

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUMENIS LTD. and POLLOGEN LTD.
Petitioner

v.

THE GENERAL HOSPITAL CORPORATION
Patent Owner

Case IPR2019-01181
Patent 9,510,899

EXPERT DECLARATION OF ROBERT E. GROVE, PH.D.

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Lumenis Ex. 1006
U.S. Patent No. 9,510,899

***Inter Partes* Review of U.S. Patent No. 9,510,899**
Expert Declaration of Robert E. Grove, Ph.D.
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I, Robert E. Grove, declare as follows:

I. Overview and Summary of Opinions

1. I am over the age of eighteen (18) and competent to make this declaration.

2. I have been retained as an expert witness on behalf of Lumenis Ltd. and Pollogen Ltd. (collectively “Lumenis”) for the above-captioned *inter partes* review (“IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$750 per hour. My compensation is not contingent upon the outcome of this IPR. I understand that the petition for IPR involves U.S. Patent No. 9,510,899 (Ex. 1001, “the ’899 patent”) titled “Method and Apparatus for Dermatological Treatment and Tissue Reshaping.” The ’899 patent, which issued on December 6, 2016 from U.S. Application No. 14/458,644, names Dieter Manstein as the sole inventor. (’899 patent, Cover Page.) I further understand that according to the USPTO records, the ’899 patent is currently assigned to The General Hospital Corporation. I understand that the earliest possible priority date for the ’899 patent is April 1, 2004.

3. I have been asked to provide my independent technical review, analysis, insights, and opinions regarding the ’899 patent and the references that form the basis for the grounds of rejection set forth in the petition for IPR of the ’899 patent. In preparing this declaration, I have reviewed the ’899 patent and its file history

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(Ex. 1002, “’899 PH”; Ex. 1003, “’357 PH”; Ex. 1004, “’394 PH”; Ex. 1005, “’476 Provisional”), and I have considered each of the documents cited herein, in light of general knowledge in the art (i.e., field) before April 2004. In formulating my opinions, I have relied upon my more than 35 years’ experience, education, and knowledge in the relevant art. In formulating my opinions, I have also considered the viewpoint of a person of ordinary skill in the art (“POSA”) before April 1, 2004. I am familiar with the technology described in the ’899 patent and the state of the art as of its earliest possible priority date, April 1, 2004. A summary of my opinions follows.

4. The ’899 patent claims a skin treatment device that includes a housing with a plurality of needles configured to be inserted into the dermal layer of the skin and a controller to control delivery of radiofrequency (“RF”) energy to the needles. The needles transmit RF energy into the dermal layer to induce a pattern of fractional damage and stimulate formation of new collagen in the skin.

5. As discussed in this Declaration, the prior art taught all of the features of the ’899 patent’s claimed skin treatment device. And as further discussed in this Declaration, before the earliest claimed priority date of the ’899 patent (April 1, 2004), a person of ordinary skill in the art would have had a reason to combine the prior art references to arrive at the claimed skin treatment device and in so doing, they would have had a reasonable expectation of success.

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6. Claims 1-2, 4, 6-7, 10-11, 15, and 20-21 of the '899 patent would have been obvious in view of the disclosures of U.S. Patent No. 6,277,116 to Utely *et al.* (Ex. 1008, "Utely") and PCT Publication No. WO 02/053050 to Altshuler *et al.* (Ex. 1009, "Altshuler"). Utely disclosed a skin treatment device that uses needles extending from a housing and into the dermis to transmit RF energy "to the dermis in a targeted, selective fashion, to dissociate and contract collagen tissue." (Utely, 4:26-30, 7:56-58, FIG. 7.) Utely's device included a controller that "governs the power levels, cycles, and duration that the radio frequency energy is distributed... to achieve the desired treatment objectives." (*Id.*, 4:64-5:1.) Moreover, Utely's device was capable of "form[ing] defined energy application patterns." (*Id.*, 8:24-28.) Altshuler taught a fractional damage pattern by teaching the "use of spatially confined and concentrated EMR to create areas of treatment or damage substantially surrounded by areas of sparing." (Altshuler, 1:8-11.)

7. As discussed herein, a POSA would have had a reason to combine Utely and Altshuler. Specifically, Altshuler taught that "treatments which are performed over a relatively large area, such as skin rejuvenation and hair removal... can cause varying degrees of skin damage over a substantial treatment area," which "can frequently take several weeks or more to heal." (*Id.*, 1:28-2:1.) Accordingly, Altshuler taught that performing the procedures "in a manner which would result in smaller, spaced areas of damage which heal more quickly" would "enhanc[e]

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both patient comfort and the ability to more quickly perform follow-up treatments.” (*Id.*, 2:1-4.) At the same time, Altshuler taught that “such treatments can be *more effectively performed* by heating selective portions 214, with perhaps a 30% to 50% fill factor, resulting in *significant collagen regeneration* with *less trauma and pain* to the patient.” (*Id.*, 18:29-19:2 (emphasis added).) A POSA would have wanted to improve both treatment outcomes and patient experience by implementing Altshuler’s fractional damage pattern with Utely’s device.

8. Moreover, as discussed herein, a POSA reading Utely and Altshuler would have had a reasonable expectation of successfully arriving at the claimed invention by using Utely's controller to achieve Altshuler's fractional damage pattern because Altshuler expressly taught that its teachings could be used in an RF system, such as Utely’s. (*Id.*, 10:11-24.) And a POSA would have understood that achieving Altshuler’s fractional damage pattern was simply a matter of varying energy parameters, which Utely disclosed were governed by its controller. Using Utely’s controller to achieve Altshuler’s fractional damage pattern with Utely’s RF needle system could have been done using only ordinary skill. As discussed herein, there are no objective indicia of nonobviousness. Thus, claims 1-2, 4, 6-7, 10-11, 15, and 20-21 would have been obvious in view of Utely and Altshuler.

9. Claims 9, 12, 17, and 23 would have been obvious in view of the disclosures of Utely, Altshuler, and U.S. Publication No. 2004/0162551 to Brown

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et al. (Ex. 1010, “Brown”). Brown disclosed a spacer with holes through which needles are configured to move between an extended position and a retracted position. (Brown, ¶[0054], FIGS. 8-9.) Brown also disclosed a motion-inducing device, such as a transducer, to vibrate its needles. (*Id.*, ¶¶[0070], [0071], FIG. 17A.)

10. As discussed herein, a POSA would have had a reason to combine Utely, Altshuler, and Brown. A POSA would have modified Utely with Altshuler’s teachings for the reasons discussed above. Additionally, a POSA would have had a reason to combine Brown’s teachings with Utely and Altshuler for safety (e.g., by providing a retracted position for the needles) and to aid in needle insertion (e.g., by vibrating the needles). Moreover, as discussed herein, a POSA would have had a reasonable expectation of success in implementing Brown’s features into Utely’s device. Thus, claims 9, 12, 17, and 23 would have been obvious in view of Utely, Altshuler, and Brown.

11. Claims 1-2, 4, 6, 10-11, 15-16, and 20-22 of the ’899 patent would have been obvious in view of the disclosures of U.S. Publication No. 2002/0087155 to Underwood *et al.* (Ex. 1011, “Underwood”) and PCT Publication No. WO 2005/007003 to Debendictis *et al.* (Ex. 1012, “Debendictis”). Underwood disclosed a skin treatment device that uses needles extending from a housing into the dermis to “create a heat injury to a target tissue within the patient’s dermis

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layer” and “stimulate the growth of neo-collagen in the tissue layers underlying the epidermal tissue.” (Underwood, ¶¶[0029]-[0030], [0035], [0051], FIGS. 1, 6.) Underwood’s device included “[a] controller ... connected to a control input of the switching power supply for adjusting the generator output power by supply voltage variation.” (*Id.*, ¶[0038].) Debendictis taught “intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue.” (Debendictis, ¶[0014].)

12. As discussed herein, a POSA would have had a reason to combine Underwood and Debendictis. Specifically, Debendictis taught that its fractional damage pattern “offers numerous advantages over existing approaches in terms of safety and efficacy,” both “minimiz[ing] the undesirable side effects” and “stimulat[ing] the tissue’s wound repair system, by sparing healthy tissue around the thermally altered tissue, whereby the repair process is more robust.” (*Id.*) A POSA would have wanted to improve both treatment outcomes and patient experience by implementing Debendictis’s fractional damage pattern with Underwood’s device.

13. Moreover, as discussed herein, a POSA reading Underwood and Debendictis would have had a reasonable expectation of successfully arriving at the claimed invention by using Underwood’s controller to achieve Debendictis’s fractional damage pattern. Underwood disclosed that its controller “adjust[s] the generator output power by supply voltage variation” and that its system is

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equipped with an input system that “allows the surgeon to remotely adjust the energy level applied to” its electrodes. (Underwood, ¶¶[0038], [0035].) And Underwood taught to confine the current “to the immediate region around the electrodes which is the target area of the dermis 166” and to use additional electrodes “advanced into the patient’s skin to more precisely control the heat injury within the dermis.” (*Id.*, ¶¶[0054], [0015].) Accordingly, a POSA would have recognized Underwood’s device as a suitable system for applying Debendictis’s teachings. As discussed herein, there are no objective indicia of nonobviousness. Thus, claims 1-2, 4, 6, 10-11, 15-16, and 20-22 would have been obvious in view of Underwood and Debendictis.

14. Claims 9, 12, 17, and 23 would have been obvious in view of the disclosures of Underwood, Debendictis, and Brown. Brown disclosed a spacer with holes through which needles are configured to move between an extended position and a retracted position. (Brown, ¶[0054], FIGS. 8-9.) Brown also disclosed a motion-inducing device, such as a transducer, to vibrate its needles. (*Id.*, ¶¶[0070], [0071], FIG. 17A.)

15. As discussed herein, a POSA would have had a reason to combine Underwood, Debendictis, and Brown. A POSA would have modified Underwood with Debendictis’s teachings for the reasons discussed above. Additionally, a POSA would have had a reason to combine Brown’s teachings with Underwood

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and Debendictis for safety (e.g., by providing a retracted position for the needles) and to aid in needle insertion (e.g., by vibrating the needles). Moreover, as discussed herein, a POSA would have had a reasonable expectation of success in implementing Brown's features into Underwood's device. Thus, claims 9, 12, 17, and 23 would have been obvious in view of Underwood, Debendictis, and Brown.

16. Further, I have reviewed the '899 patent file history and did not see any evidence of objective indicia of nonobviousness. And I am not otherwise aware of any publicly available evidence of objective indicia of nonobviousness that would support patentability of the claims of the '899 patent.

17. Therefore, I conclude that the challenged claims would have been obvious in view of the disclosures in the prior art references.

II. My Background and Qualifications

18. I am an expert in the field of treatment systems for delivery of electromagnetic radiation to skin or other tissues. I have been an expert in this field since well before 2004. I have been involved in the design, development, clinical research, and commercialization of medical devices for aesthetic dermatologic applications for over thirty-five years.

19. I received a B.S. in Engineering Physics from Cornell University in 1970 and graduated as salutatorian of the entire engineering class. The following year I received an M.S. in Aeronautics and Astronautics from MIT. In 1975 I received a

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Ph.D. in Instrumentation, specifically in the field of laser applications, from MIT. I also completed post-graduate training in 1976 at MIT as the head research associate in the research laboratory of Professor Shaoul Ezekiel.

20. After completing my academic training, I worked from 1976 to 1981 for Lawrence Livermore National Laboratory (“LLNL”) as a project leader. I directed Copper Laser Development for the Atomic Vapor Laser Isotope Separation Program. My team developed the largest laser pump source ever built for pulsed dye lasers.

21. In 1981, I left LLNL and co-founded the world’s first commercial copper vapor laser company, Plasma Kinetics, Inc. I was the President and CEO of the company. While leading Plasma Kinetics, I sold the company’s first laser for dermatology research to Leon Goldman, M.D., now considered universally as the father of laser medicine. Dr. Goldman was the co-founder of the American Society for Lasers in Medicine and Surgery in 1980. Three years after I co-founded Plasma Kinetics, the company was acquired by Cooper LaserSonics, Inc. where I continued working until 1987 as President of the Laser Products Division. Our team focused on identifying innovative procedures, such as laser treatment of port-wine stain (PWS) hemangiomas. At that time, there was a pressing need to find a way to improve the appearance of these red, disfiguring birthmarks. The lesions most often occur on the face and neck, affecting about 0.3% of births, with

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devastating impact to the family. Treatment methods at that time, including skin grafting and treatment with continuous-wave argon lasers, inevitably resulted in severe scarring and a lack of improvement, if not worsening, of the cosmetic outcome. Thus, there was an intense effort to find an effective treatment for PWS.

22. During the mid- to late-80's, an Australian laser surgeon named Dr. Adrianna Scheibner pioneered a treatment method that was ultimately shown to provide essentially complete clearing of PWS without scarring. The procedure involved focusing the argon laser beam, typically a few millimeters or more in diameter, to a micro-spot of perhaps 100 microns (0.1 mm) and tracing over each of the microvessels, which were visible to the physician through head-mounted magnifiers. Since the laser micro-spot was continuously moved, each spot received a brief "pulse" of thermal energy from the laser. The microvessels would then coagulate in a microscopically thin line, with less-heated (or un-heated) tissue on either side of the destroyed microvessel.

23. The work by Dr. Scheibner in 1985-1990 may very well have been the first successful so-called "fractional" treatment of skin. To pursue this particularly promising avenue of PWS research, I left LaserSonics in 1987 to form another company, DermaCare, Inc.

24. DermaCare was one of the first laser med-spas in the United States, specializing in the laser treatment of PWS and other vascular abnormalities. There,

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the physicians implemented the Scheibner method for treatment of PWS. As President and CEO of DermaCare, I directed operation of two clinics in Southern California and became familiar with a wide variety of various skin treatment procedures and devices, including pulsed lasers for PWS as well as Q-switched lasers for tattoo removal. I continued with DermaCare until 1991.

25. In 1993, I again co-founded a company in the aesthetic skin treatment industry called Star Medical Technologies, Inc. We developed, manufactured, and marketed the first successful FDA-cleared laser hair removal system, known as the *LightSheerTM*. The system achieved remarkable therapeutic benefits by generating localized heating through selective absorption of optical radiation. Specifically, for the hair removal application, laser energy is applied over a large area; but with the proper wavelength of light, heating occurs only in the hair shaft and follicle due to the absorption of that EMR by melanin, which causes localized non-uniform heating.

26. I served as President and CEO of Star Medical until it was acquired in 1999 by Coherent Medical Group (CMG), the world's largest medical laser company at the time. I continued to work on the *LightSheerTM* business as President of the Coherent Star subsidiary of Coherent Medical until 2001, when CMG was acquired by the Israeli company ESC. The combined companies now

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operate under the name Lumenis, one of the largest manufacturers of lasers and other energy-based devices (EBD) for dermatologic applications.

27. I co-founded yet another company, TRIA Beauty Inc., in 2003 to develop, manufacture, and market consumer laser devices for permanent hair removal, acne, and facial wrinkle treatment at home. I served as the CEO from 2003 to 2008 and as the CTO from 2009 to 2010. The founding principle of TRIA was to incorporate EBD technologies utilized daily in the dermatologists' offices into much smaller, lower-cost devices suitable for use by consumers at home. At TRIA, we developed and marketed a fractional laser device for home use incorporating a near-infrared laser for the removal of fine lines and wrinkles. This TRIA consumer laser device is still sold today for treatment of fine lines and wrinkles.

28. After my time at TRIA Beauty, I founded two more companies. In 2011 I founded Once Again Me, Inc. and served as its President and CEO. There I created an over-the-counter laser beauty device based on the same process of creating fractional damage to the skin to improve appearance, but with an even lower-cost design. This company was acquired by TRIA Beauty in December 2011. In 2012 I founded Intellectual Light, Inc. ("ILI") and served as its President and CEO. At ILI, I developed a new laser diode source for over-the-counter

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devices that is especially well-suited to the development of low-cost non-ablative fractional laser devices for home use. I continued with ILI until 2017.

29. From 2013 to 2016, I also directed a start-up company, ON Light Sciences, Inc., as its Executive Chairman. ON Light Sciences developed transparent gel patches for accelerated tattoo removal with short-pulse lasers. The company was acquired in 2017 by Merz, a dermatology company in Germany with annual sales of over \$1 billion.

30. Over the course of my career, I have worked with several companies directly involved in skin treatment devices and methods. In addition to the companies described above, I have also served as a consultant, advisor, and Board member for several different companies in the skin treatment industry. From 1990 to 1993 I consulted with JLE Associates, where I worked with two other laser experts to formulate a plan for a new laser business. From 2014 to 2018, I consulted for Arbonne International LLC, where we conceived, designed, and developed a novel, home-use ultrasound device for application of topicals to the skin. In 2018 I was appointed to Arbonne's Scientific Advisory Board.

31. In 2014 I was an Independent Director for Ellman International, Inc., a leading manufacturer of advanced radio-frequency (RF) products used around the world for precision surgical and aesthetic dermatologic procedures.

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32. Over the years I have also been involved with American Society for Laser Medicine and Surgery, Inc. (“ASLMS”). For example, I was elected to the position of Industry Research and Development Representative in 1995. I served in this position until 1998 and again from 2008 to 2011 when I was elected to a second term. At the Society’s 39th Annual Conference, I received a Presidential Citation Award, including a plaque with the text “For your tireless commitment to upholding and applying the highest scientific and ethical standards in developing and actualizing novel, useful lasers and energy-based devices to serve the public good.” (Denver, Colorado – March, 2019.)

33. Since 2017 I have served as an advisor to the CEO and minor shareholder of Joylux, Inc. Joylux is an early-stage company developing and marketing the world’s first home-use device for women’s intimate wellness incorporating photobiomodulation and thermal energy. While seemingly a departure from my career in dermatology, in fact, many dermatologists have purchased energy-based systems to treat a variety of gynecologic issues due to the similarity of response of vaginal and dermal tissue to the application of optical or RF electromagnetic radiation.

34. Since 2017, I have also served as an advisor to the CEO and more recently as a director and minor shareholder of Candasant, Inc. Candasant is an early-stage company developing a safe, in-office, non-drug solution to

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hyperhidrosis, and other less-severe forms of excessive sweating. The Candasant device incorporates an alkali-metal patch applied to an underarm previously dried with an alcohol wipe. Sweat ducts (like hair follicles) cover only a very small portion of the skin and have a characteristic diameter of the order of $\sim 100\ \mu\text{m}$. When perspiration (water) reappears at the duct opening on the surface of the skin, a reaction between the alkali metal and the water produces very localized, non-uniform heating, which disables the duct for four to six weeks. The remainder of the skin surface is unaffected.

35. I also currently serve as an Independent Director for IRIDEX Corporation, an industry-leading ophthalmic laser manufacturer. I began serving in this position in October of 2018.

36. In addition to my personal experience developing medical devices for aesthetic dermatologic applications for over thirty-five years, I was also aware of other energy-based devices, including RF-based devices, that were used in the aesthetic dermatology field. My laser-based experience is directly applicable to the use of other forms of electromagnetic radiation for skin treatment. In particular, the damage, and damage patterns, caused by different forms of electromagnetic radiation, like RF energy, are similar. And the body responds in similar ways to the damage. People in this field (including myself) understood that laser and RF devices simply operate at different frequencies in the electromagnetic radiation

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spectrum. Thus, a specific treatment technique used in a laser skin treatment is often transferable to other devices that employ different types of electromagnetic radiation.

37. In summary, I have more than 35 years of industry experience designing, testing, and developing laser and other energy-based skin treatment devices and procedures. I am named as an inventor on 25 patents and 30 published applications, many of which relate to skin treatment devices and methods as listed in my curriculum vitae (Ex. 1007, “Grove CV”). Thus, throughout my career, I have had extensive experience with various devices and methods used to treat skin conditions and in particular with those used for cosmetic treatment of the skin (e.g., to address skin wrinkles and other defects).

38. In view of my education, experience, and expertise described above and set forth in my CV, I am an expert in the field of treatment systems for delivery of electromagnetic radiation energy to skin or other tissues.

III. List of Documents I Considered in Formulating My Opinions

39. In formulating my opinions, I considered all of the references cited in this Declaration, including the documents listed below. The information contained in the exhibits below is the type of information an expert in the field of treatment systems for delivery of electromagnetic radiation to skin or other tissues would reasonably rely upon when forming opinions.

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Exhibit No.	Description
1001	U.S. Patent No. 9,510,899 B2 to Manstein (“899 patent”)
1002	Prosecution History of U.S. Patent No. 9,510,899 (“899 PH”)
1003	Prosecution History of U.S. Patent No. 9,095,357 (“357 PH”)
1004	Prosecution History of U.S. Patent No. 7,824,394 (“394 PH”)
1005	U.S. Provisional Application No. 60/558,476 (“476 Provisional”)
1007	Dr. Robert E. Grove Curriculum Vitae (“Grove CV”)
1008	U.S. Patent No. 6,277,116 B1 to Utely <i>et al.</i> (“Utely”)
1009	WO Publication No. 02/053050 A1 to Altshuler <i>et al.</i> (“Altshuler”)
1010	U.S. Patent Application Publication No. 2004/0162551 to Brown <i>et al.</i> (“Brown”)
1011	U.S. Patent Application Publication No. 2002/0087155 A1 to Underwood <i>et al.</i> (“Underwood”)
1012	WO Publication No. 2005/007003 A1 to Debendictis <i>et al.</i> (“Debendictis”)
1013	U.S. Patent No. 6,126,657 to Edwards <i>et al.</i> (“Edwards”)
1014	Orentreich, David, <i>et al.</i> , “Subcutaneous Incisionless (Subcision) Surgery for the Correction of Depressed Scars and Wrinkles,” <i>Elsevier Science Inc.</i> (1995) (“Orentreich”)
1015	Pozner, Jason N., <i>et al.</i> , “Nonablative Laser Resurfacing: State of the Art 2002,” <i>Aesthetic Surgery Journal</i> , Vol. 22, No. 5, <i>Scientific Forum</i> (2002) (“Pozner”)
1016	Goats, Geoffrey C., “Continuous short-wave (radio-frequency) diathermy,” <i>British Journal of Sports Medicine</i> , Vol. 23, No. 2 (1989) (“Goats”)
1017	Capon, Alexandre <i>et al.</i> , “Can Thermal Lasers Promote Skin Wound Healing?” <i>American Journal of Clinical Dermatology</i> Vol. 4, No. 1 (2003) (“Capon”)
1018	Fitzpatrick, Richard, <i>et al.</i> , “Multicenter Study of Noninvasive Radiofrequency for Periorbital Tissue Tightening,” <i>Lasers in Surgery and Medicine</i> , Vol. 33, No. 4 (2003) (“Fitzpatrick”)
1019	Hsu, Te-Shao, <i>et al.</i> , “The Use of Nonablative Radiofrequency Technology to Tighten the Lower Face and Neck,” <i>Seminars in Cutaneous Medicine and Surgery</i> , Vol. 22, No. 2 (2003) (“Hsu”)
1020	Narins, David, <i>et al.</i> , “Non-Surgical Radiofrequency Facelift,” <i>Journal of Drugs in Dermatology</i> , Vol. 2, Issue 5 (2003) (“Narins”)
1021	U.S. Patent Application Publication No. 2003/0120269 A1 to

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Exhibit No.	Description
	Bessette <i>et al.</i> (“Bessette”)
1022	U.S. Patent Application Publication No. 2002/0120260 A1 to Morris <i>et al.</i> (“Morris”)
1023	Arnoczky, Steven P., <i>et al.</i> , “Thermal Modification of Connective Tissues: Basic Science Considerations and Clinical Implications,” Journal of the American Academy of Orthopaedic Surgeons, Vol. 8, Issue 5 (2000) (“Thermal Modification”)
1024	U.S. Patent Application Publication No. 2002/0111615 A1 to Cosman <i>et al.</i> (“Cosman”)
1025	Complainants’ Petition for Review of Order No. 21, ITC Litigation 337-TA-1112, filed April 3, 2019 (“Petition for Review”)
1026	U.S. Provisional Application No. 60/486,304 (“304 Application”)
1027	Chang, Isaac, “Finite Element Analysis of Hepatic Radiofrequency Ablation Probes using Temperature-Dependent Electrical Conductivity,” BioMedical Engineering OnLine, Vol. 2, No. 12 (2003) (“Chang”)

IV. Person of Ordinary Skill in the Art

40. The technical field of the ’899 patent is treatment systems for delivery of electromagnetic radiation energy to skin or other tissues. A person of ordinary skill in the art (“POSA”) of the ’899 patent would have had knowledge of the technical literature concerning skin and other tissue treatments, including various electromagnetic radiation techniques and the body’s reaction to these techniques, before April 1, 2004. Typically, a POSA would have had (1) seven to ten years of experience with development and/or use of treatment systems for delivery of electromagnetic radiation energy to skin or other tissues, and (2) a related M.D. or graduate engineering degree.

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41. A POSA may have worked as part of a multidisciplinary team and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team when solving a technical problem.

V. State of the Art Before April 1, 2004

42. Delivering electromagnetic energy to human tissue has been an important aspect of the medical industry for decades. This electromagnetic energy may be at optical frequencies, such as the visible or non-visible light produced by lasers and other optical systems, or at radio frequencies (RF). As discussed above, I have extensive personal experience with devices that deliver electromagnetic energy to human tissue, particularly for aesthetic procedures. By the 2000's, such devices were well-known and well-developed. (Altshuler, 1:14-16; Debendictis, ¶[0002]; Utely, 1:40-56, 4:22-41; Underwood, ¶¶[0005], [0007], [0027]-[0028]; Ex. 1013, "Edwards," 9:25-36.) These devices typically included an energy source to provide the needed electromagnetic energy, an apparatus to deliver the energy to the tissue (e.g., needles, optical systems, etc.), and a controller to regulate the energy delivery. (*See, e.g.*, Utely, 4:31-47, 4:61-5:3; Underwood, ¶¶[0035]-[0038]; Altshuler, 10:3-20, 11:17-26; Debendictis, ¶[0076].)

43. Although these devices can be used in a variety of different applications, one well-known application of these devices was the treatment of skin, including for aesthetic or cosmetic purposes (e.g., hair removal, skin rejuvenation, etc.). (*See,*

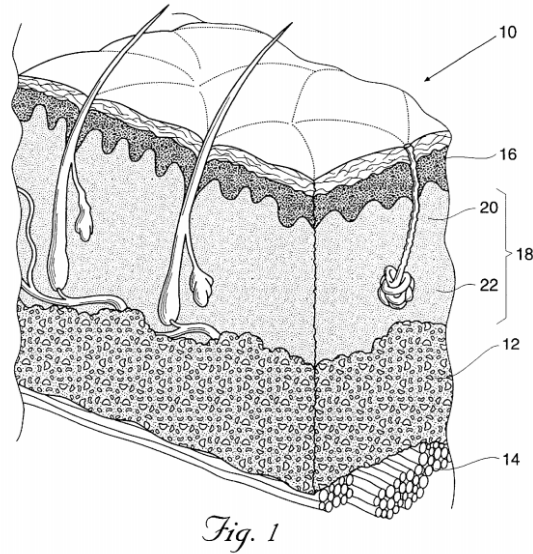
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e.g., Altshuler, 1:14-19; Debendictis, ¶[0002]; Utely, 3:49-50; Underwood, ¶¶[0003]-[0004], [0027].) Again, the treatment of skin with electromagnetic radiation was the main focus of my entire career. One aesthetic skin treatment approach involved damaging and rejuvenating collagen in the dermal layer of skin, as I discuss below.

A. Therapeutic use of the skin's wound healing process was well-known.

44. With the emphasis on appearance in the U.S. and abroad, there is great demand for aesthetic procedures that repair various skin defects, including wrinkles, discoloration, unwanted hair growth, and others. For background, the skin covers and protects the underlying body tissue (*e.g.*, subcutaneous and muscle tissue) and is predominantly made of two layers: the epidermis and the dermis. (Utely, 3:57-67; Altshuler, 9:20-22.) Below I have copied a representation of skin from the prior art that shows the epidermis 16 lying on top of the dermis 18. (Utely, FIG. 1.) The dermis, which acts to support the overlying epidermis, is primarily made of collagen fibers. Thus, collagen fibers are an important source of the strength and physical properties of the dermis. (*Id.*, 4:4-6.)

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(Utely, FIG. 1.)

45. As such, the condition of the dermis and its collagen fibers have an effect on the epidermis, which is the layer of skin that is visible. It was well-known that intentionally damaging collagen tissue could improve the outward appearance of the skin. (Utely, 4:8-15; Altshuler 9:24-10:2; Underwood, ¶[0029]; Debendictis, ¶[0002].) Specifically, skin defects, such as those caused by aging, disease, or trauma, can be improved by purposely wounding the skin to induce the natural wound healing process in the dermis, and specifically to the collagen in the dermis. (Altshuler, 9:24-10:2; Underwood, ¶[0029]; Debendictis, ¶[0006], [0014].) As was well-known, introducing “trauma initiates wound healing with consequent formation of connective tissue” and results in repair of both the induced damage and reduction of previously existing skin defects in its vicinity such as wrinkles or scars. (Ex. 1014, “Orentreich,” pp. 543, 548-49; Ex. 1015, “Pozner,” p. 428.) This

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phenomenon stems from the fact that the collagen in the dermis provides significant structural support for the epidermis. When the collagen is damaged, the natural healing process results in collagen formation in the dermis that provides improved support for the overlying epidermis, which minimizes the appearance of skin defects such as wrinkles.

46. There were various known techniques for inducing damage (or trauma) in the skin. Mechanical damage techniques included, for example, puncturing the skin with needles to induce a controlled damage pattern. (*See, e.g.,* Orentreich, 543-544.) Thermal damage techniques generally involved applying electromagnetic radiation to the tissue of the skin to induce heat-based damage to the tissue and subsequent generation of collagen. (*See, e.g.,* Pozner, p. 428; Utely, 2:12-17, 4:8-15; Underwood, ¶¶[0010]-[0011], Debendictis, ¶[0002], Altshuler, 18:21-25.) Using RF energy to induce heating or thermal damage in skin tissue was well-known decades before the '899 patent was filed. (Ex. 1016, "Goats," 123 (discussing therapeutic use of RF energy dating back to 1928).)

