

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

In re *Inter Partes* Review of:

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

DECLARATION OF DANY BÉRUBÉ, PH.D.

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I. INTRODUCTION

1. I, Dany Bérubé, Ph.D., declare as follows:

2. I have been retained as a technical consultant on behalf of Ilooda Co., Ltd. and Jeisys Medical Inc. (collectively “Petitioner”), who I understand is the petitioner in the present proceeding. I have been asked to consider whether the references listed as Exhibits 1005-1009 below disclose or render obvious the limitations recited in claims 1-29 of U.S. Patent No. 9,480,836 (the “’836 patent”). I have also been asked to consider the state of the art and the prior art available before the time of the alleged invention of the ’836 patent. My opinions are provided in this declaration.

3. To the best of my knowledge, I have no financial interest in Petitioner. I have been informed that a company known as Serendia, LLC (“Serendia” or “Patent Owner”) purports to own the ’836 patent. To the best of my knowledge, I have no financial interest in Serendia and, to the best of my recollection, I have had no contact with Serendia or the named inventor of the ’836 patent, Jongju Na. To the best of my knowledge, I similarly have no financial interest in the ’836 patent. To the extent any mutual funds or other investments that I own have a financial interest in the Petitioner, the Patent Owner, or the ’836 patent, I am not aware of, nor do I have control over, any financial interest that would affect or bias my judgment.

4. I am being compensated at my standard consulting rate for my time. My compensation is in no way contingent on the results of these or any other proceedings relating to the '836 patent.

II. BACKGROUND AND QUALIFICATIONS

5. My name is Dany Bérubé. My qualifications and professional experience are described in my curriculum vitae, a copy of which is provided as Exhibit 1004. The following is a brief summary of my relevant qualifications and professional experience.

6. I currently work for Lutronic Aesthetic, Inc. as Vice President of Advanced Research and Innovations. I started the position on August 11, 2023.

7. I previously held the position of Vice President of Scientific Affairs and Innovations with Sofwave Medical. In that position, I identified and developed strategies and products aimed at addressing existing and new market opportunities in the area of skin treatment technology in the aesthetic industry. In addition, I developed the company's intellectual property portfolio, including IP related to the company's skin treatment technology. While working for Sofwave Medical, I performed finite element analyses (FEA) to model tissue heating for skin treatment devices for the treatment of wrinkles and skin laxity in the aesthetic industry using different energy types, including ultrasound and radiofrequency (RF). I have also used FEA to model

various competitive devices such as RF microneedling devices. I have extensive experience in thermal analysis, acoustic, RF, microwave, and laser modeling.

8. I received a Doctor of Philosophy degree from École Polytechnique de Montréal in Biomedical Engineering in 1998. I received my First Degree (Bachelor's) in 1993 from Université Laval in Quebec, Canada in Physic Engineering. During my Ph.D. thesis, I developed and characterized Microwave Ablation Systems for the Treatment of Cardiac Arrhythmias using electromagnetic energy. The aim of the study was to overcome known issues and limitations with current and traditional RF ablation systems.

9. During my studies, I received numerous Scholarships and Awards, such as a High Distinction form the Montreal University for Ph.D. thesis, which was selected in the top three best thesis of the year. I received scholarships from the Canadian government during my Ph.D. studies, and from the government of Quebec during my Master studies. I also received scholarships from the Canadian government during my undergraduate studies, and have been selected as member of the Table of Honor after the completion of my Engineering studies.

10. I have worked in the area of biomedical engineering for over 25 years, always involved with products using electromagnetic, radiofrequency, or ultrasonic energy interaction with biological tissues to treat medical issues or conditions. I have experience in research and development of medical devices, scientific affairs, patent

strategies, finite element analysis, and the treatment of skin using RF and other energy modalities. In particular, I am experienced in modeling the effects of treatment devices on biological tissue using thermal, acoustic, RF, microwave, and laser modeling. I have also written and published peer-reviewed articles related to RF microneedling technology, science, and clinical results. In particular, I published peer-reviewed article characterizing the thermodynamic aspects of collagen denaturation and its influence on clinical results for the treatment of facial wrinkles and skin laxity.

11. From 2008 to 2020, I worked as Vice President of Research and Development (Profound Division) and Vice President of Global Business Development and Strategy for Candela Medical (f/k/a Syneron) and for Primaeva Medical before its acquisition by Syneron. I led the development of the company's RF microneedling technology called "Profound" from inception to commercial release and managed all products and software updates during my tenure. In addition, I developed and implemented the IP portfolio related to the Profound technology. I acted as a hands-on scientist and performed Finite Element Analysis to model the radiofrequency and laser interactions with biological tissues in order to investigate and improve treatment concepts. Shown below are some of the RF microneedling devices I developed:



12. In the past five years, I have testified at trial or by deposition in the following matters:

- ITC investigation by Syneron Medical Ltd. – Certain Radio Frequency Micro-Needle Dermatological Treatment Devices and Components Thereof, 337-TA-1112, ITC, Judge Lord.
- ITC investigation by Serendia, LLC – Certain Dermatological Treatment Devices and Components Thereof, 337-TA-1356, ITC, Judge McNamara.

13. I have been working in the cardio-vascular space from 1998 to 2008 prior to starting in the esthetic field. During my tenure at AFx, I developed the first surgical microwave ablation system to treat stand-alone atrial fibrillation (AF) on beating heart without cardio-pulmonary bypass, using thoracoscopic or robotic access. I also worked

with cardiac surgeons to develop the technical aspects of the surgical procedure. I also published several technical and clinical papers, and abstracts.

14. During my PhD study, I reviewed and characterized TTC-stained myocardium obtained acutely and 1 month after receiving microwave ablation treatments using different energy settings. I also performed similar measurements during my tenure at AFx to provide data aimed at obtaining 510k clearance for the microwave ablation devices. During my tenure at Primaeva/Syneron/Candela, I have also been directly involved in reading histology slides in human skin to characterize the zones of thermal injuries created by an array of bipolar radiofrequency needles, and to distinguish between collagen denaturation and coagulation. I have been involved in techniques used to evaluate skin tissue sections in order to properly characterize the maximal cross-sectional dimensions of a thermal injury. I received direct in-house training from Dr. Basil Hantash, PhD, who is a board-certified dermatologist with direct expertise in the field of skin science and research. I published a peer-reviewed article where a simulation model of a pair of bipolar RF needle used to create thermal injuries in the skin was validated using human skin histology results. I have also reviewed numerous histology slides to assess human adipocyte apoptosis or necrosis obtained with a clinical prototype using RF energy. During my tenure with Sofwave, I reviewed numerous histology slides obtained with a non-focused ultrasonic transducer to create thermal injuries in the skin of an animal model. I presented the results of a

simulation model validation during an international dermatology meeting (ASLMS 2021) where histology data was used, and where I showed how to compensate the measurements data for tissue shrinkage.

III. MATERIALS REVIEWED

15. I am not an attorney and offer no legal opinions, but in my work, I have had experience studying and analyzing patents and patent claims from the perspective of a person skilled in the art.

16. In preparing this declaration, I reviewed the '836 patent, including the claims of the patent in view of the specification, and I have reviewed the prosecution history of the '836 patent and numerous prior art and technical references from the time of the alleged invention. More specifically, I have reviewed each of the following:

Exhibit	Description
1001	U.S. Patent No. 9,480,836 (the "'836 patent")
1002	File History for U.S. Patent No. 9,480,836
1005	U.S. Patent Application Publication No. 2007/0208340 ("Ganz")
1006	International Publication Number WO 2008/005477 ("Livneh")
1007	International Publication Number WO 2007/064718 ("Hantash")
1008	Korean Patent No. 20-0441552 ("Lee") (translation)
1009	Korean Patent No. 20-0441552 ("Lee") (original Korean)
1010	Macrene Alexiades-Armenakas et al., <i>Prospective Multicenter Clinical Trial of a Minimally Invasive Temperature-Controlled Bipolar</i>

	<i>Fractional Radiofrequency System for Rhytids and Laxity Treatment</i> , Dermatol. Surg. 1 (2012)
1011	Barry D. Sudbeck et al., <i>Collagen-stimulated Induction of Keratinocyte Collagenase Is Mediated via Tyrosine Kinase and Protein Kinase C Activities</i> , 269, 47 J. Biol. Chem. 30022 (1994)
1012	Sayaka Kanai et al., <i>Peptide Precursors that Acquire Denatured Collagen- hybridizing Ability by O-to-N acyl Migration at Physiological pH</i> , 18 Org. Biomol. Chem. 2823 (2020)
1013	Kristin M. Kirsch et al., <i>Ultrastructure of Collagen Thermally Denatured by Microsecond Domain Pulsed Carbon Dioxide Laser</i> , 134 Arch. Dermatol 1255 (Oct. 1998)
1014	U.S. Publication No. 2005/0222565 (“Manstein”)
1015	Melissa A. Bogle, <i>Radiofrequency Energy and Hybrid Devices</i> , in NON-SURGICAL SKIN TIGHTENING AND LIFTING 21 (Murad Alam & Jeffrey S. Dover eds., 2009) (“Bogle”)
1016	THE IEEE STANDARD DICTIONARY OF ELECTRICAL AND ELECTRONICS TERMS (6th ed. 1997)
1017	THE ILLUSTRATED DICTIONARY OF ELECTRONICS (8th ed. 2001)
1018	BASIC ELECTRONICS THEORY (1981)
1019	R. James Koch & Brian P. Kim, <i>Radiofrequency Tissue Tightening</i> , in Non-Invasive Cosmetic Procedures 63 (2011)
1020	Heather Woolery-Lloyd & Jenna N. Kammer, <i>Skin Tightening</i> , in BASICS IN DERMATOLOGICAL LASER APPLICATIONS 147 (Inja Bogdan Allemann & David J. Goldberg eds., 2011)
1021	Antois S. Manolis et al., <i>Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias</i> , 121 Ann Intern Med. 452 (1994)

1022	David E. Haines, <i>Biophysics of Radiofrequency Lesion Formation</i> , in CATHETER ABLATION OF CARDIAC ARRHYTHMIAS 2 (Shoei K. Stephen Huang & Mark A. Wood eds., 2010)
1023	Seong Kuk Yoon, <i>Radiofrequency Ablation of Renal Cell Carcinoma: A Systematic Review</i> , in ADVANCED LAPAROSCOPY 127 (Ali Shamsa ed., 2011)
1024	Diane Irvine Duncan & Michael Kreindel, <i>Basic Radiofrequency: Physics and Safety and Application to Aesthetic Medicine</i> , in RADIOFREQUENCY IN COSMETIC DERMATOLOGY 1 (Moshe Lapidoth & Shlomit Halachmi eds., 2015)
1025	Korean Published Patent App. No. 10-2011-0074842 (translation)
1026	Korean Published Patent App. No. 10-2011-0074842 (original Korean)
1027	U.S. Patent Application Publication No. 2006/0047281 (“Kreindel”)
1028	Order No. 35: Construing Certain Terms of the Asserted Claims, Inv. No. 337-TA-1356.
1029	U.S. Patent Application Publication No. 2010/0262135
1030	International Standard, IEC 60601-2-2, Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
1031	George Hruza et al., <i>Skin Rejuvenation and Wrinkle Reduction Using a Fractional Radiofrequency System</i> , Vol. 8 Issue 3 Journal of Drugs in Dermatology 259 (2009)
1034	Birefringence Definition, https://www.merriam-webster.com/dictionary/birefringence
1035	Declaration of R. James Koch, M.D.

IV. RELEVANT LEGAL STANDARDS

17. I am not an attorney. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to forming my opinions. I have applied the following understanding of the law:

18. I have been informed that a patent claim may be “anticipated” if each element of that claim is present either explicitly or inherently in a single prior art reference, and that the elements should be arranged in the reference as in the claim. Petitioner’s counsel has informed me that for a claimed limitation to be inherently present, the prior art need not expressly disclose the limitation, so long as the claimed limitation necessarily flows from a disclosure in the prior art.

19. I have been informed that a patent claim can be considered to have been obvious to a person of ordinary skill in the art at the time the application was filed. This means that, even if all of the requirements of a claim are not found in a single prior art reference, the claim is not patentable if the differences between the subject matter in the prior art and the subject matter in the claim would have been obvious to a person of ordinary skill in the art at the time the application was filed.

20. I have been informed that a determination of whether a claim would have been obvious should be based upon several factors, including, among others:

- the level of ordinary skill in the art at the time the application was filed;
- the scope and content of the prior art; and

- what differences, if any, existed between the claimed invention and the prior art.

21. I have been informed that a single reference can render a patent claim obvious if any differences between that reference and the claims would have been obvious to a person of ordinary skill in the art. Alternatively, the teachings of two or more references may be combined in the same way as disclosed in the claims, if such a combination would have been obvious to one having ordinary skill in the art. In determining whether a combination based on either a single reference or multiple references would have been obvious, it is appropriate to consider, among other factors:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, and when combined, would yield predictable results;
- whether a person of ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person of ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;

- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the innovation applies a known technique that had been used to improve a similar device or method in a similar way.

22. Petitioner's counsel has informed me that one of ordinary skill in the art has ordinary creativity and is not an automaton. Petitioner's counsel has informed me that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

V. TECHNOLOGY BACKGROUND

23. The earliest priority date listed on the cover of the '836 patent is June 14, 2011. Ex-1001. Thus, for purposes of this analysis, I assume that the time of the purported invention of the '836 patent was June 14, 2011 and have provided an overview of the background of the relevant technology by that time.

A. Radio Frequency (RF) Microneedles for Skin Treatment

24. Before the priority date of the '836 patent, it was well known to use microneedles alone for skin treatment. Ex-1008, <17> ("The multi-hole treatment method, which is simple and safe as well as free of side effects, newly reconstructs and rearranges dermal tissues by using *a process of natural wound healing that occurs when a plurality of needles are inserted into the skin*, thereby making scars thinner as well as tightening the skin. As a result, fine wrinkles decrease and

hyperpigmentation improves, restoring healthy and clean skin.”) (emphasis added).

Creating small holes in skin would start a natural healing process that results in skin tightening. Ex-1008, <17>. These microneedle devices are designed with multiple needles attached to a base, the needles being designed to penetrate in dermis to generate multiple small skin cut injuries mainly aimed at triggering a wound healing effect to produce new dermal collagen.

25. For additional impact, it was also well known to power such microneedles with a radio frequency (RF) energy source. Ex-1007, [0035] (“While the needles 115 are located within the skin 150, they can be powered by the RF source 110 to create an array of treatment zones 160 through resistive heating of the tissue.”); Ex-1010 at 8 (“Recently, successful generation of fractional thermal injuries directly within the reticular dermis using a minimally invasive temperature-controlled bipolar RF investigational device was reported.”). The ’836 patent confirms this understanding. Ex-1001, 2:1-6 (“Korean patent 2000-0058346 describes a device to reduce skin wrinkles by verifying wrinkle thickness, length and shape and setting pulse, time, elevation current and wattage to magnify the cell tissue. Via a hand piece, the needle length may be selected based on the length and depth of wrinkle to be reduced.”); Ex-1001, 2:7-14 (“Korean patent 10-2009-23494 describes employing high frequency to treat skin. In detail, it attempts to revitalize cell tissue and maintain elasticity in skin, and minimizing skin aging by directly delivering high frequency

energy into skin dermis (between epidermis and subcutaneous layer). The skin treatment device includes a pair of electrodes in a main body that deliver high frequency energy into the dermis reticular layer.”).

26. I also filed a patent application for a device using RF microneedles:

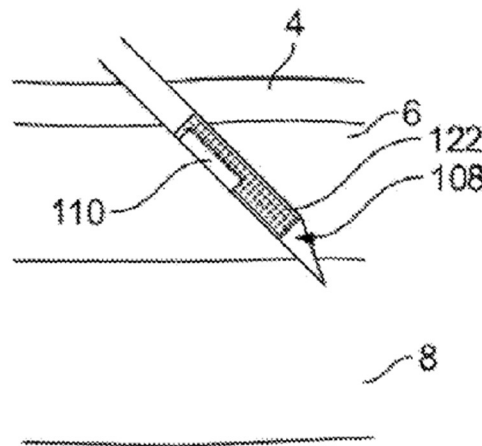


FIG. 8A

Ex-1029, Fig. 8A; Ex-1029, [0185] (“the probe 108 can employ an RF energy mode to denature or coagulate collagen in a dermal layer.”). The RF energy would generate heat from the microneedles, causing denaturation and/or coagulation of collagen, as further discussed in Section V.B below.

