

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ILOODA CO., LTD. and JEISYS MEDICAL INC.,
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

Case No. IPR2024-00386
Patent No. 9,480,836

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,480,836
UNDER 35 U.S.C. §§ 311–319 AND 37 C.F.R. § 42.100 *et seq.***

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LIST OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 9,480,836 (the “’836 patent”)
1002	File History for U.S. Patent No. 9,480,836
1003	Declaration of Dany Bérubé, Ph.D.
1004	<i>Curriculum Vitae</i> of Dany Bérubé, Ph.D.
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 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)

Exhibit	Description
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)
1032	Docket Report - Serendia, LLC v. Cutera, Inc, 1:23-cv-00222-RGA (D. Del.)
1033	Docket Report - Serendia, LLC v. Cynosure, LLC, 1:23-cv-00223-RGA (D. Del.)
1034	Birefringence Definition, https://www.merriam-webster.com/dictionary/birefringence

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Exhibit	Description
1035	Declaration of R. James Koch, M.D.
1036	<i>Curriculum Vitae</i> of R. James Koch, M.D.

I. INTRODUCTION

Ilooda Co., Ltd. and Jeisys Medical Inc. (collectively “Petitioner”) petition for *inter partes* review seeking cancellation of claims 1-29 of U.S. Patent No. 9,480,836 (Ex-1001, “’836 patent”), assigned to Serendia, LLC (“Serendia” or “Patent Owner”).

The ’836 patent is directed to skin treatment apparatus and method. Figure 5 illustrates an embodiment:

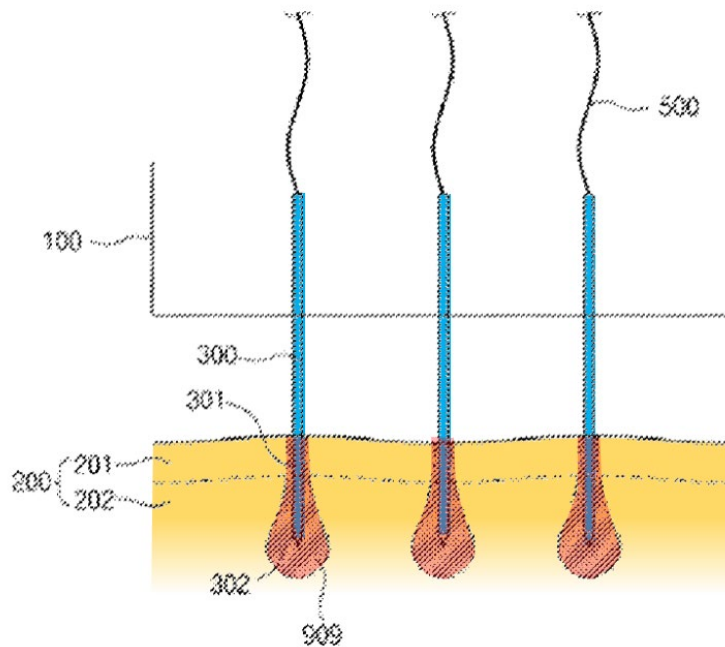
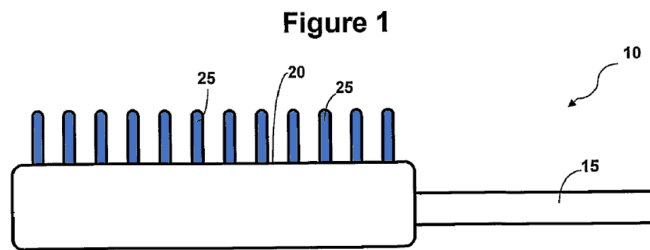


FIGURE 5

Ex-1001, Fig. 5 (annotated). In Figure 5 above, needles 300 (blue) are inserted into skin 200 (yellow). Ex-1001, 5:5-10. The needles 300 may be bipolar needles, that is, needles having opposite polarities. Ex-1001, 3:46-48, 3:56-60, 7:45-48. When radio frequency (RF) energy is applied to the needles 300, areas of coagulation 909 (red)

are formed, Ex-1001, 5:17-18, 5:35-42, which improves skin condition. Ex-1001, 2:65-66, 3:21-24. The claims require that zones of coagulation 909 (red) form around each electrode (blue), rather than between the electrodes. Ex-1001, 3:25-20.

Ganz, a published patent application, disclosed a similar device several years before the priority date of the '836 patent. Figure 1 below a side view of a skin treatment device with electrode pins 25 (blue):



Ex-1005, Fig. 1 (annotated). Ganz discloses inserting electrode pins 25 into skin and applying RF energy. Ex-1005, [0051], [0011]. The electrode pins 25 (blue) may be bipolar. Ex-1005, [0056]. The RF electrode pins 25 create perforations, as well as zones of coagulation surrounding the perforations. Ex-1005, [0010], [0048]. A person of ordinary skill in the art would have known that RF signals used in skin treatment devices (such as the device disclosed in Ganz) are alternating currents (AC) radio frequency. Prior art references, such as Livneh, expressly state that.

While Ganz discloses a skin treatment devices using bipolar electrodes employing RF energy, it does not expressly disclose routine implementation details. Such details were known in the art. For example, Hantash discloses a skin treatment

device with RF electrodes, Ex-1007, [0014], provides specific RF and electrode parameters, such as RF pulse duration, needle arrangement, RF range, needle diameter, and needle length. 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). Similarly, Lee discloses a skin treatment device that uses microneedles, Ex-1008, <13>, and an actuator and mode switch to control the precise insertion depth of the microneedles. Ex-1008, <33>, <44>.

The challenged claims of the '836 patent were not inventive, and Petitioner requests that the challenged claims be cancelled.

II. STANDING, MANDATORY NOTICES, AND FEE AUTHORIZATION

Grounds for Standing: Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '836 patent is available for IPR and that Petitioner is not barred or estopped from requesting an IPR challenging the '836 patent on the grounds identified in this petition.

Real Parties-in-Interest: Petitioner identifies Illooda Co., Ltd. and Jeisys Medical Inc. as real parties-in-interest.

Related Matters: Petitioner identifies the following related matters.

- *Certain Dermatological Treatment Devices and Components Thereof*, 337-TA-1356 ("ITC Investigation")

- *Serendia, LLC v. Cuter, Inc.*,¹ 1:23-cv-00222 (D. Del.)
- *Serendia, LLC v. Cynosure, LLC*,² 1:23-cv-00223 (D. Del.)
- *Serendia, LLC v. EndyMed Medical, Inc.*, 1:23-cv-00224 (D. Del.)
- *Serendia, LLC v. Lutronic Aesthetics, Inc.*, 1:23-cv-00225 (D. Del.)
- *Serendia, LLC v. Rohrer Aesthetics, Inc.*, 1:23-cv-00226 (D. Del.)

