate and Late Effects of Pulse Widths and Cycles on Bipolar, and Gated Radiofrequency-Induced Reactions in In Vivo Rat Skin</i> , 16 CLINICAL COSM. INVESTIGATIONAL DERM. 721 (2023)                                       |
| 2057 | S. Tyler Hollmig & Basil M. Hantash, <i>Radiofrequency in Cosmetic Dermatology, Recent &amp; Future Developments</i> , 24 COSM. DERM. 565 (2011)                                                                                                         |
| 2058 | U.S. Patent No. 8,142,426 B2 (“Knopp ’426”)                                                                                                                                                                                                              |
| 2060 | Dany Berube et al., <i>A Predictive Model of Minimally Invasive Bipolar Fractional Radiofrequency Skin Treatment</i> , 41 LASERS SURG. MED. 473–478 (2009)                                                                                               |
| 2061 | Exclusive Distribution and License Agreement between ViOL Co., Ltd. and Serendia LLC, dated February 7, 2018 (PROTECTIVE ORDER MATERIAL)                                                                                                                 |
| 2062 | Presentation: Sylfirm X Clinical Training (2021) (PROTECTIVE ORDER MATERIAL)                                                                                                                                                                             |
| 2063 | Sylfirm Video2                                                                                                                                                                                                                                           |
| 2064 | Transcript of Exhibit 2063 - Sylfirm Video2                                                                                                                                                                                                              |
| 2065 | Presentation: Koh Seikoh, <i>Skin Rejuvenation Treatment of Asian Skin Using Pulse Oscillation Needle RF</i> , 38TH ANN. MTG. JAP. SOC’Y AESTHETIC DERM. (Sept. 13, 2020) (PROTECTIVE ORDER MATERIAL)                                                    |
| 2066 | Martin Braun, Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling, 12 PRIME INT’L J. AESTHETIC ANTI-AGEING [SIC] MED. 50 (2022)                                                                                                 |
| 2067 | World-Class Product of Korea 2020, Certificate to ViOL Co., Ltd., dated December 9, 2020 (“Sylfirm X Award”)                                                                                                                                             |
| 2069 | Baze Mpinja, <i>A New Filler for Laugh Lines &amp; More Procedures That Are Safe for Dark Skin</i> , ALLURE (Mar. 20, 2023), <a href="https://www.allure.com/story/inclusive-skin-procedures">https://www.allure.com/story/inclusive-skin-procedures</a> |

| Ex.  | Description                                                                                                                                                                         |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2143 | Declaration of Daniel van der Weide in Support of '836 Patent Owner's Preliminary Response, dated November 11, 2024 ("VDW Decl.") (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS) |
| 2148 | Andrew I. Brill, <i>Bipolar Electrosurgery: Convention and Innovation</i> , 51 CLINICAL OBSTETRICS GYNECOLOGY 153 (2008)                                                            |

#### IV. SUMMARY OF OPINIONS

8. Based on my analysis, I have arrived at certain opinions throughout this declaration.

9. First, based on my study, I have concluded that Ganz is directed to cauterizing and removing tissue. Specifically, Ganz is directed to "a device and method for treating one or more layers of tissue, ... by simultaneously imparting perforations into the one or more layers." *See* Ex. 1005 (Ganz) at [0001]. Ganz is not directed to the same types of treatments claimed by the '836 Patent—imparting energy around each needle electrode to cause coagulation localized around each needle electrode.

10. Second, it is my opinion that certain objective indicia having a nexus to the '836 Patent claims show that those claims would not have been obvious.

#### V. LEGAL PRINCIPLES

11. Counsel for Serendia has instructed me on the legal standards relevant to my analysis in this declaration.

12. I am informed that a patent may be invalid if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. I am informed that, when considering whether a patent is obvious, objective indicia of non-obviousness must be considered.

13. I am informed that objective indicia of non-obviousness may include, for example, a long-felt but unsolved need that was satisfied by the claimed invention, commercial success attributable to the claimed invention, and praise by those in the field of the claimed invention. I also understand that there must be a relationship, or nexus, between any such objective indicia and the claimed invention, i.e., objective evidence of non-obviousness must be attributable to the claimed invention.

## **VI. TECHNICAL BACKGROUND**

14. Radiofrequency (“RF”) microneedling is a cosmetic procedure that uses tiny needles and radiofrequency waves to rejuvenate facial skin. Microneedling technology, also known as collagen induction therapy, has been used by physicians since 1995. *See* Kesty and Goldberg, Radiofrequency microneedling for acne, acne scars, and more, *Dermatological Reviews* (January 31, 2020). RF microneedling is a type of microneedling in which each needle releases a radiofrequency current and creates small zones of neocollagenesis that are termed “radiofrequency thermal

zones.” *Id.* During treatment, trauma to the dermis induces neocollagenesis.<sup>1</sup> Put simply, RF microneedling treatment is a form of controlled skin injury. The damage stimulates the growth of healthy new skin, which can benefit common skin issues like acne scars and wrinkles. Compared with treatments like chemical peels and dermabrasion, radiofrequency microneedling is minimally invasive.

15. As the RF energy heats the skin, different effects occur to the tissue. For example, at low temperatures (i.e., 40-45°C), reversible cell damage occurs; at temperatures over 60°C, coagulation may occur; and at higher temperatures (i.e., near 100°C), vaporization and carbonization (also known as ablation) of the tissue may occur. *See, e.g.*, Ex. 2056 (Choi et al., Effect of Pulse Widths and Cycles on Invasive, Bipolar, and Gated Radiofrequency-Induced Thermal Reactions in ex vivo Bovine Liver Tissue, Clinical, Cosmetic and Investigational Dermatology (January 13, 2023)); *see also* Ex. 2032 (Na. et al., Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes, Scientific Reports (November 13, 2015) (“Na Nature Paper”)).

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<sup>1</sup> The dermis is a layer of skin underneath the epidermis, and the epidermis layer is typically between 0.5 to 1.5 mm thick.

16. With respect to how the RF energy is delivered, RF energy can be emitted into the skin via a monopolar mode that utilizes an active electrode and a grounded electrode or via a bipolar mode that employs two active electrodes. Ex. 2032 (Na Nature Paper) at 97. In monopolar modes, an electrical circuit formed by an electron current that flows from the active electrode to the grounded electrode is generated in the patient's body. The first widely accepted aesthetic radiofrequency microneedling technology was a monopolar device called the Thermage device. *See* Ex. 2057 (Hollmig Paper) at 769. "[I]n an early landmark study" the Thermage "achieved its first US Food and Drug Administration approval in 2002" for periorbital rhytides. *Id.* However, "early results with this device were somewhat inconsistent and often were statistically insignificant after photographic analysis." *Id.* In addition, the Thermage was known to cause "unwanted energy passing to the epidermis," which "creates the risk of unwanted collateral damage to the skin." Ex. 2058 (USP 8,142,426) at 1:61-2:5. In short, while prior monopolar RF microneedling systems allowed for localized thermal damage, these prior systems also carried several risks.

17. Bipolar electrosurgery systems induce an electrical circuit between the two active electrodes that is limited to regionally targeted tissues. *Id.* Because bipolar electrode configurations induce an electrical circuit between two active electrodes, RF microneedling devices employing bipolar electrode configurations at

first resulted in thermal responses between electrodes during treatment. *See, e.g.*, Ex. 2060 (Berube, D., Renton, B. & Hantash, B. M., A predictive model of minimally invasive bipolar fractional radiofrequency skin treatment, *Lasers Surg. Med.* 41, 473–478 (2009)). VelaShape was an early example of an aesthetic bipolar radiofrequency device with two electrodes attached to the skin. The VelaShape was designed to help with body contouring and was not a microneedling device. However, the VelaShape would transmit energy between its two active electrodes.