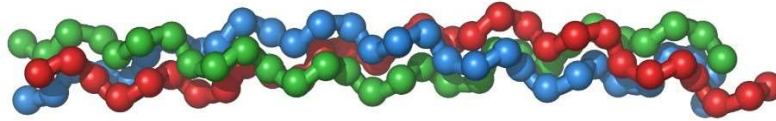
27. Before filing of the ’836 patent, Hruza et al. conducted a study on *in vivo* human skin using a RF device consisting of “parallel rows of bipolar arranged electrode-pins, forming an array of positively and negatively charged electrodes for multiple delivery of 1 MHz of RF energy.” Ex-1031 at 260. This study used electrode-pins to heat “areas which are directly targeted by the electrode-pins to temperatures

leading to ablation and resurfacing of the skin directly in contact with and below the array, leaving intact or slightly affected zones in between the targeted areas.” Ex-1031 at 260. The RF device used for this study was “tunable in the sense that the relative proportion of ablation/coagulation/necrosis . . . and the extent of the surrounding coagulated tissue may be controlled.” Ex-1031 at 263. Hruza et al. concluded that it was advantageous to deliver energy in a non-homogenous fractional form, leaving undamaged tissue between electrode-pins, for a safe, tolerable and effective improvement in skin texture and reduction of wrinkles. Ex-1031 at Abstract, 259-60 (“In fractional resurfacing, thermally ablated microscopic zones of epidermis and dermis are spaced in a grid over the skin surface; the nonablated zones in the uninjured surrounding tissue serves as a reservoir of cells that accelerate and promote safe and rapid healing.”).

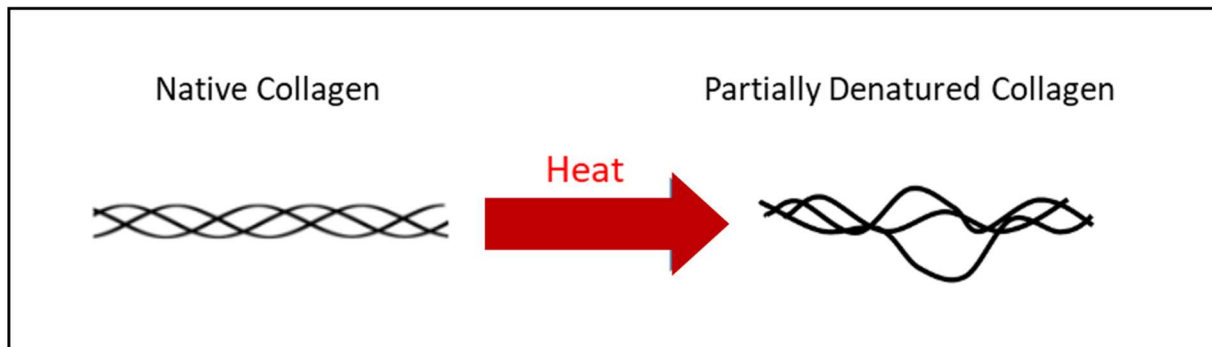
B. Collagen Denaturation and Coagulation

28. Skin consists of three layers: epidermis, dermis, and subcutaneous layer. Ex-1001, 1:36-39 (“Generally, skin is the largest protective organ that covers the entire body and maintains homeostasis on surface of the body with three layers consisting of epidermis, dermis, and subcutaneous layer.”). Dermis is composed of protein called collagen. Ex-1029, [0096] (“Most of the dermis 18 comprises collagen fibers.”); Ex-1001, 2:42 (“dermis is composed of protein called collagen”).

29. Collagen is a long biopolymer molecule with a triple helix structure composed of several amino acids as shown in the figure below:

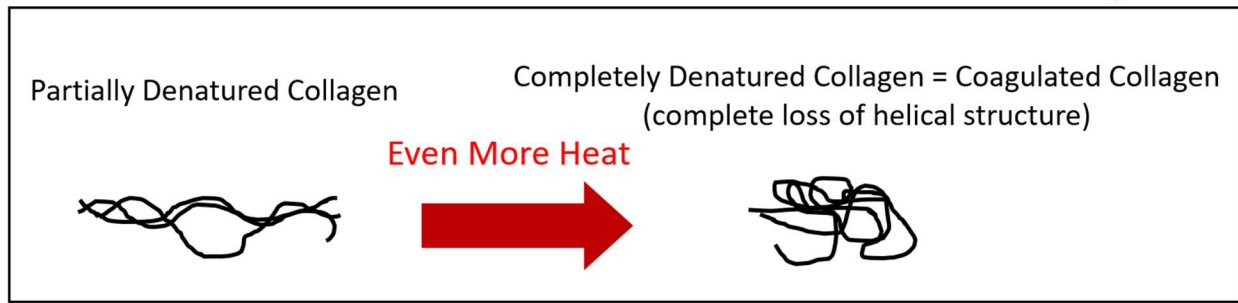


30. When submitted to elevated heat, the triple helix collagen structure starts to denature and change its 3D configuration by unfolding and shrinking¹ as depicted in the figure below:



31. When even more heat is applied, collagen denatures completely and starts to coagulate as depicted in the figure below:

¹ Ex-1010; Ex-1011; Ex-1012.



32. The process of collagen denaturation to coagulation is well known, and the differences between denatured collagen and coagulated collagen have been observed and reported in literature. For example, Kirsch et al.² described an experiment where two different states of collagen, coagulated (coagulation zone) and denatured, were observed histologically after the application of electromagnetic energy. In Kirsch, two zones of thermally altered collagen were described. “Within the ‘coagulation zone,’ collagen fibers were swollen and devoid of optical birefringence³ and periodicity.” Ex-1013, 1256. In other words, the molecules were completely collapsed and coagulated together. “Within the ‘transition zone,’ both denatured and normal collagen fibers were intermixed.” Ex-1013, 1256. “Birefringence of fibers within the zone was reduced and their periodicity ‘partly recognizable.’” Ex-1013, 1256. Since partially denatured collagen maintains some linear configurational aspects, the

² Ex-1013.

³ According to Meriam-Webster, Birefringence is: “the refraction of light in an anisotropic material . . . in two slightly different directions to form two rays.” Ex-1034. With collagen, this happens due to the linear aspect of the molecule. Within the coagulation zone, the collagen molecules were completely shrunk or denatured and completely loss their linear characteristics.

birefringence was still present, although reduced. These changes were correlated with those found in murine (a small rodent animal) skin immersed for 160 seconds in a controlled temperature bath. Under these conditions, collagen fiber denaturation began at 57°C; the number and diameter of swollen fibers increased at 65°C (periodicity partly maintained); and fiber coagulation was nearly complete at 73°C. Under these conditions, collagen fiber denaturation began at 57°C; the number and diameter of swollen fibers increased at 65°C (periodicity partly maintained); and fiber coagulation was nearly complete at 73°C. skin immersed for 160 seconds in a controlled temperature bath. Under these conditions, collagen fiber denaturation began at 57°C; the number and diameter of swollen fibers increased at 65°C (periodicity partly maintained); and fiber coagulation was nearly complete at 73°C.

33. Collagen denaturation helps remove wrinkles because of the shrinking of the collagen fibers. Ex-1007, [0005] (“This denaturing is accompanied by shrinking of the collagen fibers and this shrinking can provide sagging or wrinkled skin with a tightened youthful appearance.”). Partially denatured collagen triggers a wound-healing sequence capable of recreating new dermis and is therefore effective at treating wrinkles by re-volumizing the dermal space. Ex-1029, [0098] (“[T]he eventual wound healing response may further cause additional collagen production. This latter effect may further serve to tighten and bulk up the skin 10.”). Moreover, forming small zones of coagulation is beneficial because coagulation leads to tissue regeneration,

replicating skin treatment using ablative lasers such as CO₂ lasers. Ex-1005, [0028]

(“These zones of coagulation are beneficial as coagulation leads to tissue regeneration.”).

C. Basic Electrical Principles

34. In a conductive medium, the voltage V is proportional to the current I , and the proportion coefficient is defined as the impedance Z . The governing equation is called the Ohms’ law, which stipulate that the voltage drop created by a current flowing in a resistive medium follow this relationship: $V = Z * I$.

35. When a conductive current flows through a resistive medium such as a biological tissue, the charged particles collides against each other and the electrical energy they carry is lost and transferred in the resistive medium—the biological tissue in this case. The absorption of electrical energy in tissue creates a localized temperature elevation, which is used to create a desired biological effect.

36. The power P lost in a resistive medium is given by the product of the voltage V and the current I , which is mathematically described as follows: $P = V * I$. This can be rearranged using the Ohm’s law described above in terms of voltage and impedance as: $P = V^2/Z$, or in terms of current and impedance as: $P = Z * I^2$. When a power is absorbed in a 3D volume, it is useful to express it as a power density (in unit of power per unit of volume) for calculation purposes. In this mathematical expression, the current I (measured in Ampere) can be replaced by the current density J (in Ampere

per unit of surface). The current density is essentially the amount of current going through a surface perpendicular to the direction of the current lines. The power absorbed per unit of volume in tissue is therefore proportional to the square of the current density.

VI. OVERVIEW OF U.S. PATENT NO. 9,480,836

A. Summary

37. Entitled “Skin Treatment Apparatus and Method,” the ’836 patent relates to devices and methods for skin treatment. The Asserted Claims of the ’836 patent generally describe treating dermatological tissue with a device comprising a plurality of bipolar electrodes insertable into skin, a radio frequency (RF) generation module electrically coupled to the plurality of electrodes to provide an alternating current (AC) RF signal to the plurality of electrodes configured to cause coagulation.

38. The specification describes “different AC signals having opposite polarities [] applied to needles 300” and the needles “configured to have opposite polarities when signals are applied by the RF signal generator 14.” Ex-1001, 7:45-48; *see also* Ex-1001, 7:30-32. The specification does not describe an AC RF signal.

39. The specification discloses that “applying energy to achieve coagulation” is used synonymously with “to raise temperature” and that “[t]he invention may be configured ‘to raise temperature’ by applying energy to achieve coagulation.” Ex-1001, 2:65-3:8. For example, “the temperature may be raised and the heat may be

concentrated at an area in dermis by the needle(s) to cause coagulation.” Ex-1001, 3:21-24.

40. The specification discloses that “each needle may independently form an energy field about its tip.” Ex-1001, 3:57-59. The specification generally describes that the “energy duty cycle,” “voltage,” “needles with particular lengths and thicknesses,” and “needles having a desired distance and shape” may be regulated to generate a desired energy field 909, 949 as shown in Figures 5 and 9B. Ex-1001, 8:9-14, 8:54-56, 9:25-28, 9:58-61.

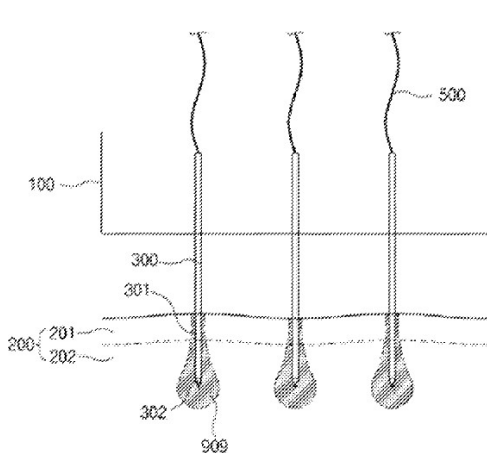


FIGURE 5

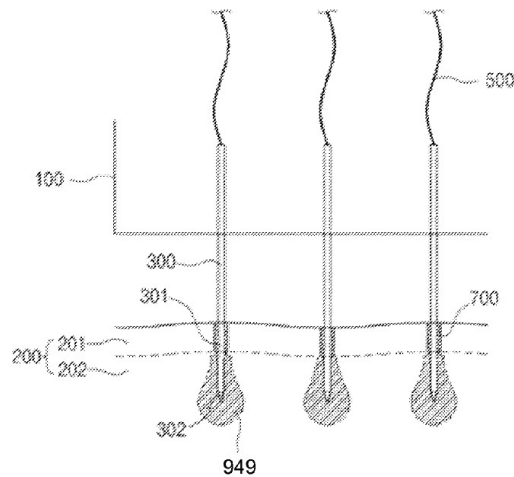


FIGURE 9B

Ex-1001, Figs. 5 and 9B. The specification discloses that the needles “may not be located close proximity” because “if the distance between electrodes or needles is too close, the energy field and the heated area generated by the applied energy field about each needle may be connected or intersect.” Ex-1001, 5:60-65.

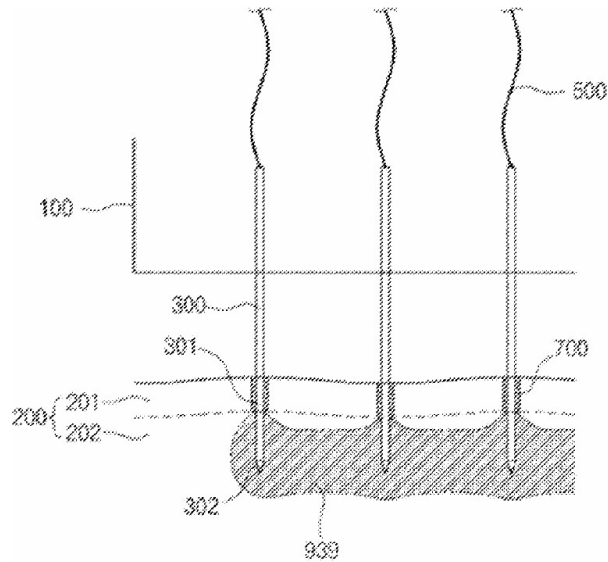


FIGURE 9A

Ex-1001, Fig. 9A.

41. Figure 1 purportedly shows that “the power supply 12 may provide required energy to the radio frequency (RF) generator 14.” Ex-1001, 5:33-35.

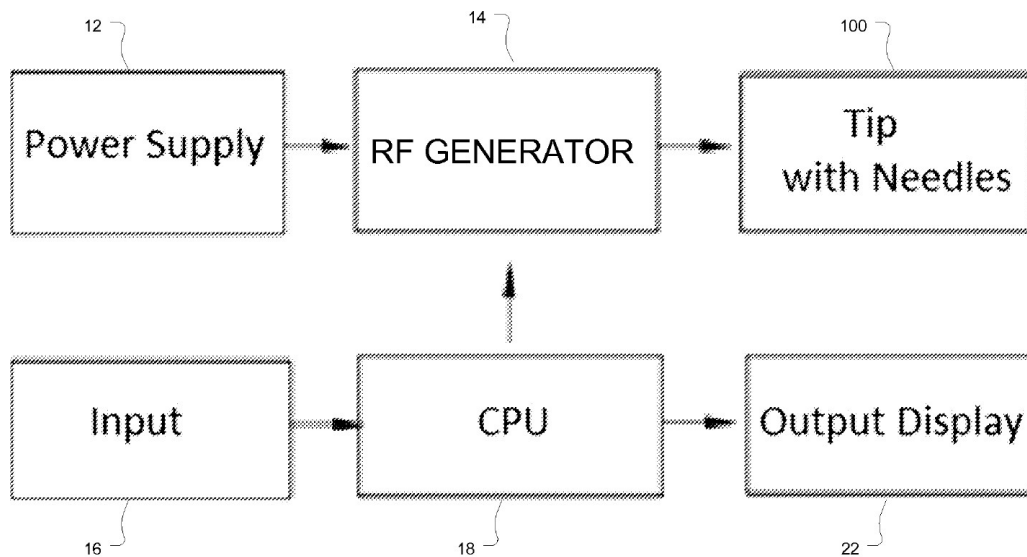


FIGURE 1

10

Ex-1001, Fig. 1. The specification further discloses that the applied voltage “may be directly related to the amount of energy created at a needle.” Ex-1001, 8:29-30.

42. The specification describes that “energized needles may be completely electrically insulated, un-insulated, and only insulated near its tip.” Ex-1001, 6:66-7:1. The specification discloses that “[t]he present invention may have a definite advantage over the systems that employ insulated needles.” Ex-1001, 3:39-40.