In addition, a request for *inter partes* review of the '836 patent (IPR2022-00594) was filed by Cartessa Aesthetics, LLC on February 10, 2022. The Board denied Cartessa Aesthetics's request for IPR.

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¹ Cuter, Inc. is a distributor for Ilooda with respect to Ilooda accused products sold in the U.S.

² Cynosure, LLC is a distributor for Jeisys with respect to Jeisys accused products sold in the U.S.

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37 C.F.R. §42.8(b)(4) Service Information: Service information is provided in the designation of counsel above. Petitioner consents to service of all documents via electronic mail at the email addresses above and at llooda-IPR@cov.com and Jeisys-IPR@leydig.com.

Payment of Fees Under 37 C.F.R. §42.103: The Office is authorized to charge the fee set forth in 37 C.F.R. §42.15(a)(1) for this Petition to Deposit Account No. 60-3160. Review of 20 claims is requested. The undersigned further authorizes payment for any additional fees that may be due in connection with this Petition.

III. SUMMARY OF CHALLENGE

Petitioner requests IPR of claims 1-29 of the '836 patent based on the following grounds:

- **Ground I:** Claims 1-2, 11-15, 23-24, and 26 would have been obvious based on Ganz (Ex-1005) in view of a POSITA's knowledge under 35 U.S.C. § 103.

- **Ground II:** Claims 1-2, 11-15, 23-24, and 26 would have been obvious based on Ganz in view Livneh (Ex-1006) under 35 U.S.C. § 103.
- **Ground III:** Claims 2-10, 15-22, and 25 would have been obvious based on Ganz in view of Hantash (Ex-1007) under 35 U.S.C. § 103.
- **Ground IV:** Claims 2-10, 15-22, and 25 would have been obvious based on Ganz in view of Livneh and Hantash under 35 U.S.C. § 103.
- **Ground V:** Claims 27-29 would have been obvious based on Ganz in view of Lee (Exs. 1008, 1009) under 35 U.S.C. § 103.
- **Ground VI:** Claims 27-29 would have been obvious based on Ganz in view of Livneh and Lee under 35 U.S.C. § 103.

The '836 patent was filed on June 14, 2012, and claims priority to foreign applications filed on June 14, 2011. Each of the asserted references is available as prior art under 35 U.S.C. § 102 (pre-AIA),³ as shown in the following table.

Exhibit	Reference	Date(s)	Availability as Prior Art
Ex-1005	U.S. Patent Application Publication No. 2007/0208340 (“Ganz”)	August 5, 2005 (filed) September 6, 2007 (published)	§§ 102(a), (b), (e)
Ex-1006	International Publication Number	July 5, 2007 (filed) January 10, 2008 (published)	§§ 102(a), (b)

³ Because the application for the '836 patent was filed prior to March 16, 2013, the pre-AIA conditions for patentability apply.

Exhibit	Reference	Date(s)	Availability as Prior Art
	WO 2008/005477 ("Livneh")		
Ex-1007	International Publication Number WO 2007/064718 ("Hantash")	November 29, 2006 (filed) June 7, 2007 (published)	§§ 102(a), (b)
Ex-1008	Korean Patent No. 20- 0441552 ("Lee") (translation)	June 5, 2007 (filed) August 25, 2008 (published)	§§ 102(a), (b)
Ex-1009	Korean Patent No. 20- 0441552 ("Lee") (original Korean)	June 5, 2007 (filed) August 25, 2008 (published)	§§ 102(a), (b)

IV. OVERVIEW OF THE '836 PATENT

As discussed in Section I above, the '836 patent is directed to skin treatment apparatus and method. Figure 5 illustrates an embodiment:

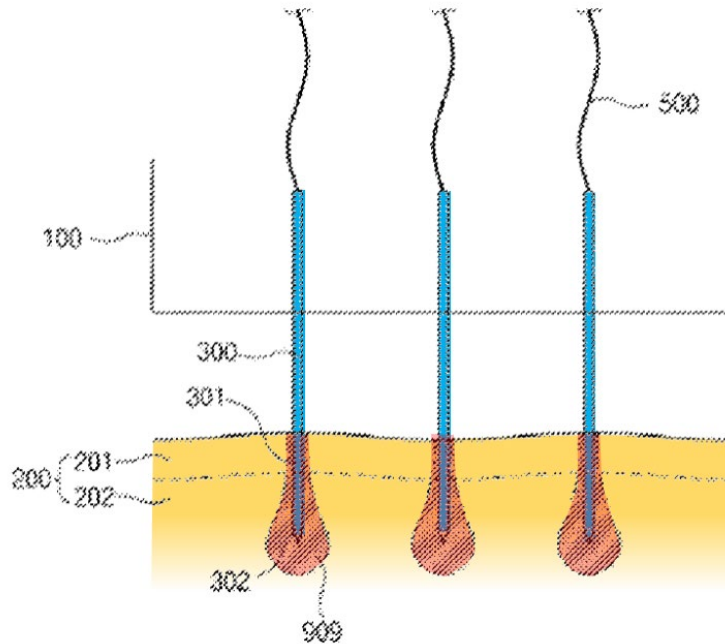


FIGURE 5

Ex-1001, Fig. 5 (annotated).

A. Prosecution History

During prosecution, 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. In response, the applicant amended the claims twice. Ex-1002, 309, 335, 370. The examiner issued a Notice of Allowance. Ex-1002, 385, 427. The examiner stated that the reason for the allowance was 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 appears to have been unaware that RF signals

for skin treatment are AC signals operating at a radio frequency. Ex-1003 ¶ 48; 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).

V. LEVEL OF ORDINARY SKILL

In the ITC Investigation, the ALJ specified the level of skill of a person of ordinary skill in the art (“POSITA”) of the ’836 patent. Ex-1028, 15; Ex-1003 ¶¶ 50-51.

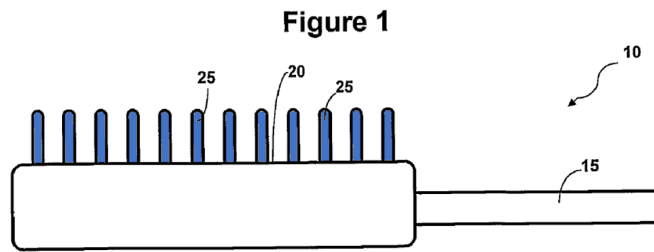
VI. CLAIM CONSTRUCTION

In the ITC Investigation, Petitioner and Patent Owner have agreed to certain constructions, Ex-1028, 39-40, and the Administrative Law Judge adopted the certain constructions, Ex-1028, 41-62, as further discussed in Section VIII below.