### Radiofrequency Technologies

Thermage, Exilis, and Pelleve are all monopolar RF devices that use applications for the face and some use for body, including wrinkle reduction. Thermage was FDA cleared in 2002 and utilizes a cooling compartment to reduce the skin temperature. Technically the depth of the RF wave travels throughout the body to the grounding pad, with the therapeutic depth being very shallow in the epidermis or superficial dermis. This has led to some significant challenges for the technology as a whole. Studies on tissue cooling have previously been reported [5]. The hand piece for Thermage has different tips for different areas of the body to be treated, and vibration for the patient's comfort. The internet reviews from patients do not support long term use for wrinkle reduction. Other limitations with mono-polar RF reside with small applicators treating large areas such as the abdomen. While this may work for smaller areas such as eyelids it is just not practical from a time standpoint to use for large areas. Another issue with some of the first models of mono-polar RF was temperature control with practitioners having to use external infrared guns to determine temperatures.

In 2005 VelaShape™ was the first non-surgical FDA cleared device for non-invasive face and body contouring using bi-polar RF. The contour improvement required three stages designed to reduce circumferential fat and cellulite reduction with a maximum depth of 1.5 cm. The procedure can be performed anywhere in the body, and patients with a BMI below 30 were preferred. The VelaShape combines four different technologies: infrared light, bipolar radiofrequency, a pulsed vacuum, and mechanical rollers. The vacuum technology lifts targeted tissue closer to the energy source, and the bipolar RF evenly distributes the heat to targeted cells. The rollers help mechanically reduce cellulite. The VelaShape™ is more powerful 50W than the VelaSmooth™ (25W). [6] The infrared component of the devices target dermal water and the radiofrequency target deeper layers of the skin. The thermal energy results in skin tightening.

Sadick and Mulholland [7] reported 40% improvement in cellulite and a large percentage of thigh circumference in 35 patients undergoing VelaSmooth treatments. Alster and Tanzi [8], reported 90% improvement in thigh and buttock, and cellulite reduction in 20 patients who underwent VelaSmooth treatments, twice weekly for 3 weeks. Sadick and Magro showed a reduction in thigh circumference in 71.9% of treated patients after 4 weeks of treatments using VelaSmooth. However, the study did not show improvement at 8 weeks follow up. In a series of 29 postpartum women, Brightman et al. [9] showed significant reduction in upper arm and abdominal circumference at 1 and 3 month follow ups following VelaShape treatments.

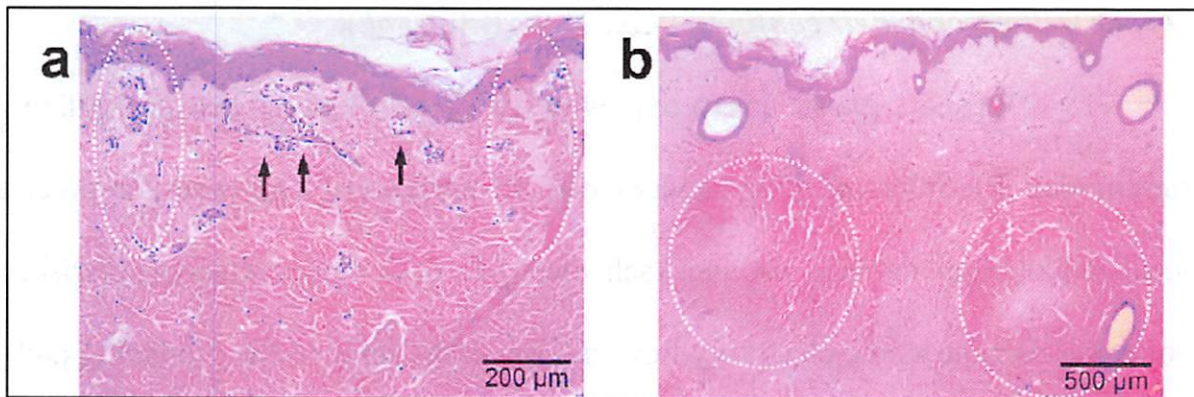
*See Id.* This heating of the entire area extending between the needles risked overheating areas of treated tissue, which could cause scarring and limited the practical use of prior bipolar RF microneedling devices. For example, prior bipolar

systems were “*not always predictable*,” as they could generate “[*u*]nwanted thermal injury,” and could “*carbonize tissue*,” and further cause the thermal damage to “*occur well beyond their confines*.” Ex. 2148 (Brill *et al.*).

18. In short, physicians were previously forced to choose between utilizing **monopolar** RF microneedling devices that advantageously allowed for precise localized thermal damage *around* each electrode (but disadvantageously risked collateral damage as the electricity flowed through the body to the grounding pad), or **bipolar** RF microneedling devices that advantageously had less collateral damage (but disadvantageously resulted in thermal damage extending *between* electrodes that risked scarring due to overheating areas of tissue).

19. As discussed in the 2015 Nature Article by Dr. Jongju Na (Ex. 2032 (Na Nature Paper)), Dr. Na demonstrated that under certain parameters, RF microneedling devices with bipolar electrodes can create thermal responses, including coagulation of tissue, around each needle electrode rather than between the needle electrodes. This approach avoided the disadvantages of each system to provide a “best of both” approach. For example, using Dr. Na’s technique, “[i]n *ex vivo* bovine liver tissue, the thermal coagulation columns were found to be concentrated maximally around the pointed tips of each electrode” *using bipolar electrodes*. Ex. 2032 (Na Nature Paper), 1. This is illustrated in the below

histological images (where non-intersecting zones of RF-induced coagulation are shown in the white circles/ovals):



*Id.*, Figs. 1(a) and 1(b). As shown in these figures, tissue around each electrode was not ablated to create holes; instead, the benefits of inducing coagulation were achieved *directly* around where each electrode was inserted.

20. Based on my experience it was not until after Dr. Na came up with this new approach to skin treatment that bipolar radiofrequency delivered through skin penetrating microneedles started to be adopted by dermatological practices. The aesthetic use of this type of technology took off around the time Dr. Na's article was published and has continued to the present day. Countless bipolar RF microneedling procedures are being performed by both myself and my peers throughout the world.

#### **VII. GANZ IS NOT DIRECTED TO THE SAME PRINCIPLE AS THE '836 PATENT**

21. In my opinion, Ganz is directed to creating holes in tissue when needles are inserted by causing death of the tissue, in contrast to techniques, such as the

approach in the '836 Patent, that cause localized coagulation where energy is applied by a laser or needles.

22. In the Background, Ganz refers to “the FRAXEL infrared laser scanning laser” as an “example of a device which treats tissue” “without removing entire layers of tissue.” Ex. 1005 (Ganz) at [0006]. FRAXEL, in fact, is a laser and not a radiofrequency device. It does not place microneedling-induced holes into the skin. In fact, the mode of laser delivery to the skin is that of an inverted cone with most of the energy on or near the surface of the skin. Bipolar radiofrequency microneedling devices deliver energy in the exact opposite manner — i.e., the energy is delivered in a cone shape distribution, with the bulk of energy deeper into the skin and very little energy delivered to the surface.