B. It was known to use various electromagnetic radiation techniques to induce damage to skin.

47. Thermal damage treatments in the prior art used various electromagnetic radiation techniques to induce damage to skin. (Altshuler, 1:14-26.) As noted in the '899 patent, electromagnetic radiation techniques can be generally categorized into two groups: ablative laser skin resurfacing ("LSR") and non-ablative collagen

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remodeling (“NCR”). (Ex. 1017, “Capon,” pp. 7-9; Ex. 1018, “Fitzpatrick,” pp. 232-233; Utely, 1:40-56; Underwood, ¶¶[0004]-[0011]; Debendictis, ¶¶[0004], [0008]-[0010].) As indicated in its name, LSR used electromagnetic radiation (typically in the form of a laser) to remove the top layers of skin “to promote the development of new, more youthful looking skin and stimulate the generation and growth of new skin.” (Debendictis, ¶¶[0002], [0004]; Utely, 1:40-50; Underwood, ¶[0005].)

48. Because LSR techniques “lead[] to prolonged redness of the skin, infection risk, increased or decreased pigmentation, and scarring” and other negative side effects (e.g., down time) from the extensive thermal damage to the epidermis and dermis (Utely, 1:48-50; Underwood, ¶¶[0006], [0009]; Capon, pp. 7-8), various NCR techniques were developed. (Fitzpatrick, pp. 232-233.) These techniques rely on thermal damage of the dermal tissue without ablation of the epidermis. (Capon, p. 8; Utely, 1:60-64; Underwood, ¶¶[0010]-[0011]; Debendictis, ¶¶[0008]-[0010].) The thermal damage to the dermis induces collagen shrinkage and stimulates the body’s natural wound healing process, which results in biological repair and formation of new dermal collagen. (Pozner, p. 428; Capon, p. 8.) Because the new dermal collagen restores the strength and physical properties of the dermis and ultimately improves the outward appearance of the skin, these skin treatment techniques are often called “collagen remodeling.”

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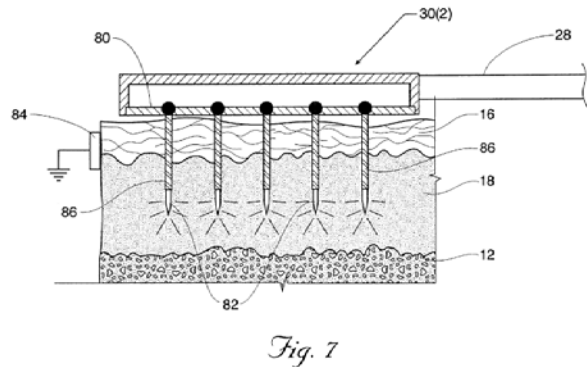
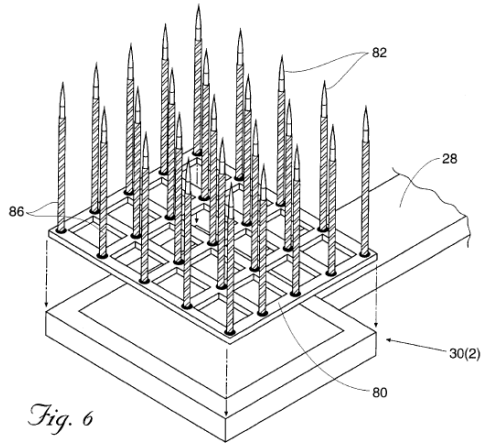
(Pozner, p. 428; Capon, p. 8.) NCR treatments utilize electromagnetic radiation at various frequencies, including non-ablative laser frequencies (including visible light and infrared) (Capon, p. 8; Altshuler, 6:9-19, 10:3-7; Debendictis, ¶[0019]) and RF frequencies (Utely, 4:38-41; Underwood, ¶¶[0011], [0032], [0036]; Altshuler, 10:8-14).

C. The prior art used needles to deliver RF energy to skin and other tissue.

49. By 2001, it was well-known that RF energy could be used to cause thermal damage to induce collagen shrinkage. (*See, e.g.*, Utely, 1:51-55.) Specifically, when RF energy is applied to the dermis, collagen's triple helix structure is changed by breaking certain intramolecular bonds to cause collagen shrinkage. (Ex. 1019, "Hsu," p. 120; Ex. 1020, "Narins," p. 496.) New collagen forms by such thermal damage. (Hsu, p. 120.)

50. Needles were a well-known way to deliver RF energy to skin and other tissue. (Ex. 1021, "Bessette," ¶¶[0019]-[0020], [0082]-[0083], [0093], [0097]; Ex. 1022, "Morris," Abstract, ¶¶[0082], [0114].) For example, Utely applied RF energy to skin with an array of needle electrodes 82, as shown in Utely's Figures 6 and 7 (reproduced below). (Utely, 7:40-47, 7:56-63.) Similarly, Underwood used an array of needle-shaped electrodes advanced into the dermis to deliver RF energy. (Underwood, ¶¶[0016], [0032], [0052]-[0054], FIGS. 5-8.) Edwards is another example of using needles to deliver RF energy into body tissue. (Edwards,

4:61-65, 5:10-11, 10:10-13, FIG. 6.) As was known, using needles to deliver RF energy allows for precise control over the delivery of the RF energy to the target tissue.



(Utely, FIGS. 6-7.)

51. In short, collagen shrinkage (i.e. damage) caused by RF energy delivered through needles was well-known, and the formation of new collagen is simply an end result of the natural healing process. (Underwood, ¶¶[0015], [0029].) The introduction of RF energy through a needle to create a wound does not change the underlying, well-known science; namely, that a wound healing mechanism will form new collagen through the natural healing process.

D. The benefits of inducing fractional damage patterns in the skin were well-known.

52. It was also well-known in the art to modify the parameters of energy applied to the skin (e.g., energy level) based on desired treatment objectives. (Utely, 4:64-5:1; Altshuler 15:1-3, 15:29-6:1 Debendictis, ¶¶[0004], [0016],

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[0086]; Underwood, ¶¶[0034]-[0035]; Edwards, 9:48-51.) Such variations in application parameters were, and are, desirable because skin treatments can be tailored to the specific needs of individual patients.

53. The prior art taught that a controller can govern the applied RF energy to produce different energy intensities and application patterns. (Utely, 8:24-33.) It was also well-known that “radio-frequency heating... may easily cause nonhomogeneous heating.” (Ex. 1023, “Thermal Modification,” p. 307.) “[S]tandard RF devices... [were known to] concentrate energy....” (Fitzpatrick, p. 233.) In addition, “hot spots [were known to] occur around each [RF needle] electrode” (Ex. 1024, “Cosman,” ¶[0014].) “The precise heat-induced behavior [of collagen] ... [was known to be] dependent on several factors, including the maximum temperature reached and exposure time.” (Thermal Modification, p. 306.) Illustrations were published of “the distribution of heating temperature as a function of the radial distance from the [RF needle] electrode.” (Cosman, FIGS. 3-4, ¶¶[0052]-[0054].)

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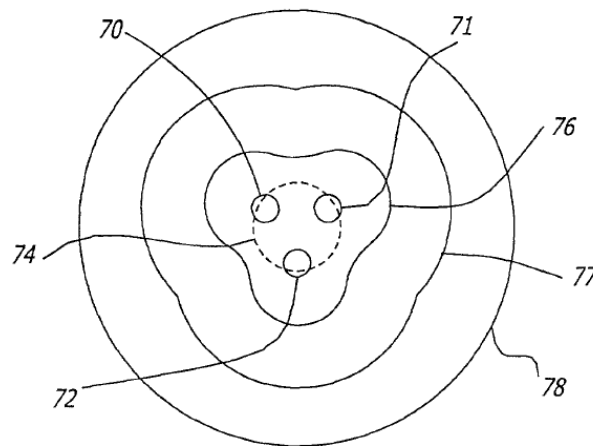
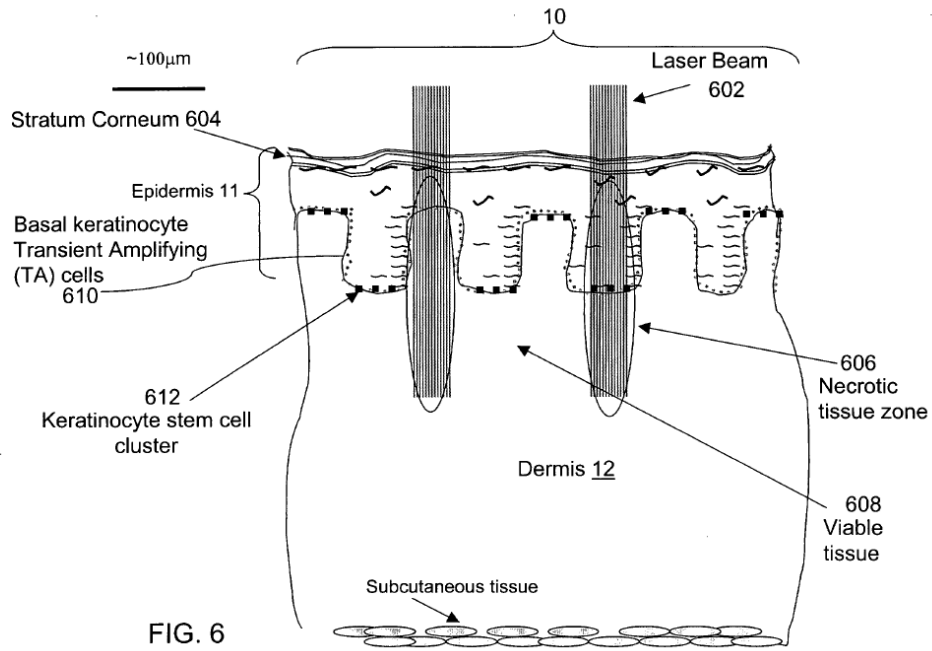


FIG. 3

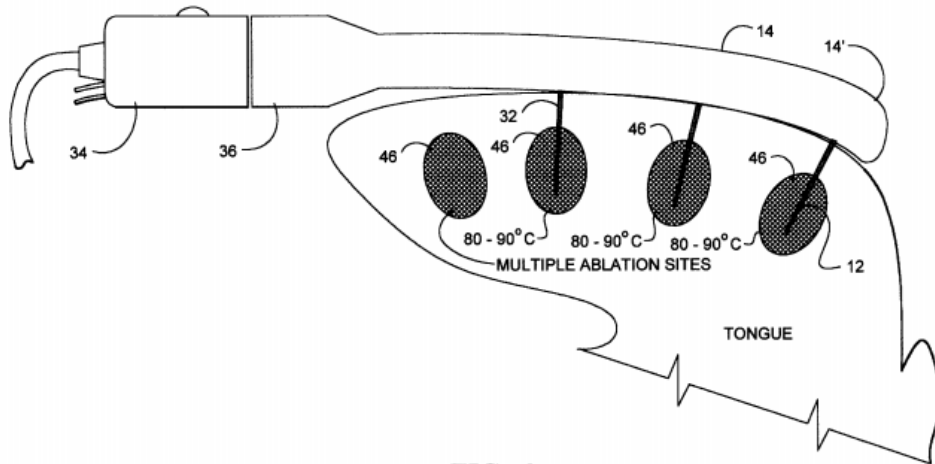
(Cosman, FIG. 3.)

54. Beyond these teachings of modifying energy parameters, nonhomogenous heating, and energy application patterns, the prior art also specifically taught damage patterns from electromagnetic radiation in which areas of damaged tissue were surrounded by areas of sparing (i.e., undamaged tissue). (Altshuler, 1:8-11, 4:25-5:10, 8:14-17, 13:20-22; Debendictis, Abstract, ¶¶[0014], [0017]; Edwards, 10:10-13, 10:32-35, FIG. 6.) With only a portion or a fraction of the tissue being damaged, this type of damage pattern is sometimes called fractional damage. (See Debendictis, ¶[0044].)

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(Debendictis, FIG. 6.)



(Edwards, FIG. 6.)

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55. The prior art understood the benefits of a pattern of fractional damage. Specifically, fractional damage was known to produce “significant collagen regeneration.” (Altshuler, 18:21-19:2.) The areas of sparing surrounding the damaged areas permit the skin to recover and make the repair process more robust. (Altshuler, 13:11-23; Debendictis, ¶¶[0014], [0044].) At the same time, the significant collagen regeneration was accompanied by “less trauma and pain to the patient.” (Altshuler, 18:21-19:2; Debendictis, ¶¶[0014].) Accordingly, the prior art described fractional damage patterns and understood its benefits.

VI. Overview of the '899 Patent

56. I understand that this Declaration is being submitted together with a petition for IPR of claims 1-2, 4, 6-7, 9-12, 15-17, and 20-23 of the '899 patent. I have reviewed the '899 patent and its file history. In assessing the '899 patent, I have considered the teachings of the technical literature before April 1, 2004, in light of general knowledge in the art before that date.

57. The '899 patent is directed at devices and methods “for skin treatment and tissue remodeling” using “an array of needles that penetrate the skin and serve as electrodes to deliver radio frequency current or other electrical or optical energy into the tissue being treated.” ('899 patent, Abstract.) The energy “caus[es] thermal damage in controlled patterns” in which the “damaged regions promote beneficial

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results such as uniform skin tightening by stimulation of wound healing and collagen growth.” (*Id.*)

58. In my opinion, the '899 patent disclosed nothing more than well-known concepts. As shown in Figure 3 (reproduced below), the '899 patent's device includes “a plurality of needles 350 attached to a base 310.” (*Id.*, 5:40-44.) Base 310 “is attached to housing 340 or formed as a part of the housing.” (*Id.*, 5:44-45.) A source of RF energy 320 “is electrically connected to each of the needles 350” and a “control module 330 permits variation of the characteristics of the RF electrical current, which can be supplied individually to one or more of the needles.” (*Id.*, 5:45-49.) “Optionally, energy source 320 and/or control module 330 may be located outside of the housing.” (*Id.*, 5:49-51.)

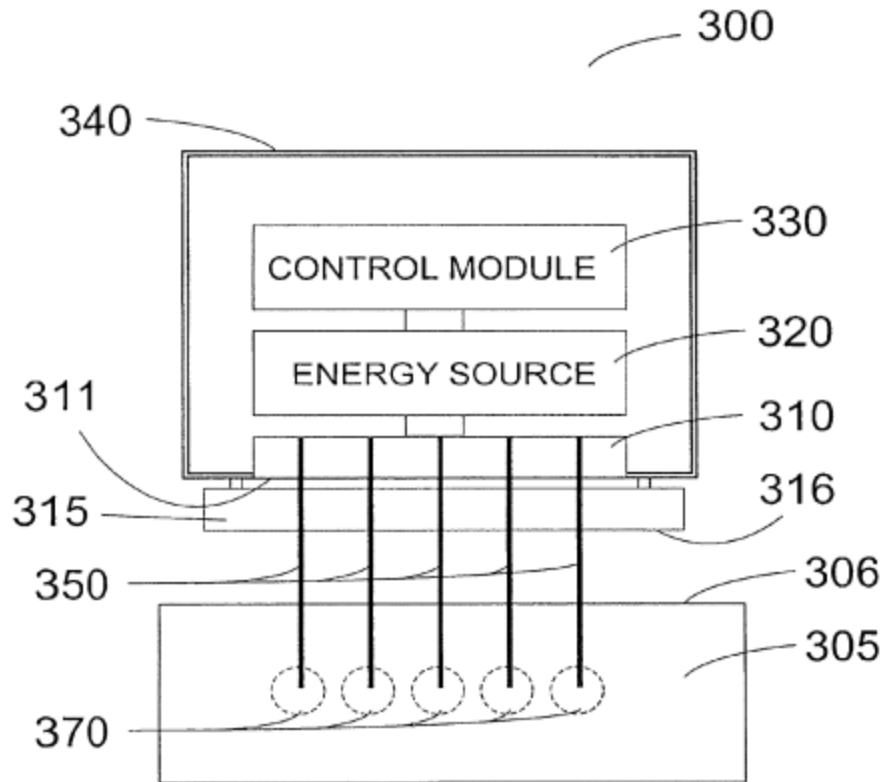


FIG. 3

('899 Patent, FIG. 3.)

59. As part of a skin treatment method, the needles are inserted into the skin to a desired depth. (*Id.*, 6:7-17.) RF energy is then transmitted through the needles to create areas of thermal damage 370 in the skin. (*Id.*, 6:33-47.) These damage areas can be configured in different patterns to create fractional wounding of the targeted tissue. (*Id.*, 4:13-24.)

60. As is apparent from my discussion of the state of the art above, each of these elements was known in the art before the alleged invention of the '899 patent. (Section V.) Indeed, the '899 patent's background section described various

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prior art LSR and NCR techniques. (*Id.*, 1:61-3:52.) As I discussed above, and as confirmed by the '899 patent, both of these skin treatment techniques were well-known. I note that the '899 patent referenced U.S. Publication No. 2002/0161357 as providing “[e]xamples of NCR techniques.” (*Id.*, 3:6-8). This reference provides the same disclosure as Altshuler, including teachings of fractional damage. And the sole inventor of the '899 patent, Dieter Manstein, is also listed as an inventor on this reference. However, the '899 patent omits the fact that this reference specifically disclosed fractional damage patterns and specifically mentioned an RF system. (*Id.*, 1:61-3:52.)

61. This omission stands out to me, especially after reviewing Provisional Application No. 60/558,476, from which the '899 patent claims priority. Altshuler's description is remarkably similar to the description in the '476 provisional application. For example, both specifications describe electromagnetic radiation (EMR) as the energy source to induce damage. ('476 Provisional, ¶¶[0001], [0035]-[0038]; Altshuler, 1:8-11, 10:3-14.) Just like Altshuler, the '476 provisional discusses the principle of sparing areas of skin tissue. ('476 Provisional, ¶[0032]; Altshuler, 13:20-23.) The sizes of the damaged areas are also similar ('476 Provisional, ¶[0032] (1 mm or less), claim 30 (0.1 mm diameter); Altshuler, 13:7-10 (100 microns).)

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62. Another omission from the '899 patent's background section that stands out to me is the well-known application of RF energy with needles inserted into the dermis. (See Utely, 7:40-47, 7:56-63, FIGS. 6-7; Underwood, ¶¶[0016], [0032], [0052]-[0054], FIGS. 5-8.) Instead of noting this known application of RF energy to the dermal layer through needles, the '899 patent only discussed the application of RF energy "at the surface of the skin." ('899 patent, 3:31-34.)

63. In short, the '899 patent does not claim anything that goes beyond what was well-known in the art. Independent claim 1 is copied below:

1. A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein, wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.

('899 patent, 12:34-47.)

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64. I understand that claims 2, 4, 6-7, 9-12, and 16 are “dependent” from claim 1 because they refer directly or indirectly to claim 1. (*Id.*, 12:48-13:23.) I highlight these dependent claims below:

- Claim 2 requires that “*the plurality of needles are associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.*” (*Id.*, 12:48-54.)
- Claim 4 requires that “*the control module is further configured to receive a selection of an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.*” (*Id.*, 12:57-62.)
- Claim 6 requires “*a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.*” (*Id.*, 12:65-67.)
- Claim 7 requires that “*at least one of the plurality of needles is a hollow needle, and further comprising a delivery mechanism for*

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delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.” (Id., 13:1-5.)

- Claim 9 requires “*a spacer having holes through which the needles are configured to move.*” (Id., 13:9-11.)
- Claim 10 requires that “*the control module is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with undamaged regions between the damaged regions.*” (Id., 13:12-17.)
- Claim 11 requires that “*each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.*” (Id., 13:18-21.)
- Claim 12 requires “*a vibrator for vibrating at least one of the plurality of needles.*” (Id., 13:22-23.)
- Claim 16 requires that “*the control module is configured to cause necrosis in the dermal layer.*” (Id., 13:46-47.)

65. Independent claim 15 is copied below:

15. A skin treatment device, comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured for

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application of radio frequency (RF) energy from a RF energy source;
and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to cause a pattern of fractional damage to be produced in the dermal layer in a vicinity of the tips of the needles,

wherein delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer, and wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.

(*Id.*, 13:30-45.)

66. I understand that claim 17 is “dependent” from claim 15 because it refers directly or indirectly to claim 15. (*Id.*, 13:48-49.) Claim 17 requires “*a vibrator for vibrating at least one of the plurality of needles.*” (*Id.*)

67. Independent claim 20 is copied below:

20. A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base and arranged in a group of bipolar pairs, the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

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wherein the pattern of fractional damage includes damaged regions between tips of needles of the bipolar pairs, and undamaged regions between bipolar pairs of needles in the group.

(*Id.*, 14:1-17.)

68. I understand that claims 21-23 are “dependent” from claim 20 because they refer directly or indirectly to claim 20. (*Id.*, 14:17-23.)

- Claim 21 requires that “*the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.*” (*Id.*, 14:17-19.)
- Claim 22 requires that “*the control module is configured to cause necrosis.*” (*Id.*, 14:20-21.)
- Claim 23 requires “*a vibrator for vibrating at least one of the plurality of needles.*” (*Id.*, 14:22-23.)

VII. Claim Construction

69. I understand that terms of the claims are to be given their ordinary and customary meaning as understood by a POSA in light of the '899 patent specification and prosecution history. I have been informed that Lumenis and Patent Owner have submitted constructions before the International Trade Commission (“ITC”) for several of the claim terms. Below I discuss several terms for construction. For those claim terms not expressly discussed, I also use the ordinary and customary meaning in my analysis below.

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A. “a pattern of fractional damage”

70. In my opinion, a POSA would have understood “a pattern of fractional damage” to mean “the pattern of damage caused by non-uniform heating.” I understand that the ITC adopted this meaning of the term in the related ITC case. Although the ’899 patent specification does not include the term “a pattern of fractional damage,” the specification uses the term “fractional wounding” three times. (’899 patent, 1:33-37, 4:18-21, 9:20-23.) In particular, the specification states that “using arrays of needles to damage *selected regions* of the skin” by directing electromagnetic radiation “to *portions of a target area* within the skin ... caus[es] fractional wounding.” (*Id.*, 1:33-37, 4:13-24 (emphases added).) And during prosecution, Patent Owner alleged a distinction between a pattern of fractional damage and “achiev[ing] uniformity of heating at a collagen shrinkage target temperature” in the dermis. (’357 PH, 178.) Thus, a POSA would have understood “a pattern of fractional damage” to mean “the pattern of damage caused by non-uniform heating” (e.g., the regions include a damaged portion and an undamaged portion).

71. I have been informed that at the ITC, Patent Owner argued that the construction of this claim term should be “a distribution of small localized regions of thermal damage.” I also understand that Lumenis argued that the construction of

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this claim term should be “regions of non-uniform damage.” In my opinion the Grounds below render the claims obvious under any of these constructions.

B. “a control module”

72. I understand that during the ITC proceeding, Patent Owner asserted that “persons of ordinary skill in the art use the term ‘control module’ to refer to a known structure in the medical device field.” (Ex. 1025, “Petition for Review,” p. 2.) Indeed, Patent Owner stated that “a control module in the claimed invention could be an off-the-shelf-product” or “a standard controller.” (*Id.*, 5, 35; *see also id.*, 17, 27, 34-35.) Based on Patent Owner’s assertions, for purposes of this proceeding I interpret the term “a control module” to mean “a controller.”

C. Other Terms

73. I have been informed that the parties submitted other terms for construction at the ITC, as shown in the chart below. In my opinion, none of these terms are in need of construction to resolve the Grounds of unpatentability set forth below because the prior art reads on either construction.

	Lumenis	Patent Owner
“dermal layer of skin”	Portion of skin extending from the epidermis up to a depth of approximately 3000µm.	Plain and ordinary meaning: known portion of the body.
“non-ablative damage”	Damage that does not remove tissue.	Damage that does not remove tissue.
“regions of thermal damage”	Regions damaged by heat energy.	Plain and ordinary meaning. The regions

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		referred to are areas within the dermal layer (a/k/a the dermis).
damaged regions “between tips” of needles	Plurality of regions including damage in the middle of the tips of two needles.	Plain and ordinary meaning: damage occurs at a location between the distal ends of the needles.
“undamaged regions”	Region(s) devoid of damage.	Plain and ordinary meaning.
“needles”	Needles having sharp distal ends capable of piercing the surface of the skin.	Plain and ordinary meaning.
arranged for insertion/inserted/inserting	The needles pierce through the epidermis to a dermal layer.	Plain and ordinary meaning.
“bipolar pairs of needles”	Pairs of two needles spaced and electrically configured such that most of the current from the first needle in a pair flows to the second needle in that pair.	Plain and ordinary meaning: includes “a group of needles in which one needle in the group acts as a positive electrode and another needle in the group acts as a grounding electrode.”
“needles being attached to the base”	Needles fixed relative to the base which is attached to the housing or formed as part of the housing.	Plain and ordinary meaning.
controlling delivery/control the delivery of the RF energy	Delivering RF energy in a manner that results in non-uniformity of heating.	Plain and ordinary meaning.

VIII. Basis of My Analysis with Respect to Obviousness

74. I understand that an obviousness analysis involves properly construing a patent claim and then comparing that claim to the prior art to determine whether

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the claimed invention would have been obvious to a skilled person in view of the prior art and in light of the general knowledge in the art. I also understand that obviousness is ultimately a legal conclusion based on underlying facts of four general types, all of which must be considered: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness.

75. I also understand that obviousness may be established by combining or modifying the teachings of the prior art. Specific teachings, suggestions, or motivations to combine any first prior art reference with a second prior art reference can be explicit or implicit, but must have existed before the date of purported invention. I understand that prior art references themselves may be one source of a specific teaching or suggestion to combine features of the prior art, but that such suggestions or motivations to combine art may come from the knowledge of a person of ordinary skill in the art. Specifically, a rationale to combine the teachings of references may include logic or common sense available to a person of ordinary skill in the art. It is also my understanding that where there is a reason to modify or combine the prior art to achieve the claimed invention, there must also be a reasonable expectation of success in so doing.

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76. I understand that a reference may be relied upon for all that it teaches, including uses beyond its primary purpose. I understand that though a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, the mere disclosure of alternative designs does not teach away.

77. I understand there may be a number of rationales that may support a conclusion of obviousness, including:

- Combining prior art elements according to known methods to yield predictable results;
- Substitution of one known element for another to obtain predictable results;
- Use of a known technique to improve similar devices (methods, or products) in the same way;
- Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and

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- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art teachings to arrive at the claimed invention.

78. I understand that it is not proper to use hindsight to combine references or elements of references to reconstruct the invention using the claims as a guide. My analysis of the prior art is made from the perspective of a person of ordinary skill in the art at the time of the purported invention.

79. I understand that so-called objective indicia may be relevant to the determination of whether a claim is obvious should the Patent Owner allege such evidence. Such objective indicia can include evidence of commercial success caused by an invention, evidence of a long-felt need that was solved by an invention, evidence that others copied an invention, or evidence that an invention achieved a surprising result. I understand that such evidence must have a nexus, or causal relationship to the elements of a claim (beyond what was available in the prior art), in order to be relevant to the obviousness or non-obviousness of the claim.

80. I understand that for a reference to be used to show that a claim is obvious, the reference must be analogous art to the claimed invention. I understand that a reference is analogous to the claimed invention if the reference is from the same field of endeavor as the claimed invention, even if it addresses a different

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problem, or if the reference is reasonably pertinent to the problem faced by the inventor, even if it is not in the same field of endeavor as the claimed invention. I understand that a reference is reasonably pertinent based on the problem faced by the inventor as reflected in the specification, either explicitly or implicitly.

IX. Summary of Grounds

A. Prior Art Applied

81. I have been informed by counsel that because Utely, Underwood, and Altshuler issued or published more than a year before the earliest possible priority date of the '899 patent, each of these references are prior art to the '899 patent. I have been informed by counsel that although Brown published after the earliest possible priority date of the '899 patent, Brown's filing date antedates the earliest possible priority date of the '899 patent, and thus Brown is also prior art to the '899 patent.

82. I have also been informed by counsel that although Debendictis published after the earliest possible priority date of the '899 patent, it is prior art to the '899 patent if its provisional application (which was filed before the earliest possible priority date of the '899 patent) describes the invention claimed in the Debendictis publication in a way that both (1) shows possession of the claimed invention (i.e., at least one claim), and that (2) would have enabled a POSA to practice the claimed invention. In other words, the provisional application must

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provide support for at least one claim of Debendictis. I have reviewed Debendictis and its provisional application (Ex. 1026, “the ’304 Provisional”), which was filed on July 11, 2003. In my opinion the ’304 Provisional provides support for claims of Debendictis, including, for example, at least claims 1, 2, 20, and 21. Below is a claim chart that shows non-limiting examples of support for the elements of claims 1, 2, 20, and 21 of Debendictis in the ’304 Provisional.

Debendictis Claim	The ’304 Provisional
1. A method for achieving beneficial effects in a target tissue in skin comprising treating the target tissue using optical radiation to create a plurality of microscopic treatment zones in a predetermined treatment pattern, wherein a subset of said plurality of discrete microscopic treatment zones includes individual discrete microscopic treatment zones comprising necrotic tissue volumes having an aspect	“1. A method for achieving beneficial effects in a target tissue in skin comprising treating the target tissue using optical radiation to create one or more microscopic treatment zones such that the ratio of the sum of the treatment zones to the target tissue volume is less than one, and the treatment zones are created by a predetermined treatment pattern.” (’304 Provisional, claim 1.) The ’304 Provisional disclosed treatment zones having “necrotic” tissue volumes. (<i>See, e.g., id.</i> , 11:16-21, 13:7-9, 16:15-17, FIGS. 9A-9D.) The “1:2 aspect ratio” element of claim 1 is shown at least in Figures 4 and 9A-9D of the ’304 Provisional, which disclosed treatment depths and widths that result in aspect ratios within the range disclosed in

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<p>ratio of at least about 1:2.</p>	<p>claim 1. (<i>Id.</i>, FIGS. 4, 9A-9D.)</p> <p>In my opinion, a POSA would have understood the '304 Provisional to enable claim 1. (<i>See, e.g.</i>, '304 Provisional, 16:6-18:21.)</p>
<p>2. The method of claim 1, wherein the microscopic treatment zones are separated by thermally unaltered tissue.</p>	<p>“3. A method of claim 1, where the treatment zones are separated by thermally unaltered tissue.” ('304 Provisional, Claim 3.)</p> <p>Claim 3 of the '304 Provisional is almost identical to and fully supports claim 2 of Debendictis. And as indicated by claim 1 of the '304 Provisional, the treatment zones in the '304 Provisional are “microscopic” treatment zones. (<i>Id.</i>, claim 1.)</p> <p>Further, the '304 Provisional discussed the treatment zones being separated by thermally unaltered tissue. ('304 Provisional, 12:14-23, 16:6-22.)</p> <p>In my opinion, a POSA would have understood the '304 Provisional to enable claim 2. (<i>See, e.g.</i>, '340 Provisional, 16:6-18:21.)</p>
<p>20. A method for achieving beneficial effects in skin tissue comprising treating the tissue by exposing a targeted part of the tissue to</p>	<p>13. A method for achieving beneficial effects in skin tissue comprising treating the skin by exposing a targeted part of the skin tissue to optical radiation to create one or more microscopic treatment zones such that the volume of the target tissue that remains</p>

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<p>optical radiation to create a plurality of microscopic treatment zones such that the volume of the target tissue that remains substantially unaffected by the optical radiation is controlled.</p>	<p>substantially unaffected by the optical radiation is controlled. ('304 Provisional, claim 13.)</p> <p>Claim 13 of the '304 Provisional is almost identical to and fully supports claim 20 of Debendictis. ('304 Provisional, 26:5-8; <i>see also id.</i>, 23:7-17.)</p> <p>In my opinion, a POSA would have understood the '304 Provisional to enable claim 20. (<i>See, e.g.</i>, '340 Provisional, 16:6-18:21.)</p>
<p>21. The method of claim 20 wherein the control is achieved by focusing the optical radiation to desired depths in the skin.</p>	<p>14. A method of claim 13 where the control is achieved by focusing the optical radiation to desired depths in the skin. ('304 Provisional, claim 14.)</p> <p>Claim 14 of the '304 Provisional is almost identical to and fully supports claim 21 of Debendictis. (<i>Id.</i>, 26:9-10; <i>see also id.</i>, 23:3-13.)</p> <p>In my opinion, a POSA would have understood the '304 Provisional to enable claim 20. (<i>See, e.g.</i>, '340 Provisional, 16:6-18:21.)</p>

83. Utely, Altshuler, Underwood, Debendictis, and Brown (like the '899 patent) all relate to treatment systems for delivery of electromagnetic radiation energy to skin or other tissues.