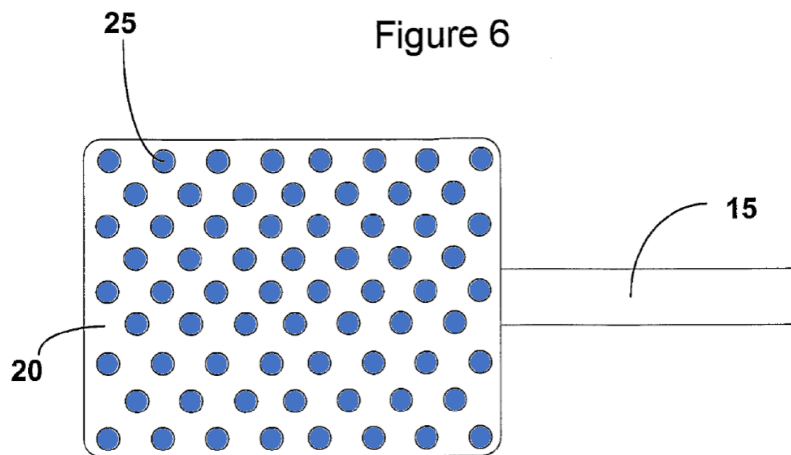
VII. OVERVIEW OF THE PRIOR ART

A. Ganz (Ex-1005)

Like the ’836 patent, Ganz discloses a skin treatment device that uses radio frequency (RF) electrodes that create zones of coagulation. Ex-1005, [0001], [0058]; Ex-1003 ¶ 54; Ex-1035 ¶¶ 28-31. Figure 1 is a side view of such a device with electrode pins 25 (blue):



Ex-1005, Fig. 1 (annotated). Figure 6 further illustrates the device in a planar view:



Ex-1005, Fig. 6 (annotated).

Ganz discloses inserting the electrode pins into skin to create perforations. Ex-1005, [0051]; Ex-1003 ¶ 55; Ex-1035 ¶¶ 28-30, 32-36, 41. “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].

Ganz discloses an improvement over prior art FRAXEL laser. Ex-1003 ¶ 56; Ex-1035 ¶¶ 35, 40. 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). 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]. 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]; Ex-1035 ¶¶ 28, 40.

B. Livneh (Ex-1006)

Like the '836 patent, Livneh discloses a skin treatment device that uses radio frequency (RF) electrodes. Ex-1006, [0002], [0032], [0039]; Ex-1003 ¶ 58. Livneh 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).

C. Hantash (Ex-1007)

Like the '836 patent, Hantash discloses a skin treatment device that uses RF electrodes. Ex-1007, [0014]; Ex-1003 ¶ 60. 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)

Like the '836 patent, Lee discloses a skin treatment device that uses microneedles. Ex-1008, <13>; Ex-1003 ¶ 63. Lee discloses inserting the needles into skin to create perforations. Ex-1008, <15>. Lee discloses an actuator and mode switch to control the precise insertion depth of the microneedles. Ex-1008, <44>, <33>.

VIII. APPLICATION OF PRIOR ART TO THE CHALLENGED CLAIMS

Ganz and the '836 patent are from the same field of endeavor and are directed to solving the same problem in the same way. Ex-1003 ¶ 66; *see also generally* Ex-1035.

A. Grounds I & II: Claims 1-2, 11-15, 23-24, and 26 Would Have Been Obvious Based on Ganz Alone and/or in View of Livneh

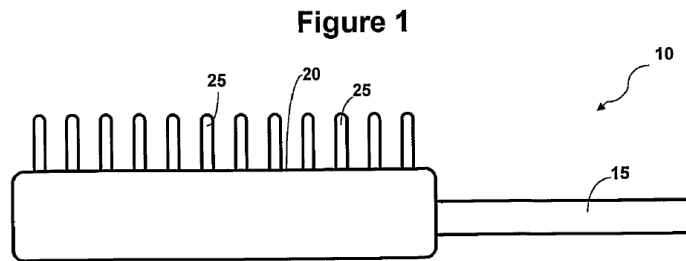
As shown below, claims 1, 2, 11-15, 23-24, and 26 would have been obvious based on Ganz in view of the knowledge of a POSITA. Ex-1003 ¶ 66.

1. Claim 1

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

Ganz discloses the preamble. Ex-1003 ¶ 68.

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); Ex-1003 ¶ 69; Ex-1035 ¶ 28. “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.

Therefore, Ganz discloses the preamble.

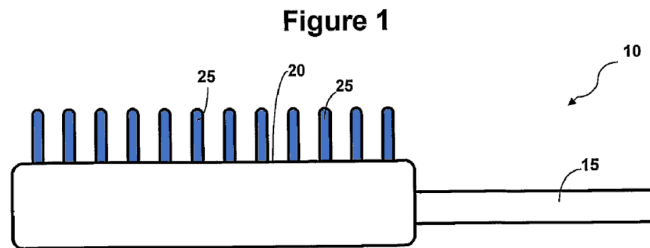
- b) 1[a]: “a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated; and”**

Ganz discloses this limitation. Ex-1003 ¶ 71

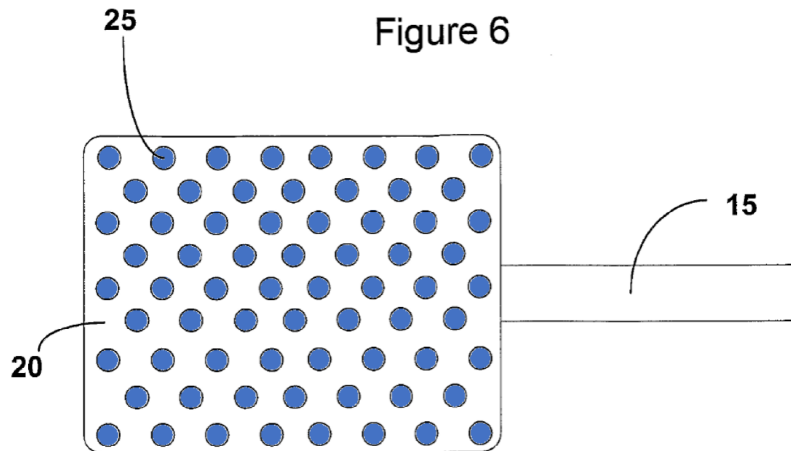
- (1) “a plurality of electrodes”**

Ganz discloses “a plurality of electrodes,” i.e., “two or more electrodes (which can be needles or pins).” Ex-1003 ¶ 73; Ex-1035 ¶¶ 30, 43.