B. Prosecution History

43. I have reviewed the prosecution history of Application No. 14/006,930 that led to the ’836 patent.

44. On August 4, 2015, the examiner rejected the proposed claims based on anticipation by U.S. Publication No. 2005/0222565 (“Manstein”) and obviousness by Manstein and U.S. Patent No. 5,546,954 (“Yamada”). Ex-1002, 294-297 (Aug. 4, 2015 Non-Final Rejection). In response, the applicant amended the claims. Ex-1002, 309 (Oct. 18, 2015 Response). The amended claim 17 (later issued as claim 1) is shown below:

17. (Currently Amended) A skin treatment apparatus that enables non-intersecting coagulation of skin dermis about electrodes, comprising:

~~a set at least three of bipolar~~ electrodes configured to be insertable into skin to be treated; and

a signal generation module, the signal generation module electrically coupled to the ~~at least three set of bipolar~~ electrodes and providing a high frequency Alternating Current (AC) signals signal for a predetermined time interval to the ~~at least three set of bipolar~~ electrodes to form bipolar pairs between electrodes of the at least three electrodes ~~to that enable non-intersecting coagulation about each electrode of the bipolar set.~~

Ex-1002, 309 (Oct. 18, 2015 Response).

45. When the examiner rejected the amended claims again based on anticipation and obviousness, Ex-1002, 323 (Jan. 22, 2016 Final Rejection), the applicant amended the claims again. Ex-1002, 335 (Mar. 1, 2016 Response), 370 (May 5, 2016 Supplemental Response). The amended claim 17 is shown below:

17. (Currently Amended) A skin treatment apparatus ~~that enables non-intersecting coagulation of skin dermis about electrodes~~, comprising:

~~at least three~~ a plurality of electrodes, ~~the electrodes being bipolar and~~ configured to be insertable into skin to be treated; and

a ~~signal~~ radio frequency (RF) generation module, the ~~signal~~ RF generation module electrically coupled to the ~~at least three~~ plurality of electrodes and configured to providing provide a high frequency an Alternating Current (AC) RF signal ~~for a predetermined time interval to the at least three~~ to the plurality of electrodes to ~~form bipolar pairs between electrodes of the at least three electrodes~~ coagulate around each electrode rather than coagulating between the electrodes.

Ex-1002, 335 (Mar. 1, 2016 Response), 370 (May 5, 2016 Supplemental Response).

46. The applicant noted that the amendment was made to add “an alternating current (AC) RF signal to a plurality of electrodes (that are bipolar) to coagulate around each electrode rather than coagulating between the electrodes.” Ex-1002, 344-45 (Mar. 1, 2016 Response), 379-80 (May 5, 2016 Supplemental Response).

47. Following the amendments, the examiner issued a Notice of Allowance. Ex-1002, 385 (May 18, 2016 Notice of Allowance), 427 (July 11, 2016, Corrected Notice of Allowance). For the reason for the allowance, the examiner stated 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.” Ex-1002, 390 (May 18, 2016 Notice of Allowance). The examiner

cited paragraph [0032] of Manstein, which states, “In one exemplary embodiment, the energy source 320 is a radio frequency (RF) device capable of outputting [sic] signals having frequencies in a desired range. In another exemplary embodiment, the energy source is capable of outputting an AC or DC electric current.” Ex-1014, [0032].

48. The examiner appears to have been unaware that RF signals for skin treatment are AC signals operating at a radio frequency. Ex-1006, [0037] (“The power supply 50 preferably converts commercial AC electrical power, e.g., a 120 volt, 60 hertz signal, to *a radio frequency (RF) signal, i.e., an AC signal operating at a radio frequency.*”) (emphasis added).

C. Level of Ordinary Skill in the Art

49. It is my understanding that factors defining the level of ordinary skill in the art include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of technology; and (5) the educational level of active workers in the field.

50. I understand that, in the ITC investigation by Serendia, LLC – Certain Dermatological Treatment Devices and Components Thereof, 337-TA-1356, ITC, Judge McNamara (“ITC Investigation”), the Administrative Law Judge ruled that a person of ordinary skill in the art (“POSITA”) would have had “(1) 7-10 years of experience with developing and/or using treatment systems for delivery of

electromagnetic radiation energy to skin or other tissues, and (2) a related graduate engineering degree or M.D. and may have worked as part of a multidisciplinary team and drawn upon not only his or her own skills, but also would have taken advantage of certain specialized skills of others on the team when solving a technical problem.” Ex-1028, 15.

51. I applied this definition of a POSITA in forming my opinion in this declaration.

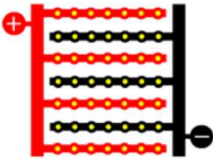
D. Claim Construction

52. In forming my opinion in this declaration, I have been asked to assume that the following terms have the meaning that the Petitioner and the Patent Owner have agreed to in the ITC Investigation, shown below. Ex-1028, 39-40.

Term	Claims	Agreed Construction
Preamble	1, 14	Preambles are limiting
“configured to”	1, 2, 14	Plain and ordinary meaning: adapted to
“radio frequency (RF) generation module”	1, 2	Plain and ordinary meaning: a device that generates electrical signal(s) having a radio frequency
“electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes”	1, 14	Plain and ordinary meaning: two or more electrodes adapted to cause coagulation around each electrode without such coagulation fully extending from one electrode to another electrode
“electrodes being bipolar”	1, 14	Plain and ordinary meaning: electrodes change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one

		or more ground electrodes)
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53. I understand that the Administrative Law Judge in the ITC Investigation adopted the following constructions. Ex-1028, 41-62.

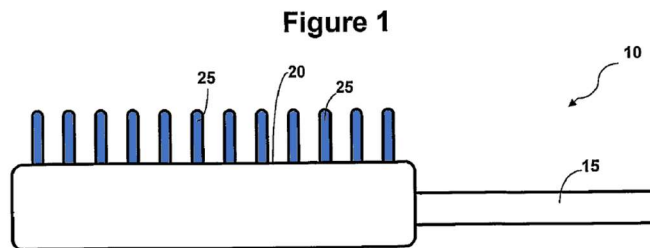
Term	Claims	Adopted Construction
“plurality of electrodes”	1, 2, 4, 6, 12, 13, 14, 15, 17, 24, 25, 26, 27, 28, 29 ⁴	Plain and ordinary meaning, which is two or more electrodes (which can be needles or pins)
“a plurality of electrodes, the electrodes being bipolar”	1, 14	two or more electrodes (which can be needles or pins) that change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes); excludes the Intracel configuration (alternating rows of commonly-polarized electrodes): 
“[a/an] Alternating Current (AC) [RF/Radio Frequency (RF)] signal”	1, 2, 14	Plain and ordinary meaning: an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz)

⁴ The Administrative Law Judge’s claim construction order appears to contain a typographical error in listing the follows claims for “plurality of electrodes”: claims 1, 2, 5, 9, 11, 12, 13, 14, 17, and 22. Ex-1028, 41. Although the order lists claims 5, 9, 11, and 22, those claims do not recite “plurality of electrodes.” Moreover, although the order omits claims 4, 6, 15, 24, 25, 26, 27, 28, and 29, those claims recite “plurality of electrodes.”

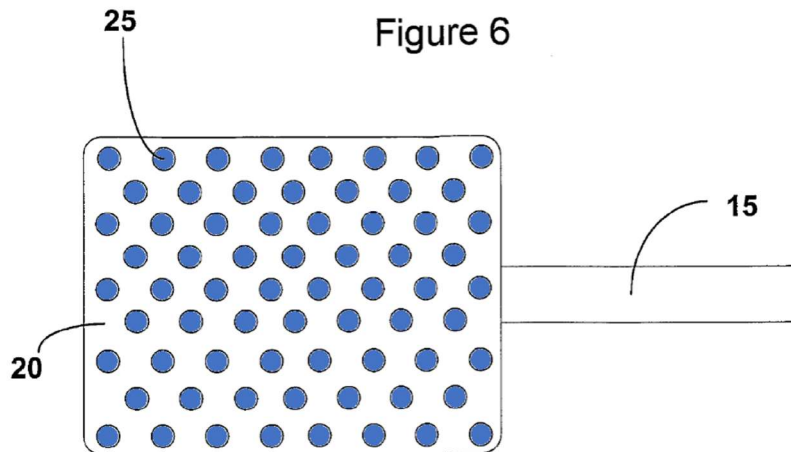
VII. OVERVIEW OF THE PRIOR ART

A. Ganz (Ex-1005)

54. Like the '836 patent, Ganz discloses a skin treatment device that uses radio frequency (RF) electrodes that create zones of coagulation. Ex-1005, [0001] (“the invention relates to a device and method for treating one or more layers of the skin to elicit a healing response which produces a more desirable skin appearance”); Ex-1005, [0058] (“In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes.”). Figure 1 is a side view of such a device with electrode pins 25 (blue):



Ex-1005, Fig. 1 (annotated); Ex-1005, [0017] (“FIG. 1 is a side view of the distal end of a treatment device in accordance with one embodiment of the invention.”). Figure 6 further illustrates the device in a planar view. Ex-1005, [0022].



Ex-1005, Fig. 6 (annotated).

55. Ganz discloses inserting the electrode pins into skin to create perforations. Ex-1005, [0051] (“[W]hen it is desirable to provide a deeper perforation, the electrode pins are placed all the way into the tissue, so that more than one layers of tissue are treated. When it is desirable to provide an even deeper perforation, the electrode pins can be providing [sic] having longer lengths, so that the tips are placed even deeper into the tissue layers.”). “The device does not remove entire layers of tissue, but rather creates perforations in one or more layers.” Ex-1005, [0027]. “***These perforations create holes, which extend vertically into the tissue and across one or more layers.***” Ex-1005, [0027]. Therefore, “the term ‘perforation’ means vertical areas of thermal damage or ablation to the tissue causing tissue necrosis.” Ex-1005, [0027]. “Such perforations are so small that they cannot be seen with the naked eye.” Ex-1005, [0029].

56. Ganz discloses an improvement over prior art FRAXEL laser. Ganz teaches that creating perforations as discussed above leads to a better result than that of prior art FRAXEL laser, which “*does not create perforations* or vertical holes in the tissue, *but only causes zones of coagulation.*” Ex-1005, [0006] (emphasis added); *see also* Ex-1005, [0006] (“Applicant has discovered that it is desirable to create vertical perforations or ablation holes in tissue, as this prompts an even more aggressive wound healing response than is currently seen.”); Ex-1005, [0032] (“The creation of actual perforations leads to more aggressive healing responses. Additionally, the use of perforations into skin rather than removal of entire skin layers reduces the chances of scarring and promotes a faster healing time.”).

57. Ganz, however, does *not* teach creating perforations to the exclusion of zones of coagulation. Rather, Ganz discloses creating both perforations *and* zones of coagulation. Ex-1005, [0032] (“The device *also imparts perforations* into the skin, *rather than merely imparting coagulations* into the skin.”) (emphasis added); Ex-1005, [0028] (“*The treated area 4 is clearly a perforation*, which extends vertically into the skin. *Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation 4.*”) (emphasis added). Ganz discloses that zones of coagulation “extend into the tissue in all directions originating from the perforation site.” Ex-1005, [0028]. “These zones of coagulation are beneficial as coagulation leads to tissue regeneration.” Ex-1005, [0028]. “The zones of coagulation created in the

tissue area surrounding each perforation . . . help to revitalize and rejuvenate [sic] skin.” Ex-1005, [0030].

B. Livneh (Ex-1006)

58. Like the '836 patent, Livneh discloses a skin treatment device that uses radio frequency (RF) electrodes. Ex-1006, [0002] (“This invention relates to an apparatus and method for skin tightening. More specifically, the present invention provides an apparatus and method for introducing thermal and mechanical injury to skin via electrodes carrying an electric current.”), [0032] (“The apparatus 30 is capable of delivering electrical current to skin using a plurality of electrodes 32 which enter the skin. Preferably, the apparatus 30 is utilized in skin tightening procedures.”), [0039] (“Specifically, in bipolar operation, as shown in Figure 1, the RF signal is applied through a first set 54 of the electrodes 32 and utilizes a second set 56 of electrodes 32 as a return path to the power supply 50.”). Livneh discloses that its device “creates mechanical and thermal injuries to the skin.” Ex-1006, [0060]. “As these injuries heal, the effect is tightening of the skin, which is normally perceived to be the appearance of younger and tighter skin.” Ex-1006, [0060].

59. For the RF signal, Livneh discloses “a power supply 50 for supplying the electrical current to the electrodes 32.” Ex-1006, [0037]. “Preferably, a cable (not shown) or other electrical connection allows transmission of the RF signal from the power supply 50 in the control unit 48 to the electrodes 32 in the handheld unit 34.”

Ex-1006, [0037]. “The power supply 50 preferably converts commercial AC electrical power, e.g., a 120 volt, 60 hertz signal, to *a radio frequency (RF) signal, i.e., an AC signal operating at a radio frequency.*” Ex-1006, [0037] (emphasis added).

C. Hantash (Ex-1007)

60. Like the '836 patent, Hantash discloses a skin treatment device that uses RF electrodes. Ex-1007, [0014] (“The invention provides a dermatological treatment apparatus for selectively treating zones of tissue within the skin. Such selective tissue treatment is achieved using an array of electrically conductive microneedles that are connected to a radio frequency energy source.”).

61. Hantash discloses inserting the electrodes into skin and applying RF energy to the electrodes to create perforations and denaturation and/or coagulation surrounding the perforations. Ex-1007, [0035] (“While the needles 115 are located within the skin 150, they can be powered by the RF source 110 to create an array of treatment zones 160 through resistive heating of the tissue.”); Ex-1007, [0060] (“The treatment pattern 164 shown in FIGS. 7 A and 7B is particularly useful because it can create a line of tension within the skin 150 due to collagen denaturation.”); Ex-1007, [0079] (“[Various treatment device] parameters can be used to coagulate collagen within the skin and to kill or injure cells to stimulate the wound healing response in surrounding healthy tissue.”).

62. Hantash discloses certain operational parameters of applying RF energy and physical parameters of electrodes. Ex-1007, [0077]-[0078] (RF pulse duration); Ex-1007, Fig. 7A (needle arrangement); Ex-1007, [0040] (RF range); Ex-1007, [0039] (needle diameter); Ex-1007, [0077] (needle length).

D. Lee (Exs. 1008, 1009)

63. Like the '836 patent, Lee discloses a skin treatment device that uses microneedles. Ex-1008, <13> (“The present invention relates to a skin regeneration apparatus capable of controlling the insertion depth of microneedles and, more particularly, to a skin regeneration apparatus capable of controlling microneedles that can provide effective multi-hole treatment as well as safety and precision as to the depth of microneedles by making it possible to automatically control the insertion depth of the microneedles during multi-hole treatment.”).

64. Lee discloses inserting the needles into skin to create perforations. Ex-1008, <15> (“In this method, for example, hundreds to tens of thousands of tiny holes are created on the human skin to regenerate tissues by using its self-healing ability to heal the skin that is damaged in the process of making the tiny holes”).

65. Lee discloses an actuator and mode switch to control the precise insertion depth of the microneedles. Ex-1008, <44> (“the present invention provides an actuator means that can control the insertion depth of the microneedles”); Ex-1008, <33> (“Pressing the mode switch changes the mode. The selected mode controls the speed

of reciprocating insertions (number of repetitive insertions) and the insertion depth of the needles.”).

VIII. CLAIMS ANALYSIS

A. Ganz Alone or in Combination with Livneh Renders Claim 1-2, 11-15, 23-24, and 26 Obvious.

66. Ganz alone or in combination with Livneh renders all limitations of claims 1-2, 11-15, 23-24, and 26 obvious, for the reasons I discuss below. Ganz and the '836 patent are from the same field of endeavor and are directed to solving the same problem in the same way.