23. Ganz explains that the FRAXEL laser “create[s] small vertical zones of coagulated tissue.” Ex. 1005 (Ganz) at [0006]. In this respect, the FRAXEL laser is similar to the approach described in the '836 Patent, which involves creating a small vertical zone of coagulated tissue around each needle. *See, e.g.*, Ex. 1001 ('836 Patent) at 3:20-29. However, the approach described in the '836 Patent involves the use of RF energy, rather than a laser, which has certain advantages. For example, the approach described in the '836 Patent entails less downtime for patients than FRAXEL laser treatment. FRAXEL laser treatment also presents increased risk of affecting skin pigmentation, and FRAXEL laser treatment is generally considered

more painful. In my experience, because devices using the '836 Patent deliver less energy to the surface of the skin than FRAXEL lasers, they are generally safer for darker skin and may lead to less discomfort during treatment.

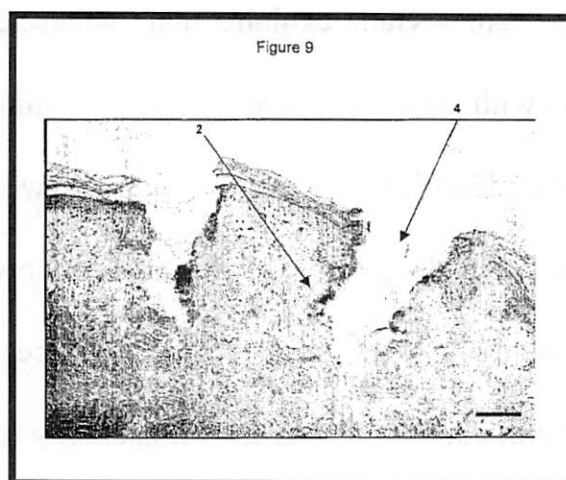
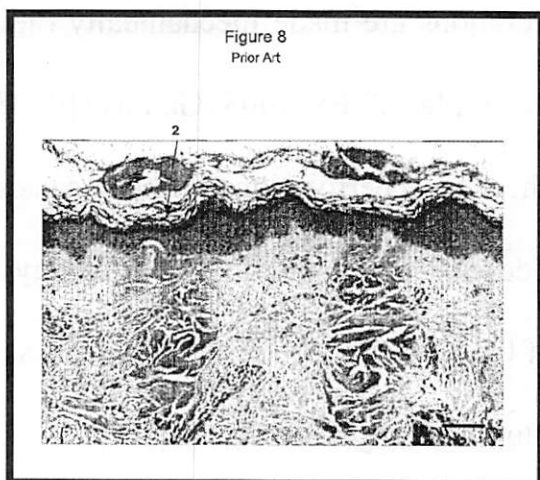
24. Ganz states that the fact that the FRAXEL “does not create perforations or vertical holes in the tissue” is a “drawback,” teaching that “it is desirable to create vertical perforations or ablation holes in tissue” to “prompt[] an even more aggressive wound healing response.” Ex. 1005 (Ganz) at [0006]. As Ganz explains, “[p]erforations allow for a faster regeneration and healing time” in comparison to the FRAXEL laser. *Id.* However, Ganz does not describe or show any clinical results of how the skin responds to this more aggressive approach to evaluate its effects from a clinical perspective.

25. I note that Dr. James Koch provided a declaration in support of the '836 Patent Petition for IPR, and that Dr. Koch asserts that “a person of ordinary skill in the art would not have expected the Ganz device to result in scarring of the skin.” Ex. 1035 (Koch Decl.) ¶ 41. I disagree with Dr. Koch. Ganz’s approach of removing tissue is aggressive and would leave a patient with small holes in the skin, increasing downtime, pain, and infection risk compared to the approach described in the '836 Patent. This inevitably will greatly enhance the risk of scarring — the exact opposite of the aesthetic approach for improving skin quality taught by the '836 Patent.

26. Ganz explains that “when perforations are made mechanically rather than with the use of energy, excess bleeding takes place.” Ex. 1005 (Ganz) at [0008]. Ganz identifies “a need for a device which creates perforations without causing undue bleeding,” and, as discussed below, describes a device that uses energy to create the perforations so that the surfaces of the holes that Ganz creates in the skin are burned, or cauterized, by this energy to stop bleeding.

27. For example, Ganz’s approach “creates perforations,” and Ganz states that “[t]hese perforations create holes, which extend vertically into the tissue.” Ex. *Id.* at [0027]. Ganz states that “the term ‘perforation’ means vertical areas of thermal damage or ablation to the tissue causing tissue necrosis.” *Id.* at [0027]. Necrosis refers to the cell death in body tissue.

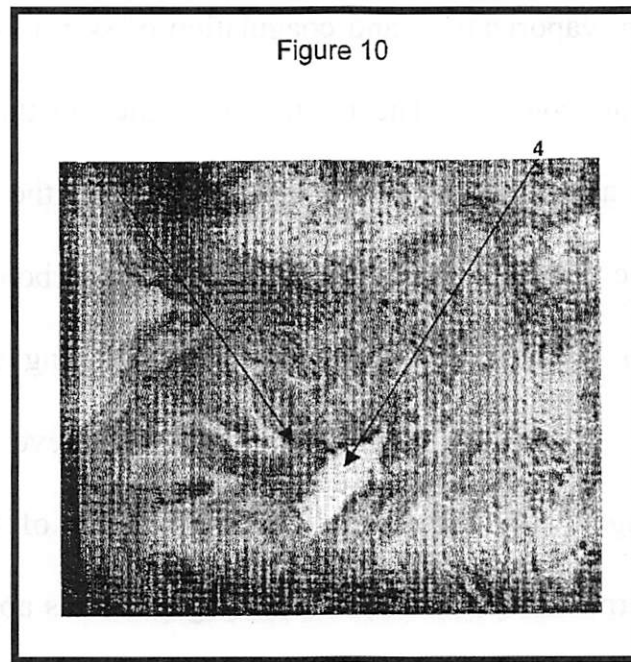
28. Ganz also illustrates how his approach is different from producing localized coagulation. For example, Ganz shows the localized “coagulation,” “indicated at reference number 2,” in skin “treated using a FRAXEL infrared scanning laser” in Figure 8, copied below on the left. *Id.* at [0028]. Ganz contrasts this treated area 2, which has no perforation, with the “treated area 4” in Figure 9, which shows “a skin area treated in accordance with [his] invention.” *Id.* As Ganz explains, the “treated area 4 is clearly a perforation, which extends vertically into the skin.” As can be seen in Figure 9, the skin that was in treated area 4 prior to treatment has been removed.



29. Ganz refers to “[a]reas or zones of coagulation 2 [that] can also be seen in the areas surrounding the perforation 4” in Figure 9. *Id.* at [0028]. Ganz also refers to “zones of coagulation surrounding the perforation 4” in Figure 10, which is “a top view of the treated skin.” *Id.* at [0026], [0028].<sup>2</sup> However, as shown in these figures, the areas “2” representing the zones of coagulation in Figures 9 and 10 are the sides of the holes in the skin that have been burned or cauterized. Neither Figure 9 nor Figure 10 show zones of the coagulation of collagen within the dermis as shown in Figure 8.

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<sup>2</sup> As a top view, Figure 10 shows a view of the epidermis.