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]; Ex-1003 ¶ 74. 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). Figure 6 further illustrates the plurality of electrode pins 25 (blue) in a planar view:



Ex-1005, Fig. 6 (annotated).

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

(2) “the electrodes being bipolar”

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).” Ex-1003 ¶ 76.

Ganz discloses that “[t]he electrodes can be either monopolar or bipolar electrodes.” Ex-1005, [0055]; Ex-1003 ¶ 77; Ex-1035 ¶ 30. “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].

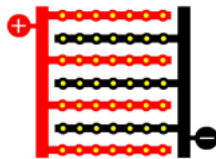
Moreover, a POSITA would understand that the bipolar electrodes disclosed in Ganz “change or alternate between being positive or negative as the current alternates between them,” because as further explained in Section VIII.A.1.c.2 below, Ganz discloses that radio frequency (RF) energy is delivered to the bipolar electrodes to generate heat for skin treatment, Ex-1005, [0011], [0048]; Ex-1003 ¶ 78; Ex-1035 ¶ 31. 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. Ex-1003 ¶ 78 (citing Ex-1016, 25; Ex-1017, 22).

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,”

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



Ex-1003 ¶ 80.

As discussed in Sections VIII.A.1.b.1-2 above, Ganz discloses “a plurality of electrodes” and “the electrodes being bipolar.” Ex-1003 ¶ 81; Ex-1035 ¶¶ 30-31.

Moreover, Ganz’s disclosure of bipolar electrodes are *not* limited to the Intracel configuration (alternating rows of commonly-polarized electrodes). Ex-1003 ¶ 82. 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

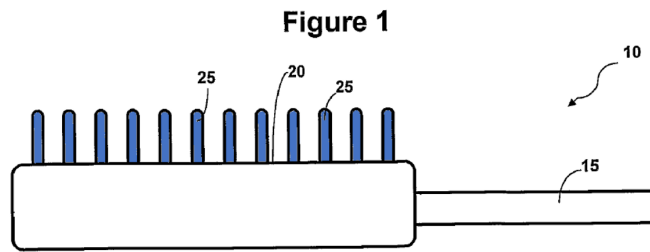
serve as treating electrodes.” Ex-1005, [0056]; *Upsher-Smith Lab ’ys, Inc. v. PamLab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (holding that a prior art reference that disclosed both a composition with antioxidants and a composition without antioxidants anticipated claims that required a composition without antioxidants). For example, a POSITA would understand that other configurations may include a configuration where the positive and negative electrodes are arranged in a checkerboard pattern. Ex-1003 ¶ 82. In such a configuration, the positive and negative electrodes would not have alternating rows of commonly-polarized electrodes. Ex-1003 ¶ 82. A POSITA would understand that such a configuration is better than the Intracel configuration because the energy deposition will be more uniform compared to the Intracel configuration. Ex-1003 ¶ 82.

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”

Ganz discloses that the plurality of electrodes are “configured to [i.e., adapted to] be insertable into skin to be treated.” Ex-1003 ¶ 84; Ex-1035 ¶ 28.

Ganz discloses that “*the electrode pins are placed all the way into the tissue*” to create deep perforations. Ex-1005, [0051] (emphasis added); Ex-1003 ¶ 85. “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].

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

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”**

Ganz alone or in combination with Livneh discloses this limitation. Ex-1003

¶ 88.

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

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.” Ex-1003 ¶ 90; Ex-1035 ¶ 31.

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); Ex-1003 ¶ 91; Ex-1035 ¶ 31. 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], [0058]. 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].

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”

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. Ex-1003 ¶ 93.

As explained below, a POSITA would understand that Ganz’s energy source provides the electrodes with alternating current (AC) having a radio frequency (RF). Ex-1003 ¶ 94. 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]. 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].

As Dr. Bérubé explains, 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. Ex-1003 ¶ 95. 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. Ex-1003 ¶ 95 (citing Ex-

1019, 63; Ex-1020, 150; Ex-1021, 452; Ex-1015, 21; Ex-1023, 128; Ex-1024, 1). 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 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.

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; Ex-1003 ¶ 96. 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).

A POSITA would understand that use of direct current (DC) for skin treatment is undesirable. Ex-1003 ¶ 97. Indeed, an international standard for safety of high frequency surgical equipment, IEC 60601-2-2, prohibits use of DC signals. Ex-1003 ¶98 (citing Ex-1030, 20). 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. Thus, 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.

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.

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]; Ex-1003 ¶ 100. “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).

As discussed in Section VIII.A.1.e below, a POSITA would have been motivated to combine Ganz with Livneh. Ex-1003 ¶ 101.

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.”

Ganz discloses this limitation. Ex-1003 ¶ 103.

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.” Ex-1003 ¶ 105.

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); Ex-1003 ¶ 106; Ex-1035 ¶¶ 28-31. 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].

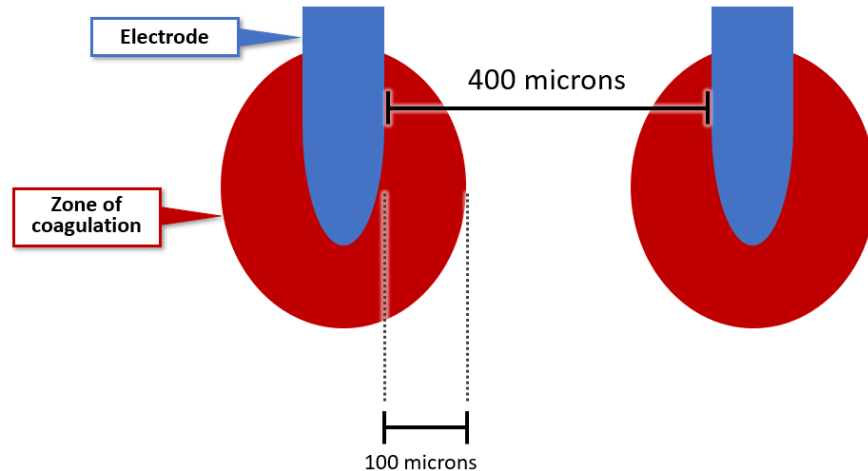
It was well known that inserting small needles into skin creates small holes. Ex-1008, <36>; Ex-1003 ¶ 107; Ex-1035 ¶ 36. “Such perforations are so small that they cannot be seen with the naked eye.” Ex-1005, [0029]. Even the inventor of the ’836 patent, Jongju Na, admitted in another patent application that inserting small needles into skin creates small holes. Ex-1025, claim 3.

As discussed in Section VII.A above, however, Ganz does *not* teach creating perforations to the exclusion of zones of coagulation. Ex-1003 ¶ 108. 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].