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B. Summary of the Grounds

84. The table below summarizes the grounds for unpatentability set forth in this Declaration. Throughout my discussion of the grounds below, I refer to the state of the art discussed in Section V. The discussion in Section V is relevant throughout the entirety of this Declaration.

Ground	References	Basis	Claims Challenged
1	Utely and Altshuler	Obviousness	1-2, 4, 6-7, 10-11, 15, 20-21
2	Utely, Altshuler, Brown	Obviousness	9, 12, 17, 23
3	Underwood and Debendictis	Obviousness	1-2, 4, 6, 10-11, 15-16, 20-22
4	Underwood, Debendictis, Brown	Obviousness	9, 12, 17, 23

85. In my opinion, Grounds 1–4 stated below are substantially different than the art and arguments previously considered by the Office. Specifically, during prosecution of the '899 patent and its parent applications, the Office never relied on a reference that explicitly disclosed fractional damage the way that Altshuler and Debendictis do. ('357 PH, 117, 163.) Instead, the Office initially relied on Utely alone for a pattern of fractional damage. Based on the Patent Owner's arguments, the Examiner eventually allowed the case. (*Id.*, 176, 190.)

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86. In contrast, Grounds 1-4 rely on Altshuler and Debendictis, respectively, for the fractional damage limitation. Altshuler expressly disclosed the creation of fractional damage patterns using RF energy and explained the benefits of doing so. (Altshuler, 13:11-23, 18:21-19:2.) Debendictis similarly expressly disclosed fractional damage patterns, as well as the benefits of using fractional damage patterns. (Debendictis, ¶¶[0014], [0041], [0044].) Thus, the combination of Utely and Altshuler and the combination of Underwood and Debendictis are substantially different than the prior art examined during prosecution. And the arguments are substantially different than the Examiner's rejection based on Utely.

X. Ground 1: Claims 1-2, 4, 6-7, 10-11, 15, and 20-21 would have been obvious over Utely in view of Altshuler.

87. Before April 1, 2004, claims 1-2, 4, 6-7, 10-11, 15, and 20-21 of the '899 patent would have been obvious over Utely (Ex. 1008) and Altshuler (Ex. 1009). As illustrated in the claim charts and discussion below, Utely and Altshuler disclosed each element of claims 1-2, 4, 6-7, 10-11, 15, and 20-21. Moreover, a POSA would have had a reason to use Utely's controller to achieve Altshuler's fractional damage pattern, thereby achieving significant collagen regeneration and better patient experience (e.g., less trauma and pain to the patient). And a POSA would have had a reasonable expectation of success in using Utely's controller to achieve Altshuler's fractional damage pattern. Thus, claims 1-2, 4, 6-7, 10-11, 15,

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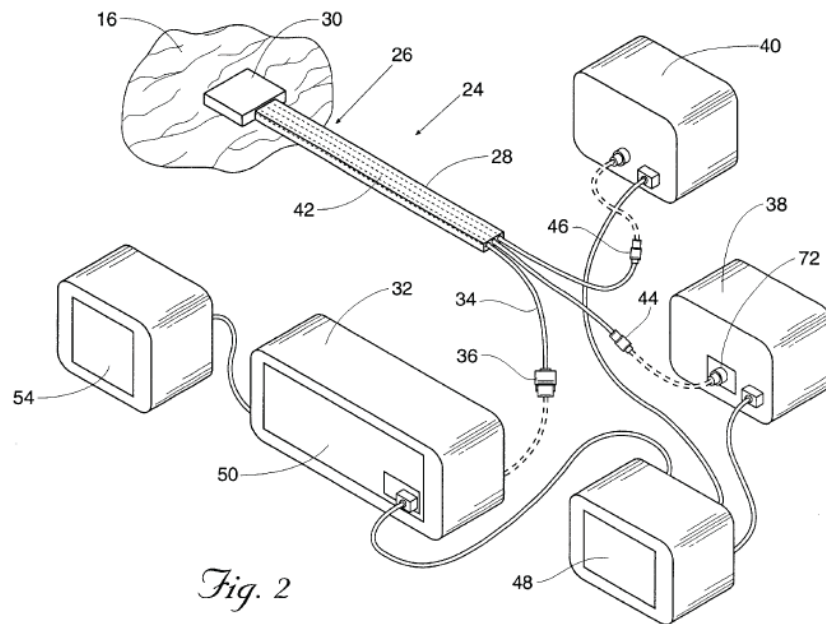
and 20-21 would have been obvious in view of the disclosures in Utely and Altshuler, notwithstanding any objective indicia of nonobviousness.

A. Overview of Utely

88. Utely issued as a U.S. Patent on August 21, 2001. (Utely, Cover Page.) According to its cover page, Utely's application was filed on February 17, 1999. (Utely, Cover Page.) I understand that Utely qualifies as prior art to the '899 patent.

89. Utely is from the same field of endeavor as the '899 patent because it disclosed skin treatment devices (specifically for treating cosmetic conditions of the skin) that deliver electromagnetic radiation energy to the skin or other tissue. (*See, e.g., id.*, Abstract, 1:16-22, 3:49-50.) Utely disclosed "a system 24 for renovating and reconstituting the dermis" by "appl[ying] energy to the dermis in a targeted, selective fashion, to dissociate and contract collagen tissue." as shown below. (*Id.*, 4:22-28.) I have reproduced Utely's Figure 2 below, which illustrates Utely's system 24.

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(Utely, FIG. 2.)

90. Utely's system includes "an array of spaced-apart needle electrodes 82" that are "arranged for insertion into the dermis." (*Id.*, 7:42-43, 7:56-58, FIG. 7.) Utely's system also included a controller that "governs the power levels, cycles, and duration that the radio frequency energy is distributed ... to achieve the desired treatment objectives." (*Id.*, 4:64-5:1.) For example, "[e]ach electrode 82 comprises a discrete transmission source of radio frequency energy, which the controller 48 governs." (Utely, 7:45-47.) I have reproduced Utely's Figure 7 below, which illustrates needles 82 inserted into the dermis 18.

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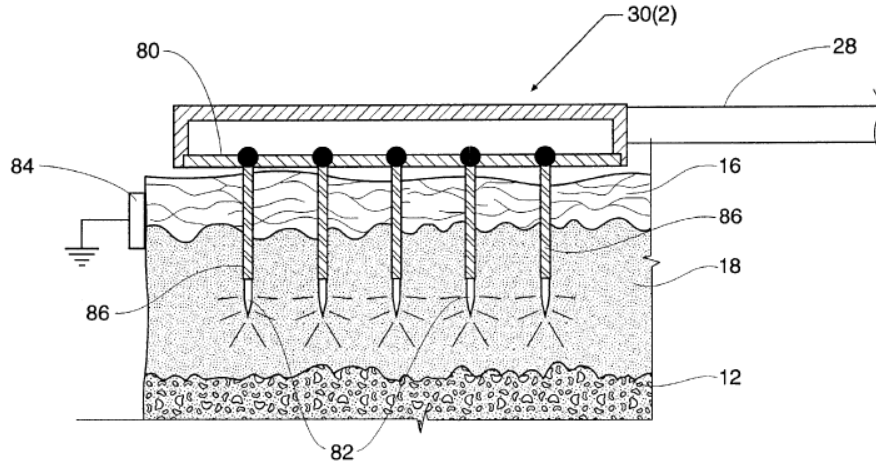


Fig. 7

(Utely, FIG. 7.)

B. Overview of Altshuler

91. Altshuler published as a PCT application on July 11, 2002. (Altshuler, Cover Page.) According to its cover page, Altshuler's application was filed on December 27, 2001. (Altshuler, Cover Page.) I understand that Altshuler qualifies as prior art to the '899 patent.

92. Altshuler is from the same field of endeavor as the '899 patent because it disclosed skin treatment devices that deliver electromagnetic radiation energy to the skin or other tissue. (*See, e.g.,* Altshuler, Abstract, 1:8-11.) Specifically, Altshuler is directed at methods and systems “for using electromagnetic radiation (EMR) for various therapeutic treatments and more particularly to methods and apparatus for dermatological treatment.” (*Id.*) In Altshuler, the EMR is applied in small “areas of treatment or damage substantially surrounded by areas of sparing,”

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or untreated areas. (*Id.*, 1:8-11, 2:1-4.) Specifically, Altshuler disclosed “concentrat[ing] the radiation to at least one depth within the depth coordina[tes] of the volume and to *selected areas* within the area coordina[tes] of the volume” while leaving “untreated portions” within the tissue. (*Id.*, 5:4-10 (emphasis added).)

93. Altshuler taught that “smaller, spaced areas of damage [would] heal more quickly” and “enhanc[e] both patient comfort and the ability to more quickly perform follow-up treatments.” (*Id.*, 2:1-4.) And Altshuler explained that its fractional damage teachings are “particularly adapted for skin rejuvenation treatments by collagen regeneration” because “such treatments can be *more effectively performed* by heating selective portions 214, with perhaps a 30% to 50% fill factor, resulting in *significant collagen regeneration* with *less trauma and pain* to the patient.” (*Id.*, 18:21-22, 30-19:2 (emphasis added).)

94. Altshuler disclosed various types of EMR that may be used for achieving its disclosed fractional damage pattern, including “[a]coustic, RF or other EM[R] sources.” (*Id.*, 10:8.)

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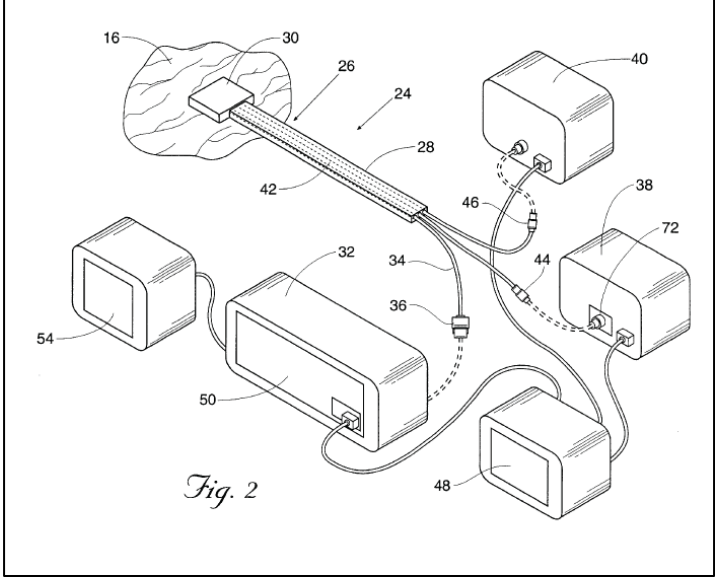
C. Independent claim 1 would have been obvious over Utely in view of Altshuler.

95. The claim chart below lists disclosures from Utely and Altshuler that taught each element of claim 1 of the '899 patent.¹

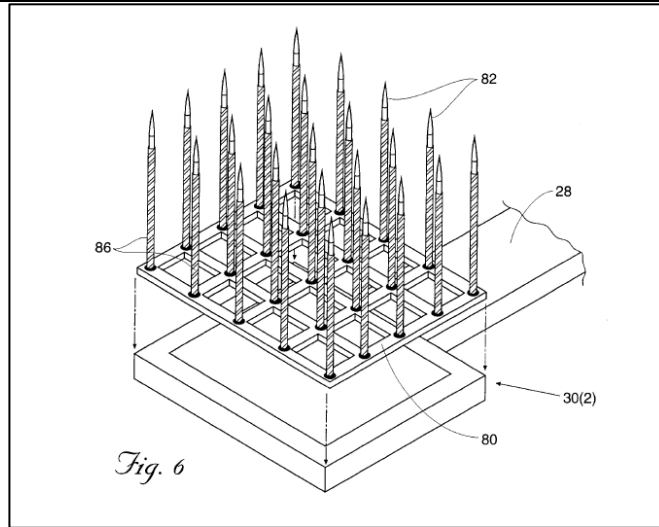
Claim	Disclosures in Utely and Altshuler
1. A skin treatment device comprising:	<p>“The invention provides systems and methods of treating cosmetic conditions affecting the skin. The system and methods are applicable for use throughout the body. However, the systems and methods are particularly well suited for treating cosmetic conditions in the facial or neck area of the body.” (Utely at 3:49-55; <i>see also</i> Utely, Abstract; Altshuler, Abstract.)</p> <p>“[A] system 24 for renovating and reconstituting the dermis.” (Utely, 4:22-23.)</p> <p>“The system 24 includes a treatment device 26. The device 26 includes a handle 28 made, e.g., from molded plastic. The handle 28 carries at its distal end a treatment energy applicator 30, which, in use, contacts the epidermis.” (<i>Id.</i>, 4:31-34.)</p>

¹ Here, and throughout the claim charts in this Declaration, I have added bold emphasis to portions of the cited pages in the claim charts.

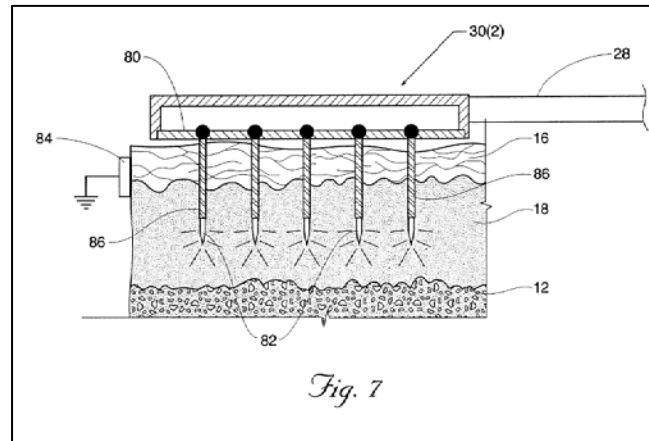
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	 <p style="text-align: center;"><i>Fig. 2</i></p> <p>(Utely, FIG. 2.)</p>
<p>[1.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base,</p>	<p>“As shown in FIG. 6, the second category of energy applicator 30(2) includes a carrier 80 on the distal end of the handle 28. The carrier 80 supports an array of spaced-apart needle electrodes 82.” (Utely, 7:40-43.)</p> <p>“The carrier can provide physical connections between control wires and each electrode 82, e.g., by solder or adhesive.” (Utely, 7:48-50.)</p> <p>“In use (as FIG. 7 shows), the electrodes 82 are intended to be inserted as a unit on the carrier 80 through the epidermis 16 and into the dermis 18.” (Utely, 7:56-58.)</p>

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(Utely, FIG. 6.)



(Utely, FIG. 7.)

[1.2] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

“The system 24 further includes a **device 32 to generate treatment energy**. In the illustrated embodiment, the **generator 32 generates radio frequency energy**, e.g., having a frequency in the range of about 400 kHz to about 10 MHz. A cable 34 extending from the proximal end of the handle 28 terminates with an electrical connector 36. The cable 34 is electrically coupled to the applicator 30, e.g., by wires that extend through the interior of the handle 28. When connector 36 **plugs into the generator 32, to convey the generated energy to the applicator 30 for transmission to the skin.**” (Utely, 4:38-47.)

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	<p>“Each electrode 82 comprises a discrete transmission source of radio frequency energy, which the controller 48 governs.” (Utely, 7:45-47.)</p>
<p>[1.3] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,</p>	<p>“The system 24 also includes a controller 48. The controller 48, which preferably includes a central processing unit (CPU), is linked to the generator 32, the fluid delivery apparatus 38, and the aspirating apparatus 40. The controller 48 governs the power levels, cycles, and duration that the radio frequency energy is distributed to the applicator 30, to achieve and maintain power levels appropriate to achieve the desired treatment objectives.” (Utely, 4:61-5:1.)</p> <p>“In this way, the system applies energy to the dermis in a targeted, selective fashion, to dissociate and contract collagen tissue, while preserving and protecting epithelial cells against thermal damage.” (Utely, 4:26-30.)</p> <p>“After insertion, the controller 48 conditions the electrodes 82 for operation in a unipolar mode. In this mode, energy transmitted by one or more of the electrodes 82 is returned by an indifferent patch electrode 84, which is coupled to patient ground. Alternatively, the controller 48 can condition pairs of electrodes 82 to operate in a bipolar mode, with one electrode serving to transmit radio frequency energy, and the other electrode serving as the return path.” (Utely, 7:58-67.)</p> <p>“The controller 48 governs the application of radio frequency energy to the electrodes 82 to ohmically heat adjacent dermal tissue. The electrodes 82 can be operated individually or in groups to form defined energy application patterns.” (Utely, 8:25-29.)</p> <p>“This invention relates to methods and apparatus for using electromagnetic radiation (EMR) for various therapeutic treatments and more particularly to methods</p>

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	<p>and apparatus for dermatological treatment by use of spatially confined and concentrated EMR to create areas of treatment or damage substantially surrounded by areas of sparing.” (Altshuler, 1:8-11.)</p> <p>“In accordance with the above, this invention provides a method and apparatus for performing a treatment on a volume located at area and depth coordinants of a patient’s skin, the method involving providing a radiation source and applying radiation from the source to an optical system which concentrates the radiation to at least one depth within the depth coordinants of the volume and to selected areas within the area coordinants of the volume, the at least one depth and the selected areas defining three-dimensional treatment portions in the volume within untreated portions of the volume.” (Altshuler, 5:4-10.)</p> <p>“Similarly, where the treatment is skin remodulation by treatment of collagen or hair removal, treatment parameters, including the optical system and the radiation wavelength are selected so that the at least one depth is the depth of interdermal collagen and the depth of at least one of the bulge and matrix of the hair follicle, respectively. (Altshuler, 6:24-27.)</p> <p>“It is important that there be at least some area of sparing around each of the islands or areas of treatment/damage 214 and that this area of sparing be sufficient to permit the skin to recover, such recovery being facilitated by melanosome migration.” (Altshuler, 13:20-24.)</p> <p>“The teachings of this invention are also particularly adapted for skin rejuvenation treatments by collagen regeneration. ... While such treatments may be made only along the line of a wrinkle or other blemish to be treated, such treatment is typically performed over a relatively large area undergoing treatment. In accordance with the teachings of this</p>
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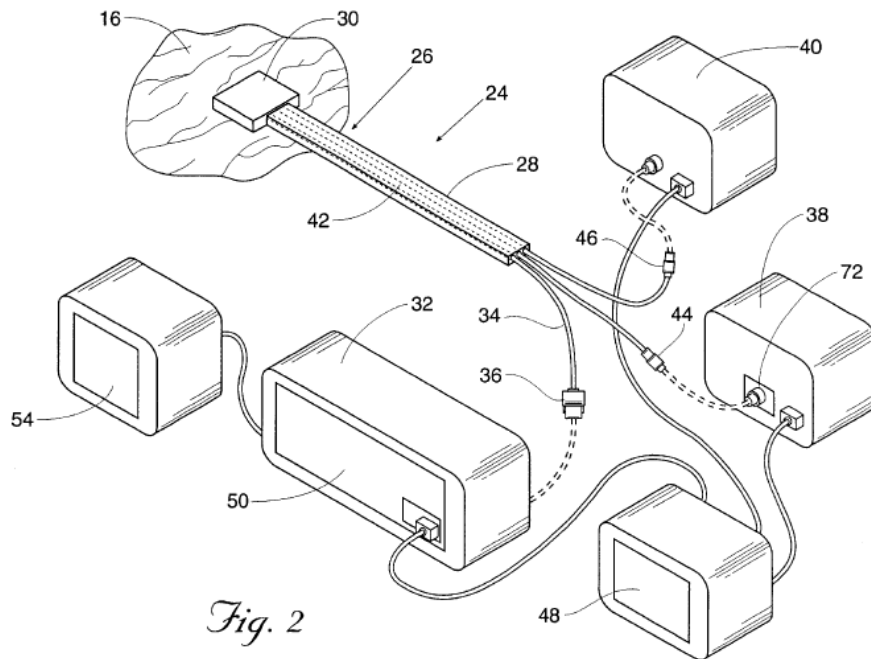
	<p>invention, such treatments can be more effectively performed by heating selective portions 214, with perhaps a 30% to 50% fill factor, resulting in significant collagen regeneration with less trauma and pain to the patient.” (Altshuler 18:21-19:2.)</p> <p>“Acoustic, RF or other EMF sources may also be employed in suitable applications.” (Altshuler, 10:8.)</p> <p>“Where an acoustic, RF or other non-optical EMR source is used as source 210, system 212 would be a suitable system for concentrating or focusing such EMR, for example a phased array, and the term ‘optical system’ should be interpreted, where appropriate, to include such system.” (Altshuler, 10:11-14.)</p>
[1.4] wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.	<p>“In such treatments, since collagen is not itself a chromophor, a chromophor such as water in the tissues or blood in the papillary dermis or below typically absorbs radiation and is heated to heat the adjacent collagen, causing selective damage or destruction thereof which results in collagen regeneration.” (Altshuler, 18:22-25.)</p> <p>“In accordance with the teachings of this invention, such treatments can be more effectively performed by heating selective portions 214, with perhaps a 30% to 50% fill factor, resulting in significant collagen regeneration with less trauma and pain to the patient.” (Altshuler, 18:29-19:2.)</p>

96. As shown in the claim chart above and discussed herein, Utely and Altshuler disclosed all of the limitations of claim 1.

97. There is no question that Utely disclosed “[a] skin treatment device” because Utely expressly “provide[d] systems and methods of treating cosmetic conditions affecting the skin.” (Utely, 3:49-50.) Utely’s “system 24 for renovating

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and reconstituting the dermis” “includes a treatment device 26.” (*Id.*, 4:22-23, 4:31-34, FIG. 2.) In my opinion, a POSA would have considered system 24, including, treatment device 26, to be a skin treatment device, as shown in Utely’s Figure 2 reproduced below. The treatment device 26 “includes a handle 28” and “a treatment energy applicator 30” that is carried on the handle. (*Id.*, 4:31-34, FIG. 2.) A POSA would have also considered the device to include other aspects of system 24 that allow treatment device 26 to operate (e.g., controller 48, generator 32).



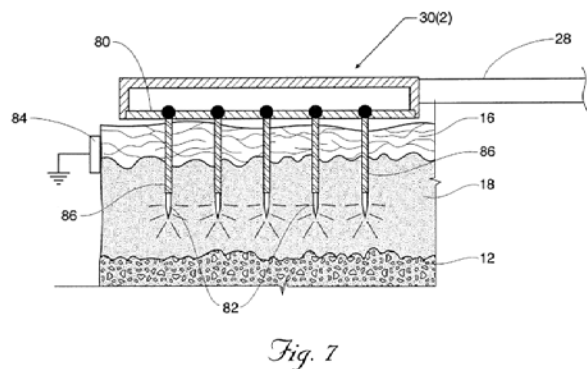
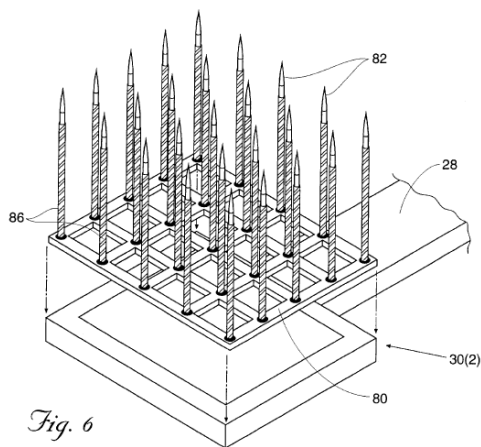
(Utely, FIG. 2.)

98. Utely also disclosed “a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base.” Utely taught that the “structure of the treatment device

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26 and associated electrical energy applicator 30 can vary” and disclosed “four representative categories of energy applicators 30.” (*Id.*, 5:17-20.) One of these categories was an intradermal treatment energy applicator 30(2) that “transmits energy internally directly into the dermis” through a plurality of needles. (*Id.*, 5:25-27, FIGS. 6-7.) A POSA would have understood Utely’s intradermal treatment energy applicator 30(2) to be a “housing” as claimed.

99. First, Utely disclosed that intradermal treatment energy applicator 30(2) “includes a carrier 80 on the distal end of handle 28.” (*Id.*, 7:40-42.) “[C]arrier 80 supports an array of spaced-apart needle electrodes 82.” (*Id.*, 7:42-43.) Figures 6 and 7 (reproduced below) show the needles supported on carrier 80. (*Id.*, FIGS. 6-7.) Based on these teachings, a POSA would have understood intradermal treatment energy applicator 30(2) (with its carrier 80) to be “*a housing configured to support a plurality of needles.*”



(Utely, FIGS. 6-7.)

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100. Second, Utely also disclosed that the needle electrodes 82 “are intended to be inserted as a unit on the carrier 80 through the epidermis 16 and *into the dermis 18.*” (*Id.*, 7:56-58 (emphasis added).) In fact, Figure 7 shows needles 82 actually inserted into the dermis 18. (*Id.*, FIG. 7.) Thus, Utely’s needles must be “*arranged for insertion into a dermal layer of skin.*”

101. Third, in my opinion a POSA would have understood Utely’s carrier 80 to be a “base” as claimed. For example, Utely’s Figures 6 and 7 show carrier 80 as a base from which the needles extend. (*Id.*, FIGS. 6-7.) And Utely’s Figure 6 shows that carrier 80 is attached to intradermal treatment energy applicator 30(2). (*Id.*, FIG. 6.) Being attached to the housing is one of the options for the base disclosed in the ’899 patent. Specifically, the ’899 patent explains that the base can be either “attached to housing 340 or formed as a part of the housing.” (’899 patent, 5:44-45.) Moreover, Utely explains that “carrier 80 *supports* an array of spaced-apart needle electrodes 82” and “can provide physical connections between control wires and each electrode 82.” (*Id.*, 7:42-43, 7:48-50.) Thus, Utely’s needles are “*attached to a base.*”

102. Based on these three points, a POSA would have understood Utely’s intradermal treatment energy applicator 30(2) to be a “housing” as claimed: “*a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base.*”

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103. Utely also disclosed “*the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source.*” First, Utely’s “system 24 further includes a device 32 to generate treatment energy.” (Utely, 4:38-39.) A POSA would have understood device 32 (also referred to as generator 32 to be an “*RF energy source.*” For example, Utely taught that “generator 32 generates radio frequency energy” and that a cable 34 with an electrical connector 36 “plugs into the generator 32, to convey the generated energy to the applicator 30 for transmission to the skin.” (*Id.*, 4:39-47.) By generating and conveying RF treatment energy, generator 32 is, by definition, an RF energy source.

104. Moreover, Utely taught how this energy was applied to the skin in its intradermal treatment energy applicator 30(2). Specifically, “[e]ach electrode 82 comprises a discrete transmission source of radio frequency energy, which the controller 48 governs.” (*Id.*, 7:45-47.) This teaching makes clear that the RF energy generated by generator 32 is conveyed to the needles 82. Thus, a POSA would have understood that Utely’s needles (i.e. electrodes 82) are “*further configured for application of radio frequency (RF) energy from a RF energy source*” (i.e. generator 32).

105. Utely disclosed “*a control module for controlling delivery of the RF energy from the RF energy source.*” Specifically, Utely’s “system 24 also includes

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a controller 48” that “is linked to the generator 32.” (*Id.*, 4:61-64.) “The controller 48 governs the power levels, cycles, and duration that the radio frequency energy is distributed to the applicator 30, to achieve and maintain power levels appropriate to achieve the desired treatment objectives.” (*Id.*, 4:64-5:1.) Thus, a POSA would have understood controller 48 to be a “*control module for controlling delivery of the RF energy from the RF energy source.*”

106. Moreover, Utely’s RF energy delivery is “*to the plurality of needles to induce a pattern of ... damage by the RF energy in the dermal layer when the needles are inserted therein.*” Utely taught that its “system applies energy to the dermis in a targeted, selective fashion, to dissociate and contract collagen tissue.” (*Id.*, 4:26-30.) A POSA would have understood dissociation and contraction of collagen tissue to be damage. The term “dissociation” would have been understood by a POSA to mean breaking apart or damaging the collagen. And a POSA would have known that contraction of the collagen was a result of inducing thermal damage to the collagen.