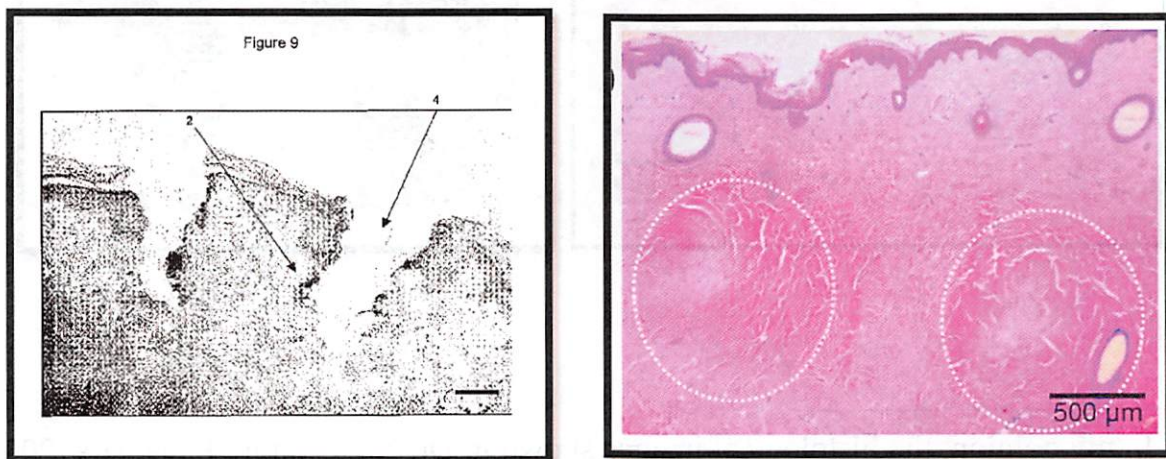
30. As illustrated in Figures 9 and 10, energy delivered to Ganz's electrodes is used to cause the death of the cells in the tissue around each electrode and remove that tissue, leaving a hole in the skin. There is not coagulation around each electrode using Ganz's approach because Ganz supplies sufficient energy to burn the skin around each electrode sufficiently to remove that tissue. A patient subjected to Ganz's approach accordingly loses the tissue around each electrode. *See, e.g., id.* at [0043] ("The areas of tissue in contact with the electrodes are those areas which are perforated.").

31. In my opinion, the localized coagulation around each needle electrode taught in the '836 Patent is very different from Ganz's approach of removing tissue around each electrode to create holes in the skin. The '836 Patent distinguishes

among carbonization, vaporization, and coagulation of skin tissue. *See, e.g.*, Ex. 1001 ('836 Patent) at 2:64-3:6. The treatment claimed in the '836 Patent thus concentrates energy around each electrode while limiting the energy applied to ensure that the tissue surrounding each electrode is not carbonized or vaporized. While the invention in the '836 Patent involves “applying energy to achieve coagulation,” Ganz involves applying energy to achieve carbonization or vaporization, burning away tissue and leaving the sides of the resulting hole cauterized by the burn. *Id.* at 3:5-6. Ganz distinguishes his approach from those that impart coagulation into the skin rather than remove tissue around each electrode, such as the FRAXEL laser and the invention described in the '836 Patent. *See, e.g.*, Ex. 1005 (Ganz) at [0032] (“The device also imparts perforations into the skin, rather than merely imparting coagulations into the skin.”).

32. The Ganz treatment, which ablates tissue causing necrosis to form holes in skin (*see* Ex. 1005 (Ganz) at [0006], [0027]), is an example of a prior art treatment distinguished in the '836 Patent associated with “side effect[s]” caused by “overheating or burning,” “which may cause permanent skin damage,” such as “scars created in overheated or burned epidermis.” Ex. 1001 ('836 Patent) at 4:4-19. By contrast, a benefit of the invention described in the '836 Patent is that it prevents or limits overheating, avoiding such side effects, which makes it attractive in a clinical setting. *See id.*

33. As discussed above, the 2015 Nature Article by Dr. Jongju Na showed that under certain parameters, RF microneedling devices with bipolar electrodes can create thermal responses, including coagulation of tissue, around each needle electrode rather than between the needle electrodes, as shown in the histology results in his article. Ex. 2032 (Na Nature Paper). The contrast between Ganz's perforations and the Na Effect as shown in Dr. Na's article is shown below. For example, as shown on the right, the invention described in the '836 Patent leaves the epidermis and dermis intact, "merely imparting coagulations into the skin," which Ganz distinguishes from his approach that "imparts perforations into the skin" by removing the epidermal and dermal layers in the vicinity of the electrodes. Ex. 1005 (Ganz) at [0032].

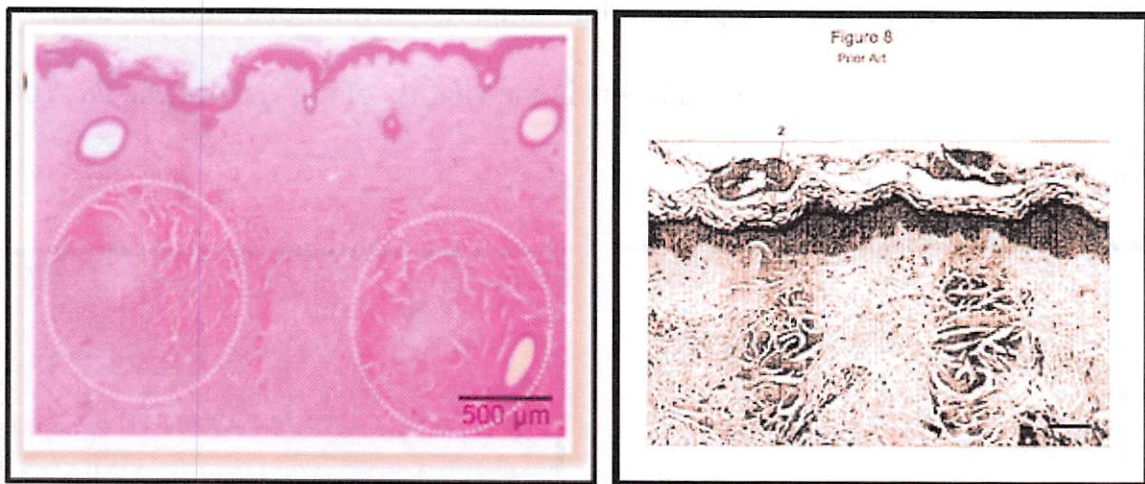


*Compare Ex. 1005 (Ganz) at Fig. 9 (left) with Ex. 2032 (Na Nature Paper) (right).*

34. As shown in the above images, the '836 Patent's claimed treatment approach creates coagulation around where each electrode was inserted (shown in

the dotted lines in the figure on the right)—*while not destroying and removing the tissue*. This is contrasted against the Ganz approach, which results in burning away tissue to create ablation holes (shown as item “4” in the figure on the left).<sup>3</sup>

35. The distinction between the '836 Patent's claimed treatment approach and Ganz's approach is further illustrated by comparing the histological images of tissue treated using the '836 Patent's claimed approach (shown on the left below), with images taken from the prior art FRAXEL approach *that Ganz distinguishes* (shown on the right below):