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*

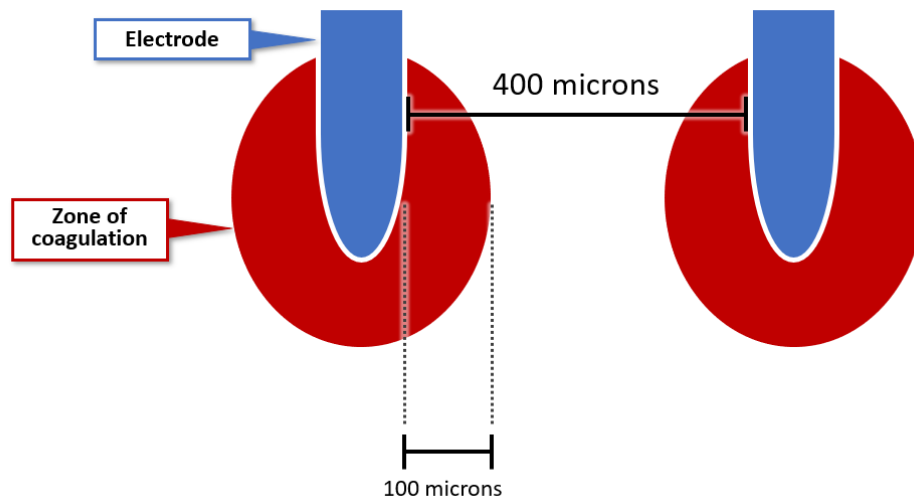
100 microns.”) (emphasis added); Ex-1003 ¶ 109; Ex-1035 ¶¶ 29, 44. Below is an illustration of this embodiment, where electrodes are still in place in perforations.



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).

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. Ex-1003 ¶ 110. 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.”

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. Ex-1003 ¶ 111. 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].”).

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

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. Ex-1003 ¶ 113. 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. Ex-1003 ¶ 113.

(1) Same field of endeavor

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]; Ex-1006, [0032], [0039]; Ex-1003 ¶ 114. In particular, both Ganz and Livneh disclose using bipolar electrodes. Ex-1005, [0056]; Ex-1006, [0039]. Both Ganz and Livneh disclose using heat for skin treatment. Ex-1005, [0030]; Ex-1006, [0002].

(2) Teaching, suggestion, motivation

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; Ex-1003 ¶ 117. As Dr. Bérubé explains, the generation of heat causes collagen denaturation and/or coagulation that are favorable for skin treatment. Ex-1003, Section V.B. 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). Ex-1003 ¶ 117.

(3) Other factors and reasonable expectation of success

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). Ex-1003 ¶ 118. Livneh's power supply was well known in the art to yield predictable results. Ex-1003 ¶ 118.

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). Ex-1003 ¶ 119. 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. Ex-1003 ¶ 119.

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). Ex-1003 ¶ 120. Livneh's power supply was well known in the art to yield predictable results. Ex-1003 ¶ 120.

Livneh's power supply was well known in the art to yield predictable results. Ex-1003 ¶ 121. Because it was well known, a POSITA would have had a reasonable expectation of success in using Livneh's power supply. Ex-1003 ¶ 121.

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.”**

Ganz discloses this limitation. Ex-1003 ¶ 122.

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. Ex-1003 ¶ 123.

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); Ex-1003 ¶ 124; Ex-1035 ¶ 31. 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.

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.”**

Ganz renders this limitation obvious. Ex-1003 ¶ 126.

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”); Ex-1003 ¶ 127. 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. Ex-1003 ¶ 127.

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.” Ex-1003 ¶ 128.

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.”**

Ganz discloses this limitation. Ex-1003 ¶ 130.

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); Ex-1003 ¶ 131; Ex-1035 ¶ 30. That the plurality of electrodes “can also be insulated” shows that the plurality of electrodes are non-insulated by default.

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.”**

Ganz discloses this limitation. Ex-1003 ¶ 133.

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); Ex-1003 ¶ 134. 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. Ex-1003 ¶ 134.

Therefore, Ganz discloses this limitation.

6. Claim 14

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

Ganz discloses the preamble. Ex-1003 ¶ 136.

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”**

Ganz discloses this limitation. Ex-1003 ¶ 139.

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”**

Ganz discloses this limitation. Ex-1003 ¶ 141.

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.”**

Ganz discloses this limitation. Ex-1003 ¶ 143.

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.”**

Ganz discloses this limitation. Ex-1003 ¶ 145.

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.”**

Ganz discloses this limitation. Ex-1003 ¶ 147.

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.”**

Ganz discloses this limitation. Ex-1003 ¶ 149.

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.”**

Ganz discloses this limitation. Ex-1003 ¶ 151.

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

B. Ground III: Claims 2-10, 15-22, and 25 Would Have Been Obvious Based on Ganz in View of Hantash

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 154.

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. Ex-1003 ¶ 155. 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).

Similarly, Hantash discloses a radio frequency (RF) energy source connected to an array of microneedles. Ex-1007, [0014]; Ex-1003 ¶ 156. 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.

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. Ex-1003 ¶ 157.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 159.

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. Ex-1003 ¶ 160. 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).

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]; Ex-1003 ¶ 161. 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].

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. Ex-1003 ¶ 162.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 164.

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

Ganz discloses that “each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin.” Ex-1003 ¶ 165. 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. Ex-1003 ¶ 165.

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

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. Ex-1003 ¶ 166. 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).

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]; Ex-1003 ¶ 167. 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].

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. Ex-1003 ¶ 168.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 170.

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]; Ex-1003 ¶ 171. 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. Ex-1003 ¶ 171.

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

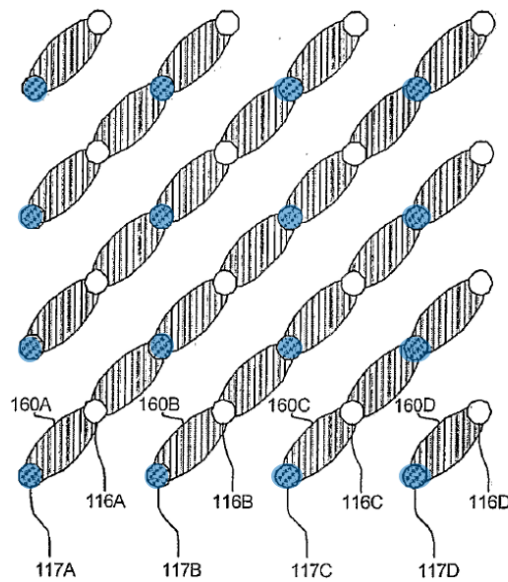


Figure 7A

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. Ex-1003 ¶ 172.