107. For the intradermal energy application 30(2), “[a]fter insertion, the controller 48 conditions the electrodes 82 for operation” in a unipolar or a bipolar mode, with one or more of the needle electrodes 82 transmitting RF energy in the dermal layer in either mode. (*Id.*, 7:56-67.) Further, Utely disclosed that “electrodes 82 can be operated individually or in groups to form defined energy

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application patterns.” (*Id.*, 8:27-29.) Thus, a POSA would have understood that the controller 48 controls the delivery of RF energy “*to the plurality of needles to induce a pattern of ... damage by the RF energy in the dermal layer when the needles are inserted therein.*”

108. Utely expressly taught “form[ing] defined energy application patterns” and “govern[ing] the power levels, cycles, and duration that the radio frequency energy is distributed ... to achieve and maintain power levels appropriate to achieve the desired treatment objectives.” (*Id.*, 8:25-29, 4:64-5:1.) Based on these teachings, a POSA would have been equipped to implement a variety of different damage patterns (including fractional damage patterns), even though Utely did not expressly use the term a fractional damage pattern. Indeed, a POSA would have understood that applying electromagnetic energy to tissue results in different damage patterns depending on the applied parameters. For example, Utely discussed several different parameters, such as “tissue temperature, time, [and] power” that may be varied by Utely’s controller during treatment. (Utely, 7:4-8.)

109. A POSA would also have understood that when delivering RF energy to tissue using the techniques disclosed in Utely, the tissue damage caused by the transmitted energy is greatest in the tissue closest to the needle electrodes and does not occur immediately, but instead builds over time. (*See* Ex. 1027, “Chang,” 7-8,

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Fig. 17 (discussing results of different models of damage caused by RF energy applied to tissue using a needle electrode).) Thus, a POSA would have understood that Utely's system can be used to apply RF energy in different patterns, and that the resulting damage would be greatest closest to the needle electrodes. For example, a POSA would have understood that increasing the RF power or treatment time would alter the tissue damage.

110. Moreover, even though Utely did not expressly use the term fractional damage, fractional damage to the dermal layer of skin was known. On top of that, the beneficial results that flow from fractional damage, such as the beneficial collagen regeneration, quicker healing, reduced pain, etc., were also known. Accordingly, it would have been obvious to use Utely's controller 48 to control RF energy delivery to the needles to induce a pattern of fractional damage.

111. Altshuler disclosed "*induc[ing] a pattern of fractional damage.*" Like Utely, Altshuler disclosed "methods and apparatus for using electromagnetic radiation (EMR) for various therapeutic treatments and more particularly to methods and apparatus for dermatological treatment." (Altshuler, 1:8-11.) Altshuler further taught the "use of spatially confined and concentrated EMR to create areas of treatment or damage substantially surrounded by areas of sparing." (*Id.*) A POSA would have understood "areas of sparing" to refer to undamaged tissue adjacent to damaged (i.e. treated) tissue. Altshuler's "apparatus for

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performing a treatment on a volume located at area and depth coordina[tes] of a patient's skin" involved "concentrat[ing] the radiation to at least one depth within the depth coordina[tes] of the volume and to *selected areas* within the area coordina[tes] of the volume, the at least one depth and the selected areas *defining three-dimensional treatment portions in the volume within untreated portions of the volume.*" (*Id.*, 5:4-10 (emphasis added).) Altshuler emphasized that "[i]t is important that there be at least some area of sparing around each of the islands or areas of treatment/damage 214." (*Id.*, 13:20-23.)

112. A POSA would have understood Altshuler's "areas of treatment or damage substantially surrounded by areas of sparing" to be "*a pattern of fractional damage.*" (*Id.*, 1:8-11.) As discussed above, the proper construction of "a pattern of fractional damage" is "the pattern of damage caused by non-uniform heating" (*Supra* Section VII.A) where "non-uniform heating" encompasses the case of heated areas separated by unheated areas. Altshuler's description falls squarely within this construction as well as the other proposed constructions at the ITC—non-uniform heating leads to areas of damage surrounded by areas of sparing. And a POSA would have understood Altshuler to disclose "*a pattern of fractional damage*" even using Patent Owner's proposed construction of "a distribution of small localized regions of thermal damage" from the ITC proceeding.

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113. Altshuler further disclosed that this pattern of fractional damage is induced “*by the RF energy in the dermal layer.*” Altshuler is clear that its teachings are not limited to optical EMR sources. Indeed, Altshuler specifically lists alternative types of energy and/or frequencies of EMR radiation that may be used: “Acoustic, RF or other EM[R] sources may also be employed in suitable applications.” (Altshuler, 10:8.) And Altshuler further stated that these options should be considered as being included throughout the disclosure, explaining that when an RF energy source is used, “system 212 would be a suitable system for concentrating or focusing such EMR... and the term ‘optical system’ should be interpreted, where appropriate, to include such system.” (*Id.*, 10:11-14.) Thus, a POSA would have understood Altshuler to disclose inducing a pattern of fractional damage by RF energy. And Altshuler taught that “where the treatment is skin remodulation by treatment of collagen ... the at least one depth is the depth of interdermal collagen.” (*Id.*, 6:24-27.) Thus, a POSA would have understood Altshuler as disclosing “*induc[ing] a pattern of fractional damage by the RF energy in the dermal layer.*”

114. Not only did Altshuler disclose a fractional damage pattern, it also disclosed the reason for creating Altshuler’s pattern of fractional damage, namely “significant collagen regeneration with less trauma and pain to the patient.” (Altshuler, 18:27-9:2.) Altshuler recognized that “treatments which are performed

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over a relatively large area, such as skin rejuvenation and hair removal... can cause varying degrees of skin damage over a substantial treatment area.” (*Id.*, 1:28-30.) Damage from such treatments “can frequently take several weeks or more to heal, and follow-up treatments can normally not be performed during this period.” (*Id.*, 1:32-2:1.) Accordingly, Altshuler taught that performing the procedures “in a manner which would result in smaller, spaced areas of damage which heal more quickly” would “enhanc[e] both patient comfort and the ability to more quickly perform follow-up treatments.” (*Id.*, 2:1-4.)

115. Moreover, Altshuler explained that its teachings are “particularly adapted for skin rejuvenation treatments by collagen regeneration.” (*Id.*, 18:21-22.) Altshuler taught that “such treatments can be *more effectively performed* by heating selective portions 214, with perhaps a 30% to 50% fill factor, resulting in *significant collagen regeneration with less trauma and pain* to the patient.” (*Id.*, 18:29-19:2 (emphasis added).) In my opinion, by “heating selective portions,” Altshuler clearly meant nonuniform heating, in this context referred to as fractional damage. Achieving this significant collagen regeneration is why “[i]t is important that there be at least some area of sparing around each of the islands or areas of treatment/damage 214 and that this area of sparing *be sufficient to permit the skin to recover.*” (*Id.* 13:20-23 (emphasis added).)

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116. Thus, a POSA would have been motivated to combine the teachings of Altshuler with the apparatus of Utely. More specifically, a POSA would have been motivated to use Utely's controller 48 to control the RF energy delivered to needle electrodes 82 so that it created areas of treatment or damage substantially surrounded by areas of sparing (i.e., a pattern of fractional damage) to more effectively rejuvenate the skin by achieving significant collagen regeneration with less trauma and pain to the patient. Because Altshuler expressly disclosed advantages of its fractional damage patterns, including significant collagen regeneration, quicker recovery, and decreased patient pain, a POSA would have found it obvious to use Utely's controller to implement Altshuler's fractional damage pattern in Utely's system. (Altshuler, 13:11-23, 2:1-4, 18:21-19:2.) Accordingly, combining Altshuler's teachings with Utely's system would be nothing more than the use of a known technique to improve similar devices in the same way.

117. Further, a POSA would have been motivated to use an array of needles to transmit RF energy into the skin, such as taught in Utely, to apply energy to the dermis to achieve the pattern of fractional damage disclosed in Altshuler because of the known limitations of using laser energy in skin treatments. For example, different skin tones absorb laser energy differently, making it difficult to use laser energy to treat certain skin types. (*Id.*, 3:14-21.) Delivering RF

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energy directly to the dermis with a needle bypasses this issue, “permit[ing] all types and pigmentations of skin to be safely treated.” (*Id.*, 3:19-21.) Laser equipment is also generally costly and complex. (*Id.*, 3:8-14.) Thus, a POSA would have been motivated to use RF energy applied using an array of needles to achieve the pattern of fractional damage taught in Altshuler.

118. In my opinion, a POSA would have had a reasonable expectation of success in using Utely’s controller 48 to implement Altshuler’s fractional damage pattern. As an initial matter, Altshuler explicitly taught that the source of energy for its treatment system may be “an acoustic, RF or other non-optical EMR source.” (*Id.*, 10:11-14.) Because Utely disclosed a skin treatment device that uses RF energy, Altshuler provided an explicit teaching to implement its teachings into a system such as Utely’s. Furthermore, Utely disclosed that its controller “governs the power levels, cycles, and duration that the radio frequency energy is distributed to the applicator 30, to achieve and maintain power levels appropriate to achieve the desired treatment objectives.” (Utely, 4:64-5:1.) And Utely taught that its “system applies energy to the dermis in a targeted, selective fashion, to dissociate and contract collagen tissue” and that “electrodes 82 can be operated individually or in groups to form defined energy application patterns.” (*Id.*, 4:26-30, 8:27-29.) Accordingly, a POSA would have recognized Utely’s device as “a suitable system for concentrating or focusing such EMR [i.e., RF].” (Altshuler, 10:11-14.) Indeed,

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using needles to concentrate RF energy would have been the primary option that occurred to a POSA.

119. Thus, a POSA would have understood that controller 48 could be used to govern the power level, cycle, and duration of RF energy to achieve the desired treatment objective of significant collagen regeneration, with less pain to the patient, by operating the needle electrodes 82 to form Altshuler's damage pattern. It would have been simple for a POSA to use Utely's controller to achieve Altshuler's damage pattern. As discussed above, a POSA would have been aware of the different parameters that affect the tissue damage (e.g., power and duration of treatment) and would have easily been able to modify those parameters as needed using Utely's controller to achieve the damage pattern of Altshuler.

120. Using RF energy transmitted by needles to create a pattern of fractional damage in tissue was also known, and practiced, in closely-related fields. For example, Edwards disclosed a device that used RF energy delivered by needles to ablate tissue in the tongue in a pattern of damaged regions alternating with undamaged regions. (Edwards, 10:10-22, FIG. 6.) Thus, a POSA would understand that using RF energy delivered by needles to create patterns of fractional damage was possible, and had in fact been practiced in a closely-related application.

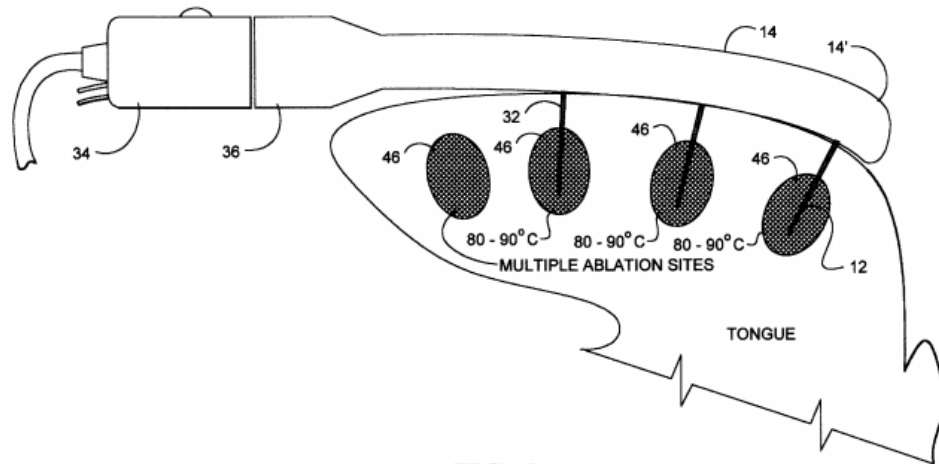


FIG. 6

(Edwards, FIG. 6.)

121. In short, the combination of Utely and Altshuler disclosed “*a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein.*”

122. Finally, the combination of Utely and Altshuler disclosed “*wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.*” As I discussed above, the formation of new collagen is the body’s natural response to collagen damage. (Section V.B.) Thus, both Utely’s and Altshuler’s controlled delivery of RF energy is configured to stimulate formation of new collagen in the skin. Further, Altshuler expressly taught that “causing selective damage or destruction [of collagen] results in collagen

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regeneration.” (Altshuler, 18:22-25.) A POSA would have understood collagen regeneration to mean the formation of new collagen. Moreover, Altshuler also taught that “treatments can be *more effectively performed* by heating selective portions 214, with perhaps a 30% to 50% fill factor, resulting in *significant collagen regeneration*.” (*Id.*, 18:29-19:2.) Thus, using Utely’s controller to achieve Altshuler’s fractional damage pattern would specifically result in the “*controlled delivery of the RF energy [being] configured to stimulate formation of new collagen in the skin*.”

123. Based on the foregoing, a POSA would have understood that Altshuler provided a known pattern of fractional damage (i.e., areas of treatment or damage substantially surrounded by areas of sparing) that resulted in significant collagen regeneration with less trauma and pain to the patient. A POSA would have therefore been motivated to combine Altshuler’s teachings with Utely’s teachings to improve the treatment results while also improving the patient experience.

124. A POSA would have had a reasonable expectation of success in using Utely’s controller to achieve Altshuler’s fractional damage pattern to arrive at the claimed invention. Altshuler made known the goal of multiple small micro-wounds as a pattern of fractional damage. And with that goal in mind, a POSA would have been able to control Utely’s RF energy to accomplish fractional damage. Indeed, a

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POSA would have known how to use Utely's controller to achieve Altshuler's pattern of fractional damage. For example, a POSA would have varied parameters already discussed in Utely (e.g., power level, cycle, and/or duration of RF energy) so that areas of treatment or damage were surrounded by areas of sparing. Altshuler itself disclosed using its system with RF energy, and Utely itself indicated that its needles could be operated to form defined energy application patterns. In short, using Utely's controller to achieve Altshuler's fractional damage pattern would be nothing more than using a known technique (areas of damage surrounded by areas of sparing) to improve a similar device in the same way. Therefore, in using Utely's controller to achieve Altshuler's fractional damage pattern, a POSA would have achieved predictable results.

125. Based on the foregoing, it is my opinion that the combination of Utely and Altshuler disclosed each limitation of claim 1 and that a POSA would have had a reason (improved treatment outcomes and patient comfort) to combine these references to arrive at the claimed invention, with a reasonable expectation of success. Thus, it is my opinion that claim 1 would have been obvious over Utely and Altshuler, notwithstanding any objective indicia of nonobviousness, which I discuss below with respect to all challenged claims.

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D. Claim 2 would have been obvious over Utely in view of Altshuler

126. Claim 2 depends from claim 1 and further recites “*wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.*” As shown in the claim chart below and discussed in this Declaration, Utely and Altshuler taught each element of claim 2 of the ’899 patent.

Claim	Disclosures in Utely and Altshuler
2. The device of claim 1, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.	<p>“Alternatively, the controller 48 can condition pairs of electrodes 82 to operate in a bipolar mode, with one electrode serving to transmit radio frequency energy, and the other electrode serving as the return path.” (Utely, 7:64-67.)</p> <p>“The controller 48 governs the application of radio frequency energy to the electrodes 82 to ohmically heat adjacent dermal tissue. The electrodes 82 can be operated individually or in groups to form defined energy application patterns.” (Utely, 8:24-29.)</p> <p>“Another aspect of the invention provides systems and methods for applying electromagnetic energy to skin, in which the arrays of electrodes on the carrier are sized so that, while the carrier contacts an epidermal skin region, the electrodes extend into tissue beneath the epidermal skin region to ohmically heat dermal tissue.” (Utely, 2:11-17.)</p>

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127. As discussed above, Utely and Altshuler disclosed all the limitations of claim 1. And Utely disclosed claim 2's additional limitations.

128. Specifically, Utely disclosed that "the controller 48 can condition pairs of electrodes 82 to operate in a bipolar mode, with one electrode serving to transmit radio frequency energy, and the other electrode serving as the return path." (Utely, 7:64-67.) Thus, Utely disclosed "*wherein the plurality of needles are associated with each other in groups of bipolar pairs*" as claimed.

129. Further, as discussed above, controller 48 is configured to control the delivery of RF energy to the electrodes to form various damage patterns. (*Id.*, 8:27-29; *supra* Section X.C.) A POSA would have understood that using RF energy to "ohmically heat dermal tissue," as disclosed in Utely, is a non-ablative form of damage to the tissue of the dermis because the underlying tissue is being heated, not removed or destroyed. (*Id.*, 2:12-17.) Thus, Utely disclosed "*wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer.*"

130. Moreover, in my opinion, a POSA would have also understood that Utely's disclosed bipolar mode, in which "one electrode serv[es] to transmit radio frequency energy, and the other electrode serv[es] as the return path," would result in tissue damage occurring along the path of the RF energy between adjacent needles of each bipolar pair of electrodes because it is the RF energy that heats the

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adjacent tissue and causes damage. (*Id.*, 7:64-67, 8:25-27.) Since the RF energy travels between the needles of each of the bipolar pairs a POSA would have understood that the damage will, therefore, occur along the paths the RF energy travels. Thus, Utely disclosed “*wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles*” as claimed.

131. A POSA would have readily implemented Altshuler’s fractional damage pattern with Utely’s controller for the reasons I discussed above with respect to claim 1. Doing so would not have affected Utely’s bipolar operation mode. For example, the areas of treatment or damage along the paths the RF energy travels would be surrounded by areas of sparing. The combination of Utely and Altshuler would have resulted in “*the plurality of needles [being] associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.*” Thus, it is my opinion that claim 2 would have been obvious over Utely and Altshuler.

E. Claim 4 would have been obvious over Utely in view of Altshuler

132. Claim 4 depends from claim 1 and further requires “*wherein the control module is further configured to receive a selection of an application-*

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specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.” As shown in the claim chart below and discussed in this Declaration, Utely and Altshuler taught each element of claim 4 of the ’899 patent.

Claim	Disclosures in Utely and Altshuler
4. The device of claim 1, wherein the control module is further configured to receive a selection of an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.	<p>“The controller 48 includes an input/output (I/O) device 50. The I/O device 50 allows the physician to input control and processing variables, to enable the controller 48 to generate appropriate command signals. The I/O device 50 also receives real time processing feedback information from one or more sensors 52 associated with the applicator, for processing by the controller 48, e.g., to govern the application of energy and the delivery of processing fluid.” (Utely, 5:5-12.)</p> <p>“The controller 48, which preferably includes a central processing unit (CPU), is linked to the generator 32, the fluid delivery apparatus 38, and the aspirating apparatus 40. The controller 48 governs the power levels, cycles, and duration that the radio frequency energy is distributed to the applicator 30, to achieve and maintain power levels appropriate to achieve the desired treatment objective.” (Utely, 4:61-5:1.)</p>

133. As discussed above, Utely and Altshuler disclosed all the limitations of claim 1. And Utely disclosed claim 4’s limitation.

134. Specifically, Utely disclosed that “controller 48 includes an input/output (I/O) device 50” that “allows the physician to input control and

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processing variables, to enable the controller 48 to generate appropriate command signals.” (Utely, 5:5-8.) A POSA would have understood controller 48, with its I/O device 50, to be “*configured to receive a selection of an application-specific setting*” because the physician’s input enables the controller to generate appropriate command signals. As discussed above, receiving such selections of settings was desirable to tailor treatments to each case.

135. And Utely’s “controller 48 governs the *power levels, cycles, and duration* that the radio frequency energy is distributed to the applicator 30, to achieve and maintain power levels appropriate to achieve the desired treatment objectives.” (*Id.*, 4:64-5:1 (emphasis added).) Thus, the selection causes the energy source to vary at least one of a duration, intensity (i.e., power level), and sequence (i.e., cycle) of the RF energy transmitted to the plurality of needles based on the selected setting. Indeed, “[t]he I/O device 50 also receives real time processing feedback information from one or more sensors 52 associated with the applicator, for processing by the controller 48, e.g., to govern the application of energy.” (Utely, 5:8-12.)

136. Using Utely’s controller to achieve Altshuler’s fractional damage pattern would not have changed this feature of Utely. It simply allows the controller to receive particular settings (e.g., settings that facilitate fractional damage patterns). The combination of Utely and Altshuler would have resulted in a

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controller that is “*configured to receive a selection of an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.*” Thus, it is my opinion that claim 4 would have been obvious over Utely and Altshuler.

F. Claim 6 would have been obvious over Utely in view of Altshuler.

137. Claim 6 depends from claim 1 and further requires “*further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.*” As shown in the claim chart below and discussed in this Declaration, Utely and Altshuler taught each element of claim 6 of the ’899 patent.

Claim	Disclosures in Utely and Altshuler
6. The device of claim 1, further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.	<p>“A cooling element 215 is also included to cool the surface of skin 200 over treatment volume V.” (Altshuler, 11:6-7.)</p> <p>“Cooling element 215 may for example be a thermoelectric element, or may be a system for passing water, preferably chilled water, a gas, preferably a chilled gas, and possibly even a cryogenic gas, over such portion of the optical system.” (Altshuler, 11:9-12.)</p> <p>“9. Cooling. Typically cooler 215 is activated before source 210 to precool the patient’s skin to a selected temperature below normal skin temperature, for example 0 to 10°C, to a depth of at least DE junction 206, and preferably to depth d</p>

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	<p>to protect the entire skin region 220 above volume V. However, in accordance with the teachings of this invention, if precooling extends for a period sufficient for the patient's skin to be cooled to a depth below the volume V, and in particular if cooling continues after the application of radiation begins, then heating will occur only in the radiated portions 214, each of which portions will be surrounded by cooled skin. Therefore, even if the duration of the applied radiation exceeds TRT for portions 214, heat from these portions will be contained and thermal damage will not occur beyond these portions. Further, while nerves may be stimulated in portions 214, the cooling of these nerves outside of portions 215, will, in addition to permitting tight control of damage volume, also block pain signals from being transmitted to the brain, thus permitting treatments to be effected with greater patient comfort... ." (Altshuler, 15:4-17.)</p>
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138. As discussed above, Utely and Altshuler disclosed all the limitations of claim 1. And the combination of Utely and Altshuler disclosed claim 6's limitation.

139. Specifically, Altshuler disclosed a "cooling element 215... to cool the surface of skin 200 over treatment volume V." (Altshuler, 11:6-7.) "Cooling element 215 may for example be a thermoelectric element, or may be a system for passing water, preferably chilled water, a gas, preferably a chilled gas, and possibly even a cryogenic gas, over such portion of the optical system." (*Id.*, 11:9-12.) Altshuler used cooling element 215 to precool the patient's skin to a depth

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below the treatment volume so that “heating will occur only in the radiated portions 214, each of which portions will be surrounded by cooled skin.” (*Id.*, 15:7-11.) Thus, “heat from these portions will be contained and thermal damage will not occur beyond these portions.” (*Id.*, 15:11-13.) Altshuler also taught that “in addition to permitting tight control of damage volume, [cooling] also block[s] pain signals from being transmitted to the brain, thus permitting treatments to be effected with greater patient comfort.” (*Id.*, 15:13-19.) Thus, Altshuler disclosed “*a cooler for cooling a surface of the skin.*”

140. As discussed above, a POSA would have been motivated to use Utely’s controller to achieve Altshuler’s fractional damage pattern. A POSA would have been further motivated to modify Utely’s system to include Altshuler’s cooling element to (1) “permit tight control of damage volume” to better accomplish fractional damage, and (2) “permit[] treatments to be effected with greater patient comfort,” as expressly taught by Altshuler. (*Id.*) Because Altshuler taught precooling and “cooling [that] continue[d] after the application of radiation beg[an]” (*id.*, 15:7-11), the cooling element, when applied to Utely’s system, would be “*for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.*”

141. A POSA would have readily implemented Altshuler’s fractional damage pattern by using Utely’s controller for the reasons discussed above. In

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addition, it would have been simple and straightforward to modify Utely to include Altshuler's cooling element. For example, a POSA would have easily implemented a thermoelectric element or other well-known cooling element in Utely's treatment device 26. Thus, a POSA would have had a reasonable expectation of success in arriving at a device "*further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.*" It is my opinion that claim 6 would have been obvious over Utely in view of Altshuler.

G. Claim 7 would have been obvious over Utely in view of Altshuler.

142. Claim 7 depends from claim 1 and further requires "*wherein at least one of the plurality of needles is a hollow needle, and further comprising a delivery mechanism for delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.*" As shown in the claim chart below and discussed in this Declaration, Utely and Altshuler taught each element of claim 7 of the '899 patent.

Claim	Disclosures in Utely and Altshuler
7. The device of claim 1, wherein at least one of the plurality of needles is a hollow needle, and further comprising a delivery mechanism for delivering an analgesic via the hollow needle to tissue surrounding a	"In the illustrated embodiment, at least some, and preferably all, of the needle electrodes 90 include interior fluid passages 94 (see FIG. 8). A manifold 96 couples a select number of the passages 94 in communication with the fluid delivery apparatus 38 . This way, processing fluid can be introduced through the electrodes 90 and into the subcutaneous tissue surrounding the distal ends of the electrodes 90. " (Utely, 9:10-17.)

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tip of the hollow needle.	“[P]ain may be controlled by the use of a local anesthetic... .” (Altshuler, 3:26-29.)
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143. As discussed above, Utely and Altshuler disclosed all the limitations of claim 1. And the combination of Utely and Altshuler disclosed claim 7’s limitation.

144. Specifically, Utely disclosed embodiments where “at least some, and preferably all, of the needle electrodes 90 include interior fluid passages 94 (see FIG. 8).” (Utely, 9:10-17.) “A manifold 96 couples a select number of the passages 94 in communication with the fluid delivery apparatus 38.” (*Id.*) The fluid is “introduced through the electrodes 90 and into the subcutaneous tissue surrounding the distal ends of the electrodes 90.” (*Id.*) Accordingly, Utely disclosed “*wherein at least one of the plurality of needles is a hollow needle*” and “*a delivery mechanism*” that can deliver a fluid to the tissue at the end of the needles.

145. In addition, Altshuler disclosed that “*pain may be controlled by the use of a local anesthetic*” during treatment. (Altshuler, 3:26-29.) Altshuler mentions that there are some risks with anesthetics. (*Id.*) However, medical practitioners frequently administer pain medications during a dermatologic treatment such as RF microneedling. Accordingly, Altshuler would not have discouraged a POSA from using analgesic. Instead, it would have been obvious to deliver an analgesic to the patient’s skin. Altshuler’s statement that “the use of needles to administer a local anesthetic is undesirable for cosmetic procedures”

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would also not have discouraged a POSA from using Utely's existing needles to deliver analgesic. (*Id.*) Altshuler's statement instead applies to a device that is not using needles at all (e.g., such as Altshuler's laser systems). In my opinion, Altshuler's teachings would have led a POSA to use Utely's disclosed hollow needles rather than using a separate needle. A POSA would have known that this modification would increase patient comfort during treatment without requiring additional needles to deliver analgesic.

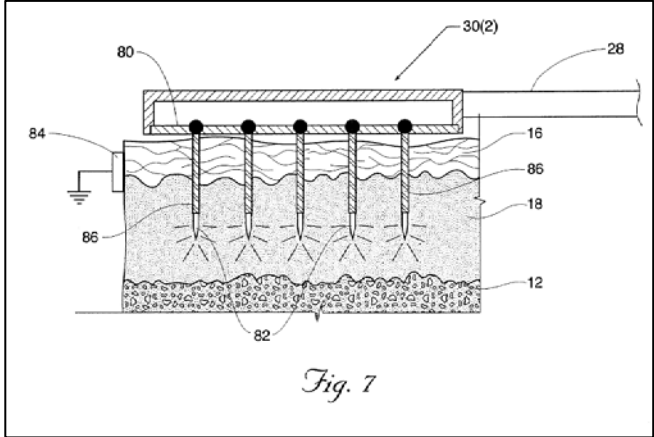
146. It would have been obvious for a POSA to use the hollow needles and fluid delivery system disclosed in Utely to deliver a local analgesic to control pain as Altshuler taught. A POSA would have had a reasonable expectation of success with such a modification because Utely's system was already capable of delivering fluid to tissue, and a POSA would have known that analgesics are often fluids. Thus, it is my opinion that claim 7 would have been obvious over Utely in view of Altshuler.

H. Claim 10 would have been obvious over Utely in view of Altshuler.

147. Claim 10 depends from claim 1 and further requires "*wherein the control module is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with undamaged regions between the damaged regions.*" As shown in the claim chart

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below and discussed in this Declaration, Utely and Altshuler taught each element of claim 10 of the '899 patent.

Claim	Disclosures in Utely and Altshuler
10. The device of claim 1, wherein the control module is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with undamaged regions between the damaged regions.	<p>“Each electrode 82 comprises a discrete transmission source of radio frequency energy, which the controller 48 governs.” (Utely, 7:45-47.)</p> <p>“The controller 48 governs the application of radio frequency energy to the electrodes 82 to ohmically heat adjacent dermal tissue.” (Utely, 8:25-27.)</p> <p>“The insulating material 82 insulates the epidermis 16 and a portion of the dermis 18 from direct exposure to radio frequency energy transmitted by the exposed distal end.” (Utely, 8:12-15.)</p> <div data-bbox="667 1094 1317 1528"></div> <p>(Utely, FIG. 7.)</p> <p>“It is important that there be at least some area of sparing around each of the islands or areas of treatment/damage 214...” (Altshuler, 13:20-23.)</p>

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148. As discussed above, Utely and Altshuler disclosed all the limitations of claim 1. And the combination of Utely and Altshuler disclosed claim 10's limitation.

149. Specifically, Utely disclosed that “[e]ach electrode 82 comprises a discrete transmission source of radio frequency energy, which the controller 48 governs” “to ohmically heat adjacent dermal tissue.” (Utely, 7:45-47, 8:25-27.) Utely further taught that an insulating material 86 “insulates the epidermis 16 and a portion of the dermis 18 from direct exposure to radio frequency energy transmitted *by the exposed distal end.*” (*Id.*, 8:12-15.) A POSA would have understood the exposed distal end of the needle to be a tip of the needle electrodes 82. (*Id.*, FIG. 7.)

150. Insulating the needle electrode in this way is desirable because it enables more precise application of the RF energy (and resulting damage). Because each needle electrode 82 is a discrete transmission source (i.e., at its exposed distal end) that heats adjacent dermal tissue, a POSA would have understood that Utely disclosed that its controller 48 “*is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles.*” A POSA would have understood that the damaged areas would be centered around each of the electrodes, as shown in Utely's Figure 7 (reproduced below).