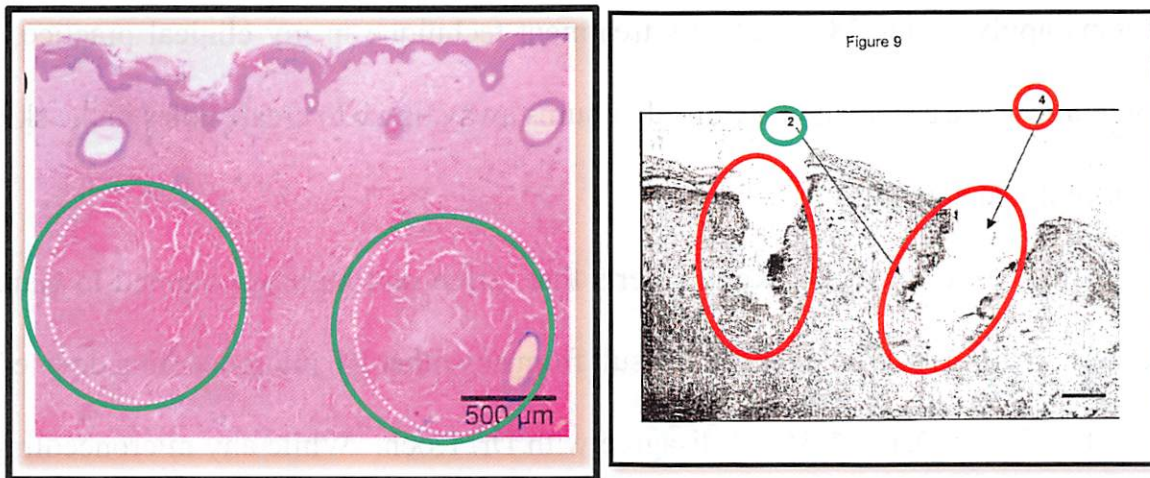


<sup>3</sup> In my opinion, the histological images shown in Dr. Na's Nature Paper (Ex. 2032 (Na Nature Paper)), correspond to treatment results using the '836 Patent's claimed treatment approach. As shown in the histological images, coagulation occurred around the region where bipolar electrode needles were inserted.

Compare Ex. 2032 (Na Nature Paper), Fig. 1b with Ex. 1005 (Ganz), Fig. 8.

36. As shown in the two above figures, both of these approaches leave the treated tissue intact (rather than ablating and removing the tissue to create large perforations or “ablation holes” like the Ganz treatment approach). Thus, just as Ganz distinguishes its approach as distinct from the prior art FRAXEL approach, Ganz’s approach is similarly distinct from the ’836 Patent’s claimed skin treatment.

37. Comparing histological images of coagulation around needle insertion sites produced using the ’836 Patent’s claimed approach (shown below on the left), with Ganz’s approach (shown below on the right), similarly confirms that Ganz teaches an entirely different approach than claimed in the ’836 Patent:



Compare Ex. 2032 (Na Nature Paper), Fig. 1b (showing “RF-induced coagulation columns” which are “generated separately around each microneedle electrode,” annotated in green), with Ex. 1005, Fig. 9 (showing only residual coagulation around the “ablation holes,” annotated in red).

38. Again, it is apparent that what Ganz produces is *not* coagulation around each inserted electrode, as shown on the left, but rather coagulation around the edges of the ablation holes that each electrode created.

39. In my opinion, Ganz does not teach applying energy around each electrode to cause localized coagulation around each electrode—as taught in the '836 Patent—but rather a distinct approach that removes the tissue around each electrode. Specifically, there's no coagulation around the microneedles because the tissue is *gone*. Ganz thus discloses cauterizing and removing tissue, which is very different from the types of treatments claimed in the '836 Patent, which cause coagulation localized around each needle electrode. Thus, while I frequently use systems applying the '836 Patent's treatment technique in my clinical practice, I would *never* use a system like Ganz that burns away tissue to create holes in the skin because it is dangerous.

40. I note that Dr. Koch asserts that “[t]he perforations obtained in Ganz are thus no different from those that result from any other RF microneedling device.” Ex. 1035 (Koch Decl.) ¶ 36. I disagree with Dr. Koch. While any microneedling device creates mechanical punctures, Ganz goes further and burns away tissue to cauterize the area and, as discussed above, create “ablation holes.” For example, Ganz refers to “a 10-50 micron zone of coagulation” at “the edge of the injury,” using electrodes spaced “500 microns apart,” but this edge was around

“perforations” that “were widest at the top (50 to 100 microns in diameter) and tapered to a point at a depth of 250-300 microns.” Ex. 1005 (Ganz) at [0065]. Based on this description, a zone of tissue was removed, spanning from 50 to 100 microns in diameter at its widest point, and the zone of coagulation was a thinner region (10-50 microns) around the edge of the resulting hole.<sup>4</sup> Because the energy applied to each needle removed the tissue around each electrode, it did not cause coagulation around each electrode but rather carbonization or vaporization of the tissue around each electrode to remove that tissue, leaving a hole (as illustrated in Figures 9 and 10 of Ganz above). This example in Ganz is consistent with Ganz’s explanation that his device “imparts perforations into the skin, rather than merely imparting coagulations into the skin,” as described in the ‘836 Patent. Ex. 1005 (Ganz) at [0032]. Once again, Ganz is directed to ablating and removal tissue, *i.e.*, cauterizing the tissue surrounding the puncture sites.

41. Finally, I note that Dr. Koch asserts that “skin histology from patients treated with RF microneedling devices (such as that of Ganz or the ‘836 patent) will look perfectly normal as a result of healing after a certain period of time.” *See* Ex. 1035 (Koch Decl.) ¶ 37. I disagree with Dr. Koch’s assertion. In view of the

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<sup>4</sup> Notably, Petitioners identify no example in Ganz of generating perforations the same size as electrodes.

disclosure of Ganz, including the histological images showing ablated holes after treatment with the Ganz approach, it is my opinion that skin histology from patients treated with an RF microneedling device like Ganz would show burned, cauterized, and damaged skin, likely leading to scarring. As discussed above, while I frequently use systems applying the '836 Patent's treatment technique in my clinical practice, I would *never* use a system like Ganz that burns away tissue to create holes in the skin because it is dangerous.

#### **VIII. OBJECTIVE INDICA OF NON-OBVIOUSNESS**

##### **A. Commercial Success**

42. I have reviewed the evidence of how products practicing the '836 Patent distribute energy during operation, including evidence related to: (i) materials explaining to the public how the products work; (ii) advertising explaining where energy is focused during operation of the products; and (iii) the nexus between the claimed inventions and the success of these products. As discussed below, it is my opinion that this evidence demonstrates that these products are configured to cause coagulation around each electrode without such coagulation fully extending from one electrode to another electrode. Configuring the coagulation in this manner can treat common skin conditions like acne scars and wrinkles without the drawbacks associated with monopolar or fractional laser configurations. In particular, this treatment reduces the risk of causing undesired damage due to excessive heat while

providing therapeutic effect. The localized heating of the skin during treatment (1) makes the treatment more effective and safer, (2) reduces patient pain and downtime, and (3) makes patient compliance more likely — i.e., patients are more likely to return for a full series of treatments when the treatments are less painful and have fewer negative side effects.

43. In my opinion, physicians select and purchase products that provide effective and safe treatment for their patients. The success of a given product is often based on its ability to provide safe and effective treatment in a manner that promotes patient compliance. Based on my clinical experience, products that practice the '836 Patent meet these objectives and are a substantial improvement over the RF-based and laser treatments that were previously available. Put simply, the '836 Patent radically revolutionized the way practitioners use RF microneedling devices and made treatments more effective, reduced patient pain and downtime, and increased the patient compliance.