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. Ex-1003 ¶ 173.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 175.

As discussed in Section VIII.B.3 above, Ganz and Hantash renders obvious the skin treatment apparatus of claim 4. Ex-1003 ¶ 176.

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); Ex-1003 ¶ 177; Ex-1035 ¶ 30.

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. Ex-1003 ¶ 177.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 179.

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

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]; Ex-1003 ¶ 180. 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].

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. Ex-1003 ¶ 181.

- (2) “the RF is about 2.0 MHz”**

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); Ex-1003 ¶ 182.

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. Ex-1003 ¶ 183.

Moreover, the ’836 patent does not explain any new and unexpected result from using the claimed RF of “about 2.0 MHz.” Ex-1003 ¶ 184.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 186.

(1) “the RF is about 2.0 MHz”

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); Ex-1003 ¶ 187.

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. Ex-1003 ¶ 188.

Moreover, the '836 patent does not explain any new and unexpected result from using the claimed RF of “about 2.0 MHz.” Ex-1003 ¶ 189.

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

As discussed in Section VIII.A.1.d above, Ganz discloses causing coagulation around each electrode rather than between the electrodes. Ex-1003 ¶ 190. As Dr. Bérubé explains, a POSITA would have known that such coagulation would form an oval shape at the tip of the electrodes because of the “edge effect,” which occurs when high frequency currents flow in an electrode that is not of uniform shape along the length. Ex-1003 ¶ 190.

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

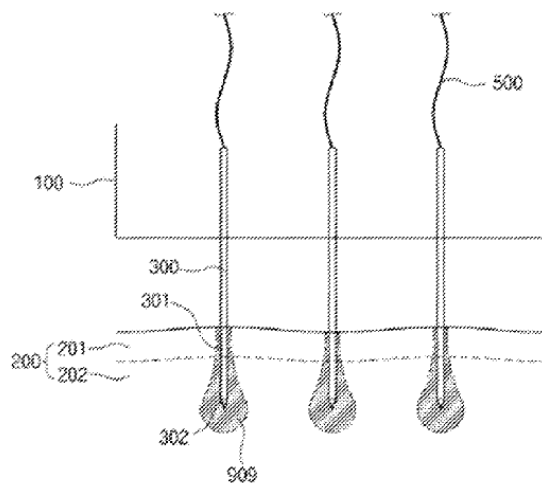


FIGURE 5

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.”); Ex-1003 ¶ 191. 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]; Ex-1007, [0002]. 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.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 193.

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); Ex-1003 ¶ 194. Because Ganz’s electrodes are pins that are inserted into skin to create perforations, they are needles. Ex-1003 ¶ 194. 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).

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]; Ex-1003 ¶ 195. “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].

Hantash discloses that “[i]n a preferred embodiment, the needles 115 are 50 to 300 μm in diameter,” or 0.05 to 0.30 mm. Ex-1007, [0039]; Ex-1003 ¶ 196. 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.”

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. Ex-1003 ¶ 197.

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.” Ex-1003 ¶ 198.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 200.

As discussed in Section VIII.B.8 above, the combination of Ganz and Hantash renders obvious the skin treatment apparatus of claim 9. Ex-1003 ¶ 201.

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]; Ex-1003 ¶ 202.

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. Ex-1003 ¶ 203.

Moreover, the ’836 patent does not explain any new and unexpected result from using the claimed length of “from 1 mm to 4 mm.” Ex-1003 ¶ 204.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 206.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 208.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 210.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 212.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 214.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 216.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 218.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 220.

(1) “the RF is from 0.5 to 10 Mhz”

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); Ex-1003 ¶ 221.

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. Ex-1003 ¶ 222.

Moreover, the ’836 patent does not explain any new and unexpected result from using the claimed RF of “from 0.5 to 10 Mhz.” Ex-1003 ¶ 223.

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

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]; Ex-1003 ¶ 224. 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].

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. Ex-1003 ¶ 225.

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.”**

The combination of Ganz and Hantash renders this limitation obvious. Ex-1003 ¶ 227.

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

19. Motivation to Combine Ganz and Hantash

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. Ex-1003 ¶ 229; Ex-1035 ¶¶ 28-31. 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. Ex-1003 ¶ 229.

a) Same field of endeavor

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]; Ex-1007, [0002]; Ex-1003 ¶ 230. Both Ganz and Hantash disclose that RF energy from electrodes generates heat that improves skin condition. Ex-1005, [0030]; Ex-1007, [0035]. 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.

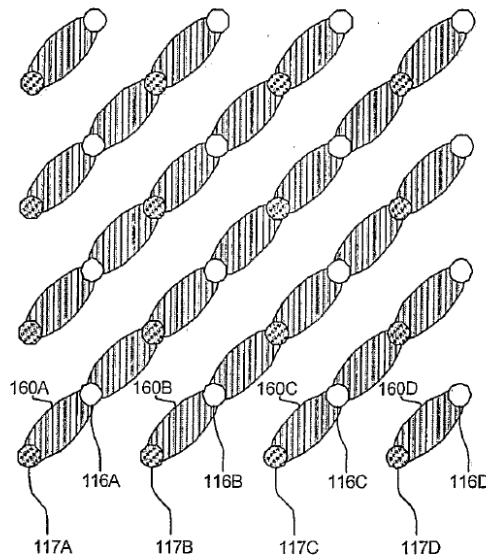


Figure 7A

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 Dr. Bérubé explains, applying heat causes collagen denaturation and applying even more heat causes collagen coagulation. Ex-1003, Section V.B. 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. Ex-1003 ¶ 231. 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

A POSITA would have been motivated to apply Hantash's pulse duration to Ganz's device in order to avoid generating too much heat. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-19 (2007); Ex-1003 ¶ 232. 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. Ex-1003 ¶ 232. 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

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. Ex-1003 ¶ 233. 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

A POSITA would have been motivated to apply Hantash’s RF range to Ganz’s device based on the desired treatment zone profile. Ex-1003 ¶ 234. 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

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. Ex-1003 ¶ 235. 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

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. Ex-1003 ¶ 236. 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]. 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) Other factors and reasonable expectation of success

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). *KSR*, 550 U.S. at 416; Ex-1003 ¶ 237. Hantash’s RF and needle parameters were well known in the art to yield predictable results. Ex-1003 ¶ 237.

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). *KSR*, 550 U.S. at 417; Ex-1003 ¶ 238. Hantash's RF and needle parameters were well known in the art. Ex-1003 ¶ 238. Using those parameters would have improved Ganz's device in the same way they were beneficial for Hantash's device. Ex-1003 ¶ 238.