1. Claim 1

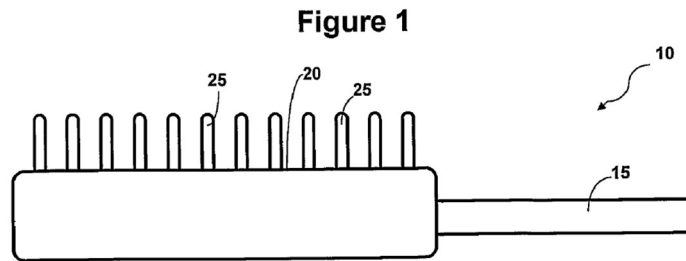
a) 1[preamble]: “A skin treatment apparatus, comprising:”

67. I understand that the Petitioner and Patent Owner agree that the preamble is limiting.

68. Ganz discloses the preamble.

69. In the Field of the Invention section, Ganz discloses that “the invention relates to *a device and method for treating one or more layers of the skin* to elicit a healing response which produces a more desirable skin appearance.” Ex-1005, [0001] (emphasis added); *see also* Ex-1005, [0025] (“FIG. 9 is a cross-sectional view of *a treated skin surface* according to an embodiment of the invention.”) (emphasis added); Ex-1005, [0026] (“FIG. 10 is a top view of *a treated skin surface* according to an

embodiment of the invention.”) (emphasis added). “FIG. 1 is a side view of the distal end of a treatment device in accordance with one embodiment of the invention.” Ex-1005, [0017].



Ex-1005, Fig. 1.

70. Therefore, Ganz discloses the preamble.

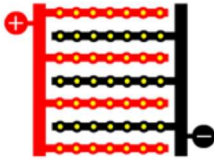
b) **1[a]: “a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated; and”**

71. Ganz discloses this limitation.

72. As discussed in Section VI.D above, I was asked to apply the following constructions for this limitation.

Term	Agreed Construction
“configured to”	Plain and ordinary meaning: adapted to
“electrodes being bipolar”	Plain and ordinary meaning: electrodes change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes)

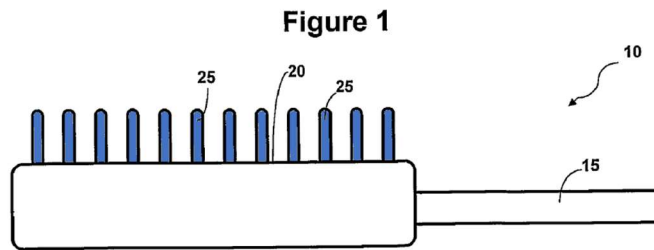
Term	Adopted Construction
“plurality of electrodes”	Plain and ordinary meaning, which is two or more

	electrodes (which can be needles or pins)
“a plurality of electrodes, the electrodes being bipolar”	two or more electrodes (which can be needles or pins) that change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes); excludes the Intracel configuration (alternating rows of commonly-polarized electrodes): 

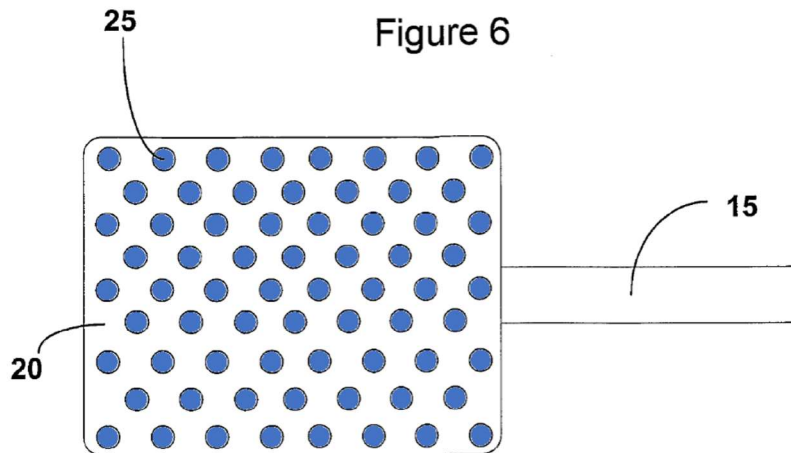
(1) “a plurality of electrodes”

73. Ganz discloses “a plurality of electrodes,” i.e., “two or more electrodes (which can be needles or pins).”

74. In the Brief Summary of the Invention section, Ganz discloses that its device “comprises a treating surface configured to be positioned in contact with tissue adjacent one or more tissue planes and *a plurality of electrodes* extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers.” Ex-1005, [0010]. Figure 1 illustrates that “[a] *plurality of electrode pins 25* [blue] are positioned about a portion of the treating surface.” Ex-1005, [0044].



Ex-1005, Fig. 1 (annotated); Ex-1005, [0017] (“FIG. 1 is a side view of the distal end of a treatment device in accordance with one embodiment of the invention.”). Figure 6 further illustrates the plurality of electrode pins 25 (blue) in a planar view. Ex-1005, [0022].



Ex-1005, Fig. 6 (annotated).

75. Therefore, Ganz discloses “a plurality of electrodes,” i.e., “two or more electrodes (which can be needles or pins).”

(2) “the electrodes being bipolar”

76. Ganz discloses “electrodes being bipolar,” i.e., “electrodes change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes).”

77. Ganz discloses that “[t]he electrodes can be either monopolar or bipolar electrodes.” Ex-1005, [0055]. “In *bipolar electrode* arrangements, both the positive and negative electrodes serve as treating electrodes.” Ex-1005, [0056] (emphasis added). “In embodiments wherein the electrodes are provided as electrode pairs, *biopolar [sic] electrodes* are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode.” Ex-1005, [0056] (emphasis added). Because current flows from positive electrodes to negative electrodes, Ganz’s bipolar electrodes are different from “a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes.” Indeed, Ganz discloses a separate monopolar electrode embodiment, where “one electrode serves as a treating electrode and another electrode is provided as a return electrode,” which “is placed out of the treated area.” Ex-1005, [0055].

78. Moreover, a POSITA would understand that the bipolar electrodes disclosed in Ganz “change or alternate between being positive or negative as the current alternates between them,” because as further explained in Section VIII.A.1.c.2

below, Ganz discloses that radio frequency (RF) energy is delivered to the bipolar electrodes to generate heat for skin treatment, Ex-1005, [0011], [0048]. From Ganz's disclosure, a POSITA would understand that ***alternating current (AC)*** having a radio frequency is delivered to the bipolar electrodes. *See* Section VIII.A.1.c.2. Alternating current is current that reverses directions (or changes polarity) at regular intervals of time.⁵

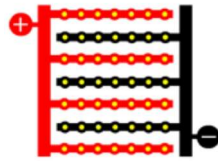
79. Therefore, Ganz discloses “electrodes being bipolar,” i.e., “electrodes change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes).”

(3) “a plurality of electrodes, the electrodes being bipolar,”

80. Ganz discloses the adopted construction for “a plurality of electrodes, the electrodes being bipolar,” which incorporates the constructions for “a plurality of electrodes” and “the electrodes being bipolar,” discussed in Sections VIII.A.1.b.1-2

⁵ Ex-1016, 25 (“**alternating current (ac)** . . . An electric current that reverses direction at regularly recurring intervals of time. *Contrast:* direct current.”); Ex-1017, 22 (“**alternating current** Abbreviation, ac. A current that periodically reverses its direction of flow. In one cycle, an alternation starts at zero, rises to a maximum positive level, returns to zero, rises to a maximum negative level, and again returns to zero.”); Ex-1018, 46 (“An AC source changes its polarity many times each second.”).

above, and adds a negative limitation that excludes the Intracel configuration (alternating rows of commonly-polarized electrodes):



81. As discussed in Sections VIII.A.1.b.1-2 above, Ganz discloses “a plurality of electrodes” and “the electrodes being bipolar.”

82. Moreover, Ganz’s disclosure of bipolar electrodes are *not* limited to the Intracel configuration (alternating rows of commonly-polarized electrodes). Although “[i]n some cases, the bipolar electrodes are biopolar [sic] axial interlaced finger electrodes,” Ganz does not limit its bipolar electrodes to such arrangements. Ex-1005, [0056] (emphasis added). Instead, Ganz generally discloses that “[i]n bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes.” Ex-1005, [0056]. For example, other configurations may include a configuration where the positive and negative electrodes are arranged in a checkerboard pattern. In such a configuration, the positive and negative electrodes would not have alternating rows of commonly-polarized electrodes. Such a configuration is better than the Intracel configuration because the energy deposition will be more uniform compared to the Intracel configuration.

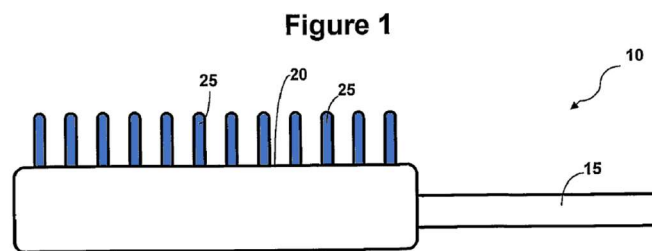
83. Therefore, Ganz discloses the adopted construction for “a plurality of electrodes, the electrodes being bipolar,” which incorporates the constructions for “a plurality of electrodes” and “the electrodes being bipolar,” and adds the negative limitation that excludes the Intracel configuration (alternating rows of commonly-polarized electrodes).

(4) “configured to be insertable into skin to be treated; and”

84. Ganz discloses that the plurality of electrodes are “configured to [i.e., adapted to] be insertable into skin to be treated.”

85. Ganz discloses that “*the electrode pins are placed all the way into the tissue*” to create deep perforations. Ex-1005, [0051] (emphasis added). “When it is desirable to provide an even deeper perforation, the electrode pins can be providing [sic] having longer lengths, so that *the tips are placed even deeper into the tissue layers*.” Ex-1005, [0051] (emphasis added). In the Field of the Invention section, Ganz explains that “[t]he invention relates to a device and method for *treating one or more layers of tissue, for example by simultaneously imparting perforations into the one or more layers*.” Ex-1005, [0001] (emphasis added). “In particular, the invention relates to a device and method *for treating one or more layers of the skin* to elicit a healing response which produces a more desirable skin appearance.” Ex-1005, [0001] (emphasis added). To that end, Ganz discloses “*a plurality of electrodes*

extending outwardly from the treating surface and *adapted for imparting simultaneous perforations into one or more tissue layers.*” Ex-1005, [0010] (emphasis added). Ganz discloses that “[t]he electrodes are arranged in a pattern to create the desired pattern of perforation in tissue.” Ex-1005, [0044]. “The electrodes are preferably configured as *spikes* or *pins* which extend outwardly from the treating surface.” Ex-1005, [0044] (emphasis added). For example, Figure 1 illustrates a treatment device 10 with a plurality of electrode pins 25 (blue). Ex-1005, [0044].



Ex-1005, Fig. 1 (annotated). “When it is desired to apply the treating surface 20 of FIG. 1, one uses a stamping motion and stamps the tissue layers with the treating surface 20.” Ex-1005, [0044].

86. Therefore, Ganz discloses that the plurality of electrodes are “configured to [i.e., adapted to] be insertable into skin to be treated.”

87. In sum, Ganz discloses this limitation.

- c) **1[b]: “a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an**

Alternating Current (AC) RF signal to the plurality of electrodes”

88. Ganz alone or in combination with Livneh discloses this limitation.

89. As discussed in Section VI.D above, I was asked to apply the following constructions for this limitation.

Term	Agreed Construction
“configured to”	Plain and ordinary meaning: adapted to
“radio frequency (RF) generation module”	Plain and ordinary meaning: a device that generates electrical signal(s) having a radio frequency

Term	Adopted Construction
“[a/an] Alternating Current (AC) [RF/Radio Frequency (RF)] signal”	Plain and ordinary meaning: an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz)

(1) “a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes”

90. Ganz discloses an energy source, which corresponds to “a radio frequency (RF) generation module,” where the RF generation module is “electrically coupled to the plurality of electrodes,” i.e., “a device that generates electrical signal(s) having a radio frequency,” where the device is “electrically coupled to the plurality of electrodes.”

91. In the Brief Summary of the Invention section, Ganz discloses that its device “includes an *energy source coupled to the plurality of electrodes.*” Ex-1005,

[0011] (emphasis added). Ganz discloses that this energy source is “configured to deliver energy selected from the group consisting of *radio frequency*, non-ionizing ultraviolet radiation, or microwave radiation.” Ex-1005, [0011] (emphasis added). Ganz discloses that it is preferred for the energy source to deliver radio frequency (RF) energy to the plurality of electrodes. Ex-1005, [0011] (“In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy.”); Ex-1005, [0058] (“In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes.”). This is because “RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively.” Ex-1005, [0058]. “RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes.” Ex-1005, [0058].

92. Therefore, Ganz discloses an energy source, which corresponds to “a radio frequency (RF) generation module,” where the RF generation module is “electrically coupled to the plurality of electrodes,” i.e., “a device that generates electrical signal(s) having a radio frequency,” where the device is “electrically coupled to the plurality of electrodes.”

(2) “configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes”

93. Ganz alone or in combination with Livneh discloses that the energy source, which corresponds to the claimed “radio frequency (RF) generation module” is “configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes,” i.e., the energy source is “adapted to” provide “an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz)” to the plurality of electrodes.

94. As explained below, a POSITA would understand that Ganz’s energy source provides the electrodes with alternating current (AC) having a radio frequency (RF). First, as discussed in Section VIII.A.1.c.1 above, Ganz discloses an energy source that delivers RF energy. Ex-1005, [0011], [0048]. Second, Ganz discloses that the energy source delivers RF energy to the bipolar electrodes. Ex-1005, [0011] (“In preferred cases, the electrodes are *RF electrodes* and are configured for receiving *RF energy*. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar electrodes whereas in other cases *the electrodes are bipolar electrodes.*”) (emphasis added). Third, Ganz discloses that the RF energy generates heat, creating “[z]ones of coagulation . . . in areas of tissue surrounding each perforation” formed by the electrodes. Ex-1005, [0048]; *see also* Ex-1005, [0010] (“The electrode pattern can . . . be selected to create a zone of coagulative tissue surrounding each perforation.”); Ex-1005, [0058] (“the electrodes are configured as RF electrodes and RF energy is delivered to the

electrodes.”); Ex-1005, [0048] (“The zone of coagulation can be varied by changes in energy and power levels.”).

95. Given Ganz’s disclosure of the energy source providing RF energy to the electrodes to generate heat for skin treatment, a POSITA would understand that Ganz’s energy source provides ***alternating current (AC)*** having a radio frequency. A POSITA would know that in the field of skin treatment using RF energy to heat the tissue, the energy is delivered by an alternating current (AC) that oscillates at the RF frequency.⁶ For example, the “Radiofrequency Energy and Hybrid Device” chapter from a book titled “Non-surgical Skin Tightening and Lifting” explains that “[r]adiofrequency (RF) energy is a form of electromagnetic energy ranging from 300 MHz to 3 kHz [or 0.003 MHz]” and that “[t]he technology has been used in many areas of medicine” Ex-1015, 21. “In skin surgery the technology has been used for electrocoagulation . . . and

⁶ See Ex-1019, 63 (“Radiofrequency is a form of ***alternating electric current (AC current)***.”) (emphasis added); Ex-1020, 150 (“RF energy is ***an alternating current*** that runs from the tip of an electrode to tissue that it contacts.”) (emphasis added); Ex-1021, 452 (“Radiofrequency energy is a form of electrical energy, generated from lower-power (15 to 60 V), ***high-frequency (30 KHz [0.030 MHz] to 300 MHz) alternating current.***”) (emphasis added)]; Ex-1022, 2 (“RF energy is a form of ***alternating electrical current***”) (emphasis added); Ex-1015, 21 (“A RF generator produces an ***alternating current*** that creates an electric field through the skin.”) (emphasis added); Ex-1023, 128 (“High-frequency, ***alternating electric current*** produced by the RF generator is delivered to target tissues through an electrode.”) (emphasis added); Ex-1024, 1 (“The main advantage of RF energy in medicine is a low or negligible reaction of nerves to high-frequency ***alternating current (AC)*** in comparison to lower frequencies.”) (emphasis added).

skin rejuvenation.” Ex-1015, 21. In this application, “[a] **RF generator produces an alternating current** that creates an electric field through the skin.” Ex-1015, 21 (emphasis added). “The electric field shifts polarity millions of times per second, causing a change in orientation of charged particles within the electric field.” Ex-1015, 21. “Tissue resistance to this particle movement generates heat.” Ex-1015, 21. “Thus, heat is generated by the skin’s resistance to the flow of current within an electric field” and “[e]nergy is able to be dispersed to 3-dimensional volumes of tissue at controlled depths.” Ex-1015, 21.