44. Since devices based on the '836 Patent have come to the market, the number of patients treated with these devices has increased exponentially. The number of such devices from multiple manufacturers has also greatly increased. Both lighter and darker skinned patients who seek skin tightening, better quality of skin or improvement of acne scars represent a never-ending group of patients. Today, patients come in seeking devices by name — all such devices being used

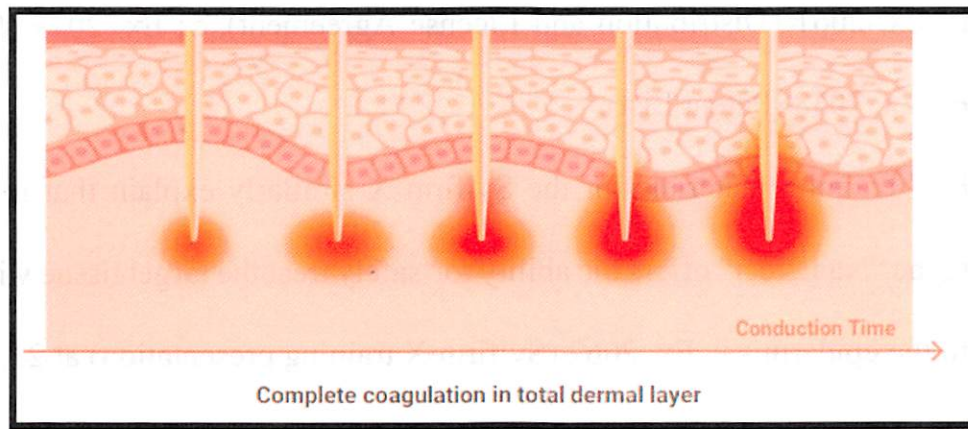
with technology based on the '836 Patent. In short, the benefits of the '836 Patent make us all busier every day.

**1. The Sylfirm X RF Microneedling System**

45. Concerning the Sylfirm X product, I understand that the Sylfirm X product is marketed as allowing for precise application of energy to tissue, enabling the physician applying the treatment to create discrete zones of coagulation around each needle. Based on Dr. Daniel van der Weide's analysis, I understand that the Sylfirm X product, its related handpieces, and needle assemblies practice the claims of the '836 Patent. Ex. 2143 (VDW Declaration) at ¶¶ 141-163.

46. The Sylfirm X's marketing material explains the benefits of the patented inventions and links the benefits of using the Sylfirm X product to the inventions claimed in the '836 Patent and cites the '836 Patent specifically. *See* Ex. 2037 (Sylfirm X Brochure) at 194, 195. For example, the Sylfirm X brochure discusses how, "[i]n 2015, ViOL's founder, Dr. Jung Ju Na, conducted a clinical study to observe the skin response to *alternating current bipolar RF energy*." Ex. 2037, 4. The Sylfirm X brochure describes the "Na Effect," explaining that "[w]hen bipolar RF energy is released through a non-insulated microneedle, tissue coagulation begins at each end of the microneedle electrode, and then forms a droplet or cocoon shape as conduction time increases," and that this configuration

“maximizes the thermal effect on the target with little to no epidermal damage, enabling effective and safe treatment.” Ex. 2037 (Sylfirm X Brochure) at 195.



See Ex. 2037 (Sylfirm X brochure) at 193, 195.

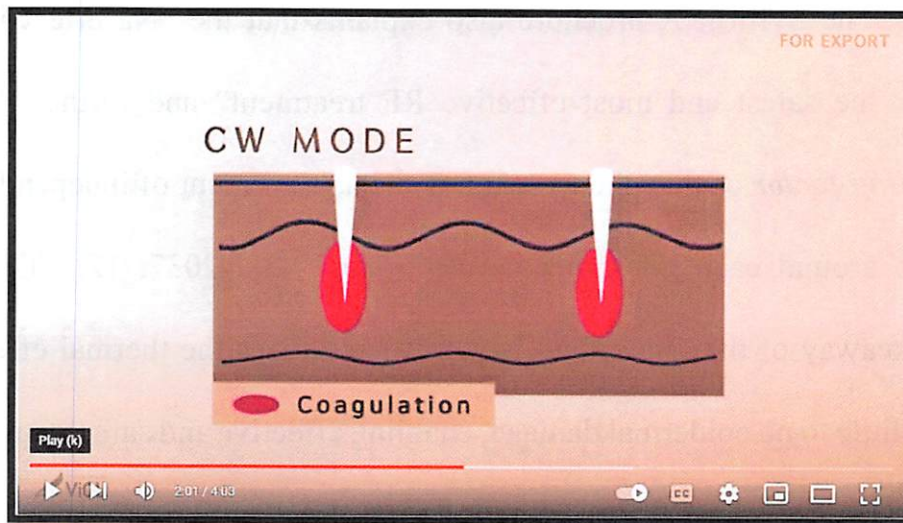
47. The Sylfirm X brochure also explains that the “Na effect is the *key method* for the safest and most effective RF treatment” and further that “[t]he *distinguishing factor* of this phenomenon is the achievement of independent tissue coagulation around each micro-needle electrode.” Ex. 2037, 12. Thus, “[t]he primary takeaway of the ‘Na effect’ is that it maximizes the thermal effect on the target with little to no epidermal damage, enabling effective and safe treatment.” *Id.*; see also Ex. 2039 (Video), 0:52.

48. Other marketing and training materials likewise focus on the treatment benefits associated with implementing the technology claimed in the ’836 Patent. Ex. 2031 (Goldberg Decl.), ¶39; Ex. 2101 (press release), 2 (“*Undoubtedly the most profound advantage seen with the Sylfirm X Ultimate Edition is the ‘Na*

*Effect[.]*”). The '836 Patent is also directly cited in the Sylfirm X marketing materials and in the exclusive distribution and license agreement between VIOL and Serendia. Ex. 2061 (Distribution and License Agreement), 5; Ex. 2079 (Product Webpage); Ex. 2038 (Patent List).

49. Training materials for the Sylfirm X similarly explain that treatment producing the “Na Effect” offers the ability to “safely treat the target tissue with little damage to the epidermis.” Ex. 2062 (Sylfirm X training presentation) at 21.

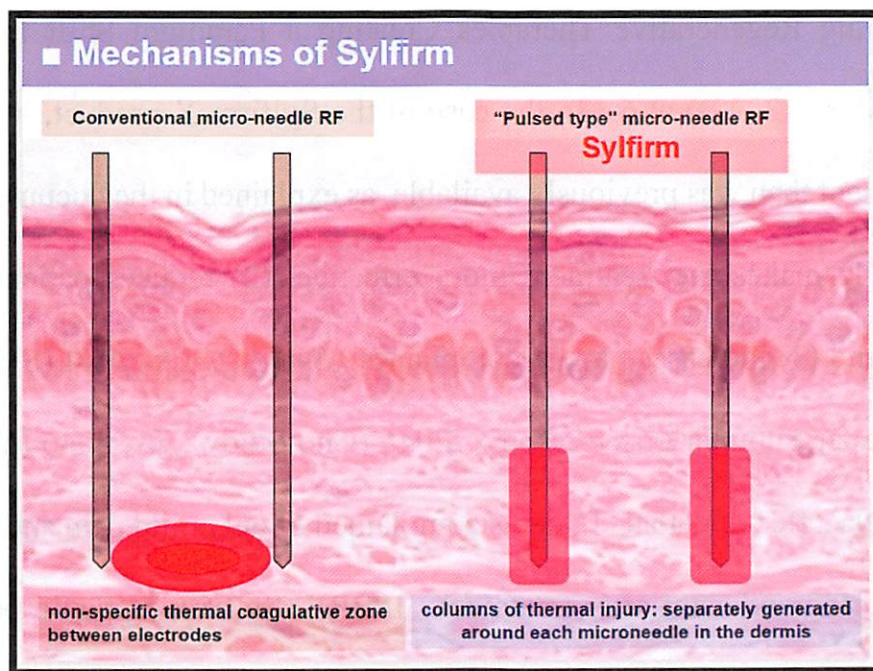
50. Likewise, a video for educating the public about the product shows coagulation around each needle electrode:



Ex. 2063 (Sylfirm Video2).