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). *KSR*, 550 U.S. at 417; Ex-1003 ¶ 239. Hantash's RF and needle parameters were well known in the art to yield predictable results. Ex-1003 ¶ 239.

Hantash's RF and needle parameters were well known in the art to yield predictable results. Ex-1003 ¶ 240. Because they were well known, a POSITA would have had a reasonable expectation of success in using Hantash's RF and needle parameters. *KSR*, 550 U.S. at 417; Ex-1003 ¶ 240.

C. Ground IV: Claims 2-10, 15-22, and 25 Would Have Been Obvious Based on Ganz in View of Livneh and Hantash

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. Ex-1003 ¶ 241.

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. Ex-1003 ¶ 242. Therefore, Ganz in combination with Livneh and Hantash renders obvious claims 2-10, 15-22, and 25.

D. Ground V: Claims 27-29 Would Have Been Obvious Based on Ganz in View of Lee

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.”**

The combination of Ganz and Lee renders this limitation obvious. Ex-1003 ¶ 244.

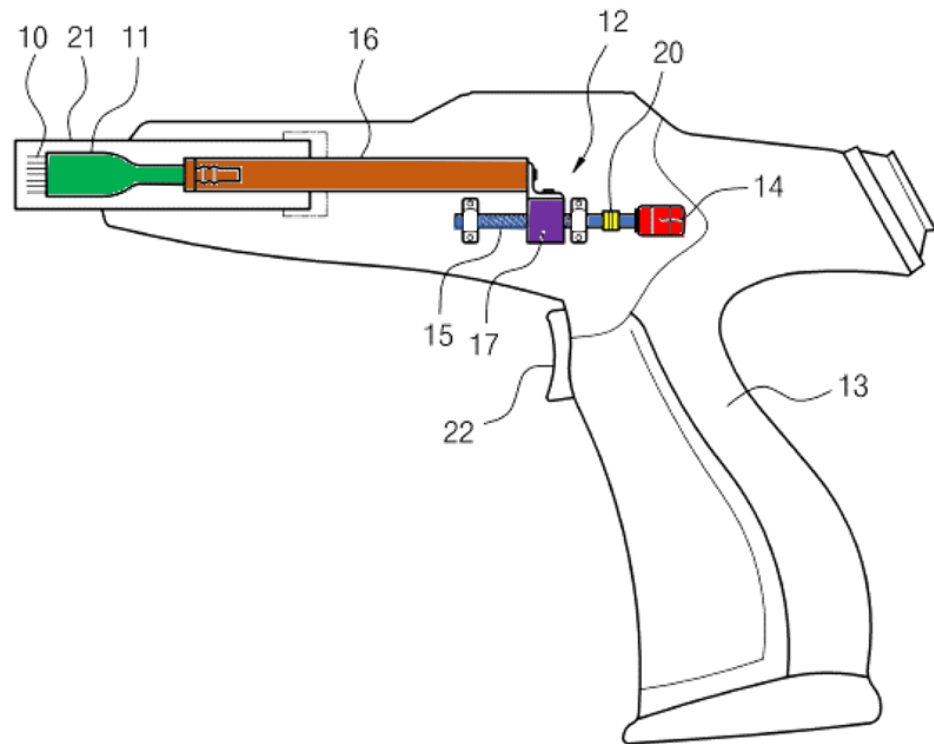
Ganz discloses that the plurality of electrodes are inserted into skin to be treated. Ex-1005, [0051]; Ex-1003 ¶ 245; Ex-1035 ¶ 28-32, 36, 40. Ganz also discloses that the depth with which that the plurality of electrodes are inserted into skin is controlled. Ex-1005, [0051].

Like Ganz, Lee discloses that microneedles are inserted into skin to be treated. Ex-1008, <13>; Ex-1003 ¶ 246.

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.*”) (emphasis added);

Ex-1003 ¶ 247. 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). A slider 17 (purple) is coupled to the screw electric motor axis 15 (blue). Ex-1008, <47>. “[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>.

As discussed in Section VIII.D.4 below, a POSITA would have been motivated to use Lee’s actuator for Ganz’s electrodes. Ex-1003 ¶ 249.

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.”**

The combination of Ganz and Lee renders this limitation obvious. Ex-1003 ¶ 251.

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.” Ex-1003 ¶ 252.

Lee further discloses a mode switch, which corresponds to “a user interface to enable a user to select the depths.” Ex-1003 ¶ 253. 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).

As discussed in Section VIII.D.4 below, a POSITA would have been motivated to use Lee’s mode switch for Ganz’s electrodes. Ex-1003 ¶ 254.

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.”**

The combination of Ganz and Lee renders this limitation obvious. Ex-1003 ¶ 255.

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.” Ex-1003 ¶ 256.

Ganz further discloses moving the electrodes “from an epidermis region to an adjacent dermis region of skin to be treated.” Ex-1003 ¶ 257. 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].

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

4. Motivation to Combine Ganz and Lee

Ganz discloses RF electrodes for skin treatment, where the RF electrodes are inserted into skin at varying depths so that RF energy is delivered to the dermis

portion of the skin. Ex-1003 ¶ 259. 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. Ex-1003 ¶ 259.

a) Same field of endeavor

Both Ganz and Lee disclose creating perforations with electrodes for skin treatment. Ex-1005, [0051]; Ex-1008, <13>; Ex-1003 ¶ 260.

b) Teaching, Suggestion, Motivation

A POSITA would have been motivated to use Lee's actuator for Ganz's device in order to enable precise, customized treatments. Ex-1003 ¶ 261. 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>.

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. Ex-1003 ¶ 262. 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. Ex-1003 ¶ 262.

c) Other factors and reasonable expectation of success

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). Ex-1003 ¶ 263. 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. Ex-1003 ¶ 263.

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). Ex-1003 ¶ 264. 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. Ex-1003 ¶ 264.

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). Ex-1003 ¶ 265. 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. Ex-1003 ¶ 265.

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. Ex-1003 ¶ 266. 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. Ex-1003 ¶ 266.

E. Ground VI: Claims 27-29 Would Have Been Obvious Based on Ganz in View of Livneh and Lee

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. Ex-1003 ¶ 267.

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. Ex-1003 ¶ 268. Therefore, Ganz in combination with Livneh and Lee renders obvious claims 27-29.

IX. DISCRETIONARY DENIAL IS NOT WARRANTED

The Board should not exercise its discretion to deny institution under 35 U.S.C. §§ 314 or 325. The district court actions involving Petitioner and Petitioner's distributors of products accused of infringement of the '836 patent have been stayed. This Petition presents compelling evidence of non-patentability based on entirely new prior art, expert testimony, and arguments. No Ground involves "roadmapping" from the outcome in the Cartessa Aesthetics IPR. And—perhaps most importantly—institution would further "the Board's mission to improve patent quality." *Code 200, UAB et al v. Bright Data Ltd.*, IPR2022-00861, -00862, 2022 WL 3646167, at *3 (P.T.A.B. August 23, 2022) (precedential).