96. The ’836 patent refers to such use of AC to generate RF energy: “Because of AC signal characteristics, the polarity of each needle may change many times per second (up to 10 MhZ in an embodiment) and cause a needle 300 polarity to change as shown in FIG. 6 at applied AC signal rate.” Ex-1001, 7:33-36. I understand that a patent application filed by Jongju Na, the inventor of the ’836 patent, confirms that RF energy is basically AC. Ex-1025, [0016] (“high frequencies such as **radio waves are basically alternating current**”) (emphasis added).

97. A POSITA would understand that use of direct current (DC) for skin treatment is undesirable. First, a POSITA would understand that use of direct current (DC) in the same direction without changing polarity during the entire energy application in tissue would result in accumulation of charged particles around one electrode over a period of time, which would cause electrode polarization, and

adversely affect the way energy is absorbed in the tissue. For example, the accumulation of electrical charges around the needles would create a galvanic reaction where ions from the metallic electrodes are dissolved within the extracellular fluid, which could create health issues such as poisoning and/or other unwanted effects. Second, in the case of an unbalanced alternating current with a DC component where the net balance of charge accumulation is not the same between the positive and negative cycles, similar charge accumulation around the electrodes could be created and lead to similar health issues and/or unwanted effects.

98. Indeed, an international standard for safety of high frequency surgical equipment, IEC 60601-2-2, prohibits use of DC signals. Ex-1030, 20. Specifically, Section 201.8.4.102 of IEC 60601-2-2 requires the use of capacitance in series with the patient circuitry between the output of the generator and the patient to block DC signals as well as low frequency AC signals. Ex-1030, 20. A capacitance is a “high-pass filter”, which blocks DC signals and low frequency AC signals, while letting higher frequency AC signals pass through. The relationship between the cutoff frequency f_c and the capacitance C can be expressed as follows: $f_c \propto 1/C$, which means that the cutoff frequency is inversely proportional to the capacitance value. The IEC standard requires that large capacitors (> 50 nF) are to be avoided to make sure that the cutoff frequency is high enough to block the DC signals and the frequency content below f_c in order to protect the patient against these unwanted and undesired signal

components. Even AC signals can be dangerous at low frequencies, causing “acute pain, muscle spasms, and even cardiac arrest.” Ex-1024, 3. “At a frequency of 100 kHz and higher, [however], the muscle- and nerve-stimulating effects decrease.” Ex-1024, 3. Therefore, AC signals with “[f]requencies in the range of 200 kHz [0.2 MHz] to 6 MHz are the most common in medicine” Ex-1024, 3.

99. Therefore, Ganz discloses that the energy source, which corresponds to the claimed “radio frequency (RF) generation module” is “configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes,” i.e., the energy source is “adapted to” provide “an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz)” to the plurality of electrodes.

100. **Ganz in combination with Livneh:** To the extent that Ganz does not disclose this limitation, however, Ganz in combination with Livneh renders this limitation obvious. Livneh discloses “a power supply 50 for supplying the electrical current to the electrodes 32.” Ex-1006, [0037]. “Preferably, a cable (not shown) or other electrical connection allows transmission of the RF signal from the power supply 50 in the control unit 48 to the electrodes 32 in the handheld unit 34.” Ex-1006, [0037]. Livneh expressly discloses that “[t]he power supply 50 preferably converts commercial AC electrical power, e.g., a 120 volt, 60 hertz signal, to *a radio frequency (RF) signal, i.e., an AC signal operating at a radio frequency.*” Ex-1006, [0037] (emphasis added).

Moreover, Livneh discloses that the power supply 50 may be used for bipolar electrodes: “[s]pecifically, *in bipolar operation* . . . the RF signal is applied through a first set 54 of the electrodes 32 and utilizes a second set 56 of electrodes 32 as a return path to the power supply 50.” Ex-1006, [0039] (emphasis added).

101. As discussed in Section VIII.A.1.e below, a POSITA would have been motivated to combine Ganz with Livneh.

102. In sum, Ganz alone or in combination with Livneh discloses this limitation.

d) 1[c]: “configured to cause coagulation around each electrode rather than coagulating between the electrodes.”

103. Ganz discloses this limitation.

104. As discussed in Section VI.D above, I was asked to apply the following agreed construction for this limitation.

Term	Agreed Construction
“electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes”	Plain and ordinary meaning: two or more electrodes adapted to cause coagulation around each electrode without such coagulation fully extending from one electrode to another electrode

105. Ganz discloses that the plurality of electrodes are “configured to cause coagulation around each electrode rather than coagulating between the electrodes,” i.e.,

“two or more electrodes [are] adapted to cause coagulation around each electrode without such coagulation fully extending from one electrode to another electrode.”

106. As discussed in Section VIII.A.1.b.4 above, Ganz discloses “***a plurality of electrodes*** extending outwardly from the treating surface and ***adapted for imparting simultaneous perforations into one or more tissue layers.***” Ex-1005, [0010] (emphasis added); *see also* Ex-1005, [0047] (“The electrodes are positioned on the treating surface in any manner to provide a desired pattern of perforations into the one or more tissue planes. Generally, the electrodes come into direct contact with the one or more tissue planes. So, the pattern of electrodes directly correspond to the pattern of perforations desired in the tissue.”). These perforations are “holes, which extend vertically into the tissue and across one or more layers.” Ex-1005, [0027]. The electrodes create deep perforations by penetrating the skin to be treated. Ex-1005, [0051] (“when it is desirable to provide a deeper perforation, ***the electrode pins are placed all the way into the tissue***, so that more than one layers of tissue are treated.”) (emphasis added); Ex-1005, [0051] (emphasis added) (“When it is desirable to provide an even deeper perforation, the electrode pins can be providing [sic] having longer lengths, so that ***the tips are placed even deeper into the tissue layers.***”) (emphasis added).

107. It was well known that inserting small needles into skin creates small holes. Ex-1008, <36> (“after the needle mount 11 is snapped into the gunpoint of the

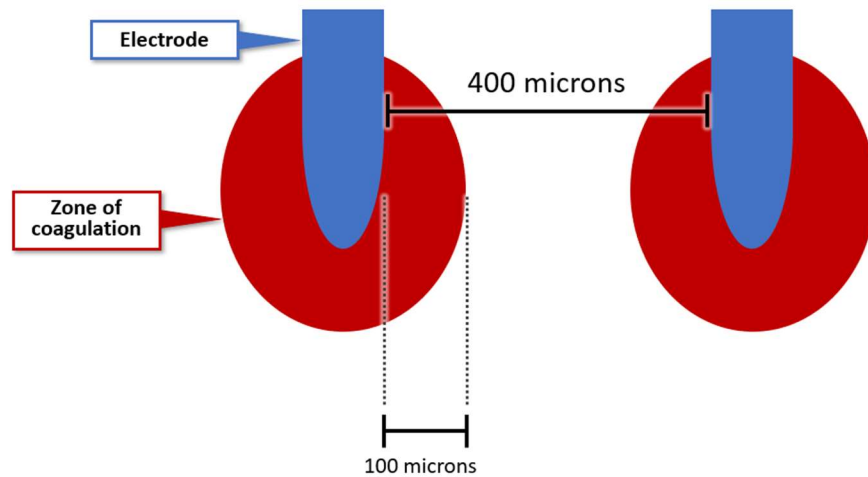
gun 13 to fasten, when the switch 22 is pressed, the needle mount 11 moves forward;

as such, *it is built to create holes on the human skin with the microneedles 10* equipped in the needle mount 11.”) (emphasis added). “Such perforations are so small that they cannot be seen with the naked eye.” Ex-1005, [0029]. Even the inventor of the ’836 patent, Jongju Na, admitted in another patent application that inserting small needles into skin creates small holes. Ex-1025, claim 3 (“the plurality of *metallic needles form micro-holes* in the skin of the treatment subject”) (emphasis added).

108. As discussed in Section VII.A above, however, Ganz does *not* teach creating perforations to the exclusion of zones of coagulation. Rather, Ganz discloses creating both perforations *and* zones of coagulation. Ex-1005, [0032] (“The device *also imparts perforations* into the skin, *rather than merely imparting coagulations* into the skin.”) (emphasis added); Ex-1005, [0028] (“*The treated area 4 is clearly a perforation*, which extends vertically into the skin. *Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation 4.*”) (emphasis added). Delivering RF energy to the electrodes that are inserted into the skin further creates “[z]ones of coagulation . . . in areas of tissue *surrounding each perforation.*” Ex-1005, [0048] (emphasis added); *see also* Ex-1005, [0010] (“The electrode pattern can . . . be selected to create a zone of coagulative tissue *surrounding each perforation.*”) (emphasis added); Ex-1005, [0058] (“the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes.”); Ex-1005, [0048] (“The zone of

coagulation can be varied by changes in energy and power levels.”). Ganz discloses that zone of coagulation “extend into the tissue in all directions originating from the perforation site.” Ex-1005, [0028]. “These zones of coagulation are beneficial as coagulation leads to tissue regeneration.” Ex-1005, [0028]. Ganz discloses that “[t]he zones of coagulation created in the tissue area surrounding each perforation . . . help to revitalize and rejuvenate [sic] skin.” Ex-1005, [0030].

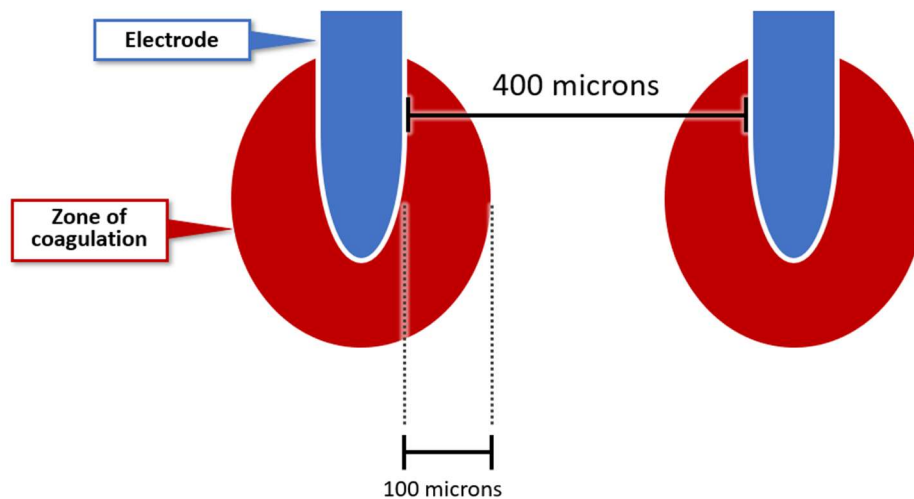
109. The perforations created by electrodes are spaced apart by about 400 microns and zones of coagulation extend from the perforations into the tissue “in all directions” to about 100 microns. Ex-1005, [0028], [0047] (“the electrodes are patterned in order to create perforations . . . spaced apart by between about 50 to ***about 400 microns***”) (emphasis added), [0048] (“The zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to ***about 100 microns***.”) (emphasis added). Below is an illustration of this embodiment, where electrodes are still in place in perforations.



As shown in the above illustration, the zones of coagulation (red) are limited to the area in the vicinity of the RF electrodes (blue) and do not fully extend from one electrode to another electrode. The above illustration depicts an embodiment where the width of the perforation is the same as the width of the electrode. Although in “many cases,” the width of the perforation created may be larger than the width of the electrode, it is not always larger. Ex-1005, [0053] (“The width of the perforation created will be at least the width of the electrode, and *in many cases larger.*”) (emphasis added).

110. Even in embodiments where the width of the perforation created is larger than the width of the electrode, however, Ganz discloses “coagulation around each electrode without such coagulation fully extending from one electrode to another electrode” that is required by the agreed construction. As shown in the below illustration, the measurements relative to perforations (white gap shown below

between the electrodes and the zones of coagulation) stay the same, even when the electrode is smaller. Ex-1005, [0047] (“the electrodes are patterned in order to create *perforations . . . spaced apart* by between about 50 to *about 400 microns*”) (emphasis added); Ex-1005, [0048] (“The zones can extend *from the perforation site* into the tissue for a length ranging from about 5 microns to *about 100 microns.*”) (emphasis added).



Moreover, the embodiment depicted in the above illustration still has “coagulation around each electrode” because the claim limitation merely requires that coagulation be formed “*around* each electrode,” not “*immediately* around each electrode.”

111. If the perforations are spaced apart by 50 microns instead of 400 microns, it is possible that the zones of coagulation may overlap each other if they extend into the tissue for about 100 microns. But as shown above, Ganz also discloses embodiments where the zones of coagulation do not overlap each other, for example,

when the perforations are spaced apart by about 400 microns. Indeed, Ganz discloses embodiments where the perforations are spaced apart by even more than 400 microns. Ex-1005, [0052] (“In certain embodiments, electrodes are provided on a treating surface have a spacing of less than about 5 mm [5000 microns], and preferably less than about 2 mm [2000 microns].”).

112. Therefore, Ganz discloses that the plurality of electrodes are “configured to cause coagulation around each electrode rather than coagulating between the electrodes,” i.e., “two or more electrodes [are] adapted to cause coagulation around each electrode without such coagulation fully extending from one electrode to another electrode.”

e) Motivation to Combine Ganz and Livneh

113. As discussed in Section VIII.A.1.c.2 above, to the extent that Ganz does not disclose the limitation “configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes,” Ganz in combination with Livneh renders this limitation obvious. While Ganz does not expressly state that its energy source provides electrodes with *alternating current* having a radio frequency, Livneh does so. Ex-1006, [0037] (“The power supply 50 preferably converts commercial AC electrical power, e.g., a 120 volt, 60 hertz signal, to *a radio frequency (RF) signal, i.e., an AC signal operating at a radio frequency.*”) (emphasis added). A POSITA implementing

Ganz's device would have been motivated to use Livneh's power supply that provides an alternating current having a radio frequency.

(1) **Same field of endeavor**

114. A POSITA would have been motivated to use Livneh's power supply for Ganz's device because both Ganz and Livneh concern using RF electrodes for skin treatment. *See* Ex-1005, [0011] ("In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy."); Ex-1006, [0032] ("The apparatus 30 is capable of delivering electrical current to skin using a plurality of electrodes 32 which enter the skin. Preferably, the apparatus 30 is utilized in skin tightening procedures."), [0039] ("Specifically, in bipolar operation . . . the RF signal is applied through a first set 54 of the electrodes 32 and utilizes a second set 56 of electrodes 32 as a return path to the power supply 50.").

115. In particular, both Ganz and Livneh disclose using bipolar electrodes. Ex-1005, [0056] ("In ***bipolar electrode*** arrangements, both the positive and negative electrodes serve as treating electrodes.") (emphasis added); Ex-1006, [0039] ("Specifically, ***in bipolar operation*** . . . the RF signal is applied through a first set 54 of the electrodes 32 and utilizes a second set 56 of electrodes 32 as a return path to the power supply 50.") (emphasis added).

116. Both Ganz and Livneh disclose using heat for skin treatment. Ex-1005, [0030] ("The zones of ***coagulation*** created in the tissue area surrounding each

perforation . . . help to revitalize and rejuvenate [sic] skin.”) (emphasis added); Ex-1006, [0002] (“This invention relates to an apparatus and method for skin tightening. More specifically, the present invention provides an apparatus and method for introducing *thermal* and mechanical injury to skin via electrodes carrying an electric current.”) (emphasis added).

(2) Teaching, suggestion, motivation

117. A POSITA would have been motivated to use Livneh’s power supply (that provides alternating current) for Ganz’s device because a POSITA would have understood that providing electrodes with alternating current having a radio frequency generates heat suitable for skin treatment. Ex-1015, 21 (“A RF generator produces an alternating current that creates an electric field through the skin. The electric field shifts polarity millions of times per second, causing a change in orientation of charged particles within the electric field. Tissue resistance to this particle movement generates heat. Thus, heat is generated by the skin’s resistance to the flow of current within an electric field Energy is able to be dispersed to 3-dimensional volumes of tissue at controlled depths.”). As discussed in Section V.B above, the generation of heat causes collagen denaturation and/or coagulation that are favorable for skin treatment. Also, as discussed in Section VIII.A.1.c.2 above, a POSITA would have understood the benefits of using alternating current (AC) as opposed to using direct current (DC).

(3) Combining prior art elements according to known methods to yield predictable results

118. Combining Ganz and Livneh would have been combining prior art elements (i.e., Livneh's power supply) according to known methods to yield predictable results (i.e., generating heat for skin treatment). Livneh's power supply was well known in the art to yield predictable results.