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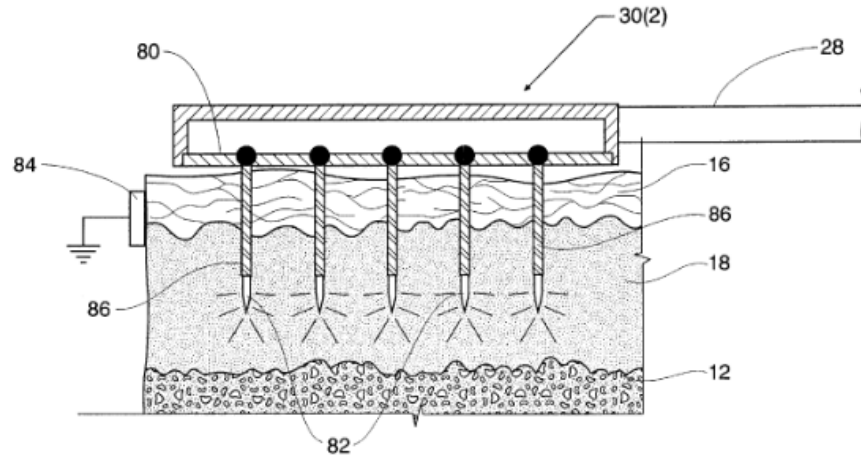


Fig. 7

(Utely, FIG. 7.)

151. Moreover, Altshuler disclosed a treatment pattern that comprises “some area of sparing around each of the islands or areas of treatment/damage 214.” (Altshuler, 13:20-23.) As discussed above, a POSA would have been motivated to use Utely’s controller to achieve Altshuler’s fractional damage pattern. (Section X.C) This would have resulted in “*undamaged regions between the damaged regions,*” as expressly taught by Altshuler. (See, e.g., Altshuler, 1:10-11.)

152. A POSA would have readily implemented Altshuler’s fractional damage pattern by using Utely’s controller for the reasons discussed above. (Section X.C.) In doing so, a POSA would have arrived at a device “*wherein the control module is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with*

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undamaged regions between the damaged regions.” Thus, it is my opinion that claim 10 would have been obvious over Utely in view of Altshuler.

I. Claim 11 would have been obvious over Utely in view of Altshuler.

153. Claim 11 depends from claim 1 and further requires “*wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.*” As shown in the claim chart below and discussed in this Declaration, Utely and Altshuler taught each element of claim 11 of the ’899 patent.

Claim	Disclosures in Utely and Altshuler
11. The device of claim 1, wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.	<p>“Each electrode 82 comprises a discrete transmission source of radio frequency energy, which the controller 48 governs.” (Utely, 7:45-47.)</p> <p>“The controller 48 governs the application of radio frequency energy to the electrodes 82 to ohmically heat adjacent dermal tissue.” (Utely, 8:25-27.)</p> <p>“The insulating material 82 insulates the epidermis 16 and a portion of the dermis 18 from direct exposure to radio frequency energy transmitted by the exposed distal end.” (Utely, 8:12-15.)</p>

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understood that the damaged areas would be centered around (i.e., localized) each of the electrodes, as shown in Utely's Figure 7 (reproduced below). As further shown in Figure 7, because there are multiple needles adjacent to each other, Utely's control module is "*configured to cause at least two adjacent regions of thermal damage.*"

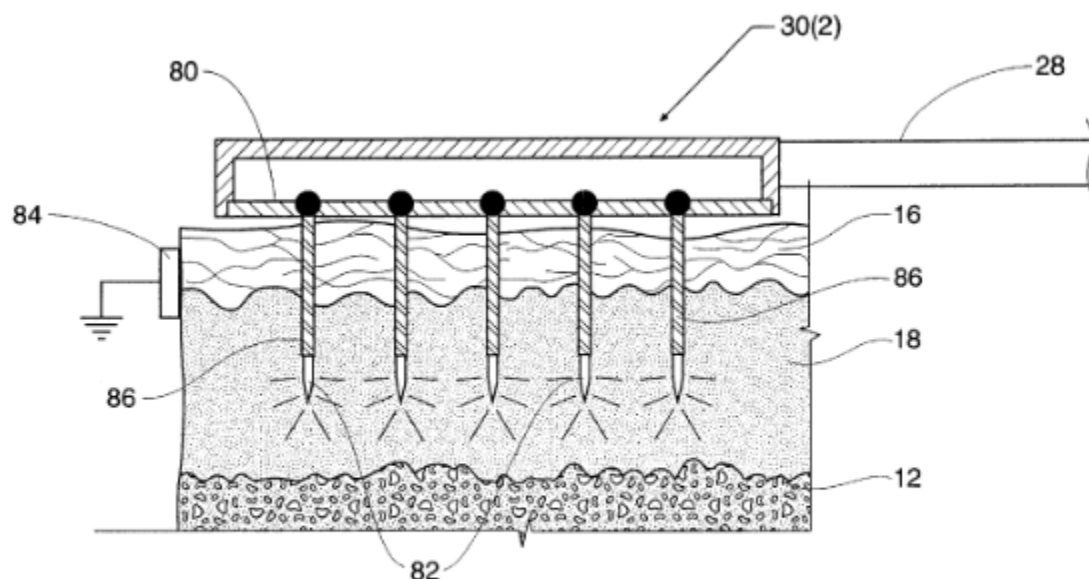


Fig. 7

(Utely, FIG. 7.)

156. Moreover, Altshuler disclosed a treatment pattern that comprises "some area of sparing around each of the islands or areas of treatment/damage 214." (Altshuler, 13:20-23.) As discussed above, a POSA would have been motivated to use Utely's controller to achieve Altshuler's fractional damage pattern. (Section X.C.) This modification would have confirmed that Utely's controller "*is configured to cause at least two adjacent regions of thermal damage,*

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with a small localized area of thermal damage surrounding each tip” because the islands or areas of treatment would be small localized areas surrounding each tip.

157. A POSA would have readily implemented Altshuler’s fractional damage pattern by using Utely’s controller for the reasons discussed above. (Section X.C.) In doing so, a POSA would have arrived at a device “*wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.*” Thus, it is my opinion that claim 11 would have been obvious over Utely in view of Altshuler.

J. Claim 15 would have been obvious over Utely in view of Altshuler.

158. Claim 15 is substantively similar to claim 1. The chart below compares claim 15 with claim 1. The portions of claim 15 that are not identical are bolded.

Claim 1	Claim 15
[1.p] A skin treatment device, comprising:	[15.p] A skin treatment device, comprising:
[1.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base,	[15.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base,
[1.2] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and	[15.2] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and
[1.3] a control module for controlling	[15.3] a control module for controlling

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delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,	delivery of the RF energy from the RF energy source to the plurality of needles to cause a pattern of fractional damage to be produced in the dermal layer in a vicinity of the tips of the needles
[1.4] wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.	[15.4] wherein delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer, and wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.

159. Where the elements are the same, the teachings of the combination of Utely and Altshuler discussed above with respect to claim 1 are equally applicable here. Specifically, the preamble [15.p], the “housing” limitation [15.1], and the “plurality of needles” limitation [15.2] of claim 15 are the same as claim 1. (’899 patent, 12:34-40 *with* 13:30-36.)

160. The “control module” limitation [15.3] in claim 15 is similar to claim 1. I address the differences below. First, claim 15 recites “*to cause a pattern of fractional damage to be produced in the dermal layer*” instead of “*to induce a pattern of fractional damage by the RF energy in the dermal layer.*” In my opinion, causing a pattern of fractional damage to be produced is the same as inducing a pattern of fractional damage. Thus, Utely’s and Altshuler’s teachings discussed above with respect to claim 1 are equally applicable to this limitation in claim 15. Second, claim 15 adds that the pattern is “*in a vicinity of the tips of the needles.*” In my opinion, this element is also taught by the combination of Utely and Altshuler.

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Specifically, in combining Utely and Altshuler as set forth above, Altshuler's pattern would be in a vicinity of the tips of Utely's needles, as shown in Utely's Figure 7, for the reasons discussed above with respect to claims 10 and 11. (Section X.H-I.)

161. Claim 15's final limitation is similar to the limitations of claims 1, 10, and 11. For example, inducing a pattern of fractional damage would result in the claim 15 feature "wherein delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer." In addition, Altshuler's pattern would result in "at least two adjacent regions of thermal damage" that "have an undamaged region therebetween" for the reasons discussed above with respect to claims 10 and 11. (Altshuler, 13:20-23; Utely, FIG. 7.) Thus, Utely's and Altshuler's teachings discussed above with respect to claims 1, 10, and 11 are equally applicable to this claim 15 limitation.

162. Accordingly, the combination of Utely and Altshuler disclosed each limitation of claim 15. And a POSA would have had reason to combine Utely and Altshuler, with a reasonable expectation of success, for the reasons discussed with respect to claim 1. (Section X.C.) In my opinion, claim 15 would have been obvious over Utely in view of Altshuler.

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K. Claim 20 would have been obvious over Utely in view of Altshuler.

163. Claim 20 is substantively similar to claim 1. The chart below compares claim 20 with claim 1. The portions of claim 20 that are not identical are bolded.

Claim 1	Claim 20
[1.p] A skin treatment device, comprising:	[20.p] A skin treatment device, comprising:
[1.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base,	[20.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base and arranged in a group of bipolar pairs,
[1.2] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and	[20.2] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and
[1.3] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,	[20.3] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,
[1.4] wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.	[20.4] wherein the pattern of fractional damage includes damaged regions between tips of needles of the bipolar pairs, and undamaged regions between bipolar pairs of needles in the group.

164. Where the elements are the same, the teachings of the combination of Utely and Altshuler discussed above with respect to claim 1 are equally applicable here. Specifically, the preamble [20.p], the “*plurality of needles*” limitation [20.2],

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and the “*control module*” limitation [20.3] of claim 20 are the same as claim 1. (’899 patent, 12:34-40 *with* 14:1-13.)

165. The “housing” limitation [20.1] in claim 20 is similar to claim 1. The only difference is that claim 20 specifies that the needles are “*arranged in a group of bipolar pairs.*” As I discussed above with respect to claim 2, Utely disclosed that the needles may be arranged in bipolar pairs. (Utely, 7:64-7:67; *supra* Section X.D.) Thus, Utely’s and Altshuler’s teachings discussed above with respect to claims 1 and 2 are equally applicable to this limitation in claim 20.

166. Claim 20’s final limitation is similar to the limitations of claim 10, but modified for the bipolar arrangement. As discussed above with respect to claim 10, a POSA would have understood that the combination of Utely and Altshuler disclosed damaged regions associated with the needles, with undamaged regions between the damaged regions. (*Supra* Section X.H.) A POSA would have understood that because it is the RF energy flowing between the adjacent needles in each of the bipolar pairs that is causing the damage, the pattern of fractional damage will include damaged regions between the tips of the needles of the bipolar pairs. These damaged regions would be surrounded by undamaged regions between the bipolar pairs to achieve fractional damage. That is, the undamaged regions would be between bipolar pairs of needles in the group (e.g., next to the flow of RF energy between the needle tips in each of the pairs). Thus, Utely’s and

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Altshuler's teachings discussed above with respect to claims 1, 2, and 10 are equally applicable to this claim 20 limitation.

167. Thus, the combination of Utely and Altshuler disclosed each limitation of claim 20. A POSA would have had reason to combine Utely and Altshuler, with a reasonable expectation of success, for the reasons discussed with respect to claim 1. In my opinion, claim 20 would have been obvious over Utely in view of Altshuler.

L. Claim 21 would have been obvious over Utely in view of Altshuler

168. Claim 21 depends from claim 20 and further recites "*wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.*" As shown in the claim chart below and discussed in this Declaration, Utely and Altshuler taught each element of claim 21 of the '899 patent.

Claim	Disclosures in Utely and Altshuler
21. The device of claim 20, wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.	<p>"Alternatively, the controller 48 can condition pairs of electrodes 82 to operate in a bipolar mode, with one electrode serving to transmit radio frequency energy, and the other electrode serving as the return path." (Utely, 7:64-67.)</p> <p>"The controller 48 governs the application of radio frequency energy to the electrodes 82 to ohmically heat adjacent dermal tissue. The electrodes 82 can be operated individually or in groups to form defined energy application patterns." (Utely, 8:25-29.)</p>

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	<p>“The size and spacing of the electrodes 82 shown in FIGS. 10 and 11 are purposely set to penetrate the skin to a depth sufficient to pass entirely through the epidermis 16 and penetrate the papillary and, preferable, extend into the reticular dermis (e.g., about 200 μm to 300 μm). When used for this purpose, the electrodes 82 each possesses a total length of about 0.5 to about 3.0 mm. The electrodes are mutually spaced apart by about 0.5 mm to 10.0 mm.” (Utely, 8:1-8.)</p>
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169. As discussed above, Utely and Altshuler disclosed all the limitations of claim 20. And the combination of Utely and Altshuler disclosed claim 21’s limitation.

170. Specifically, as discussed above with respect to claim 2, a POSA would have understood that the tissue damage is caused by the RF energy that flows between the two needles in each of the bipolar pairs of needles. (*Supra* Section X.D.) And Utely disclosed that its needles are spaced apart “by about 0.5 mm to about 10.0 mm.” (Utely, 8:7-8.) With this spacing between needles of a bipolar pair, the damaged regions would be elongated between these needles when using Utely’s controller 48 to implement Altshuler’s fractional damage pattern.

171. As discussed above, a POSA would have been motivated to use Utely’s controller to achieve Altshuler’s fractional damage pattern. When done in conjunction with bipolar needles, this modification would have confirmed that Utely’s controller “*is configured to cause the damaged regions to be elongated*

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between the needles of the bipolar pairs” because of the spacing between the needles.

172. A POSA would have readily implemented Altshuler’s fractional damage pattern by using Utely’s controller for the reasons discussed above. In doing so, a POSA would have arrived at a device “*wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.*” In my opinion, claim 21 would have been obvious over Utely in view of Altshuler.

XI. Ground 2: Claims 9, 12, 17, and 23 would have been obvious over Utely in view of Altshuler and Brown.

173. Before April 1, 2004, claims 9, 12, 17, and 23 of the ’899 patent would have been obvious in view of the disclosures in Utely, Altshuler, and Brown. Claim 9 depends directly from claim 1 and recites “*further comprising a spacer having holes through which the needles are configured to move.*” Claims 12, 17, and 23 depend from claims 1, 15, and 20, respectively, and recite “*further comprising a vibrator for vibrating at least one of the plurality of needles.*”

174. As discussed above in Sections X.C, X.J, and X.K, Utely and Altshuler rendered claims 1, 15, and 20 obvious. As shown here in Ground 2, Brown disclosed that its electrodes 134 could be “retracted entirely within the distal end of the treatment device 130” or be moved “to extended positions at which the electrodes... project through openings 142 in the device.” (Brown,

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¶[0054], FIGS. 8-9.) Brown also disclosed that “methods may be employed... to facilitate electrode insertion” into the tissue, including “vibration” of its needles through “an appropriate motion-inducing device, such as transducer 240A.” (*Id.*, ¶[0070]-[0071], FIG. 17A.) As discussed below, a POSA would have had a reason to use Brown’s teachings with Utely and Altshuler for safety (e.g., by providing a retracted position for the needles) and to aid in needle insertion (e.g., by vibrating the needles). And a POSA would have had a reasonable expectation of success in so doing. Thus, claims 9, 12, 17, and 23 would have been obvious in view of the disclosures in Utely, Altshuler, and Brown, notwithstanding any objective indicia of nonobviousness (*see* Section XIV).

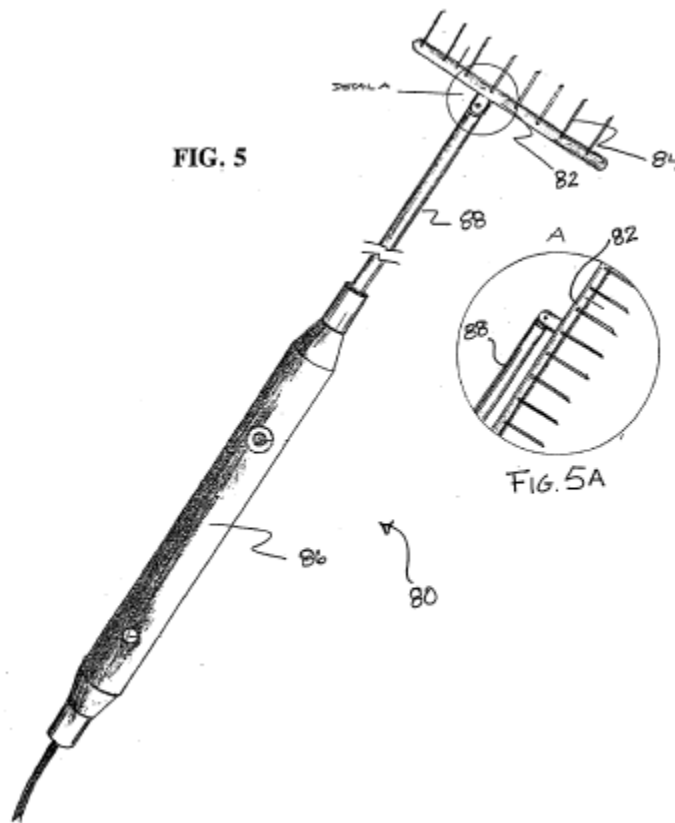
A. Overview of Brown

175. Brown published as a U.S. Publication on August 19, 2004. (Brown, Cover Page.) According to its cover page, Brown’s application was filed on February 2, 2004. (Brown, Cover Page.) I understand that Brown qualifies as prior art to the ’899 patent.

176. Brown is from the same field of endeavor as the ’899 patent because it disclosed a treatment device that delivers electromagnetic radiation energy to body tissue. (Brown, Abstract.) Specifically, Brown is directed to “an RF treatment device for creating transmural lesions in tissue” with “a plurality of tissue penetrating RF needle electrodes.” (*Id.*, ¶[0008].) Although Brown disclosed

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embodiments “for use in creating a transmural lesion in heart tissue to treat atrial fibrillation,” Brown taught that its “devices and methods ... may also be used to create continuous transmural lesions in heart tissue and other body organs and tissues to treat other conditions.” (*Id.*, ¶[0039].) I have reproduced Brown’s FIGS. 5 and 5A below, which illustrate an embodiment of Brown’s treatment device.



(Brown, FIG. 5.)

177. Brown disclosed that its needles or electrodes 134 could be “retracted entirely within the distal end of the treatment device 130” or be moved “to extended positions at which the electrodes ... project through openings 142 in the device.” (*Id.*, ¶[0054], FIGS. 8-9.) Brown also taught that various “methods may

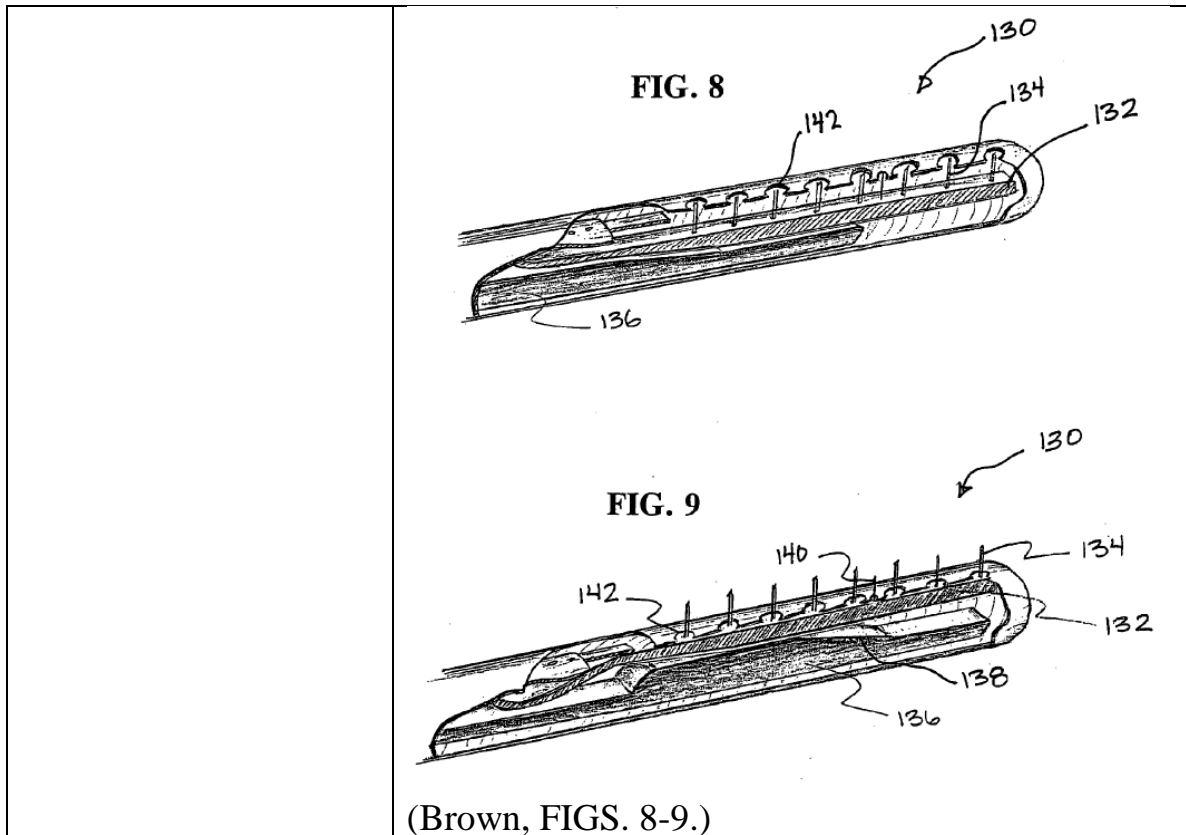
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be employed ... to facilitate electrode insertion” into the tissue, including “vibration.” (*Id.*, ¶[0070].)

B. Claim 9 would have been obvious over Utely in view of Altshuler and Brown.

178. Claim 9 depends from claim 1 and further recites “*further comprising a spacer having holes through which the needles are configured to move.*” As shown in the claim chart below and discussed in this Declaration, Utely, Altshuler, and Brown taught each element of claim 9 of the ’899 patent.

Claim	Disclosures in Utely, Altshuler, and Brown
9. The device of claim 1, further comprising a spacer having holes through which the needles are configured to move.	“FIGS. 8 and 9 illustrate a probe or catheter type treatment device 130 having electrode holder 132 at a distal end with a plurality of positive and negative electrodes 134. A mechanical pusher arm 136 within the catheter device 130 acts as a cam to cause the electrodes to extend from or retract into the catheter device. As shown in FIG. 8, when the mechanical pusher arm 136 is in a proximal position the electrodes 134 are retracted entirely within the distal end of the treatment device 130. When the mechanical pusher arm 136 is advanced to the distal position illustrated in FIG. 9, a ramp 138 on the pusher arm moves the electrodes 134 and the temperature sensor 140 to extended positions at which the electrodes and temperature sensor project through openings 142 in the device. The openings 142 may be one or more holes, as shown, or may be slots. ” (Brown, ¶[0054].)



179. As discussed above, Utely and Altshuler disclosed all the limitations of claim 1. And Brown disclosed claim 9's additional limitation.

180. Specifically, Brown disclosed “an RF treatment device for creating transmural lesions in tissue” with “a plurality of tissue penetrating RF needle electrodes.” (Brown, ¶¶[0008], [0039].) Brown's electrodes 134 could be “retracted entirely within the distal end of the treatment device 130” or be moved “to extended positions at which the electrodes ... project through openings 142 in the device.” (*Id.*, ¶[0054], FIGS. 8-9.) In my opinion, a POSA would have understood Brown's device with its openings 142 to operate as a spacer having

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holes through which the needles are configured to move. The needles 134 can be inserted into the tissue when they are in the extended position. (*Id.*, FIG. 9.)

181. A POSA would have been motivated to include a spacer, as taught by Brown, on Utely's device to improve safety. Specifically, having a retracted position within a spacer protects the needles from unwanted piercing until the device is located at the desired position for treatment. A POSA would also have had a reasonable expectation of success in including such a spacer because such devices were well-known and easily implemented on needles of various sizes and configurations. In my opinion, claim 9 would have been obvious over Utely in view of Altshuler and Brown.

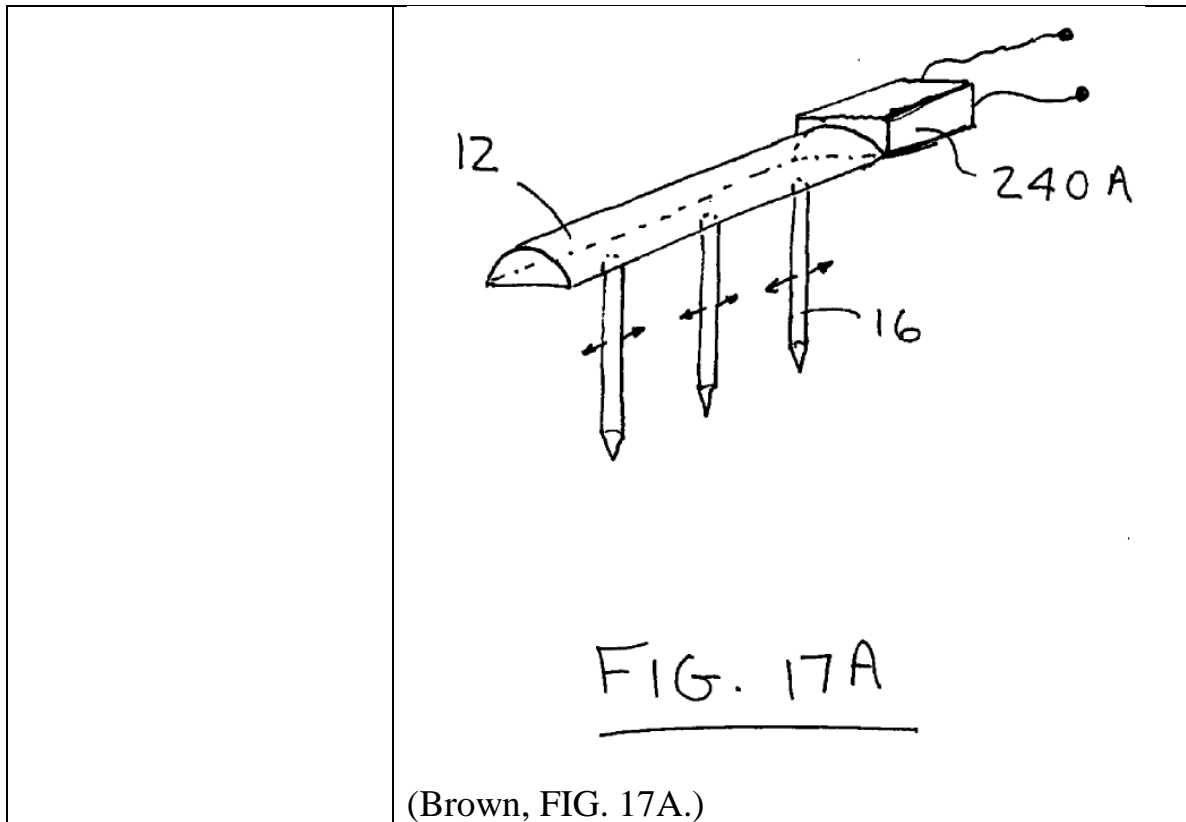
C. Claims 12, 17, and 23 would have been obvious over Utely in view of Altshuler and Brown.

182. Claims 12, 17, and 23 depend from claims 1, 15, and 20, respectively, and further recite "*further comprising a vibrator for vibrating at least one of the plurality of needles.*" As shown in the claim chart below and discussed in this Declaration, Utely, Altshuler, and Brown taught each element of claims 12, 17, and 23 of the '899 patent.

Claim	Disclosures in Utely, Altshuler, and Brown
12. The device of claim 1, further comprising a vibrator for vibrating at least one of the plurality of needles.	"One or more methods may be employed in any of the foregoing embodiments of the invention to facilitate electrode insertion. These methods include vibration , such as ultrasonic vibration , oscillation in any plane , rotation of the

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<p>17. The device of claim 15, further comprising a vibrator for vibrating at least one of the plurality of needles.</p> <p>23. The device of claim 20, further comprising a vibrator for vibrating at least one of the plurality of needles.</p>	<p>electrodes, sequential electrode insertion, coatings or lubricants on the electrodes, and tip geometries which aid in penetration (FIGS. 1A-1F). In addition, a holding device, such as a vacuum device, may be used to hold the treatment device to the tissue before and during penetration with the electrodes.</p> <p>Vibration, including ultrasonic vibration and/or and oscillation in any plane or direction or combination of directions can be provided using an appropriate motion-inducing device, such as transducer 240A shown in FIG. 17A for imparting vibration to the needles 16 in the direction indicated by the arrows, or a motor 240B which may be mechanically linked, via a suitable linkage (not shown), to the individual needles 16 for rotation thereof in the direction of the arrows in FIG. 17B. In the case of rotational motion, the needles 16 may be provided with threads or a screw-type shape (FIG. 17C) to further aid in penetration. Vibrations and motions in other directions and combinations of directions are also contemplated. One such direction is along the major axis of the needles themselves, in the direction of tissue penetration (FIG. 17D). This direction motion can also be impulsive, or impact-type motion. The vibration and oscillations are imparted by a direct or indirect connection between the needles and the motion-inducing device. A preferred connection configuration, show in FIGS. 17A and 17B, involves imparting motion to the electrode holder 12, which in turn transfers this motion to the needles 16.” (Brown, ¶¶[0070]-[0071].)</p>
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183. As discussed above, Utely and Altshuler disclosed all the limitations of claims 1, 15, and 20. And Brown disclosed the additional limitation in claims 12, 17, and 23.

184. Brown taught that various “methods may be employed ... to facilitate electrode insertion” into the tissue, including “vibration.” (Brown, ¶[0070].) “Vibration ... can be provided using an appropriate motion-inducing device, such as transducer 240A ... for imparting vibration to the needles 16.” (*Id.*, ¶[0071], FIG. 17A.) A POSA would have considered transducer 240A to be a vibrator as claimed.

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185. Thus, a POSA would have been motivated to include a vibrator on Utely's device to vibrate at least one of the needles to facilitate insertion into the patient's skin. A POSA would have known that vibrating a needle eases insertion by mechanically disrupting the tissue the needle is being inserted into. A POSA would have also had a reasonable expectation of success in including a vibrator. In my opinion, claims 12, 17, and 23 would have been obvious over Utely in view of Altshuler and Brown.