51. Additionally, presentations to medical providers discuss the effects of the Sylfirm X device on tissue and distinguish the device's ability to create precise zones of thermal injury “around each microneedle” from “conventional micro-

needle RF” that produced a “non-specific thermal coagulative zone between electrodes”:



Ex. 2064 (Sylfirm RF Presentation) at 45; *see also* Ex. 2065 (Seikoh Presentation).

52. The above video and presentation are consistent with my understanding of how the Sylfirm X product is designed and shows that the production of precise zones of thermal injury around needle electrodes is a key feature and a focus of marketing and advertising for the Sylfirm X product, in particular, when describing the benefits of the product to medical professionals. *See* <https://www.benev.com/sylfirmx/>.

53. As I explain above, in my opinion, physicians select and purchase products that provide the best and safest treatment outcomes for their patients. As

Dr. Jin notes, “Patients trust me with their treatment, and it is my responsibility to offer them the best option available.” *See* Ex. 2042 (K. Wilson, The Aesthetic Guide, Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine (March 2022)) at 6. In the case of the Sylfirm X product, it provides a better treatment than was previously available, as explained in the documents above, because it (1) makes the treatment more effective, (2) reduces patient pain and downtime, and (3) increases patient compliance. *See, e.g.*, Ex. 2044 (SYLFIRM X - Clinical Paper Summary); *see also* Ex. 2045 (Cho Study); Ex. 2046 (You Study) (noting the Na Effect and that “Patients complained of only mild pain and temporary erythema during and right after treatment. IPBRF [Sylfirm X] could be effective and safe in facial erythema patients”). These benefits are all linked to Sylfirm X’s implementation of the ’836 Patent.

54. Marketing of the Sylfirm X in industry publications and by physicians similarly touts the ability of the Sylfirm X to provide treatment by administering RF to produce localized coagulation that provides effective treatment in a safe manner. A popular industry publication, The Aesthetic Guide, noted that the Sylfirm X product allows for “[s]ofter, more selective coagulation,” and that “harnessing the ‘Na Effect’ [] is what really sets it apart from the pack and highlights why it is a leader.” *See* Ex. 2042 (K. Wilson, The Aesthetic Guide, Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine (March 2022)) at 3. The

article goes on to recite interviews with several medical providers concerning their experiences with the Sylfirm X product. For example:

- *Renato Saltz, MD, director of Saltz Plastic Surgery (Park City and Salt Lake City, Utah) — “Dr. Na is a mastermind, he didn’t just settle for good when developing an RF microneedling device, he designed the only RF microneedling device you will ever need.” Id.*
- *Gideon Kwok, DO, co-owner and medical director of eight Skin Perfect medical clinics around southern California — clinics classified within the top 1% in the U.S. — “What really separates Sylfirm X from other technologies, besides the PW and CW modes, is being able to see immediate skin tightening while the patient experiences little or no pain. This sold me on Sylfirm X.” Id. at 16.*
- *Richard Jin, MD, PhD, director of RJ Clinical Institute and Cellum BioMedical (Mission Viejo and Temecula, Calif.) — “I needed a device that could allow me to do more, and better control the outcome. I didn’t want an ordinary RF device ... Sylfirm X Ultimate Edition does more by providing me with a 300-micron depth for pain-free, no downtime treatments which encourage patient compliance. My patients are now able to come in consistently, allowing us to give them results in less time. Patients trust me with their treatment and it is my responsibility to offer them the best option available.” Id.*
- *Dr. Raminder Saluja, MD, director of Saluja Cosmetic and Laser Center (Huntsville, N.C.) — The “[s]ofter, more selective coagulation” “is something that I truly have seen the results for myself.” Id.*

55. Likewise, Dr. Martin Braun, MD, published a testimonial in another popular periodical, *Prime*, explaining how “the Na effect, provide[s] safe effective treatment because the tear drop shaped thermal effect minimizes heat damage to the epidermis and maximizes the therapeutic effect at the target.” *See* Ex. 2066 (M. Braun, Sylfirm X Revolutionizes the Clinical Application of RF Microneedling (May 2022)) at 3. Dr. Braun also explains that:

I can personally attest to the Na effect of tear dropped thermal energy dispersion as I had a treatment with 1000 pulses on my face using the 25 needle cartridge, which equals 25,000 needle insertions with no pinpoint bleeding! Redness dissipated within one hour, attesting to sparing of the superficial epidermis.

*Id.*

56. I have used the Sylfirm X product, and the benefits of safe, effective treatments, which the '836 Patent enable, provide my patients with the excellent treatment outcomes, without the safety risks of other methods, in a way that patients readily tolerate. As shown above, the evidence establishes that the claimed invention is a "distinguishing factor" in selecting RF microneedling devices, and that the inventive combination of features, such as applying AC RF energy through bipolar electrodes to achieve localized coagulation, drove the commercial success and widespread use of the Sylfirm X. Thus, in my opinion, medical providers purchase the Sylfirm X over other similar systems, at least partly because it provides the benefits associated with the '836 Patent. Therefore, I conclude that, to the extent that the Sylfirm X product has experienced commercial success, that success is attributable at least in part to its implementation of the '836 Patent.

**B. Industry Praise and Peer Recognition**

57. In addition to the evidence already discussed above, the patented functionalities claimed in the '836 Patent have been recognized through numerous awards and accolades.

**1. The Sylfirm X RF Microneedling System**

58. Concerning the Sylfirm X product, in 2020, the manufacturer of the Sylfirm X, ViOL, won the “World-Class Product of Korea” award from the Minister of Trade, Industry & Energy of South Korea due to its contributions to and developments towards Aesthetic Medical Devices, like the Sylfirm X. *See* Ex. 2067 (World Class Product of Korea Certificate 2020).

59. Additionally, as explained above, publications such as the Aesthetic Guide and Prime praised the Sylfirm X product and linked its benefits to the technology claimed by the '836 Patent. Likewise, respected key opinion leaders in the industry, such as Dr. Randy Miller and Dr. Seiko Kou, have also favorably reviewed the Sylfirm X device. *See e.g.*, Ex. 2043 (Testimony re Sylfirm X).

60. In 2015, Dr. Na published an article in Scientific Reports, an open-access journal from Nature that publishes rigorously peer-reviewed research, in which he demonstrated the RF-induced coagulation around each microneedle. *See, e.g.*, Ex. 2032 (Na Nature Paper). In that article, the authors proposed calling this new effect of independent tissue coagulation around each electrode a “Na effect,”

naming it after Dr. Na. Persons skilled in the field now refer to this “Na effect” in scientific literature. *See, e.g.,* Ex. 2044 (SYLFIRM X - Clinical Paper Summary); *see also* Ex. 2045 (Cho Study); Ex. 2046 (You Study). These publications also show the effectiveness of the patented technology and how the industry has recognized its benefits.