(4) Use of known technique to improve similar devices (methods, or products) in the same way

119. Combining Ganz and Livneh would have been a use of a known technique (i.e., Livneh's power supply) to improve similar devices in the same way (i.e., improving Ganz's device to generate heat for skin treatment). Livneh's power supply was well known in the art. Using it would have improved Ganz's device in the same way it was beneficial for Livneh's device.

(5) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results

120. Combining Ganz and Livneh would also have been applying a known technique (i.e., Livneh's power supply) to a known device ready for improvement to yield predictable results (i.e., improving Ganz's device to generate heat for skin treatment). Livneh's power supply was well known in the art to yield predictable results.

(6) Reasonable expectation of success

121. Livneh's power supply was well known in the art to yield predictable results. Because it was well known, a POSITA would have had a reasonable expectation of success in using Livneh's power supply.

2. Claim 2

- a) **“The skin treatment apparatus of claim 1, wherein the RF generation module is configured to provide an AC RF signal to the plurality of electrodes for a predetermined time interval.”**

122. Ganz discloses this limitation.

123. As discussed in Section VIII.A.1.c.2 above, Ganz discloses that the energy source, which corresponds to the claimed RF generation module, is configured to provide an AC RF signal to the plurality of electrodes.

124. Ganz further discloses that “[t]he energy source may be manually controlled by the user and be adapted to allow the user to *select the appropriate treatment time* and power setting to obtain a controlled depth and/or width of perforation.” Ex-1005, [0059] (emphasis added). Because the appropriate treatment time is measured in milliseconds, the user would need to program the treatment time before the treatment begins. Ganz's treatment time corresponds to the required “predetermined time interval” because the user pre-selects the appropriate treatment time.

125. Therefore, Ganz discloses this limitation.

3. Claim 11

- a) “The skin treatment apparatus of claim 1, wherein the closest neighboring electrodes are separated by a distance of 1.3 mm to 3.0 mm.”**

126. Ganz renders this limitation obvious.

127. Ganz discloses that “[t]he electrodes can also be *spaced apart at a desired length* so that the perforations in tissue will also be spaced apart at that length.” Ex-1005, [0052] (emphasis added); *see also* Ex-1005, [0049] (“the spacing between electrodes can be varied along the treating surface”). Ganz further discloses that “[i]n certain embodiments, electrodes are provided on a treating surface have [sic] a spacing of *less than about 5 mm, and preferably less than about 2 mm.*” Ex-1005, [0052] (emphasis added). Ganz’s distance of “less than about 5 mm” overlaps the claimed distance of “1.3 mm to 3.0 mm.” Moreover, Ganz’s distance of “less than about 2 mm” partially overlaps the claimed distance of “1.3 mm to 3.0 mm.” Although Ganz does not expressly disclose the lower bound of the range of the distance, a POSITA would have understood that the lower bound of the range of the distance has to be significantly more than 0 in order to avoid shorting the electrodes, and to facilitate the penetration of the multiple needles in skin.

128. Moreover, the ’836 patent does not explain any new and unexpected result from using the claimed distance of “1.3 mm to 3.0 mm.” In my opinion, there is nothing new or unexpected about the claimed range.

129. Therefore, Ganz renders this limitation obvious.

4. Claim 12

a) **“The skin treatment apparatus of claim 1, wherein the plurality of electrodes are non-insulated.”**

130. Ganz discloses this limitation.

131. Ganz discloses that the plurality of electrodes can optionally be insulated: “[t]he base of the treatment pad or treating surface and various portions of the proximal electrodes *can also be insulated* in order to limit the coagulation injury to the distal end of the electrode as well.” Ex-1005, [0056] (emphasis added). That the plurality of electrodes “can also be insulated” shows that the plurality of electrodes are non-insulated by default.

132. Therefore, Ganz discloses this limitation.

5. Claim 13

a) **“The skin treatment apparatus of claim 1, wherein each electrode of the plurality of electrodes is insulated except at its tip.”**

133. Ganz discloses this limitation.

134. Ganz discloses an embodiment where the proximal portion (i.e., away from the tip) of each electrode is insulated so that only the distal end (i.e., the tip) remains non-insulated and able to cause coagulation. Ex-1005, [0056] (“[t]he base of the treatment pad or treating surface and *various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the*

electrode as well.”) (emphasis added). Because Ganz discloses that the coagulation injury is limited to the distal end, a POSITA would understand that the electrodes discussed in Ganz are insulated except at their tips.

135. Therefore, Ganz discloses this limitation.

6. Claim 14

a) 14[preamble]: “A method of treating skin, comprising:”

136. I understand that the Petitioner and Patent Owner agree that the preamble is limiting.

137. Ganz discloses the preamble.

138. See Section VIII.A.1.a above regarding the preamble of claim 1.

b) 14[a]: “inserting a plurality of electrodes, the electrodes being bipolar into a section of skin to be treated; and”

139. Ganz discloses this limitation.

140. See Section VIII.A.1.b above regarding limitation 1[a].

c) 14[b]: “applying a Alternating Current (AC) Radio Frequency (RF) signal to the plurality of electrodes”

141. Ganz discloses this limitation.

142. See Section VIII.A.1.c above regarding limitation 1[b].

d) 14[c]: “configured to cause coagulation around each electrode rather than coagulating between the electrodes.”

143. Ganz discloses this limitation.

144. See Section VIII.A.1.d above regarding limitation 1[c].

7. Claim 15

- a) **“The method of treating skin of claim 14, including providing an AC RF signal to the plurality of electrodes for a predetermined time interval.”**

145. Ganz discloses this limitation.

146. See Section VIII.A.2 above regarding claim 2.

8. Claim 23

- a) **“The method of treating skin of claim 14, wherein the closest neighboring electrodes are separated by a distance of 1.3 mm to 3.0 mm.”**

147. Ganz discloses this limitation.

148. See Section VIII.A.3 above regarding claim 11.

9. Claim 24

- a) **“The method of treating skin of claim 14, wherein the plurality of electrodes are non-insulated.”**

149. Ganz discloses this limitation.

150. See Section VIII.A.4 above regarding claim 12.

10. Claim 26

- a) **“The method of treating skin of claim 14, wherein each electrode of the plurality of electrodes is insulated except at its tip.”**

151. Ganz discloses this limitation.

152. See Section VIII.A.5 above regarding claim 13.

B. Ganz in Combination with Hantash Renders Claims 2-10, 15-22, and 25 Obvious.

153. Claims 2-10, 15-22, and 25 would have been obvious to a POSITA based on the disclosures in Ganz and Hantash, for the reasons I discuss below.

1. Claim 2

- a) **“The skin treatment apparatus of claim 1, wherein the RF generation module is configured to provide an AC RF signal to the plurality of electrodes for a predetermined time interval.”**

154. The combination of Ganz and Hantash renders this limitation obvious.

155. As discussed in Section VIII.A.1.c.2 above, Ganz discloses that the energy source, which corresponds to the claimed RF generation module, is configured to provide an AC RF signal to the plurality of electrodes. Ganz further discloses that “[t]he energy source may be manually controlled by the user and be adapted to allow the user to *select the appropriate treatment time* and power setting to obtain a controlled depth and/or width of perforation.” Ex-1005, [0059] (emphasis added).

156. Similarly, Hantash discloses a radio frequency (RF) energy source connected to an array of microneedles. Ex-1007, [0014] (“Such selective tissue treatment is achieved using an array of *electrically conductive microneedles that are connected to a radio frequency energy source.*”) (emphasis added). Furthermore, Hantash discloses pulse durations of 400 ms and 200 ms for providing RF energy to

the microneedles. Ex-1007, [0077]-[0078]. Hantash's pulse duration corresponds to the claimed "predetermined time interval" because RF energy is repeatedly provided for the predetermined duration.

157. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash's RF pulse duration for Ganz's device.

158. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

2. Claim 3

a) **"The skin treatment apparatus of claim 2, wherein the predetermined time interval is from 0.05 to 0.8 seconds."**

159. The combination of Ganz and Hantash renders this limitation obvious.

160. As discussed in Section VIII.A.1.c.2 above, Ganz discloses that the energy source, which corresponds to the claimed RF generation module, is configured to provide an AC RF signal to the plurality of electrodes. Ganz further discloses that "[t]he energy source may be manually controlled by the user and be adapted to allow the user to *select the appropriate treatment time* and power setting to obtain a controlled depth and/or width of perforation." Ex-1005, [0059] (emphasis added).

161. As discussed in Section VIII.B.1 above, Hantash discloses a pulse duration, which corresponds to the claimed "predetermined time interval." Ex-1007, [0077]-[0078]. In particular, Hantash discloses pulse durations of 400 ms and 200 ms

(or 0.4 seconds and 0.2 seconds), both of which fall within the claimed predetermined time interval of “from 0.05 to 0.8 seconds.” Ex-1007, [0077]-[0078].

162. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash’s RF pulse duration for Ganz’s device.

163. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

3. Claim 4

- a) **“The skin treatment apparatus of claim 2, wherein each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin and the predetermined time interval is from 0.05 to 0.8 seconds.”**

164. The combination of Ganz and Hantash renders this limitation obvious.

- (1) **“each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin”**

165. Ganz discloses that “each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin.” Ganz discloses that “[i]n some cases, when it is desirable to provide a deeper perforation, the electrode pins are placed all the way into the tissue, so that *more than one layers of tissue are treated.*” Ex-1005, [0051] (emphasis added). The outer most layer of skin tissue is epidermis; the layer below epidermis is dermis. Ex-1001, 1:40-41 (“Dermis is the layer beneath epidermis, directly connected to a basal layer.”). Ganz’s disclosure of the electrode

pins being inserted into skin so that “more than one layers of tissue are treated” shows that the electrode pins are long enough to reach skin dermis. Moreover, Ganz further discloses that “[w]hen it is desirable to provide an even deeper perforation, the electrode pins can be providing [sic] having longer lengths, so that the tips are placed even deeper into the tissue layers.” Ex-1005, [0051]. Because the dermis is below the epidermis and Ganz discloses treating more than one layer of tissue through deeper perforations by electrode pins, Ganz discloses electrodes of sufficient length to reach skin dermis.

(2) “the predetermined time interval is from 0.05 to 0.8 seconds”

166. As discussed in Section VIII.A.1.c.2 above, Ganz discloses that the energy source, which corresponds to the claimed RF generation module, is configured to provide an AC RF signal to the plurality of electrodes. Ganz further discloses that “[t]he energy source may be manually controlled by the user and be adapted to allow the user to *select the appropriate treatment time* and power setting to obtain a controlled depth and/or width of perforation.” Ex-1005, [0059] (emphasis added).

167. As discussed in Section VIII.B.1 above, Hantash discloses a pulse duration, which corresponds to the claimed “predetermined time interval.” Ex-1007, [0077]-[0078]. In particular, Hantash discloses pulse durations of 400 ms and 200 ms

(or 0.4 seconds and 0.2 seconds), both of which fall within the claimed predetermined time interval of “from 0.05 to 0.8 seconds.” Ex-1007, [0077]-[0078].

168. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash’s RF pulse duration for Ganz’s device.

169. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

4. Claim 5

a) “The skin treatment apparatus of claim 4, wherein the closest neighboring electrodes have opposite polarities.”

170. The combination of Ganz and Hantash renders this limitation obvious.

171. As discussed in Section VIII.A.1.b.2 above, Ganz discloses bipolar electrodes being provided as pairs, “with one electrode in the pair being a positive electrode and the other electrode being a negative electrode.” Ex-1005, [0056]. Because current flows from a positive electrode to negative electrode and to better control the location of the zones of coagulation as disclosed in Ganz, a POSITA would understand that it would be efficient to arrange the electrodes such that the closest neighboring electrodes have opposite polarities.

172. Figure 7A of Hantash illustrates such an example of bipolar electrode pairs:

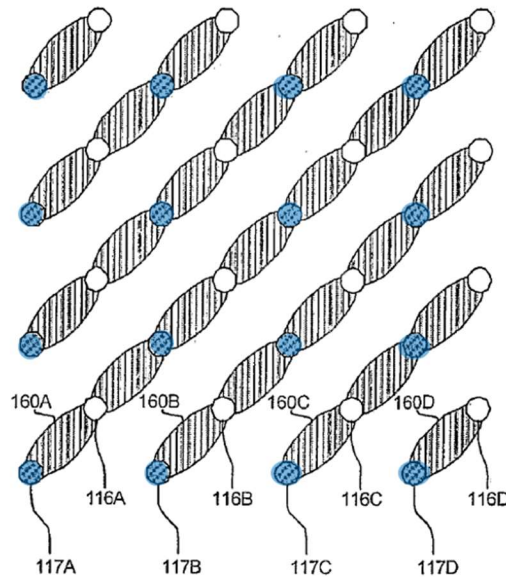


Figure 7A

Ex-1007, Fig. 7A (annotated). As shown above, the nearest neighboring positive polarity needles 117 (shaded blue) and negative polarity needles 116 (unshaded) form pairs to create treatment zones 160. Ex-1007, [0049] (“Note that needles 115 can be described generally as needles 115 or they can be further categorized as positive polarity needles 117 (shaded in FIGS. 3-9) and negative polarity needles 116 (unshaded in FIGS. 3-9). . . . Positive and negative polarities refer to opposite poles of the RF source.”); Ex-1007, [0048] (“the pulsing of the RF source 110 creates a treatment zone 160 between *nearest neighbors* within the array of needles 115”) (emphasis added). In Figure 7A above, needles 116a and 117a are the nearest neighbors; needles 116b and 117b are the nearest neighbors; and so on. Because

Hantash's RF needles 116 and 117 generate heat, the heat is most intense around the needles, which is consistent with Ganz's disclosure of forming coagulation around the needles.

173. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash's needle arrangement (shown in Figure 7A above) for Ganz's device.

174. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

5. Claim 6

- a) **“The skin treatment apparatus of claim 4, wherein a section of each electrode of the plurality of electrodes is non-insulated.”**

175. The combination of Ganz and Hantash renders this limitation obvious.

176. As discussed in Section VIII.B.3 above, Ganz and Hantash renders obvious the skin treatment apparatus of claim 4.

177. Moreover, Ganz discloses an embodiment where the proximal portion (i.e., away from the tip) of each electrode is insulated so that only the distal end (i.e., the tip) remains non-insulated and able to cause coagulation. Ex-1005, [0056] (“[t]he base of the treatment pad or treating surface and *various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well.*”) (emphasis added). Because the distal end of the

electrodes (i.e., electrode tips) is non-insulated, Ganz discloses that a section of each electrode is non-insulated.

178. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

6. Claim 7

- a) “The skin treatment apparatus of claim 2, wherein the predetermined time interval is from 0.05 to 0.8 seconds and the RF is about 2.0 MHz.”**

179. The combination of Ganz and Hantash renders this limitation obvious.

- (1) “the predetermined time interval is from 0.05 to 0.8 seconds”**

180. As discussed in Section VIII.B.1 above, Hantash discloses a pulse duration, which corresponds to the claimed “predetermined time interval.” Ex-1007, [0077]-[0078]. In particular, Hantash discloses pulse durations of 400 ms and 200 ms (or 0.4 seconds and 0.2 seconds), both of which fall within the claimed predetermined time interval of “from 0.05 to 0.8 seconds.” Ex-1007, [0077]-[0078].

181. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash’s RF pulse duration for Ganz’s device.

- (2) “the RF is about 2.0 MHz”**

182. Hantash discloses that “[i]n some preferred embodiments, the frequency range is from 0.1 to 10 MHz or *from 0.4 to 3 MHz*,” which includes the claimed range of “about 2.0 MHz.” Ex-1007, [0040] (emphasis added).

183. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash's RF range for Ganz's device.

184. Moreover, the '836 patent does not explain any new and unexpected result from using the claimed RF of "about 2.0 MHz." In my opinion, there is nothing new or unexpected about the use of 2.0 MHz. "Frequencies in the range of 200 kHz [0.2 MHz] to 6 MHz are the most common in medicine" Ex-1024, 3.

185. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

7. Claim 8

- a) **"The skin treatment apparatus of claim 1, wherein the RF is about 2.0 MHz and the coagulated area around each electrodes is oval shaped."**

186. The combination of Ganz and Hantash renders this limitation obvious.

(1) "the RF is about 2.0 MHz"

187. As discussed in Section VIII.B.6 above, Hantash discloses that "[i]n some preferred embodiments, the frequency range is from 0.1 to 10 MHz or *from 0.4 to 3 MHz*," which includes the claimed range of "about 2.0 MHz." Ex-1007, [0040] (emphasis added).

188. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash's RF range for Ganz's device.

189. Moreover, the '836 patent does not explain any new and unexpected result from using the claimed RF of “about 2.0 MHz.” In my opinion, there is nothing new or unexpected about the use of 2.0 MHz. “Frequencies in the range of 200 kHz [0.2 MHz] to 6 MHz are the most common in medicine” Ex-1024, 3.

(2) “the coagulated area around each electrodes is oval shaped”

190. As discussed in Section VIII.A.1.d above, Ganz discloses causing coagulation around each electrode rather than between the electrodes. A POSITA would have known that such coagulation would form an oval shape at the tip of the electrodes because of the “edge effect.” The “edge effect” occurs when high frequency currents, such as in the RF range, flow in an electrode that is not of uniform shape along the length. For example, the needle tips are thinner and pointed as compared to the stem of the needle. As a result of the edge effect, the current density induced by RF microneedles in skin is much higher at the tip (or the distal portion of the electrode). Consequently, the power density absorbed in tissue is much higher around the tip of the electrodes because the absorbed power density is proportional to the square of the current density. As a consequence of a higher electric power density absorption around the tip of the electrodes, the tissue temperature around this area rises faster than the tissue temperature around the proximal portion of the electrode. Therefore, the conditions necessary to obtain a desired biological effect such as the denaturation or

the coagulation of collagen will start first around the tip of the electrodes as compared to other portions of the electrodes. The resulting shape of the zone of coagulation around the electrodes will be oval shaped.

191. The '836 patent refers to such shape of coagulation around the tip of electrodes as being “oval,” as illustrated in Figure 5:

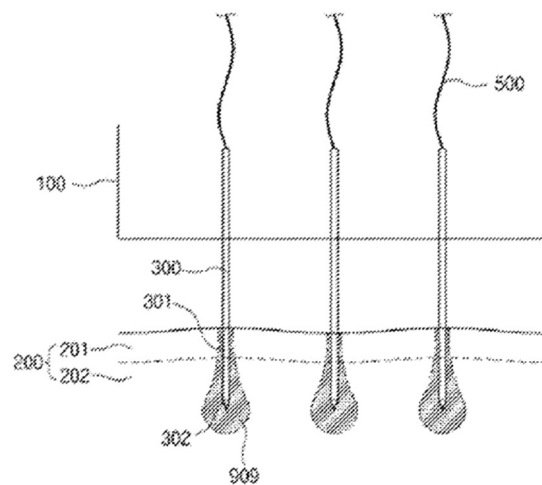


FIGURE 5

Ex-1001, Fig. 5; *see also* Ex-1001, 3:26-27 (“the heated area around the needle end tips may be **oval** or tear shaped as shown in FIG. 5.”) (emphasis); Ex-1001, 5:17-18 (“909 . . . area where the temperature is raised using non-insulated needles.”). The '836 patent does not describe any particular methodology or apparatus that must be employed to attain the “oval” shape depicted in Figure 5 above. The system in methods described in Ganz and Hantash combination are similar to the disclosure in the '836 patent: both Ganz and Hantash disclose using RF electrodes for skin treatment. *See*

Ex-1005, [0011] (“In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy.”); Ex-1007, [0002] (“This invention relates generally to biological tissue treatment using electromagnetic energy delivered through an array of needle electrodes. More particularly, it relates to *using radio frequency energy through an array of microneedles for rejuvenating human skin* by a fractional treatment.”) (emphasis added). Thus, the zone of the coagulation created by Ganz and Hantash will be oval shaped for the same reasons the coagulation in the ’836 patent is oval shaped.

192. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

8. Claim 9

- a) **“The skin treatment apparatus of claim 1, wherein the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm.”**

193. The combination of Ganz and Hantash renders this limitation obvious.

194. As discussed in Section VIII.A.1.b.4 above, Ganz discloses “*the electrode pins* are placed all the way into the tissue” to create deep perforations. Ex-1005, [0051] (emphasis added). Because Ganz’s electrodes are pins that are inserted into skin to create perforations, they are needles. Indeed, Ganz also refers to its electrode pins as needles. Ex-1005, [0065] (“The array consisted of two 0.3 mm length *needles*”) (emphasis added).

195. Ganz discloses that “[t]he width or diameter of each electrode pin can . . . be varied to provide a perforation having a desired width.” Ex-1005, [0053]. “The width of the perforation created will be at least the width of the electrode, and in many cases larger.” Ex-1005, [0053]. Ganz discloses an example perforation of “about 0.5 mm in width.” Ex-1005, [0047].

196. Hantash discloses that “[i]n a preferred embodiment, the needles 115 are 50 to 300 μ m in diameter,” or 0.05 to 0.30 mm. Ex-1007, [0039]. Hantash’s needle diameter range of 0.05 mm to 0.30 mm overlaps with the claimed range of “from 0.25 mm to 0.30 mm.”

197. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash’s needle diameter for Ganz’s electrodes.

198. Moreover, the ’836 patent does not explain any new and unexpected result from using the claimed diameter of “from 0.25 mm to 0.30 mm.” In my opinion, there is nothing new or unexpected about the claimed range.

199. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

9. Claim 10

a) “The skin treatment apparatus of claim 9, wherein the needles have a length from 1 mm to 4 mm.”

200. The combination of Ganz and Hantash renders this limitation obvious.

201. As discussed in Section VIII.B.8 above, the combination of Ganz and Hantash renders obvious the skin treatment apparatus of claim 9.

202. Hantash further discloses “a needle pair that penetrated approximately 1-2 mm into the skin,” which overlaps with the claimed range of “1 mm to 4 mm.” Ex-1007, [0077].

203. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash’s needle length for Ganz’s electrodes.

204. Moreover, the ’836 patent does not explain any new and unexpected result from using the claimed length of “from 1 mm to 4 mm.” In my opinion, there is nothing new or unexpected about the claimed range.

205. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

10. Claim 15

- a) “The method of treating skin of claim 14, including providing an AC RF signal to the plurality of electrodes for a predetermined time interval.”**

206. The combination of Ganz and Hantash renders this limitation obvious.

207. See Section VIII.B.1 above regarding claim 2.

11. Claim 16

- a) **“The method of treating skin of claim 15, wherein the predetermined time interval is from 0.05 to 0.8 seconds.”**

208. The combination of Ganz and Hantash renders this limitation obvious.

209. See Section VIII.B.2 above regarding claim 3.

12. Claim 17

- a) **“The method of treating skin of claim 15, wherein the skin segment to be treated is skin dermis and each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin and the predetermined time interval is from 0.05 to 0.8 seconds.”**

210. The combination of Ganz and Hantash renders this limitation obvious.

211. See Section VIII.B.3 above regarding claim 4.

13. Claim 18

- a) **“The method of treating skin of claim 17, wherein the closest neighboring electrodes have opposite polarities.”**

212. The combination of Ganz and Hantash renders this limitation obvious.

213. See Section VIII.B.4 above regarding claim 5.

14. Claim 19

- a) **“The method of treating skin of claim 14, wherein the RF is about 2.0 MHz and the coagulated area around each electrode is oval shaped.”**

214. The combination of Ganz and Hantash renders this limitation obvious.

215. See Section VIII.B.7 above regarding claim 8.

15. Claim 20

- a) **“The method of treating skin of claim 14, wherein the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm.”**

216. The combination of Ganz and Hantash renders this limitation obvious.

217. See Section VIII.B.8 above regarding claim 9.

16. Claim 21

- a) **“The method of treating skin of claim 20, wherein the needles have a length from 1 mm to 4 mm.”**

218. The combination of Ganz and Hantash renders this limitation obvious.

219. See Section VIII.B.9 above regarding claim 10.

17. Claim 22

- a) **“The method of treating skin of claim 14, wherein the RF is from 0.5 to 10 Mhz and the predetermined time interval is from 0.05 to 0.8 seconds.”**

220. The combination of Ganz and Hantash renders this limitation obvious.

(1) “the RF is from 0.5 to 10 Mhz”

221. Hantash discloses that “[i]n some preferred embodiments, the frequency range is from **0.1 to 10 MHz** or from 0.4 to 3 MHz,” which includes the claimed range of “from 0.5 to 10 Mhz.” Ex-1007, [0040] (emphasis added).

222. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash’s RF range for Ganz’s device.

223. Moreover, the '836 patent does not explain any new and unexpected result from using the claimed RF of “from 0.5 to 10 Mhz.” In my opinion, there is nothing new or unexpected about the claimed range. “Frequencies in the range of 200 kHz [0.2 MHz] to 6 MHz are the most common in medicine” Ex-1024, 3.

(2) “the predetermined time interval is from 0.05 to 0.8 seconds”

224. As discussed in Section VIII.B.1 above, Hantash discloses a pulse duration, which corresponds to the claimed “predetermined time interval.” Ex-1007, [0077]-[0078]. In particular, Hantash discloses pulse durations of 400 ms and 200 ms (or 0.4 seconds and 0.2 seconds), both of which fall within the claimed predetermined time interval of “from 0.05 to 0.8 seconds.” Ex-1007, [0077]-[0078].

225. As discussed further in Section VIII.B.19 below, a POSITA would have been motivated to use Hantash’s RF pulse duration for Ganz’s device.

226. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

18. Claim 25

a) “The method of treating skin of claim 14, wherein a section of each electrode of the plurality of electrodes is non-insulated.”

227. The combination of Ganz and Hantash renders this limitation obvious.

228. See Section VIII.B.5 above regarding claim 6.

19. Motivation to Combine Ganz and Hantash

229. As discussed above, Ganz discloses RF electrodes for skin treatment, where the RF electrodes are inserted into skin so that RF energy is delivered to the dermis portion of the skin. However, Ganz does not specify certain parameters for the application of RF energy and certain parameters of the electrodes. In contrast, Hantash not only discloses using RF electrodes for skin treatment, but also discloses certain parameters for the application of RF energy and certain parameters of the electrodes. For the reasons discussed below, a POSITA implementing Ganz's device would have been motivated to look to Hantash for the parameters for the application of RF energy and the parameters of the electrodes.

a) Same field of endeavor

230. A POSITA would have been motivated to use Hantash's RF and electrode parameters for Ganz's device because both Ganz and Hantash disclose using RF electrodes for skin treatment. *See* Ex-1005, [0011] ("In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy."); Ex-1007, [0002] ("This invention relates generally to biological tissue treatment using electromagnetic energy delivered through an array of needle electrodes. More particularly, it relates to *using radio frequency energy through an array of microneedles for rejuvenating human skin* by a fractional treatment.") (emphasis added).

231. Both Ganz and Hantash disclose that RF energy from electrodes generates heat that improves skin condition. Ex-1005, [0030] (“The zones of coagulation created in the tissue area surrounding each perforation . . . help to revitalize and rejuvenate [sic] skin.”); Ex-1007, [0035] (“While the needles 115 are located within the skin 150, they can be powered by the RF source 110 to create an array of treatment zones 160 through resistive heating of the tissue.”). While Ganz focuses on creating zones of *coagulation around RF electrodes*, Ex-1005, [0030], Hantash focuses on creating zones of *denaturation between RF electrodes*, Ex-1007, [0005] (“It is now well established that collagen is sensitive to heat treatment and *denatures* when heated above its transition temperature. This *denaturing* is accompanied by shrinking of the collagen fibers and this shrinking can provide sagging or wrinkled skin with a tightened youthful appearance.”) (emphasis added). Figure 7A of Hantash illustrates example treatment zones 160 (i.e., denatured zones, not coagulation zones) formed between needles 116 and 117.

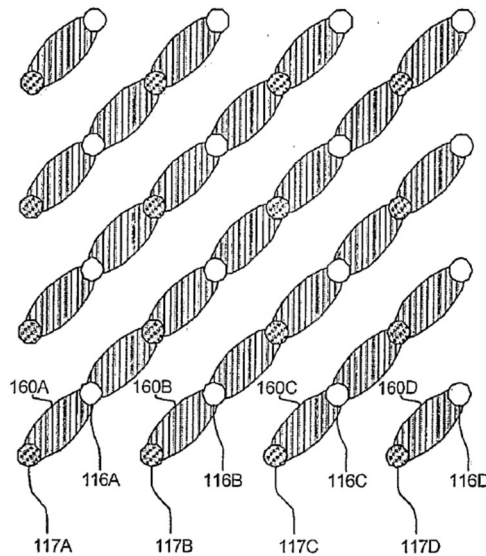


Figure 7A

Ex-1007, Fig. 7A; *see also* Ex-1007, [0060] (“The treatment pattern 164 shown in FIGS. 7A and 7B is particularly useful because it can create a line of tension within the skin 150 due to collagen **denaturation**.”) (emphasis added). As discussed in Section V.B above, applying heat causes collagen denaturation and applying even more heat causes collagen coagulation. Because Hantash’s RF needles 116 and 117 generate heat, the heat is most intense around the needles, which is consistent with Ganz’s disclosure of forming coagulation around the needles. Indeed, Hantash explains that its device can also form coagulation, not just denaturation. Ex-1007, [0079] (“These parameters can be used to **coagulate collagen** within the skin and to kill or injure cells to stimulate the wound healing response in surrounding healthy tissue.”) (emphasis added).

b) Teaching, suggestion, motivation: RF pulse duration

232. A POSITA would have been motivated to apply Hantash's pulse duration to Ganz's device in order to avoid generating too much heat. It was well known that, when using RF electrodes for skin treatment, RF energy needs to be provided with a predetermined limited duration in order to avoid generating too much heat. As one example, a prior art reference Kreindel taught providing RF energy to RF electrodes in pulses in order to avoid generating too much heat. Ex-1027, [0025]-[0026] ("FIG. 1 shows a system for applying RF energy to a plurality of discrete regions of skin in accordance with the invention. . . . *The pulse duration is preferably short enough to prevent significant heat diffusion far from the tips.*") (emphasis added). Hantash discloses such short pulse durations of 400 ms and 200 ms suitable for providing RF energy to the microneedles. Ex-1007, [0077]-[0078].

c) Teaching, suggestion, motivation: needle arrangement

233. A POSITA would have been motivated to apply Hantash's needle arrangement to Ganz's device in order to create a line of tension within the skin due to collagen denaturation. Hantash teaches that "[t]he treatment pattern 164 shown in FIGS. 7A and 7B is *particularly useful because it can create a line of tension* within the skin 150 due to collagen denaturation." Ex-1007, [0060] (emphasis added). "Collagen denaturation causes collagen fibers to shrink in length by up to

approximately 60% or 70% and thus can provide considerable tension along a particular direction.” Ex-1007, [0060].

d) Teaching, suggestion, motivation: RF range

234. A POSITA would have been motivated to apply Hantash’s RF range to Ganz’s device based on the desired treatment zone profile. Hantash teaches that two of the “preferred” RF ranges are 0.4 to 3 MHz or 0.1 to 10 MHz. Ex-1007, [0040]. Hantash also teaches that “[t]he resistance of the skin varies with the frequency of RF source.” Ex-1007, [0040]. “The frequency range of the RF source can be chosen based on the desired treatment zone profile including for example treatment zone size, treatment zone shape, treatment zone aspect ratio, and treatment zone spacing.” Ex-1007, [0040].

e) Teaching, suggestion, motivation: needle diameter

235. A POSITA would have been motivated to apply Hantash’s needle diameter to Ganz’s electrodes in order to ensure that they are thick enough to be strong to facilitate multiple insertions but thin enough to allow close packing, as well as reducing visual disruption to the skin after treatment. Hantash teaches that “[t]he diameter of the needles 115 is preferably at least 50 μm [0.05 mm] to reduce breakage of the needles 115.” Ex-1007, [0039]. Hantash also teaches that “[t]he diameter of the needles 115 is preferably less than 300 μm [0.30 mm] to allow close packing of the

needles 115 and to reduce disruption to the skin 150 and purpura, as the needles 115 penetrate into the skin 150.” Ex-1007, [0039].

f) Teaching, suggestion, motivation: needle length

236. A POSITA would have been motivated to apply Hantash’s needle length to Ganz’s electrodes in order to ensure that they have a length sufficient to reach skin dermis when inserted into skin. As discussed in Section VIII.B.3.a.1 above, Ganz teaches that each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin. Ex-1005, [0051] (“In some cases, when it is desirable to provide a deeper perforation, the electrode pins are placed all the way into the tissue, so that more than one layers of tissue are treated.”). Hantash’s needle length of approximately 1-2 mm is long enough to reach skin dermis when inserted into skin. Ex-1001, 9:40-41 (“dermis depth may be between 1 mm and 4 mm (from the skin boundary)”).

g) Combining prior art elements according to known methods to yield predictable results

237. Combining Ganz and Hantash would have been combining prior art elements (i.e., Hantash’s RF pulse duration, needle arrangement, RF range, needle diameter, and needle length) according to known methods to yield predictable results (i.e., improving Ganz’s device for better skin treatment). Hantash’s RF and needle parameters were well known in the art to yield predictable results.