A. The Board Should Not Exercise Its Discretion to Deny Institution Under 35 U.S.C. § 314(a)

The existence of a parallel ITC proceeding should not be a factor for consideration in determining whether the Board may exercise its discretion to deny institution. Vidal, K., Memorandum—Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation, USPTO (June 21, 2022) ("Interim Procedure") at 6-7 ("The PTAB will not discretionarily deny petitions based on applying *Fintiv* to a parallel ITC proceeding").

Neither Petitioner is a named defendant in any pending litigation. All district court litigation in which Patent Owner asserts Petitioner's products are infringing has been stayed. Exs. 1032, 1033. There have been no Scheduling Conferences,

and no trial dates have been set. Exs. 1032, 1033. The Board will issue a final written decision in this IPR long before any such litigation would go to trial, and, accordingly, whatever estoppel effect this IPR has, if any, would go into effect then. Therefore, the Board should not discretionarily deny institution of IPR in view of any parallel proceeding. *See* Interim Procedure at 7.

This Petition presents exceptionally compelling evidence of unpatentability. Under § 314(a), there is far more than a “reasonable likelihood that the petitioner would prevail.” Refusing to grant the petition “would undercut the congressional grant to the United States Patent and Trademark Office of significant power to revisit and revise earlier patent grants as a mechanism to improve patent quality and restore confidence in the presumption of validity that comes with issued patents.” *Code200*, 2022 WL 3646167, at *2 (internal quotations omitted). The “AIA was designed to encourage the filing of meritorious patentability challenges, by any person who is not the patent owner.” *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, IPR2015-01092, Paper 19 at 4 (P.T.A.B. Sept. 25, 2015); Interim Procedure at 4-5 (clarifying, where there is compelling evidence of unpatentability, “the PTAB should not discretionarily deny institution under *Fintiv*”).

General Plastic Indus. v. Canon Kabushiki Kaisha, IPR2016-01357, Paper 19 at 15-19 (P.T.A.B. Sept. 6, 2017) (precedential) (“*General Plastic*”) and its progeny also do not apply. This is an exceptionally strong petition, and neither Petitioner was

a real party in interest or in privity with the petitioner in the earlier Cartessa Aesthetics IPR. *See Illumina v. Ravgen*, IPR2021-01271, Paper 12, at 15-20 (P.T.A.B. Jan. 26, 2022). Neither Petitioner has a “significant relationship” with Cartessa Aesthetics, had control over the Cartessa Aesthetics IPR, participated or provided input into the Cartessa Aesthetics IPR, or had knowledge of it prior to its being filed. *See Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062, Paper 11 at 2, 10 (P.T.A.B. Apr. 2, 2019); *Toyota Motor Corp. v. Intellectual Ventures II*, IPR2022-00708, Paper 12, at 10 (P.T.A.B. Oct. 12, 2022). Petitioner filed the present petition on their own behalf and as the real parties in interest, and not “at the behest of [anyone else].” *See Western Digital Techs. Inc. v. Viasat, Inc.*, IPR2022-01126, Paper 13, at 15 (P.T.A.B. Nov. 29, 2022).

Of great significance, Petitioner is not using the earlier proceedings as a “roadmap” here. Petitioner employs entirely different art, different arguments and different experts. They make no use of the art, argument, responses, or holdings in the Cartessa Aesthetics IPR to “refine” failed arguments there. *Toyota Motor*, IPR2022-00708, Paper 12, at 10 (quoting *Code200*) (“[F]actors 1-3 only weigh in favor of discretionary denial when there are ‘road-mapping’ concerns under factor 3 or other concerns under factor 2.”).

This is Petitioner’s first petition for IPR of the ’836 patent and the timing of its filing involves no improper gamesmanship. *Netflix, Inc. et al. v. Uniloc 2017 LLC*,

IPR2020-00041, Paper 10, at 12 (P.T.A.B. Mar. 25, 2020) (holding factor 2, 4, and 5 do not weigh in favor of denying institution). This Petition should be granted because it presents new and strong evidence of unpatentability of claims 1-29 “by a different petitioner..., applying substantially different prior art, based on substantially different arguments,” and thus “cannot be said to be wasteful of resources of the Board.” *Western Digital Corp. v. SPEX Techs., Inc.*, IPR2018-00082, 2018 WL 1990246, at *9 (P.T.A.B. Apr. 25, 2018); *see also Code200*, IPR2022-00861, 2022 WL 3646167, at *3 (factor 6 must consider Board’s mission to improve patent quality); Interim Procedure at 2 (should not discretionarily deny institution where “petition presents compelling evidence of unpatentability”).

B. The Board Should Not Exercise Its Discretion to Deny Institution Under 35 U.S.C. § 325(d)

The Petition also involves substantially different prior art than previously considered by the Patent Office. Under 35 U.S.C. § 325(d), “[i]n determining whether to institute...the Director may take into account whether...the same or substantially the same prior art or arguments previously were presented to the Office.” That Section does not apply here because the prior art references used herein are new and different from any prior art considered earlier. Accordingly, the arguments presented here are entirely new and different from any presented earlier.

Under § 325(d), the Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented to the Office

or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics, LLC v. Med-el Elektromedizinische Geräte GmbH*, IPR2019-01469, 2020 WL 740292, at *3 (P.T.A.B. Feb. 13, 2020) (precedential). In this case, these factors counsel for the grant of the petition.

None of Ganz, Livneh, Hantash, or Lee was of record in the original examination or earlier Cartessa Aesthetics IPR. These references provide compelling new evidence of anticipation and obviousness that demands consideration by the Office. None of this new evidence is cumulative or overlaps with any art or arguments presented earlier. These factors strongly argue in favor of institution of IPR.

X. CONCLUSION

Petitioner respectfully requests *inter partes* review and cancellation of claims 1-29 of the '836 patent.

Respectfully submitted,

Dated: January 8, 2024

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CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that the foregoing complies with the type-volume limitation of 37 C.F.R. § 42.24 and contains 13,806 words based on the word count indicated by the word-processing system used to prepare the paper, and excluding those portions exempted by § 42.24(a).

Date: January 8, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.105, I hereby certify that on January 8, 2024, I caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 9,480,836 supporting exhibits, and Power of Attorney to be served via Priority Mail Express on the Patent Owner at the following correspondence address of record as listed on the USPTO Patent Center:

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