## **2. Peer Recognition**

61. In addition, the patented technology claimed in the '836 Patent has become widely recognized and is extensively copied and advertised by competitors and used within their products. The benefits provided by the '836 Patent are often cited as important and valuable features of these products showing general recognition of the '836 Patent by the industry. For example, an academic paper funded by Aesthetics Biomedical and using the Vivace RF Microneedling device expounds the value of “narrow and concentrated coagulation zone[s]” “around the tip of needles.” *See* Ex. 2047(Wootten Study) at 65.

62. Likewise, technical and marketing material for the Virtue ULTRA RF Microneedling device focus on how the Vivace ULTRA is designed to avoid bad outcomes like “heat-induced hyperpigmentation.” *See* Ex. 2069 (Allure Article) at 972. As explained above, the narrow and concentrated coagulation zones around the tips of needles as taught by the '836 Patent reduces the risk of “heat-induced

hyperpigmentation.” *Id.* Therefore, these companies are recognizing the benefits associated with focused coagulation, as taught by the '836 Patent.

63. Additionally, the benefits of the '836 Patent, such as a decrease in patient downtime, increased treatment effectiveness, and less pain compared to other treatments (such as fractional lasers), are also recognized by EndyMed and are advertised as benefits of the EndyMed RF Microneedling systems. *See* Ex. 2048 (Harth Study) at 707.

64. Therefore, in my opinion, the industry has been fast to adopt and recognize the technology described in the '836 Patent because of the many benefits they provide.

**C. Long-Felt but Unfulfilled Need for the Inventions**

65. In my opinion, the '836 Patent fulfills long-felt needs in the industry. As I explained above, the prior art had known and long-understood drawbacks.

66. Based on my experience, prior art devices risked overheating both the epidermis and dermis, causing negative side effects like post-inflammatory hyperpigmentation and hypopigmentation. The invention described in the '836 Patent avoids these drawbacks, making microneedle treatments more effective and safer while reducing patient pain and downtime and increasing patient compliance.

67. Based on my experience in the industry, the problem of overheating, burning, and harming skin from applying too much energy to the skin was well-

documented, which could cause scarring, hyperpigmentation, and increased pain. *See, e.g.*, Ex. 2044 (SYLFIRM X - Clinical Paper Summary); Ex. 2037 (Sylfirm X Patient Brochure) at 14.

68. The '836 Patent overcame drawbacks associated with the prior art, as does the Sylfirm X product which I understand practices the '836 Patent. For example, the “[s]oft, more selective coagulation” provided by the “harnessing the ‘Na Effect’ [] is what really sets it apart from the pack and highlights why it is a leader.” *See* Ex. 2042 (K. Wilson, The Aesthetic Guide, Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine (March 2022)) at 3. Dr. Martin Braun explains that the “Na effect, providing safe effective treatment because the tear drop shaped thermal effect minimizes heat damage to the epidermis and maximizes the therapeutic effect at the target.” *See* Ex. 2066 (M. Braun, Sylfirm X Revolutionizes the Clinical Application of RF Microneedling (May 2022)) at 3. Shaun Wootten also explains that “narrow and concentrated coagulation zone[s]” are beneficial. *See* Ex. 2047 (Wootten Study) at 65.

69. Additionally, a study conducted by EndyMed noted a decrease in patient downtime, increased treatment effectiveness, and less pain than other treatments (such as fractional lasers) when using products where “RF is emitted selectively heating the dermis while sparing the epidermis.” *See* Ex. 2048 (Harth Study) at 707.

70. Based on my experience, prior art monopolar devices had several known drawbacks that were solved by the '836 Patent. In particular, it was known that monopolar configurations “results in a heated region developed below the electrode that damages a relatively large volume of the dermis, and epidermal damage is minimized by the active cooling of the surface electrode during treatment.” *See* Ex. 2049 (USP 9,510,899 to Manstein (“Manstein 899”)) at 3:31-56. However, this type of treatment “can be painful, and can lead to short-term swelling of the treated area. Also, because of the relatively large volume of tissue treated and the need to balance application of RF current with surface cooling, this RF tissue remodeling approach does not permit fine control of damage patterns and subsequent skin tightening.” *Id.* Likewise, because the system is “relying on a remote grounding on the patient to complete the current flow from the single electrode,” the current “must flow through the patient's body to the remote ground, which can lead to unwanted electrical stimulation of other parts of the body.” *Id.* The grounding pad can also cause “tissue desiccation or destruction at its contact point with the patient’s tissue.” *See* Ex. 2050 (USP 6,770,071 to Woloszko (“Woloszko”)) at 2:35-50. Therefore, there was a need to balance the drawbacks of monopolar configurations with some of its benefits, such as “RF current [that] can generate heating around the tip regions of the needles.” *See* Ex. 2051 (US Patent Application 2008/0082090 to Manstein (“Manstein 090”)) at [0040]. The '836

Patent addressed and eliminated the drawbacks of monopolar configurations while maintaining the beneficial heating of tissue around the tips of the needles.

71. In my opinion, the '836 Patent addressed a long-felt need in the industry for a safer, effective RF microneedling treatment that avoided the drawbacks of earlier RF-based approaches, e.g., monopolar treatment and laser-based approaches. Put simply, the '836 patent radically revolutionized the way we use these devices for skin tightening, acne scarring, aging skin, a whole different variety of entities and all different skin types and colors.

#### **IX. RESERVATIONS OF RIGHTS**

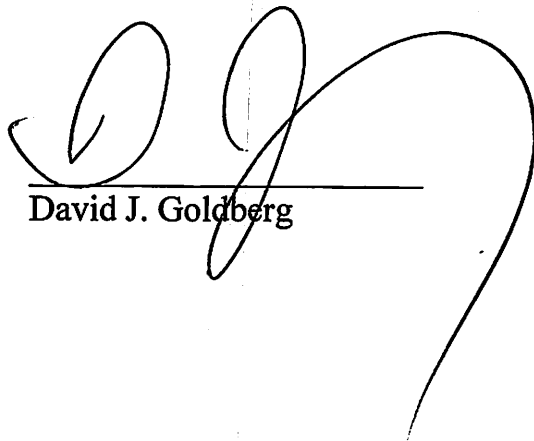
72. This declaration is based upon my present experience, education, and analysis of the materials available to me. I also reserve the right to supplement my opinions in response to any additional material or information made available to me. In addition, I also reserve the right to present my opinions, including through the preparation of demonstratives, graphics, charts, etc., to further illustrate my testimony. The citations provided in my declaration are exemplary, and I reserve the right to rely on any other portions of the cited documents, or any other available documents or information, which help to better explain my opinions or rebut any opinions offered by Petitioners or their experts. I also reserve the right to rely on documents and information discussed in my other declaration and testimony in this action. I also reserve the right to testify on issues that help to better explain my

opinion for the benefit of the Board. In addition, to the extent that my opinions are challenged or rebutted during deposition or at a hearing, and there is additional evidence to clarify or rebut the opinions of Petitioners' experts or lawyers, I reserve the right to offer that testimony.

**X. CONCLUSION**

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

Executed on 11<sup>th</sup> November 2027 (date), in Hickory, NC (city, state).



David J. Goldberg