**h) Use of known technique to improve similar devices
(methods, or products) in the same way**

238. Combining Ganz and Hantash would have been a use of a known technique (i.e., Hantash's RF pulse duration, needle arrangement, RF range, needle diameter, and needle length) to improve similar devices in the same way (i.e., improving Ganz's device for better skin treatment). Hantash's RF and needle parameters were well known in the art. Using those parameters would have improved Ganz's device in the same way they were beneficial for Hantash's device.

**i) Applying a known technique to a known device
(method, or product) ready for improvement to yield
predictable results**

239. Combining Ganz and Hantash would also have been applying a known technique (i.e., Hantash's RF pulse duration, needle arrangement, RF range, needle diameter, and needle length) to a known device ready for improvement to yield predictable results (i.e., improving Ganz's device for better skin treatment). Hantash's RF and needle parameters were well known in the art to yield predictable results.

j) Reasonable expectation of success

240. Hantash's RF and needle parameters were well known in the art to yield predictable results. Because they were well known, a POSITA would have had a reasonable expectation of success in using Hantash's RF and needle parameters.

C. Ganz in Combination with Livneh and Hantash Renders Claims 2-10, 15-22, and 25 Obvious.

241. As discussed in Section VIII.B above, claims 2-10, 15-22, and 25 would have been obvious to a POSITA based on the disclosures in Ganz and Hantash.

242. To the extent Ganz does not render obvious “an Alternating Current (AC) RF signal,” however, Ganz in combination with Livneh renders the limitation obvious, as discussed in Section VIII.A.1.c.2 above. Therefore, Ganz in combination with Livneh and Hantash renders obvious claims 2-10, 15-22, and 25.

D. Ganz in Combination with Lee Renders Claims 27-29 Obvious.

243. Claims 27-29 would have been obvious to a POSITA based on the disclosures in Ganz and Lee, for the reasons I discuss below.

1. Claim 27

- a) **“The skin treatment apparatus of claim 1, further comprising a drive module to controllably move one or more of the plurality of electrodes into skin to be treated.”**

244. The combination of Ganz and Lee renders this limitation obvious.

245. Ganz discloses that the plurality of electrodes are inserted into skin to be treated. Ex-1005, [0051] (“In some cases, when it is desirable to provide a deeper perforation, the electrode pins are placed all the way into the tissue, so that more than one layers of tissue are treated.”). Ganz also discloses that the depth with which that the plurality of electrodes are inserted into skin is controlled. Ex-1005, [0051] (“When

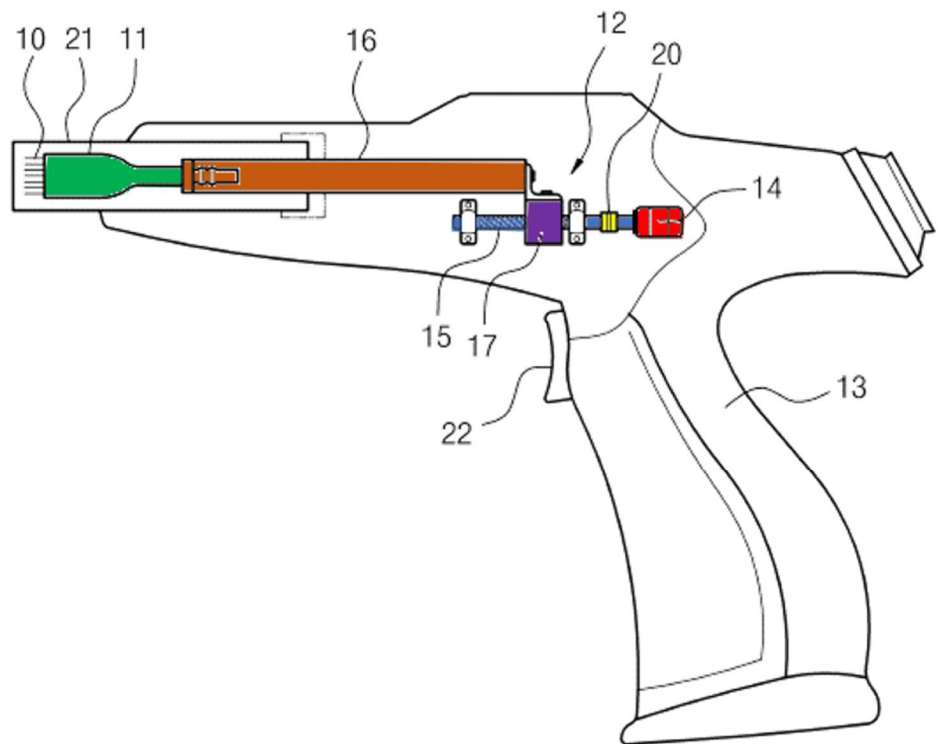
it is desirable to provide an even deeper perforation, the electrode pins can be providing [sic] having longer lengths, so that the tips are placed even deeper into the tissue layers.”).

246. Like Ganz, Lee discloses that microneedles are inserted into skin to be treated. Ex-1008, <13> (“The present invention relates to a *skin regeneration apparatus capable of controlling the insertion depth of microneedles* and, more particularly, to a skin regeneration apparatus capable of controlling microneedles that can provide effective multi-hole treatment as well as safety and precision as to the depth of microneedles by making it possible to automatically control the insertion depth of the microneedles during multi-hole treatment.”) (emphasis added), <17> (“*The multi-hole treatment method*, which is simple and safe as well as free of side effects, newly reconstructs and rearranges dermal tissues by using *a process of natural wound healing that occurs when a plurality of needles are inserted into the skin*, thereby making scars thinner as well as tightening the skin. As a result, fine wrinkles decrease and hyperpigmentation improves, restoring healthy and clean skin.”) (emphasis added).

247. Lee further discloses an actuator means, which corresponds to the claimed “drive module to controllably move one or more of the plurality of electrodes into skin to be treated.” Ex-1008, <44> (“the present invention provides *an actuator means that can control the insertion depth of the microneedles*. By being capable of

controlling the degree of microneedle insertion, it provides precise treatment as well as stability during treatment and, above all, brings about an advantage of performing precise treatment customized depending upon the area of treatment as well as the patient.”) (emphasis added). Figure 2 illustrates an example actuator consisting of a screw electric motor axis 15 (blue), a coupling 20 (yellow), and a motor 14 (red):

FIG. 2



Ex-1008, Fig. 2 (annotated); *see also* Ex-1008, <45> (“For this, as an example of an actuator, as illustrated in FIG. 2, a screw electric motor axis 15 [blue] is installed inside the gun 13 with a structure in which both ends are supported by interposed bearings and the like to make it rotatable. One end of the screw electric motor axis 15 [blue]

installed this way is connected to the motor 14 [red] through a coupling 20 [yellow], allowing the screw electric motor axis to rotate along with the operation of the motor.”).

248. A slider 17 (purple) is coupled to the screw electric motor axis 15 (blue). Ex-1008, <47> (“In addition, a slider 17 [purple], which is coupled with said screw electric motor axis that can electrically motorize the screw, is installed on the screw electric motor axis 15 [blue] . . .”). “[A] rod 16 [brown] with a needle mount 11 [green] coupled therewith is connected to this slider 17 [purple] with a bracket or the like, thereby allowing the entire rod including the needle mount to move back and forth along with the operation of the slider.” Ex-1008, <47>. “Accordingly, when the screw electric motor axis 15 [blue] rotates by the forward rotation of the motor 14 [red], the slide 17 [purple] moves forward by electrically motorizing the screw and, at the same time, the needle mount 11 [green] having microneedles 10 and the rod 16 [brown] move forward in the entirety, allowing the microneedles to be inserted into the skin.” Ex-1008, <49>. “Here, said motor 14 [red] rotates to the extent of the pre-programmed setting in accordance with the mode selected; therefore, the strokes of the slider 17 [purple], the rod 16 [brown] and the needle mount 11 [green] can be controlled and, ultimately, the insertion depth of the microneedles can be controlled to fit in with the parameters at this time.” Ex-1008, <50>.

249. As discussed in Section VIII.D.4 below, a POSITA would have been motivated to use Lee's actuator for Ganz's electrodes.

250. Therefore, the combination of Ganz and Hantash renders this limitation obvious.

2. Claim 28

- a) **“The skin treatment apparatus of claim 27, further comprising a user interface to enable a user to select the depths that the drive module controllably moves one or more of the plurality of electrodes into skin to be treated.”**

251. The combination of Ganz and Lee renders this limitation obvious.

252. As discussed in Section VIII.D.1 above, the combination of Ganz and Lee renders obvious “the drive module [that] controllably moves one or more of the plurality of electrodes into skin to be treated.”

253. Lee further discloses a mode switch, which corresponds to “a user interface to enable a user to select the depths.” Lee refers to its treatment device as a “gun” because of the shape of the device. Ex-1008, Abstract. Lee discloses that its gun comes with a cart for controlling the gun. Ex-1008, <31>. The cart has a mode switch. Ex-1008, <33>. “Pressing the mode switch changes the mode.” Ex-1008, <33>. ***“The selected mode controls . . . the insertion depth of the needles.”*** Ex-1008, <33> (emphasis added); *see also* Ex-1008, <59> (“For starters, as a preparatory step, power supply is connected first; after that, the cart and the gun are connected to each other;

the power supply switch is turned on; and the mode switch is manipulated to set the mode in line with each patient's traits."); Ex-1008, <60> ("In other words, the operational parameter (amount of rotation) of the motor is *set to determine the insertion depth of the needles.*") (emphasis added); Ex-1008, <61> ("Here, for the method of setting the mode such as the operational parameter of the motor, any method typically known in the conventional art of the technical field of this invention may be adopted without any particular limitation.").

254. As discussed in Section VIII.D.4 below, a POSITA would have been motivated to use Lee's mode switch for Ganz's electrodes.

3. Claim 29

- a) **"The skin treatment apparatus of claim 1, further comprising a drive module to controllably move one or more of the plurality of electrodes from an epidermis region to an adjacent dermis region of skin to be treated."**

255. The combination of Ganz and Lee renders this limitation obvious.

256. As discussed in Section VIII.D.1 above, the combination of Ganz and Lee renders obvious "a drive module to controllably move one or more of the plurality of electrodes."

257. Ganz further discloses moving the electrodes "from an epidermis region to an adjacent dermis region of skin to be treated." As discussed in Section VIII.B.3.a.1 above, Ganz discloses that "[i]n some cases, when it is desirable to provide a deeper

perforation, the electrode pins are placed all the way into the tissue, so that *more than one layers of tissue are treated.*” Ex-1005, [0051] (emphasis added). The outer most layer of skin tissue is epidermis; the layer below epidermis is dermis. Ex-1001, 1:40-41 (“Dermis is the layer beneath epidermis, directly connected to a basal layer.”). Ganz’s disclosure of the electrode pins being inserted into skin so that “more than one layers of tissue are treated” shows that the electrodes move “from an epidermis region to an adjacent dermis region of skin to be treated.” Moreover, Ganz further discloses that “[w]hen it is desirable to provide an even deeper perforation, the electrode pins can be providing [sic] having longer lengths, so that the tips are placed even deeper into the tissue layers.” Ex-1005, [0051].

258. Therefore, the combination of Ganz and Lee renders this limitation obvious.

4. Motivation to Combine Ganz and Lee

259. As discussed above, Ganz discloses RF electrodes for skin treatment, where the RF electrodes are inserted into skin so that RF energy is delivered to the dermis portion of the skin. However, Ganz does not discuss in detail how to deploy the needle into the skin and how to customize the insertion depth of the needles. On the other hand, Lee discloses an actuator to insert needles into skin for treatment and how to control the depth of insertion of the needles into the skin through a mode switch. For the reasons discussed below, a POSITA implementing Ganz’s device would have been

motivated to use Lee's actuator and mode switch to insert the needles into the skin up to the desired depth.

a) Same field of endeavor

260. Both Ganz and Lee disclose creating perforations with electrodes for skin treatment. Ex-1005, [0051] ("In some cases, when it is desirable to provide a deeper perforation, the electrode pins are placed all the way into the tissue, so that more than one layers of tissue are treated."); Ex-1008, <13> ("The present invention relates to a skin regeneration apparatus capable of controlling the insertion depth of microneedles and, more particularly, to a skin regeneration apparatus capable of controlling microneedles that can provide effective multi-hole treatment as well as safety and precision as to the depth of microneedles by making it possible to automatically control the insertion depth of the microneedles during multi-hole treatment.").

b) Teaching, Suggestion, Motivation

261. A POSITA would have been motivated to use Lee's actuator for Ganz's device in order to enable precise, customized treatments. Lee teaches the benefits of using Lee's actuator: "[b]y being capable of controlling the degree of microneedle insertion, [Lee's actuator] provides precise treatment as well as stability during treatment and, above all, brings about an advantage of performing precise treatment customized depending upon the area of treatment as well as the patient." Ex-1008, <44>. Lee teaches further advantages of its actuator: "repetitive needle insertion can

be performed at a constant speed and at a constant depth; the size and weight of the gun are small and light, minimizing the otherwise burdensome use of the hand during treatment; it is easy to adjust the needle insertion depths by controlling the microneedles; and various modes are available to use by adopting a microprocessor chipset.” Ex-1008, <67>.

262. Moreover, a POSITA would have been motivated to use Lee’s mode switch as well because a mode switch that sets the insertion depth enables the use of the actuator for a precise, customized treatment of skin. An actuator that controls the precise insertion depth of needles would be useful only if the user is able to set the desired insertion depth.

c) Combining prior art elements according to known methods to yield predictable results

263. Combining Ganz’s electrodes and Lee’s actuator and mode switch would have been combining prior art elements according to known methods to yield predictable results (i.e., precise, customized treatment). Lee’s actuator and mode switch were well known in the art, and using them in Ganz’s device to control the needle depth would have yielded predictable results.

d) Use of known technique to improve similar devices (methods, or products) in the same way

264. Combining Ganz’s electrodes and Lee’s actuator and mode switch would have been a use of a known technique to improve similar devices in the same way (i.e.,

precise, customized treatment). Lee's actuator and mode switch were well known in the art. Using them would have improved Ganz's device in the same way they were beneficial for Lee's device.

e) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results

265. Combining Ganz's electrodes and Lee's actuator and mode switch would also have been applying a known technique to a known device ready for improvement to yield predictable results (i.e., precise, customized treatment). Lee's actuator and mode switch were well known in the art, and using them in Ganz's device to control the needle depth would have yielded predictable results.

f) Reasonable expectation of success

266. Lee's actuator and mode switch were well known in the art, and using them in Ganz's device to control the needle depth would have yielded predictable results. A POSITA would have had a reasonable expectation of success in using Lee's actuator and mode switch because they were a well known mechanism for a precise, customized treatment.

E. Ganz in Combination with Livneh and Lee Renders Claims 27-29 Obvious.

267. As discussed in Section VIII.D above, claims 27-29 would have been obvious to a POSITA based on the disclosures in Ganz and Lee.

268. To the extent Ganz does not render obvious “an Alternating Current (AC) RF signal,” however, Ganz in combination with Livneh renders the limitation obvious, as discussed in Section VIII.A.1.c.2 above. Therefore, Ganz in combination with Livneh and Lee renders obvious claims 27-29.

IX. AVAILABILITY FOR CROSS-EXAMINATION

269. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during a time as mutually agreed between the parties.

X. RIGHT TO SUPPLEMENT

270. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises. This declaration represents only those opinions that I have formed to date. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information that becomes available to me and on my continuing analysis of the materials already provided.

XI. JURAT

271. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and

further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

January 8th, 2024
Date



Dany Bérubé, Ph.D.