XII. Ground 3: Claims 1-2, 4, 6, 10-11, 15-16, and 20-22 would have been obvious over Underwood in view of Debendictis.

186. Before April 1, 2004, claims 1-2, 4, 6, 10-11, 15-16, and 20-22 of the '899 patent would have been obvious over Underwood and Debendictis. As illustrated in the claim charts and discussion below, Underwood and Debendictis disclosed each element of claims 1-2, 4, 6, 10-11, 15-16, and 20-22. Moreover, a POSA would have had a reason to use Underwood's controller to achieve Debendictis's fractional damage pattern, thereby promoting faster recovery and improving growth of collagen (i.e., improved treatment outcomes). And a POSA would have had a reasonable expectation of success in using Underwood's controller to achieve Debendictis's fractional damage pattern. Thus, claims 1-2, 4, 6, 10-11, 15-16, and 20-22 would have been obvious in view of the disclosures in Underwood and Debendictis, notwithstanding any objective indicia of nonobviousness.

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A. Overview of Underwood

187. Underwood published as a U.S. Publication on July 4, 2002. (Underwood, Cover Page.) According to its cover page, Underwood's application was filed on September 25, 2001. (*Id.*) I understand that Underwood qualifies as prior art to the '899 patent.

188. Underwood is from the same field of endeavor as the '899 patent because it disclosed skin treatment devices (specifically for treating cosmetic conditions of the skin) that deliver electromagnetic radiation energy to the skin or other tissue. (*See, e.g., id.*, Abstract.) Underwood is directed at "surgical devices and methods which employ high frequency electrical energy to treat a patient's skin." (*Id.*, ¶[0003], FIG. 1.) I have reproduced Underwood's Figure 1 below, which illustrates Underwood's electrosurgical system 2.

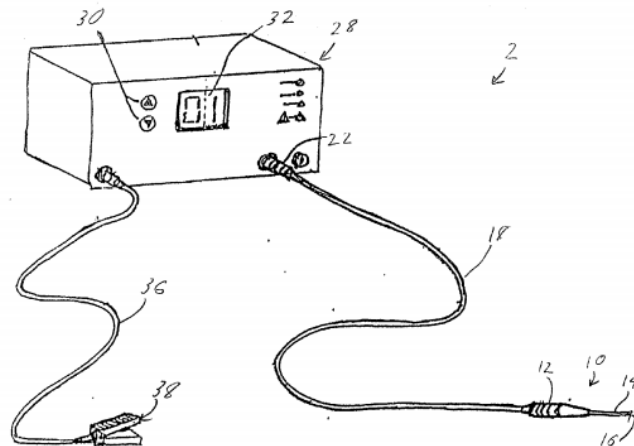


FIG. 1

(Underwood, FIG. 1.)

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189. Underwood disclosed an “electrode assembly 204 [that] comprises three needle shaped electrodes 206, 208, 210 extending from three guards 212 that are attached to electrode support 202.” (*Id.*, ¶[0051].) Further, Underwood disclosed that “[i]n use, electrode assembly 204 is positioned adjacent to the target area of the patient's tissue ... [and] electrodes 206, 208, 210 are then advanced through the epidermis 164 such that the exposed portion 216 of each electrode is positioned in the dermis 166 at a selected depth.” (*Id.*, ¶[0052].)

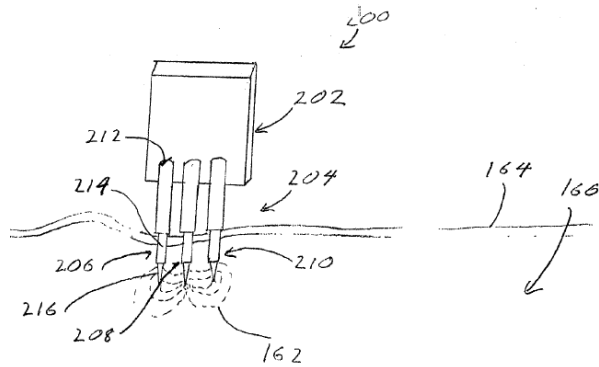


FIG. 6

(Underwood, FIG. 6.)

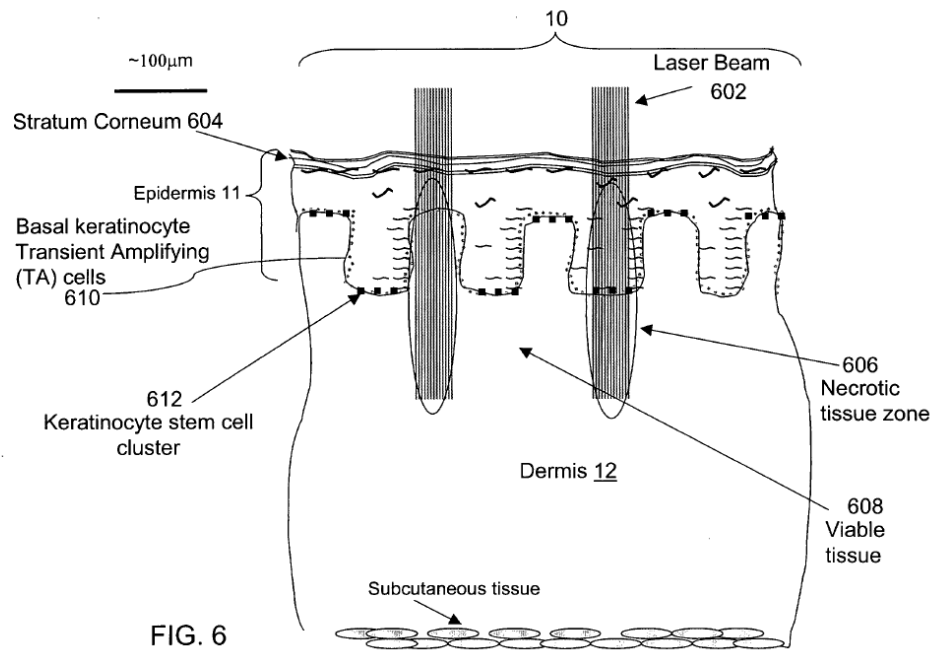
190. Further, Underwood disclosed that the “power supply generally comprises a radio frequency (RF) power oscillator (not shown) having output connections for coupling via a power output signal to the load impedance, which is represented by the electrode assembly when the electrosurgical probe is in use.” (*Id.*, ¶[0036].)

B. Overview of Debendictis

191. Debendictis published as a PCT application on January 27, 2005. (Debendictis, Cover Page.) According to its cover page, Debendictis's application was filed on July 9, 2004 and claims priority to the '304 Provisional, which was filed on July 11, 2003. (*Id.*) I note that at least one claim in Debendictis is supported by the '304 Provisional, as I discussed above. (*See* Section IX.A.) In my opinion, a POSA would have been enabled to practice these claims based on the disclosure in the '304 Provisional. Based on these facts, I understand that Debendictis qualifies as prior art to the '899 patent.

192. Debendictis is from the same field of endeavor as the '899 patent because it disclosed skin treatment devices that deliver electromagnetic radiation energy to the skin or other tissue. (*See, e.g.,* Debendictis, Abstract; '304 Provisional, Abstract.) Debendictis disclosed “a method for ... improving the appearance of tissue (e.g., skin).” (Debendictis, ¶[0014]; *see* '304 Provisional, 12:18-20.) Debendictis further taught that its “method and apparatus [was] for providing *fractional treatment* of tissue (e.g., skin).” (Debendictis, ¶[0001] (emphasis added); '304 Provisional, 1:5-7.) Specifically, Debendictis disclosed “intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue.” (*Id.*, ¶[0014]; '304 Provisional, 12:18-20.) As shown below in Figure 6, the thermally damaged tissue extended into the dermis.

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(Debendictis, FIG. 6; *see* '304 Provisional, FIG. 6.)

C. Claim 1 would have been obvious over Underwood in view of Debendictis.

193. The claim chart below lists disclosures from Underwood and Debendictis that taught each element of claim 1 of the '899 patent.

Claim	Disclosures in Underwood and Debendictis
[1.p] A skin treatment device	<p>“The present invention relates generally to the field of electrosurgery, and more particularly to surgical devices and methods which employ high frequency electrical energy to treat a patient's skin and subcutaneous tissue, particularly including skin resurfacing procedures.” (Underwood, ¶[0003].)</p> <p>“In one aspect of the invention, a method includes positioning a first electrode adjacent to, or in</p>

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contact with, a region on or within a patient's skin, and applying a sufficient high frequency voltage between the first electrode and a second electrode to create a heat injury to a target tissue within the patient's dermis layer without ablating the epidermis layer overlying the target tissue. In these procedures, it is desirable **to stimulate the growth of neo-collagen in the tissue layers underlying the epidermal tissue. ...**

The **electrosurgical instrument** of the present invention **comprises a shaft or a handpiece having a proximal end and a distal end which supports one or more electrode(s).** The shaft or handpiece may assume a wide variety of configurations, with the primary purpose being to mechanically support the electrode(s) and permit the treating physician to manipulate the electrode(s) from a proximal end of the shaft.” (Underwood, ¶¶[0029]-[0030].)

“Referring to FIG. 1, an **electrosurgical system 2 generally comprises an electrosurgical handpiece or probe 10 connected to a power supply 28 for providing high frequency voltage to a target site. Probe 10 generally includes a proximal handle 12 and an elongate shaft 14 for supporting an electrode assembly 16 at the distal end of shaft 14.**” (Underwood, ¶[0035].)

“Referring now to FIGS. 5-8, another embodiment of the present invention is illustrated. As shown in FIG. 5, **a disposable tip 200 comprises an electrode support 202 coupled to an electrode assembly 204.** The electrode support 202 includes a mechanical connection (not shown) for attaching disposable tip to an instrument (not shown), such as the instruments described above or other suitable handpieces or probes designed for handling by the physician. Electrode support 202 further includes the necessary electrical connections (not shown) for

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coupling electrode assembly 204 to a power supply through a handpiece or probe.” (Underwood, ¶[0051].)

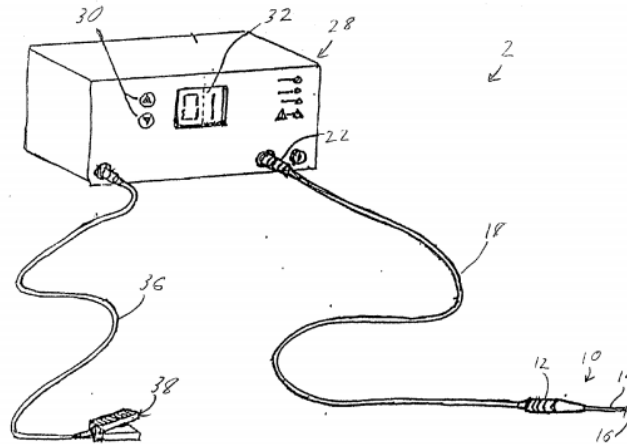


FIG. 1

(Underwood, FIG. 1.)

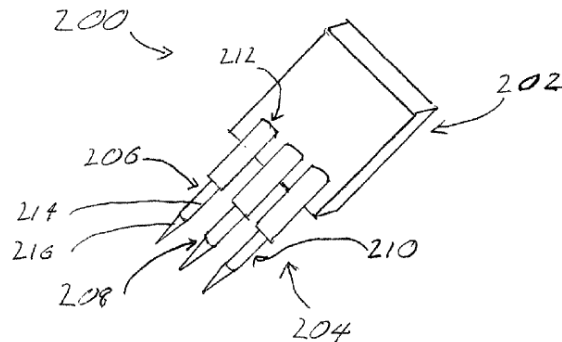


FIG 5

(Underwood, FIG. 5.)

[1.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of

“Referring to FIG. 1, an electrosurgical system 2 generally comprises **an electrosurgical handpiece or probe 10** connected to a power supply 28 for providing high frequency voltage to a target site. **Probe 10 generally includes a proximal handle 12 and an elongate shaft 14 for supporting an**

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<p>needles being attached to a base,</p>	<p>electrode assembly 16 at the distal end of shaft 14.” (Underwood, ¶[0035].)</p> <p>“The electrosurgical instrument of the present invention comprises a shaft or a handpiece having a proximal end and a distal end which supports one or more electrode(s). The shaft or handpiece may assume a wide variety of configurations, with the primary purpose being to mechanically support the electrode(s) and permit the treating physician to manipulate the electrode(s) from a proximal end of the shaft. For cosmetic surgery or dermatology procedures, the shaft will have any suitable length and diameter that would facilitate handling by the surgeon.” (Underwood, ¶[0030].)</p> <p>“Referring now to FIGS. 5-8, another embodiment of the present invention is illustrated. As shown in FIG. 5, a disposable tip 200 comprises an electrode support 202 coupled to an electrode assembly 204. The electrode support 202 includes a mechanical connection (not shown) for attaching disposable tip to an instrument (not shown), such as the instruments described above or other suitable hand pieces or probes designed for handling by the physician. Electrode support 202 further includes the necessary electrical connections (not shown) for coupling electrode assembly 204 to a power supply through a handpiece or probe. As shown, electrode assembly 204 comprises three needle shaped electrodes 206, 208, 210 extending from three guards 212 that are attached to electrode support 202.” (Underwood, ¶[0051].)</p> <p>“In use, electrode assembly 204 is positioned adjacent to the target area of the patient's tissue. Electrodes 206, 208, 210 are then advanced through the epidermis 164 such that the exposed portion 216 of each electrode is positioned in the dermis 166 at a selected depth. In the</p>
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representative embodiment, electrodes 206, 208, 210 are advanced manually by the physician by advancing the entire disposable tip.” (Underwood, ¶[0052].)

“FIGS. 7 and 8 are distal end views of two more embodiments of the disposable tip shown in FIG. 6. In these embodiments, tip 250 comprises an electrode support 252 and **an electrode assembly 254 comprising an array of electrodes 256 extending from support 252.**” (Underwood, ¶[0055].)

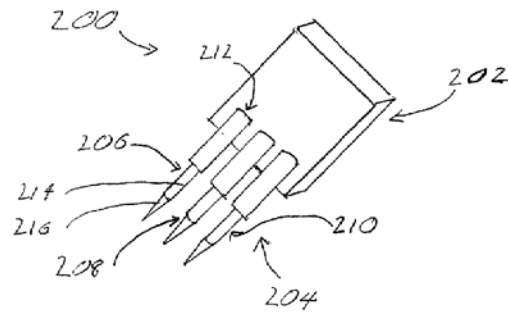


FIG 5

(Underwood, FIG. 5.)

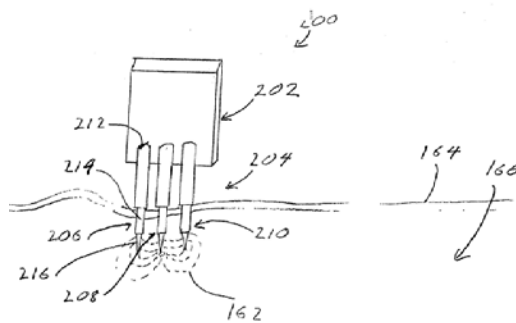


FIG. 6

(Underwood, FIG. 6.)

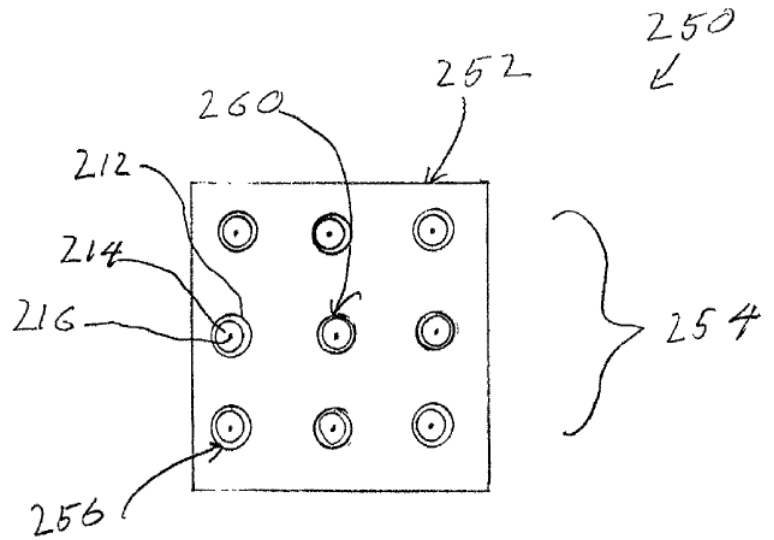


FIG. 7

(Underwood, FIG. 7.)

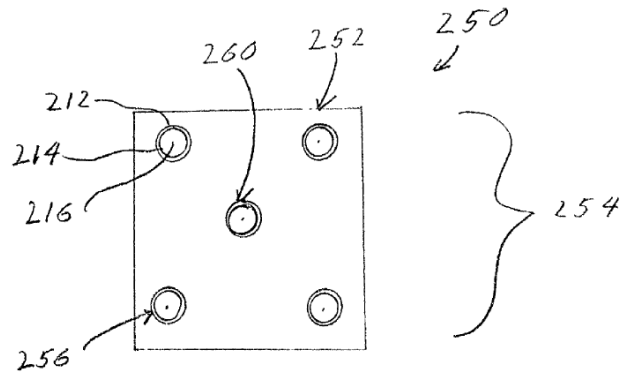


FIG. 8

(Underwood, FIG. 8.)

[1.2] the plurality of "The **voltage applied between the return**

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<p>needles being further configured for application of radio frequency (RF) energy from a RF energy source; and</p>	<p>electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, preferably being between about 50 kHz and 600 kHz, in some embodiments less than 350 kHz, and, in exemplary embodiments between about 100 kHz and 200 kHz.” (Underwood, ¶[0032].)</p> <p>“The power supply generally comprises a radio frequency (RF) power oscillator (not shown) having output connections for coupling via a power output signal to the load impedance, which is represented by the electrode assembly when the electrosurgical probe is in use.” (Underwood ¶[0036].)</p> <p>“Electrodes 206, 208, 210 will each include a proximal insulated portion 214 and a distal exposed portion 216 for applying electric current to the patient.” (Underwood, ¶[0051].)</p> <p>“In use, electrode assembly 204 is positioned adjacent to the target area of the patient's tissue. Electrodes 206, 208, 210 are then advanced through the epidermis 164 such that the exposed portion 216 of each electrode is positioned in the dermis 166 at a selected depth. In the representative embodiment, electrodes 206, 208, 210 are advanced manually by the physician by advancing the entire disposable tip.” (Underwood, ¶[0052].)</p>
<p>[1.3] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of</p>	<p>“A controller (not shown) coupled to the operator controls (i.e., foot pedals and voltage selector) and display, is connected to a control input of the switching power supply for adjusting the generator output power by supply voltage variation. The controller may be a microprocessor or an integrated circuit.” (Underwood ¶[0038].)</p>

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<p>fractional damage by the RF energy in the dermal layer when the needles are inserted therein,</p>	<p>“In one aspect of the invention, a method includes positioning a first electrode adjacent to, or in contact with, a region on or within a patient’s skin, and applying a sufficient high frequency voltage between the first electrode and a second electrode to create a heat injury to a target tissue within the patient’s dermis layer without ablating the epidermis layer overlying the target tissue. Typically, the voltage applied to the first and second electrodes is sufficient to induce heating of the dermis layer to about 60°-80° C., preferably about 65°-75° C. This induced heating causes the patient’s body to undergo a wound healing response in the slightly inflamed tissue of the dermis. The wound healing process involves the generation of neo-collagen in the dermis layer, which fills in the wrinkle in the patient’s skin. In the present invention, this stimulation of collagen growth within the dermis is accomplished while minimizing or suppressing the damage caused to the outer epidermis layer, which reduces the overall pain and wound healing time for the patient.” (Underwood, ¶[0011].)</p> <p>“As shown in FIG. 6, the central electrode 208 has an opposite polarity from the outer electrodes 206, 210 such that electric current 162 flows between central electrode 208 and outer electrodes 206, 210 when a voltage is applied therebetween. In this manner, the current is generally confined to the immediate region around the electrodes which is the target area of the dermis 166. The voltage level will be selected to induce heating of the dermis 166 to a temperature in the range of about 60° to 80° C., typically about 65° to 75° C., without causing necrosis, ablation or vaporization of the tissue. As in previous embodiments, electrically conductive fluid (e.g., saline) may be delivered to the target site to modify the impedance of the tissue,</p>
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	<p>if desired.” (Underwood, ¶[0054].)</p> <p>“The present invention relates generally to methods and apparatus for providing medical or surgical treatment using optical energy, and in particular to a method and apparatus for providing fractional treatment of tissue (e.g., skin) using optical radiation.” (Debendictis, ¶[0001]; <i>see</i> ’304 Provisional, 1:5-7.)</p> <p>“In general, the present invention features a method for treating either existing medical (e.g., dermatological) disease conditions or for improving the appearance of tissue (e.g., skin) by intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue. The thermally altered tissue may include a necrotic zone. This approach offers numerous advantages over existing approaches in terms of safety and efficacy. This invention minimizes the undesirable side effects of pain, erythema, swelling, fluid loss, prolonged reepithelialization, infection, and blistering generally associated with laser skin resurfacing. Another aspect of this invention is to stimulate the tissue’s wound repair system, by sparing healthy tissue around the thermally altered tissue, whereby the repair process is more robust. Yet another distinguishing feature of this invention is to reduce or eliminate the side effects of repeated laser treatment to tissue by controlling the extent of tissue necrosis due to laser exposure.” (Debendictis, ¶[0014]; <i>see</i> ’304 Application, 12:18-13:6.)</p> <p>“A primary mechanism of the present invention is the sparing of volumes of tissue within a larger tissue treatment area. In other words, leaving healthy tissue between and around necrotic treatment zones and HSZs has a number of beneficial effects that are exploited by various</p>
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	<p>embodiments of the present invention. If the HSZs surrounding adjacent necrotic treatment zones are appropriately spaced and/or epidermal injury is limited, the viable tissue bordering thermal coagulation zones will be subjected to less inflammation from the products of cell death, thereby favoring cell survival over apoptosis.” (Debendictis, ¶[0039]; <i>see</i> ’304 Provisional, 13:19-22.)</p> <p>“If the entire volume of the target tissue is not treated but only a fraction of the tissue is treated by laser beams 602 thereby permitting the existence of viable tissue 608 (which typically includes HSZs and untreated, healthy tissue) between necrotic tissue zones 606, with multiple treatments, macroscopic areas of tissue regeneration will occur at the maximum rate within the surrounding micro-HSZs and spared epidermal surfaces, creating a 'fractional wound repair field' within the target treatment area 10.... Fractional wound repair fields are fundamentally different from previous techniques because the areas of epidermal tissue that are spared between necrotic zones contain both epidermal stem cells 612 and TA cell populations 610. ” (Debendictis, ¶[0041]; <i>see</i> ’304 Provisional, 9:17-10:7.)</p> <p>“By creating isolated, non-contiguous (i.e. discrete) treatment zones having necrotic tissue surrounded by zones of viable (i.e. heat altered viable tissue and often untreated, unaltered healthy tissue) tissue that are capable of promoting healing, the present invention induces multiple sites of tissue regeneration to produce ‘micro-thermal wound repair fields’. We call this process fractional photo therapy, as fractional volumes of the target tissue volume are thermally altered, as opposed to the conventional treatments where the entire target volume is</p>
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	thermally altered or damaged.” (Debendictis, ¶[0044]; <i>see</i> ’304 Provisional, 11:16-12:5.)
[1.4] wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.	<p>“Typically, the voltage applied to the first and second electrodes is sufficient to induce heating of the dermis layer to about 60°-80° C., preferably about 65°-75° C. This induced heating causes the patient's body to undergo a wound healing response in the slightly inflamed tissue of the dermis. The wound healing process involves the generation of neo-collagen in the dermis layer, which fills in the wrinkle in the patient's skin. In the present invention, this stimulation of collagen growth within the dermis is accomplished while minimizing or suppressing the damage caused to the outer epidermis layer, which reduces the overall pain and wound healing time for the patient.” (Underwood, ¶[0011].)</p> <p>“This temperature elevation causes sufficient damage to the collagen connective fibers to enhance or stimulate regrowth of new collagen fibers in the underlying tissue.” (Underwood, ¶[0045].)</p>

194. As shown in the claim chart above and discussed herein, Underwood and Debendictis disclosed all of the limitations of claim 1.

195. Underwood disclosed “[a] *skin treatment device*.” Specifically, Underwood disclosed “surgical devices and methods which employ high frequency electrical energy to treat a patient’s skin.” (Underwood, ¶[0003].) Underwood’s “electrosurgical instrument... comprises a shaft or a handpiece having a proximal end and a distal end which supports one or more electrode(s).” (*Id.*, ¶[0030].) For example, Underwood’s Figure 1 (reproduced below) illustrates “an electrosurgical

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system 2 generally compris[ing] an electrosurgical handpiece or probe 10.” (*Id.*, ¶[0035], Fig. 1.) While Underwood’s Figure 1 shows electrosurgical system 2 including “electrode assembly 16,” Underwood also taught that other electrode assemblies could be connected to electrosurgical system 2, such as disposable tip 200 with electrode support 202 and electrode assembly 204. (*Id.*, ¶¶[0035], [0051], FIGS. 5-8.)

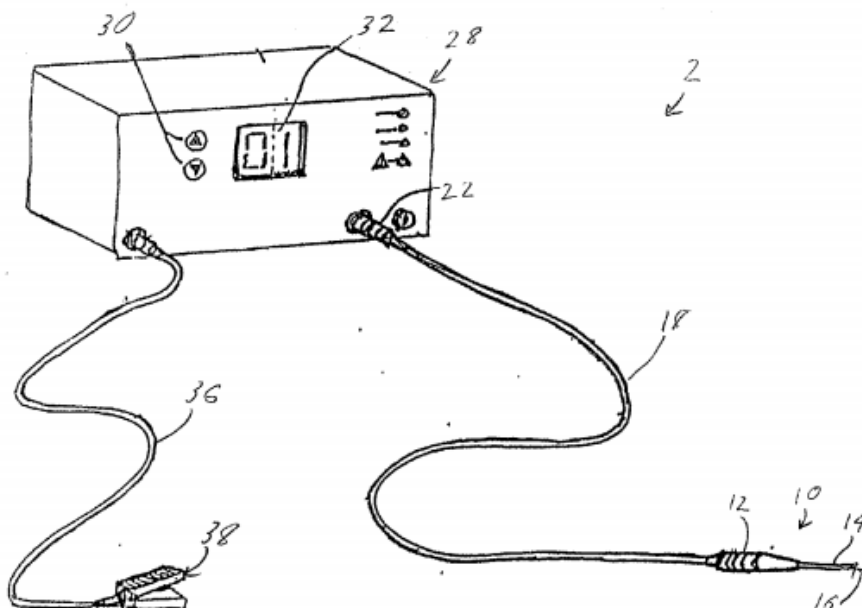


FIG. 1

(Underwood, FIG. 1.)

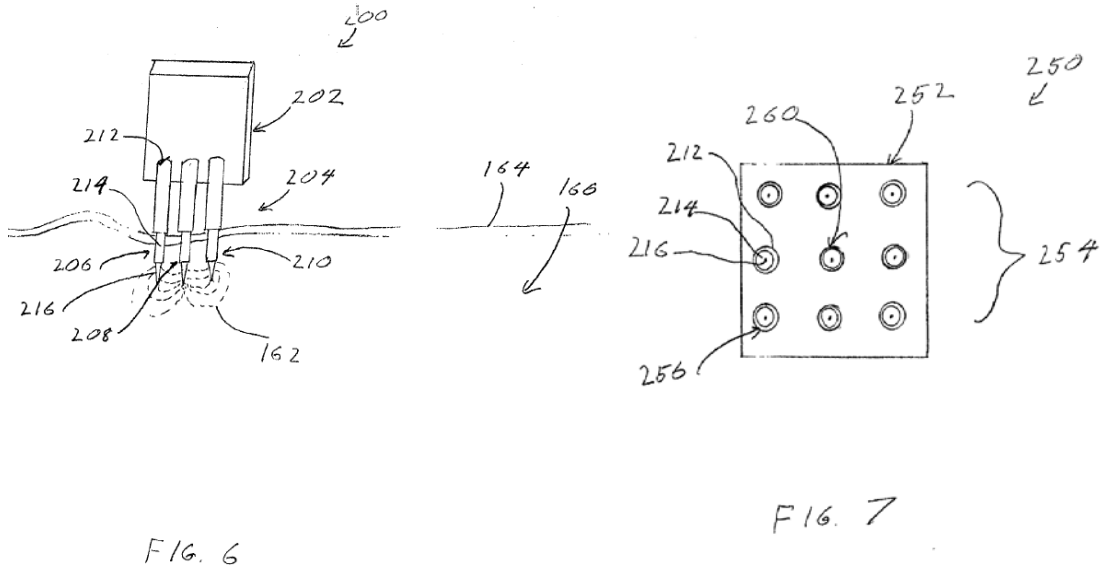
196. Underwood’s device positioned one or more electrodes “adjacent to, or in contact with, a region on or within a patient’s skin” to “create a heat injury to a target tissue within the patient’s dermis layer” and “stimulate the growth of neo-collagen in the tissue layers underlying the epidermal tissue.” (*Id.*, ¶[0029].) Thus,

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a POSA would have considered electrosurgical system 2 to be a skin treatment device.

197. Underwood also disclosed “*a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base.*” In particular, a POSA would have found that Underwood’s probe 10, including its handle 12 and elongate shaft 14, is a “*housing*” as claimed. (Underwood, ¶[0035].)

198. First, as disclosed in Underwood, the “primary purpose” of probe 10 is “to mechanically support the electrode(s).” (*Id.*, ¶[0030].) One type of electrodes disclosed by Underwood is needles. (*Id.*, ¶[0051], FIGS. 5-8.) Specifically, Underwood disclosed that “a disposable tip 200 comprises an electrode support 202 coupled to an electrode assembly 204” with “a mechanical connection... for attaching disposable tip to an instrument,” such as probe 10. (*Id.*, ¶[0051], FIG. 6.) And Underwood disclosed that “electrode assembly 204 comprises three needle shaped electrodes 206, 208, 210” or more, as shown in Figures 6 and 7 (reproduced below). (*Id.*, ¶[0051], [0055].) Thus, a POSA would have understood probe 10 to be “*a housing configured to support a plurality of needles.*”



(Underwood, FIGS. 6-7.)

199. Second, Underwood disclosed that “[i]n use, electrode assembly 204 is positioned adjacent to the target area of the patient's tissue. Electrodes 206, 208, 210 are then advanced through the epidermis 164 such that the exposed portion 216 of each electrode is positioned in the dermis 166 at a selected depth.” (*Id.*, ¶[0052].) Thus, Underwood’s needles are “*arranged for insertion into a dermal layer of skin.*”

200. Third, a POSA would have understood electrode support 202 to be a “base” as claimed. The ’899 patent explains that the base can be either “attached to housing 340 or formed as a part of the housing.” (’899 patent, 5:44-45.) And Underwood taught that “electrode support 202 includes a mechanical connection... for attaching disposable tip to an instrument” such as probe 10. (Underwood, ¶[0051].) Moreover, Underwood explained that “electrode support 202 [is] coupled

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to an electrode assembly 204” and that “needle shaped electrodes 206, 208, 210 extend[] from three guards 21 that are attached to electrode support 202.” (*Id.*; see also *id.*, ¶[0055] (“array of electrodes 256 extending from support 252), FIGS. 6-7.) Thus, Underwood’s needles are “*attached to a base.*”

201. Based on these three points, a POSA would have understood Underwood’s probe 10 to be a “*housing*” as claimed: “*a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base.*”

202. Underwood also disclosed “*the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source.*” Underwood’s “electrode support 202 further includes the necessary electrical connections (not shown) for coupling electrode assembly 204 to a power supply [e.g., power supply 28] through a handpiece or probe.” (Underwood, ¶[0051].) In Underwood, “[t]he power supply generally comprises a radio frequency (RF) power oscillator (not shown) having output connections for coupling via a power output signal to the load impedance, which is represented by the electrode assembly when the electrosurgical probe is in use.” (*Id.*, ¶[0036].) Thus, a POSA would have understood the power supply to be an “*RF energy source.*”

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203. Moreover, Underwood further taught that “[e]lectrodes 206, 208, 210 will each include a proximal insulated portion 214 and a distal exposed portion 216 for applying electric current to the patient,” particularly to “the dermis 166 at a selected depth.” (*Id.*, ¶¶[0051]-[0052].) A POSA would have known that the “electric current” referenced in Underwood is the RF energy delivered to the electrodes (i.e. needles). Accordingly, a POSA would have understood that Underwood’s needles (e.g., electrodes 206, 208, 210 or array 256) “*are further configured for application of radio frequency (RF) energy from a RF energy source.*”

204. Underwood disclosed “*a control module for controlling delivery of the RF energy from the RF energy source.*” Specifically, Underwood disclosed “[a] controller (not shown) coupled to the operator controls (i.e., foot pedals and voltage selector) and display, is connected to a control input of the switching power supply for adjusting the generator output power by supply voltage variation.” (*Id.*, ¶[0038].) Thus, a POSA would have understood the controller to be a “*control module for controlling delivery of the RF energy from the RF energy source*” because it is connected to a “control input” of the power supply.

205. Moreover, Underwood’s energy delivery is “*to the plurality of needles to induce ... damage by the RF energy in the dermal layer when the needles are inserted therein.*” For example, Underwood disclosed that the application of RF

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energy through the electrodes is configured “to create a heat injury to a target tissue within the patient’s dermis layer.” (*Id.*, ¶[0011].) Underwood taught that “the voltage applied to the first and second electrodes is sufficient to induce heating of the dermis layer to about 60°-80° C.” (*Id.*) A POSA would have understood that the “voltage” referenced in Underwood is the RF energy produced by the RF energy source. For Underwood’s needle electrodes, “the current is generally confined to the immediate region around the electrodes which is the target area of the dermis 166,” and “the voltage level will be selected to induce heating of the dermis 166 to a temperature in the range of about 60° to about 80° C.” (*Id.*, ¶[0054].) Thus, a POSA would have understood that Underwood’s controller controls the delivery of RF energy “*to the plurality of needles to induce... damage by the RF energy in the dermal layer when the needles are inserted therein.*”

206. While Underwood expressly taught confining current to the immediate region around the electrodes (Underwood, ¶[0054]), as well as using “additional active and/or return electrodes ... advanced into the patient’s skin to more precisely control the heat injury within the dermis” (*id.*, ¶[0015]; *see also id.*, ¶¶[0051], [0055], FIGS. 6-8), Underwood did not expressly use the term a pattern of fractional damage. However, fractional damage to the dermal layer of skin was known, and so was the beneficial collagen regeneration that resulted from fractional damage, as well as other benefits. (Section V.D.) And these benefits

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furthered Underwood's original goals of "stimulation of collagen growth within the dermis" and "reduc[ing] the overall pain and wound healing time for the patient." (Underwood, ¶[0011].) Accordingly, it would have been obvious to use Underwood's controller to control RF energy delivery to the needles to induce a pattern of fractional damage.

207. Debendictis disclosed "*induc[ing] a pattern of fractional damage.*" Like Underwood, Debendictis disclosed "a method for... improving the appearance of tissue (e.g., skin)." (Debendictis, ¶[0014]; *see* '304 Provisional, 12:18-20.) Debendictis further taught that its "method and apparatus [was] for providing *fractional treatment* of tissue (e.g., skin)." (Debendictis, ¶[0001] (emphasis added); *see* '304 Provisional, 1:5-7.) Specifically, Debendictis disclosed "intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue." (Debendictis, ¶[0014]; *see* '304 Provisional, 12:18-13:6.) Debendictis explained that treating "only a fraction of the tissue" permits "the existence of viable tissue 608 (which typically includes [heat shock zones] and untreated, healthy tissue) between necrotic tissue zones 606." (Debendictis, ¶[0041]; *see* '304 Provisional, 9:17-10:7.) "[C]reating isolated, non-contiguous (i.e. discrete) treatment zones having necrotic tissue surrounded by zones of viable (i.e. heat altered viable tissue and often untreated, unaltered healthy tissue) tissue that are capable of promoting healing... induces multiple sites of tissue

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regeneration to produce ‘micro-thermal wound repair fields’.” (Debendictis, ¶[0044]; *see* ’304 Provisional, 11:16-12:5.)

208. A POSA would have understood Debendictis’s “pattern of thermally altered tissue surrounded by unaltered tissue” to be “*a pattern of fractional damage*.” (Debendictis, ¶[0014]; *see* ’304 Provisional, 12:18-13:6.) As discussed above, the proper construction of “a pattern of fractional damage” is “the pattern of damage caused by non-uniform heating.” (*Supra* Section VII.A.) Debendictis’s description falls squarely within this construction as well as the other constructions made at the ITC. And a POSA would have understood Debendictis to disclose “a pattern of fractional damage” even using Patent Owner’s proposed construction of “a distribution of small localized regions of thermal damage” from the ITC proceeding.

209. The reasons for Debendictis’s pattern of fractional damage are expressly set forth in Debendictis: its “approach offers numerous advantages over existing approaches in terms of safety and efficacy,” both “minimiz[ing] the undesirable side effects” and “stimulat[ing] the tissue’s wound repair system, by sparing healthy tissue around the thermally altered tissue, whereby the repair process is more robust.” (Debendictis, ¶[0014]; *see* ’304 Provisional, 12:18-13:6.) Debendictis recognized that treatments that “leave no tissue untreated in the targeted region of the skin” “result[] in undesirable side effects,” including

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intolerable pain and extended healing times. (Debendictis, ¶[0003]; *see* '304 Provisional, 2:8-12.) Indeed, “a direct correlation exists between the size of the injury and the time required for complete repair.” (Debendictis, ¶[0007]; *see* '304 Provisional, 3:17-21.) Debendictis taught that negative side effects “can be attributed to the bulk heating of the skin with little or no healthy tissue.” (Debendictis, ¶[0007]; '304 Provisional, 4:11-14.) Accordingly, a “primary mechanism” of Debendictis “is the sparing of volumes of tissue within a larger tissue treatment area.” (Debendictis, ¶[0039]; *see* '304 Provisional, 13:19-22.)

210. Thus, a POSA would have been motivated to combine the teachings of Debendictis with the apparatus of Underwood. More specifically, a POSA would have been motivated to use Underwood's controller to control the RF energy delivered to its needles so that it created a pattern of thermally altered tissue surrounded by unaltered tissue (i.e., a pattern of fractional damage) to stimulate the tissue's wound repair system (making the repair process more robust) with less pain and shorter healing times for the patient. Because Debendictis expressly disclosed advantages of its fractional damage pattern, including improved treatment outcomes and decreased patient pain, a POSA would have found it obvious to use Underwood's controller to implement Debendictis's fractional damage pattern in Underwood's system. (Debendictis, ¶[0014]; *see* '304 Provisional, 12:18-13:6.) Accordingly, combining Debendictis's teachings with

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Underwood would be nothing more than the use of a known technique to improve similar devices in the same way.

211. Further, a POSA would have been motivated to use an array of needles to transmit RF energy into the skin, such as taught in Underwood, to apply energy to the dermis to achieve the pattern of fractional damage disclosed in Debendictis because of the known limitations of using laser energy in skin treatments, as I discussed above. Thus, a POSA would have been motivated to use RF energy applied using an array of needles to achieve the pattern of fractional damage taught in Debendictis.

212. Moreover, a POSA would have had a reasonable expectation of success in using Underwood's controller to implement Debendictis's fractional damage pattern. Underwood disclosed that its controller "adjust[s] the generator output power by supply voltage variation" and that its system is equipped with includes an input system that "allows the surgeon to remotely adjust the energy level applied to" its electrodes. (Underwood, ¶¶[0038], [0035].) And Underwood taught to confine the current "to the immediate region around the electrodes which is the target area of the dermis 166" and to use additional electrodes "advanced into the patient's skin to more precisely control the heat injury within the dermis." (*Id.*, ¶¶[0054], [0015].) Accordingly, a POSA would have recognized Underwood's device as a suitable system for applying Debendictis's teachings. A

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POSA would have understood that Underwood's controller could be used to govern the power level of RF energy to achieve the desired treatment objective of improved safety and efficacy by operating Underwood's needle electrodes to form Debendictis's damage pattern. It would have been simple for a POSA to use Underwood's controller to achieve Debendictis's damage pattern.

213. Using RF energy transmitted by needles to create a pattern of fractional damage in tissue was also known, and practiced, in closely-related fields. For example, Edwards disclosed a device that used RF energy delivered by needles to ablate tissue in the tongue in a pattern of damaged regions alternating with undamaged regions. (Edwards, 10:10-22; FIG. 6.) Thus, a POSA would understand that using RF energy delivered by needles to create patterns of fractional damage was possible, and had in fact been practiced in a closely-related application.

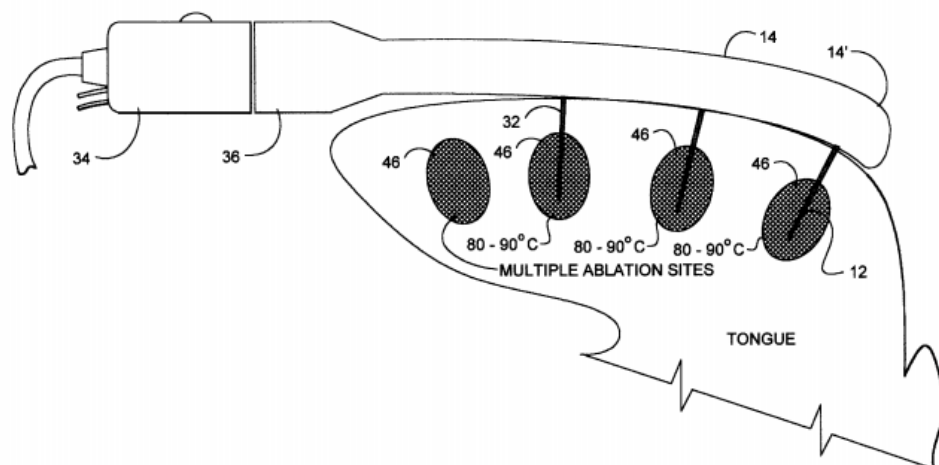


FIG. 6

(Edwards, FIG. 6.)

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214. Thus, the combination of Underwood and Debendictis disclosed “*a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein.*”

215. Underwood disclosed “*wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.*” As discussed above in the background section, the formation of new collagen is the body’s natural response to collagen damage. Thus, both Underwood’s and Debendictis’s controlled delivery of RF energy is configured to stimulate formation of new collagen in the skin.

216. Underwood explicitly disclosed that “the voltage applied to the first and second electrodes is sufficient to induce heating of the dermis layer” and that “[t]his induced heating causes the patient's body to undergo a wound healing response.” (Underwood, ¶[0011].) Further, “[t]he wound healing process involves the generation of neo-collagen in the dermis layer” and “this stimulation of collagen growth within the dermis is accomplished while minimizing or suppressing the damage caused to the outer epidermis layer.” (*Id.*) Indeed, Underwood expressly taught that its temperature range (60-80° C) achieved by its controlled delivery of RF energy “causes sufficient damage to the collagen

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connective fibers to enhance or stimulate regrowth of new collagen fibers in the underlying tissue.” (*Id.*, ¶[0045].)

217. Debendictis likewise disclosed “stimulating the generation of... collagen” or “collagen remodeling.” (Debendictis, ¶¶[0002], [0038]; *see* ’304 Provisional, 1:18-21, 20:10-12.) Specifically, Debendictis taught that its damage pattern stimulates the tissue’s wound repair system (i.e., formation of new collagen), making it more robust. (Debendictis, ¶[0014]; *see* ’304 Provisional, 12:18-13:6.) Thus, using Underwood’s controller to achieve Debendictis’s fractional damage pattern would specifically result in the “*controlled delivery of the RF energy [being] configured to stimulate formation of new collagen in the skin.*”

218. A POSA would have found that Debendictis provided a known pattern of fractional damage (i.e., pattern of thermally altered tissue surrounded by unaltered tissue) that resulted in improved efficacy and safety. A POSA would have therefore been motivated to combine Debendictis’s teachings with Underwood’s teachings to improve the treatment results while also improving the patient experience.

219. As discussed above, a POSA would have had a reasonable expectation of success in using Underwood’s controller to achieve Debendictis’s fractional damage pattern to arrive at the claimed invention. Debendictis made known the

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goal of multiple small micro-wounds as a pattern of fractional damage. And with that goal in mind, a POSA would have been able to control Underwood's RF energy to accomplish fractional damage. Indeed, a POSA would have known how to use Underwood's controller to achieve Debendictis's pattern of fractional damage. For example, a POSA would have varied parameters already discussed in Underwood (e.g., energy level, output power) so that thermally altered tissue (e.g., the immediate region around the electrodes) was surrounded by unaltered tissue. In short, using Underwood's controller to achieve Debendictis's fractional damage pattern would be nothing more than using a known technique (thermally altered tissue surrounded by unaltered tissue) to improve a similar device in the same way. Therefore, in using Underwood's controller to achieve Debendictis's fractional damage pattern, a POSA would have achieved predictable results.

220. Thus, the combination of Underwood and Debendictis disclosed each limitation of claim 1. And a POSA would have had a reason to combine these references to arrive at the claimed invention with a reasonable expectation of success. Accordingly, claim 1 is not the product of innovation. Instead, it would have been obvious over Underwood in view of Debendictis, notwithstanding any objective indicia of nonobviousness, which is discussed with respect to all challenged claims in Section XIV.

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D. Claim 2 would have been obvious over Underwood in view of Debendictis.

221. Claim 2 depends from claim 1 and further recites “*wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.*” As shown in the claim chart below and discussed in this Declaration, Underwood and Debendictis taught each element of claim 2 of the ’899 patent.

Claim	Disclosures in Underwood and Debendictis
2. The device of claim 1, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.	<p>“Applicant has found, however, that the bipolar design helps to confine the electric current to the target region.” (Underwood, ¶0055.)</p> <p>“Of course, other configurations are possible, such as providing the middle row or column of electrodes with the same polarity such that the current flows between the two outer rows or columns and the middle row/column.” (Underwood, ¶[0055].)</p> <p>“In one aspect of the invention, a method includes positioning a first electrode adjacent to, or in contact with, a region on or within a patient’s skin, and applying a sufficient high frequency voltage between the first electrode and a second electrode to create a heat injury to a target tissue within the patient’s dermis layer without ablating the epidermis layer overlying the</p>

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	target tissue. Typically, the voltage applied to the first and second electrodes is sufficient to induce heating of the dermis layer to about 60°-80° C., preferably about 65°-75° C. This induced heating causes the patient's body to undergo a wound healing response in the slightly inflamed tissue of the dermis. The wound healing process involves the generation of neo-collagen in the dermis layer, which fills in the wrinkle in the patient's skin. In the present invention, this stimulation of collagen growth within the dermis is accomplished while minimizing or suppressing the damage caused to the outer epidermis layer, which reduces the overall pain and wound healing time for the patient.” (Underwood, ¶[0011].)
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222. As discussed above, Underwood and Debendictis disclosed all the limitations of claim 1. Underwood disclosed claim 2's additional limitations.

223. Specifically, Underwood disclosed that its “bipolar design helps to confine the electric current to the target region.” (Underwood, ¶[0055].) Underwood disclosed several different needle array arrangements that a POSA would have understood to disclose “bipolar” needle pairs. For example, Underwood taught “providing the middle row or column of electrodes with the same polarity such that the current flows between the two outer rows or columns and the middle row/column.” (*Id.*) Thus, Underwood disclosed “*wherein the plurality of needles are associated with each other in groups of bipolar pairs*” as claimed.

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224. Further, as discussed above, Underwood's controller is configured to control the delivery of RF energy to the electrodes. (*Id.*, ¶¶[0011], [0015], [0038], [0054]; *supra* Section XII.C.) Underwood disclosed that an objective of the invention was "to create a heat injury to a target tissue within the patient's dermis layer without ablating the epidermis layer overlying the target tissue." (Underwood, ¶[0011].) Thus, Underwood disclosed "*wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer.*" Debendictis similarly disclosed treatment patterns "for purposes of non-ablative coagulation of a dermal layer of the targeted portion 10." (Debendictis, ¶[0078]; '304 Provisional, 21:19-20.)

225. Moreover, a POSA would have also understood that in Underwood's bipolar mode, where current flows between electrodes of each pair having opposite polarities, tissue damage would occur along the path of the RF energy between the needles of each of the bipolar pairs of electrodes because it is the RF energy that heats the tissue and causes damage. (Underwood, ¶[0055].) Since the RF energy travels between the two needles of each of the bipolar pairs, a POSA would have understood that the damage will, therefore, occur along the paths the RF energy travels. Thus, the combination of Underwood and Debendictis disclosed "*wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles*" as claimed.

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226. Using Underwood's controller to achieve Debendictis's fractional damage pattern would not have changed these features of Underwood. The areas of treatment or damage along the paths the RF energy travels would be surrounded by untreated areas of sparing. Therefore, the combination of Underwood and Debendictis would have resulted in *"the plurality of needles [being] associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles."* In my opinion, claim 2 would have been obvious over Underwood in view of Debendictis.

E. Claim 4 would have been obvious over Underwood in view of Debendictis.

227. Claim 4 depends from claim 1 and further requires *"wherein the control module is further configured to receive a selection of an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting."* As shown in the claim chart below and discussed in this Declaration, Underwood and Debendictis taught each element of claim 4 of the '899 patent.

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Claim	Disclosures in Underwood and Debendictis
<p>4. The device of claim 1, wherein the control module is further configured to receive a selection of an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.</p>	<p>“Power supply 28 has an operator controllable voltage level adjustment 30 to change the applied voltage level, which is observable at a voltage level display 32. Power supply 28 also includes an operator input, preferably a foot pedal 38, and a cable 36 which removably couples foot pedal 38 to power supply 28. The foot pedal 38 allows the surgeon to remotely adjust the energy level applied to electrode assembly 16.” (Underwood, ¶[0035].)</p> <p>“A controller (not shown) coupled to the operator controls (i.e., foot pedals and voltage selector) and display, is connected to a control input of the switching power supply for adjusting the generator output power by supply voltage variation. The controller may be a microprocessor or an integrated circuit. The power supply may also include one or more sensors for detecting the output current or voltage.” (Underwood, ¶[0038].)</p>

228. As discussed above, Underwood and Debendictis disclosed all the limitations of claim 1. Underwood disclosed claim 4’s additional limitation.

229. Specifically, Underwood disclosed “an operator input” that “allows the surgeon to remotely adjust the energy level applied to” the electrodes. (Underwood, ¶[0035].) And Underwood’s controller is “coupled to the operator controls (i.e., foot pedals and voltage selector) and display” and “is connected to a control input of the switching power supply for adjusting the generator output power by supply voltage variation.” (*Id.*, ¶[0038].) Thus, a POSA would have understood that Underwood’s controller is “*configured to receive a selection of an*

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application-specific setting” because the surgeon can select a setting, such as energy level, that is communicated to the controller, and this selection would be based on the specific application the surgeon is using. Moreover, adjusting the supply voltage, energy level, or output power is adjusting the “*intensity*” of the RF energy as claimed. Indeed, Underwood’s “power supply may also include one or more sensors for detecting the output current or voltage,” which would be used to ensure the selected setting is applied. (*Id.*)

230. Using Underwood’s controller to achieve Debendictis’s fractional damage pattern would not have changed this feature of Underwood. Therefore, the combination of Underwood and Debendictis would have resulted in a controller that is “*configured to receive a selection of an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.*” Accordingly, claim 4 would have been obvious over Underwood in view of Debendictis.

F. Claim 6 would have been obvious over Underwood in view of Debendictis.

231. Claim 6 depends from claim 1 and further requires “*further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.*” As shown in the claim chart below and

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discussed in this Declaration, Underwood and Debendictis taught each element of claim 6 of the '899 patent.

Claim	Disclosures in Underwood and Debendictis
6. The device of claim 1, further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.	<p>“[I]t may be desirable to further reduce the tissue temperature of the electrode/skin interface to further minimize damage to the epidermis layer. In one embodiment, the electrically conductive fluid, typically isotonic saline, is cooled prior to its delivery to the target site. Typically, the conductive fluid will be cooled to a temperature in the range of about 0° C. to 20° C., usually about 5 C. to 15 C.” (Underwood, ¶[0056].)</p> <p>“The shape of the necrotic zone can be controlled by the appropriate combination of one or more of the laser beam spot size, fluence (energy per unit area), pulse duration, energy per pulse, laser wavelength, optical beam profile, system optics, lotion, contact tip temperature, surface cooling, and contact tip thermal conductivity.” (Debendictis, ¶[0073].)</p> <p>“Alternately, the power supply and cooling mechanism may be placed within the handpiece.” (Debendictis, ¶[0097].)</p>

232. As discussed above, Underwood and Debendictis disclosed all the limitations of claim 1. The combination of Underwood and Debendictis disclosed the limitations of claim 6.

233. Underwood disclosed that “it may be desirable to further reduce the tissue temperature of the electrode/skin interface to further minimize damage to the epidermis layer.” (Underwood, ¶[0056].) Underwood describes a system that cools

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a fluid prior to its delivery to the treatment site. (*Id.*) And Debendictis taught the use of surface cooling to control the shape of the thermally altered tissue. (Debendictis, ¶[0073]; *see* '304 Provisional, 16:15-17, 17:21-18:10, 4:19-5:15.) Debendictis further taught that a “cooling mechanism may be placed within the handpiece.” (Debendictis, ¶[0097].) Thus, Underwood and Debendictis disclosed “*a cooler for cooling a surface of the skin.*”

234. As discussed above, a POSA would have been motivated to use Underwood’s controller to achieve Debendictis’s fractional damage pattern. A POSA would have been further motivated to modify Underwood’s system to include Debendictis’s cooling mechanism to help control the shape of the thermally altered tissue to better accomplish fractional damage, as expressly taught by Debendictis. (Debendictis, ¶[0073]; *see* '304 Provisional, 16:15-17, 17:21-18:10, 4:19-5:15.) This would have been most effective when cooling began prior to transmitting RF energy (e.g., when inserting the needles into the skin). Accordingly, a POSA would have used Debendictis’s cooling mechanism in Underwood’s system “*for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.*”

235. A POSA would have readily implemented Debendictis’s fractional damage pattern by using Underwood’s controller for the reasons discussed above. In addition, it would have been simple and straightforward to modify Underwood

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to include Debendictis's cooling mechanism. Thus, a POSA would have had a reasonable expectation of success in arriving at a device "*further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.*" In my opinion, claim 6 would have been obvious over Underwood in view of Debendictis.

G. Claim 10 would have been obvious over Underwood in view of Debendictis.

236. Claim 10 depends from claim 1 and further requires "*wherein the control module is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with undamaged regions between the damaged regions.*" As shown in the claim chart below and discussed in this Declaration, Underwood and Debendictis taught each element of claim 10 of the '899 patent.

Claim	Disclosures in Underwood and Debendictis
10. The device of claim 1, wherein the control module is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with undamaged regions between the damaged regions.	<p>"In these procedures, it is desirable to stimulate the growth of neo-collagen in the tissue layers underlying the epidermal tissue. Thus, the temperature of the electrode terminal(s) are carefully controlled such that sufficient thermal energy is transferred to these underlying layers to contract, damage or otherwise injure these layers such that the body regrows collagen in this region." (Underwood, ¶[0029].)</p> <p>"As shown, electrode assembly 204 comprises three needle shaped electrodes 206, 208, 210 extending from three guards 212 that are attached</p>

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	<p>to electrode support 202. As discussed in detail below, guards 212 function as stops to prevent the physician from advancing electrodes 206, 208, 210 beyond a selected depth in the patient's skin.</p> <p>Electrodes 206, 208, 210 will each include a proximal insulated portion 214 and a distal exposed portion 216 for applying electric current to the patient.” (Underwood, ¶[0051].)</p> <p>“In the representative embodiment, electrodes 206, 208, 210 will have an exposed length in the range of about 0.5 to 10, and the insulated portion will have a length in the range of about 0.5 to 10.</p> <p>Electrodes 206, 208, 210 will taper down to a point to facilitate the penetration into the tissue.” (Underwood, ¶[0053].)</p> <p>“As shown in FIG. 6, the central electrode 208 has an opposite polarity from the outer electrodes 206, 210 such that electric current 162 flows between central electrode 208 and outer electrodes 206, 210 when a voltage is applied therebetween. In this manner, the current is generally confined to the immediate region around the electrodes which is the target area of the dermis 166. The voltage level will be selected to induce heating of the dermis 166 to a temperature in the range of about 60° to 80° C., typically about 65° to 75° C., without causing necrosis, ablation or vaporization of the tissue. As in previous embodiments, electrically conductive fluid (e.g., saline) may be delivered to the target site to modify the impedance of the tissue, if desired.” (Underwood, ¶[0054].)</p> <p>“In general, the present invention features a method for treating either existing medical (e.g. dermatological) disease conditions or for improving the appearance of tissue (e.g., skin) by intentionally generating a pattern of thermally</p>
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	altered tissue surrounded by unaltered tissue.” (Debendictis, ¶[0014]; <i>see</i> '304 Provisional, 12:18-13:6.)
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237. As discussed above, Underwood and Debendictis disclosed all the limitations of claim 1. The combination of Underwood and Debendictis disclosed claim 10's additional limitation.

238. Underwood disclosed that “the temperature of the electrode terminal(s) are carefully controlled such that sufficient thermal energy is transferred to these underlying layers to contract, damage or otherwise injure these layers such that the body regrows collagen in this region.” (Underwood, ¶[0029].) Underwood further taught that “[e]lectrodes 206, 208, 210 will each include a proximal insulated portion 214 and a distal exposed portion 216 for applying electric current to the patient.” (*Id.*, ¶[0051].) A POSA would have understood the distal exposed portion to be a tip of each electrode, especially because it “taper[s] down to a point to facilitate the penetration into the tissue.” (*Id.*, ¶[0053], FIG. 6.)

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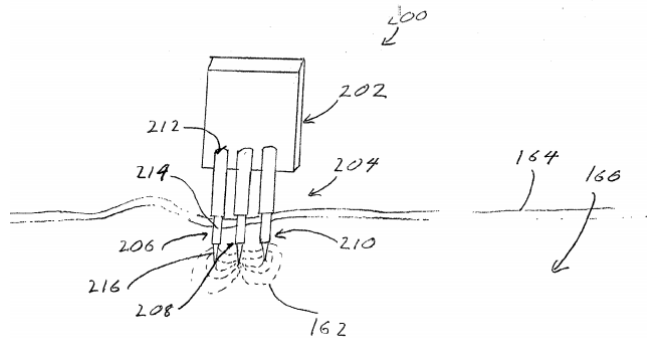


FIG. 6

(Underwood, FIG. 6.)

239. Because “the current is generally confined to the immediate region around the electrodes” (*id.*, ¶[0054]), a POSA would have understood that Underwood disclosed that its controller “*is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles.*”

240. Moreover, Debendictis disclosed “intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue.” (Debendictis, ¶[0014]; *see* ’304 Provisional, 12:18-13:6.) As discussed above, a POSA would have been motivated to use Underwood’s controller to achieve Debendictis’s fractional damage pattern. (*Supra* Section XII.C.) This would have resulted in “*undamaged regions between the damaged regions,*” as expressly taught by Debendictis.

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241. A POSA would have readily implemented Debendictis's fractional damage pattern by using Underwood's controller for the reasons discussed above. In doing so, a POSA would have arrived at a device "*wherein the control module is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with undamaged regions between the damaged regions.*" In my opinion, claim 10 would have been obvious over Underwood in view of Debendictis.

H. Claim 11 would have been obvious over Underwood in view of Debendictis.

242. Claim 11 depends from claim 1 and further requires "*wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.*" As shown in the claim chart below and discussed in this Declaration, Underwood and Debendictis taught each element of claim 11 of the '899 patent.

Claim	Disclosures in Underwood and Debendictis
11. The device of claim 1, wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of	"In these procedures, it is desirable to stimulate the growth of neo-collagen in the tissue layers underlying the epidermal tissue. Thus, the temperature of the electrode terminal(s) are carefully controlled such that sufficient thermal energy is transferred to these underlying layers to contract, damage or otherwise injure these layers such that the body regrows collagen in this region. " (Underwood, ¶[0029].)

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<p>thermal damage surrounding each tip.</p>	<p>“As shown, electrode assembly 204 comprises three needle shaped electrodes 206, 208, 210 extending from three guards 212 that are attached to electrode support 202. As discussed in detail below, guards 212 function as stops to prevent the physician from advancing electrodes 206, 208, 210 beyond a selected depth in the patient's skin. Electrodes 206, 208, 210 will each include a proximal insulated portion 214 and a distal exposed portion 216 for applying electric current to the patient.” (Underwood, ¶[0051].)</p> <p>“In the representative embodiment, electrodes 206, 208, 210 will have an exposed length in the range of about 0.5 to 10, and the insulated portion will have a length in the range of about 0.5 to 10. Electrodes 206, 208, 210 will taper down to a point to facilitate the penetration into the tissue.” (Underwood, ¶[0053].)</p> <p>“As shown in FIG. 6, the central electrode 208 has an opposite polarity from the outer electrodes 206, 210 such that electric current 162 flows between central electrode 208 and outer electrodes 206, 210 when a voltage is applied therebetween. In this manner, the current is generally confined to the immediate region around the electrodes which is the target area of the dermis 166. The voltage level will be selected to induce heating of the dermis 166 to a temperature in the range of about 60° to 80° C., typically about 65° to 75° C., without causing necrosis, ablation or vaporization of the tissue. As in previous embodiments, electrically conductive fluid (e.g., saline) may be delivered to the target site to modify the impedance of the tissue, if desired.” (Underwood, ¶[0054].)</p> <p>“In general, the present invention features a</p>
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	method for treating either existing medical (e.g. dermatological) disease conditions or for improving the appearance of tissue (e.g., skin) by intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue. " (Debendictis, ¶[0014]; <i>see</i> '304 Provisional, 12:18-13:6.)
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243. As discussed above, Underwood and Debendictis disclosed all the limitations of claim 1. The combination of Underwood and Debendictis disclosed claim 11's additional limitation.

244. Each of Underwood's electrodes 206, 208, 210 has a tip. (Underwood, FIG. 6.) Specifically, the "distal exposed portion 216" of each electrode is the portion of the needle near and including its tip. (*Id.*, ¶[0051].) The distal exposed portion 216 is "for applying electric current to the patient" to cause damage to the dermal tissue. (*Id.*) Because "the current is generally confined to the immediate region around the electrodes" (*id.*, ¶[0054]), a POSA would have understood that Underwood disclosed "*a small localized area of thermal damage surrounding each tip.*"

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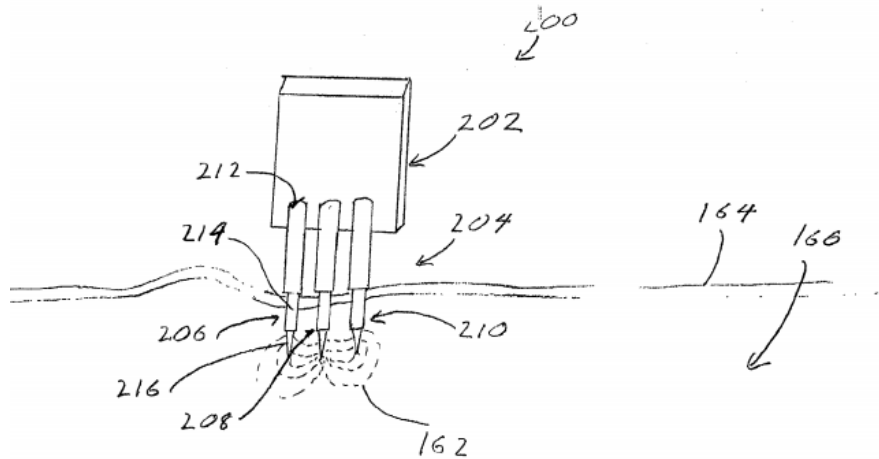


FIG. 6

(Underwood, FIG. 6.)

245. A POSA would have understood that the damaged areas would be centered around (i.e., localized) each of the electrodes, as these are the sources of the current. (See Section V.D.) As discussed above, the current density is highest immediately adjacent to the needles, and tapers off as the distance from the needle increases because the current spreads through an increasing volume of tissue. (*Id.*) And because there are multiple needles adjacent to each other, Underwood's control module is "*configured to cause at least two adjacent regions of thermal damage.*" (Underwood, FIGS. 6-8.)

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246. Moreover, Debendictis disclosed “intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue.” (Debendictis, ¶0014; *see* ’304 Provisional, 12:18-13:6.) As discussed above, a POSA would have been motivated to use Underwood’s controller to achieve Debendictis’s fractional damage pattern. (Section XII.C.) This modification would have confirmed that Underwood’s controller “*is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip*” because the thermally altered tissue would be small localized areas surrounding each tip.

247. A POSA would have readily implemented Debendictis’s fractional damage pattern by using Underwood’s controller for the reasons discussed above. (Section XII.C.) In doing so, a POSA would have arrived at a device “*wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.*” In my opinion, claim 11 would have been obvious over Underwood in view of Debendictis.

I. Claim 15 would have been obvious over Underwood in view of Debendictis.

248. Claim 15 is substantively similar to claim 1. The chart below compares claim 15 with claim 1. The portions of claim 15 that are not identical are bolded.

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Claim 1	Claim 15
[1.p] A skin treatment device, comprising:	[15.p] A skin treatment device, comprising:
[1.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base,	[15.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base,
[1.2] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and	[15.2] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and
[1.3] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,	[15.3] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to cause a pattern of fractional damage to be produced in the dermal layer in a vicinity of the tips of the needles
[1.4] wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.	[15.4] wherein delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer, and wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.

249. Where the elements are the same, the teachings of the combination of Underwood and Debendictis discussed above with respect to claim 1 are equally applicable here. Specifically, the preamble [15.p], the “*housing*” limitation [15.1], and the “*plurality of needles*” limitation [15.2] of claim 15 are the same as claim 1. ('899 patent, 12:34-40 *with* 13:30-36.)

250. The “*control module*” limitation [15.3] in claim 15 is similar to claim 1. I address the differences below. First, claim 15 recites “*to cause a pattern of*

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fractional damage to be produced in the dermal layer” instead of “*to induce a pattern of fractional damage by the RF energy in the dermal layer.*” In my opinion, causing a pattern of fractional damage to be produced is the same as inducing a pattern of fractional damage. Thus, Underwood’s and Debendictis’s teachings discussed above with respect to claim 1 are equally applicable to this limitation in claim 15. Second, claim 15 adds that the pattern is “*in a vicinity of the tips of the needles.*” In my opinion, this element is also taught by the combination of Underwood and Debendictis. Specifically, in combining Underwood and Debendictis as set forth above, Debendictis’s pattern would be in a vicinity of the tips of Underwood’s needles, for the reasons discussed above with respect to claims 10 and 11. (Section XII.G-H.)

251. Claim 15’s final limitation is similar to the limitations of claims 1, 10, and 11. For example, inducing a pattern of fractional damage would result in the claim 15 feature “*wherein delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer.*” In addition, Debendictis’s pattern would result in “*at least two adjacent regions of thermal damage*” that “*have an undamaged region therebetween*” for the reasons discussed above with respect to claims 10 and 11. (Debendictis, ¶[0014]; see ’304 Provisional, 12:18-13:6.) Thus, Underwood’s and Debendictis’s teachings

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discussed above with respect to claims 1, 10, and 11 are equally applicable to this claim 15 limitation.

252. Accordingly, the combination of Underwood and Debendictis disclosed each limitation of claim 15. And a POSA would have had reason to combine Underwood and Debendictis, with a reasonable expectation of success, for the reasons discussed with respect to claim 1. (Section XII.C.) In my opinion, claim 15 would have been obvious over Underwood in view of Debendictis.

J. Claim 20 would have been obvious over Underwood in view of Debendictis.

253. Claim 20 is substantively similar to claim 1. The chart below compares claim 20 with claim 1. The portions of claim 20 that are not identical are bolded.

Claim 1	Claim 20
[1.p] A skin treatment device, comprising:	[20.p] A skin treatment device, comprising:
[1.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base,	[20.1] a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base and arranged in a group of bipolar pairs,
[1.2] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and	[20.2] the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and
[1.3] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles	[20.3] a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles

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to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,	to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,
[1.4] wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.	[20.4] wherein the pattern of fractional damage includes damaged regions between tips of needles of the bipolar pairs, and undamaged regions between bipolar pairs of needles in the group.

254. Where the elements are the same, the teachings of the combination of Underwood and Debendictis discussed above with respect to claim 1 are equally applicable here. Specifically, the preamble [20.p], the “*plurality of needles*” limitation [20.2], and the “*control module*” limitation [20.3] of claim 20 are the same as claim 1. (’899 patent, 12:34-40 *with* 14:1-13.)

255. The “*housing*” limitation [20.1] in claim 20 is similar to claim 1. The only difference is that claim 20 specifies that the needles are “*arranged in a group of bipolar pairs.*” As I discussed above with respect to claim 2, Underwood disclosed that the needles may be arranged in bipolar pairs. (Underwood, ¶[0055]; *supra* Section XII.D.) Thus, Underwood’s and Debendictis’s teachings discussed above with respect to claims 1 and 2 are equally applicable to this limitation in claim 20.

256. Claim 20’s final limitation is similar to the limitations of claim 10, but modified for the bipolar arrangement. As discussed above with respect to claim 10, a POSA would have understood that the combination of Underwood and Debendictis disclosed damaged regions associated with the needles, with

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undamaged regions between the damaged regions. (*Supra* Section XII.G.) A POSA would have understood that because it is the RF energy flowing between the two needles of each of the bipolar pairs that is causing the damage, the pattern of fractional damage will include damaged regions between the tips of the needles of the bipolar pairs. These damaged regions would be surrounded by undamaged regions to achieve fractional damage. Accordingly, the undamaged regions would be between bipolar pairs of needles in the group (e.g., next to the flow of RF energy between needle tips). Thus, Underwood's and Debendictis's teachings discussed above with respect to claims 1, 2, and 10 are equally applicable to this claim 20 limitation.

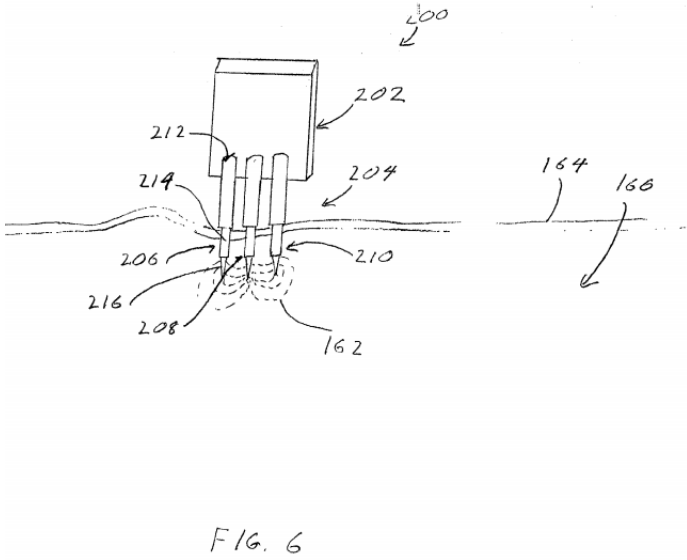
257. Thus, the combination of Underwood and Debendictis disclosed each limitation of claim 20. A POSA would have had reason to combine Underwood and Debendictis, with a reasonable expectation of success, for the reasons discussed with respect to claim 1. In my opinion, claim 20 would have been obvious over Underwood and Debendictis.

K. Claim 21 would have been obvious over Underwood in view of Debendictis

258. Claim 21 depends from claim 20 and further recites "*wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.*" As shown in the claim chart below and

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discussed in this Declaration, Underwood and Debendictis taught each element of claim 21 of the '899 patent.

Claim	Disclosures in Underwood and Debendictis
<p>21. The device of claim 20, wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.</p>	<p>“Applicant has found, however, that the bipolar design helps to confine the electric current to the target region...” (Underwood, ¶[0055].)</p>  <p style="text-align: center;">FIG. 6</p> <p style="text-align: center;">(Underwood, FIG. 6.)</p>

259. As discussed above, Underwood and Debendictis disclosed all the limitations of claim 20. The combination of Underwood and Debendictis disclosed claim 21’s additional limitation.

260. As discussed above with respect to claim 2, a POSA would have understood that the tissue damage is caused by the RF energy that flows between the needles in each of the bipolar pairs. (*Supra* Section XII.D.) And Underwood showed that energy passing between two electrodes provides an elongated shape.

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(Underwood, FIG. 6.) Accordingly, the damaged regions would be elongated between the two needles of a bipolar pair when using Underwood's controller to implement Debendictis's fractional damage pattern.

261. As discussed above, a POSA would have been motivated to use Underwood's controller to achieve Debendictis's fractional damage pattern. When done in conjunction with bipolar needles, this modification would have confirmed that Underwood's controller "*is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.*"

262. A POSA would have readily implemented Debendictis's fractional damage pattern by using Underwood's controller for the reasons discussed above. In doing so, a POSA would have arrived at a device "*wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.*" In my opinion, claim 21 would have been obvious over Underwood in view of Debendictis.

L. Claims 16 and 22 would have been obvious over Underwood and Debendictis.

263. Claims 16 and 22 depend from claims 1 and 20, respectively, and further recite "*wherein the control module is configured to cause necrosis.*" Claim 16 adds that the necrosis is "*in the dermal layer.*" As shown in the claim chart below and discussed in this Declaration, Underwood and Debendictis taught each element of claims 16 and 22 of the '899 patent.

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Claim	Disclosures in Underwood and Debendictis
16. The device of claim 1, wherein the control module is configured to cause necrosis in the dermal layer.	“In general, the present invention features a method for treating either existing medical (e.g., dermatological) disease conditions or for improving the appearance of tissue (e.g., skin) by intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue. The thermally altered tissue may include a necrotic zone. ” (Debendictis, ¶[0014]; <i>see</i> ’304 Provisional, 12:18-13:6.)
22. The device of claim 20, wherein the control module is configured to cause necrosis.	

264. As discussed above, Underwood and Debendictis disclosed all the limitations of claims 1 and 20. Debendictis disclosed claim 22’s additional limitation.

265. As discussed above, Debendictis disclosed “generating a pattern of thermally altered tissue surrounded by unaltered tissue.” (Debendictis, ¶[0014]; *see* ’304 Provisional, 12:18-13:3.) Debendictis taught that the “thermally altered tissue may include a necrotic zone.” (Debendictis, ¶¶[0014], [0039], [0041], [0044]; ’304 Provisional, 6:12-14, 8:3-6, 11:16-18, 16:15-17.) Thus, using Underwood’s controller to achieve Debendictis’s fractional damage pattern would have resulted in causing necrosis in the dermal layer. Accordingly, claims 16 and 22 would have been obvious over Underwood in view of Debendictis.

XIII. Ground 4: Claims 9, 12, 17, and 23 would have been obvious over Underwood in view of Debendictis and Brown.

266. Before April 1, 2004, claims 9, 12, 17, and 23 of the ’899 patent would have been obvious in view of the disclosures in Underwood, Debendictis,

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and Brown. Claim 9 depends directly from claim 1 and recites “*further comprising a spacer having holes through which the needles are configured to move.*” Claims 12, 17, and 23 depend from claims 1, 15, and 20, respectively, and recite “*further comprising a vibrator for vibrating at least one of the plurality of needles.*”

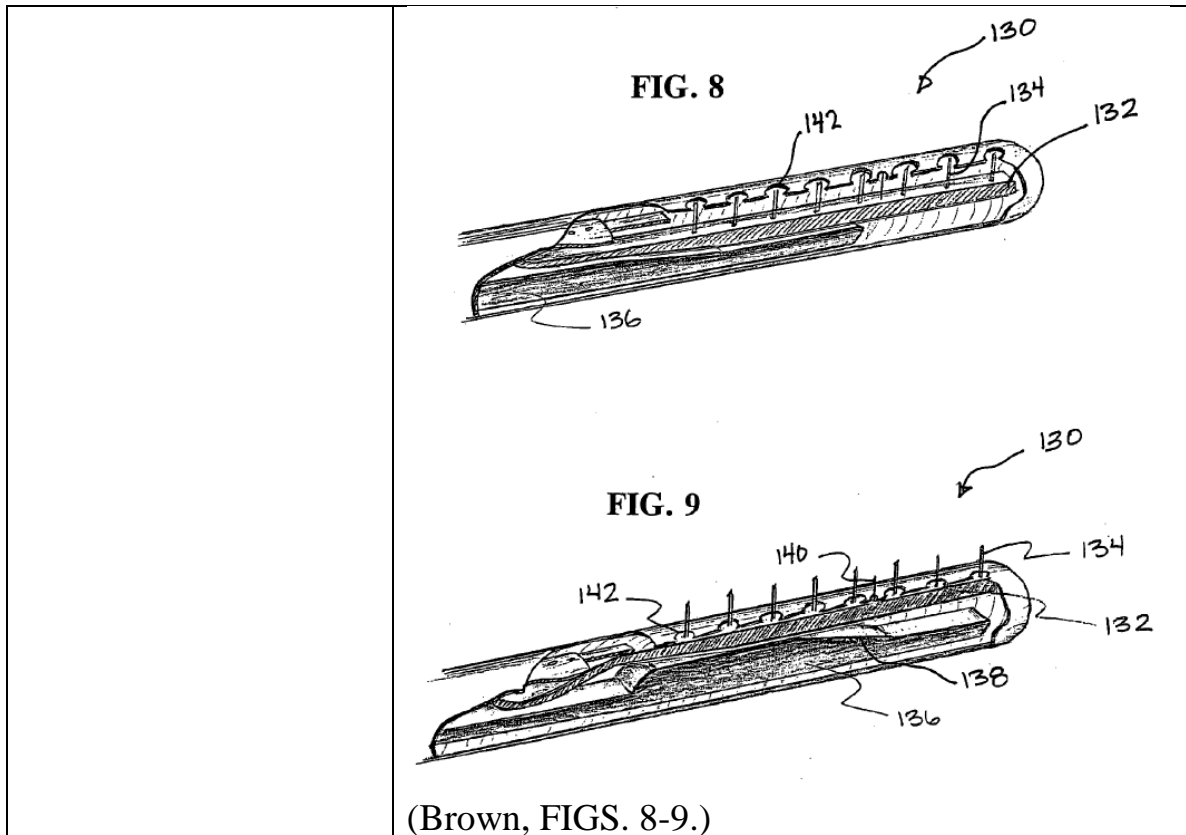
267. As discussed above in Sections XII.C, XII.I, and XII.J, Underwood and Debendictis rendered claims 1, 15, and 20 obvious. As shown here in Ground 4, Brown disclosed that its electrodes 134 could be “retracted entirely within the distal end of the treatment device 130” or be moved “to extended positions at which the electrodes... project through openings 142 in the device.” (Brown, ¶[0054], FIGS. 8-9.) Brown also disclosed that “methods may be employed ... to facilitate electrode insertion” into the tissue, including “vibration” of its needles through “an appropriate motion-inducing device, such as transducer 240A.” (*Id.*, ¶¶[0070]-[0071], FIG. 17A.) As discussed below, a POSA would have had a reason to use Brown’s teachings with Underwood and Debendictis for safety (e.g., by providing a retracted position for the needles) and to aid in needle insertion (e.g., by vibrating the needles). And a POSA would have had a reasonable expectation of success in so doing. Thus, claims 9, 12, 17, and 23 would have been obvious in view of the disclosures in Underwood, Debendictis, and Brown, notwithstanding any objective indicia of nonobviousness. (*see* Section XIV).

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A. Claim 9 would have been obvious over Underwood, Debendictis, and Brown.

268. Claim 9 depends from claim 1 and further recites “*further comprising a spacer having holes through which the needles are configured to move.*” As shown in the claim chart below and discussed in this Declaration, Underwood, Debendictis, and Brown taught each element of claim 9 of the ’899 patent.

Claim	Disclosures in Underwood, Debendictis, and Brown
9. The device of claim 1, further comprising a spacer having holes through which the needles are configured to move.	“FIGS. 8 and 9 illustrate a probe or catheter type treatment device 130 having electrode holder 132 at a distal end with a plurality of positive and negative electrodes 134. A mechanical pusher arm 136 within the catheter device 130 acts as a cam to cause the electrodes to extend from or retract into the catheter device. As shown in FIG. 8, when the mechanical pusher arm 136 is in a proximal position the electrodes 134 are retracted entirely within the distal end of the treatment device 130. When the mechanical pusher arm 136 is advanced to the distal position illustrated in FIG. 9, a ramp 138 on the pusher arm moves the electrodes 134 and the temperature sensor 140 to extended positions at which the electrodes and temperature sensor project through openings 142 in the device. The openings 142 may be one or more holes, as shown, or may be slots. ” (Brown, ¶[0054].)



269. As discussed above, Underwood and Debendictis disclosed all the limitations of claim 1. And Brown disclosed claim 9's additional limitation.

270. Specifically, Brown disclosed “an RF treatment device for creating transmural lesions in tissue” with “a plurality of tissue penetrating RF needle electrodes.” (Brown, ¶¶[0008], [0039].) Brown’s electrodes 134 could be “retracted entirely within the distal end of the treatment device 130” or be moved “to extended positions at which the electrodes... project through openings 142 in the device.” (*Id.*, ¶[0054], FIGS. 8-9.) In my opinion, a POSA would have understood Brown’s device with its openings 142 to operate as a spacer having

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holes through which the needles are configured to move. The needles 134 can be inserted into the tissue when they are in the extended position. (*Id.*, FIG. 9.)

271. A POSA would have been motivated to include a spacer, as taught by Brown, on Underwood's device to improve safety. Specifically, having a retracted position within a spacer protects the needles from unwanted piercing until the device is located at the desired position for treatment. A POSA would also have had a reasonable expectation of success in including such a spacer because such devices were well-known and easily implemented on needles of various sizes and configurations. In my opinion, claim 9 would have been obvious over Underwood in view of Debendictis and Brown.

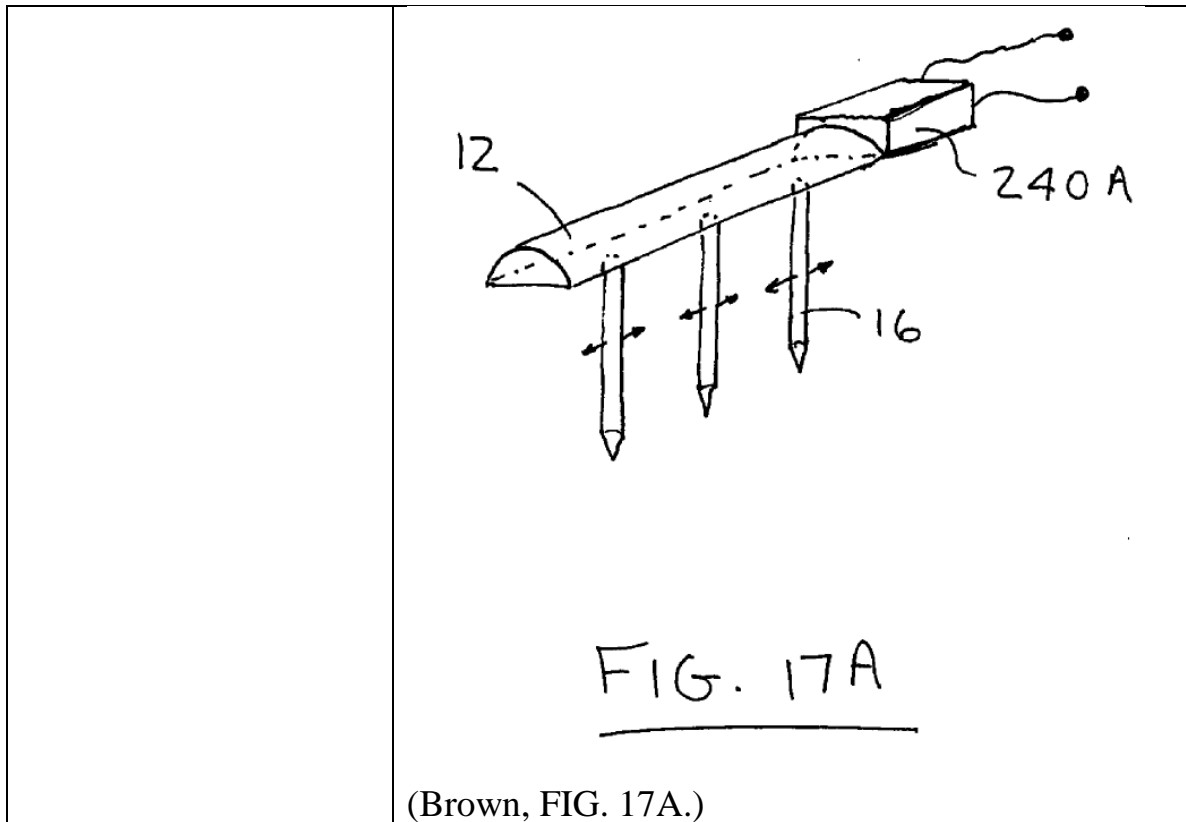
B. Claims 12, 17, and 23 would have been obvious over Underwood, Debendictis, and Brown

272. Claims 12, 17, and 23 depend from claims 1, 15, and 20, respectively, and further recite "*further comprising a vibrator for vibrating at least one of the plurality of needles.*" As shown in the claim chart below and discussed in this Declaration, Underwood, Debendictis, and Brown taught each element of claims 12, 17, and 23 of the '899 patent.

Claim	Disclosures in Underwood, Debendictis, and Brown
12. The device of claim 1, further comprising a vibrator for vibrating at least one of the plurality of needles.	"One or more methods may be employed in any of the foregoing embodiments of the invention to facilitate electrode insertion. These methods include vibration , such as ultrasonic vibration , oscillation in any plane , rotation of the

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<p>17. The device of claim 15, further comprising a vibrator for vibrating at least one of the plurality of needles.</p> <p>23. The device of claim 20, further comprising a vibrator for vibrating at least one of the plurality of needles.</p>	<p>electrodes, sequential electrode insertion, coatings or lubricants on the electrodes, and tip geometries which aid in penetration (FIGS. 1A-1F). In addition, a holding device, such as a vacuum device, may be used to hold the treatment device to the tissue before and during penetration with the electrodes.</p> <p>Vibration, including ultrasonic vibration and/or and oscillation in any plane or direction or combination of directions can be provided using an appropriate motion-inducing device, such as transducer 240A shown in FIG. 17A for imparting vibration to the needles 16 in the direction indicated by the arrows, or a motor 240B which may be mechanically linked, via a suitable linkage (not shown), to the individual needles 16 for rotation thereof in the direction of the arrows in FIG. 17B. In the case of rotational motion, the needles 16 may be provided with threads or a screw-type shape (FIG. 17C) to further aid in penetration. Vibrations and motions in other directions and combinations of directions are also contemplated. One such direction is along the major axis of the needles themselves, in the direction of tissue penetration (FIG. 17D). This direction motion can also be impulsive, or impact-type motion. The vibration and oscillations are imparted by a direct or indirect connection between the needles and the motion-inducing device. A preferred connection configuration, show in FIGS. 17A and 17B, involves imparting motion to the electrode holder 12, which in turn transfers this motion to the needles 16.” (Brown, ¶¶[0070]-[0071].)</p>
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273. As discussed above, Underwood and Debendictis disclosed all the limitations of claims 1, 15, and 20. And Brown disclosed the additional limitation in claims 12, 17, and 23.

274. Brown taught that various “methods may be employed... to facilitate electrode insertion” into the tissue, including “vibration.” (Brown, ¶[0070].) “Vibration... can be provided using an appropriate motion-inducing device, such as transducer 240A ... for imparting vibration to the needles 16.” (*Id.*, ¶[0071], FIG. 17A.) A POSA would have considered transducer 240A to be a vibrator as claimed.

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275. Thus, a POSA would have been motivated to include a vibrator on Underwood's device to vibrate at least one of the needles to facilitate insertion into the patient's skin. A POSA would have known that vibrating a needle eases insertion by mechanically disrupting the tissue the needle is being inserted into. A POSA would have also had a reasonable expectation of success in including a vibrator. In my opinion, claims 12, 17, and 23 would have been obvious over Underwood in view of Debendictis and Brown.

XIV. Objective Indicia of Nonobviousness

276. In reaching my opinions regarding obviousness in this Declaration, I also considered whether there were any objective indicia of nonobviousness. The basis for my understanding of obviousness and objective indicia of nonobviousness is provided above in Section VIII.

277. I understand that any objective indicia of nonobviousness must have a nexus, or a close connection, to the novel aspects of the claimed invention. I understand that objective indicia of nonobviousness include the following: commercial success, long-felt but unmet need, failure of others, copying, praise in the industry, and unexpectedly superior results as compared with the closest prior art.

278. Considering the information I have reviewed, my general knowledge of the field of skin treatment devices, and publications within that and related

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fields, I am not aware of any objective evidence that might support the patentability of the claims of the '899 patent. Further, from my review of the file history (Exs. 1002, 1003, 1004, 1005) of the '899 patent, I did not see that the Patent Owner raised any objective indicia of nonobviousness during prosecution. I am not otherwise aware of any publicly available evidence of objective indicia of nonobviousness.

279. It is my understanding that Patent Owner attempted to rely on objective indicia of nonobviousness at the ITC, but there has not yet been any finding that objective indicia weighs against obviousness. And I am not aware of any evidence linking the claimed pattern of fractional damage using RF needling to any objective indicia, such as copying, commercial success, or praise. Nor are the results unexpected because Altshuler and Debendictis disclosed the benefits of fractional damage. And Altshuler expressly instructed a POSA to use fractional damage in an RF system, which a POSA would have understood to include Utely's or Underwood's devices.

280. Therefore, it is my opinion that no objective indicia of nonobviousness support the patentability of the claims of the '899 patent.

XV. Conclusion

281. Claims 1-2, 4, 6-7, 10-11, 15, and 20-21 would have been obvious in view of the disclosures in Utely and Altshuler and the lack of any objective indicia

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of nonobviousness. Claims 9, 12, 17, and 23 would have been obvious in view of the disclosures in Utely, Altshuler, and Brown, and the lack of any objective indicia of nonobviousness. Claims 1-2, 4, 6, 10-11, 15-16, and 20-22 of the '899 patent would have been obvious in view of the disclosures in Underwood and Debendictis, and the lack of any objective indicia of nonobviousness. Claims 9, 12, 17, and 23 would have been obvious in view of the disclosures in Underwood, Debendictis, and Brown, and the lack of any objective indicia of nonobviousness.

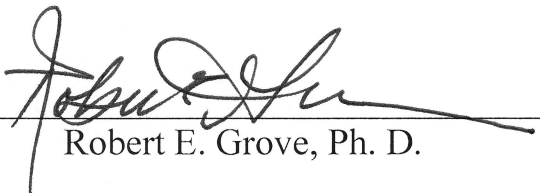
282. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination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

***Inter Partes* Review of U.S. Patent No. 9,510,899
Expert Declaration of Robert E. Grove, Ph.D.**

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

Executed this 6th day of June, 2019

Respectfully submitted,


Robert E. Grove, Ph. D.