

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

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,510,899

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U.S. Patent & Trademark Office
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EXHIBIT LIST

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”)
1006	Expert Declaration of Dr. Robert E. Grove (“Grove Decl.”)
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”)

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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 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,” <i>Journal of the American Academy of Orthopaedic Surgeons</i> , 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 Provisional”)
1027	Isaac Chang, “Finite Element Analysis of Hepatic Radiofrequency Ablation Probes using Temperature-Dependent Electrical Conductivity,” <i>BioMedical Engineering OnLine</i> , (2003) (“Chang”)

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Petitioners Lumenis Ltd. and Pollogen Ltd. (collectively “Lumenis”) request IPR and cancellation of claims 1-2, 4, 6-7, 9-12, 15-17, and 20-23 of U.S. Patent No. 9,510,899 (“the ’899 patent”), purportedly assigned to The General Hospital Corporation.

I. PRELIMINARY STATEMENT

There is nothing new claimed in the ’899 patent. The ’899 patent claims a skin treatment device that includes a housing with a plurality of needles configured to be inserted into the dermis and a controller to control delivery of radiofrequency (“RF”) energy to the needles to induce a pattern of fractional damage and stimulate formation of new collagen in the skin.

But needles that transmit RF energy into the dermis to damage the tissue were not new in skin treatment devices, a fact that Patent Owner readily conceded during prosecution. Patent Owner further conceded in an ITC investigation involving the ’899 patent that “the control module of the claimed invention is not a complicated structure.” (Ex. 1025, “Petition for Review,” p. 1.) According to Patent Owner, “the invention does not lie in the complexity of the control, it lies in the recognition that limiting the amount of energy delivery through needles to cause fractional wounding provided unexpected results.” (*Id.*, 27.)

However, fractional damage was also well-known. And rather than being unexpected, the benefits of using fractional damage, including the resulting

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significant collagen regeneration, were understood and appreciated as of the '899 patent's filing date. Indeed, the sole inventor of the '899 patent previously disclosed both the application and benefits of fractional damage, and even specifically taught the use of RF energy to induce fractional damage. And a POSA would have had a reasonable expectation of success in achieving fractional damage. Even according to Patent Owner, all that was needed was for the control module to "cause the RF generator to apply a lower amount of energy," which "simply required plugging in new set points into a standard control module to deliver less energy." (*Id.*, 1-2)

In short, the alleged inventions recited in the challenged claims would have been obvious over the cited prior art. Lumenis has also submitted an accompanying Declaration of Robert E. Grove, Ph.D., a technical expert with more than 35 years of experience with treatment systems for delivery of electromagnetic radiation energy to skin or other tissues. (Ex. 1006, "Grove Decl.," ¶¶18-38.) Lumenis requests that the Board institute trial and cancel claims 1-2, 4, 6-7, 9-12, 15-17, and 20-23 of the '899 patent as obvious.

II. BACKGROUND IN THE ART

Delivering electromagnetic energy to human tissue has been an important aspect of the medical industry for decades. (*Id.*, ¶42.) Devices for delivering electromagnetic energy to human tissue were well-known and well-developed by

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the early 2000s. (*Id.*; *see, e.g.*, Ex. 1009, “Altshuler,” 1:14-16.) Such devices typically included an energy source, an apparatus to deliver the energy to the tissue, and a controller to regulate the energy delivery. (Grove Decl., ¶42.)

One well-known application of these devices was the treatment of skin, including for cosmetic purposes (e.g., skin rejuvenation, hair removal, etc.). (*Id.*, ¶43; *see, e.g.*, Altshuler, 1:14-19.) This known application specifically included the damaging and rejuvenation of collagen in the dermis. (Grove Decl., ¶43.)

A. The prior art appreciated the skin’s wound healing process in response to damage.

The skin covers and protects the underlying body tissue and is predominantly made of two layers, as shown below: the epidermis 16 and the dermis 18. (Ex. 1008, “Utely,” 3:57-67, FIG. 1.) Collagen fibers “in large part account for the strength and physical properties of the dermis 18.” (Utely, 4:3-6; Grove Decl., ¶44.)

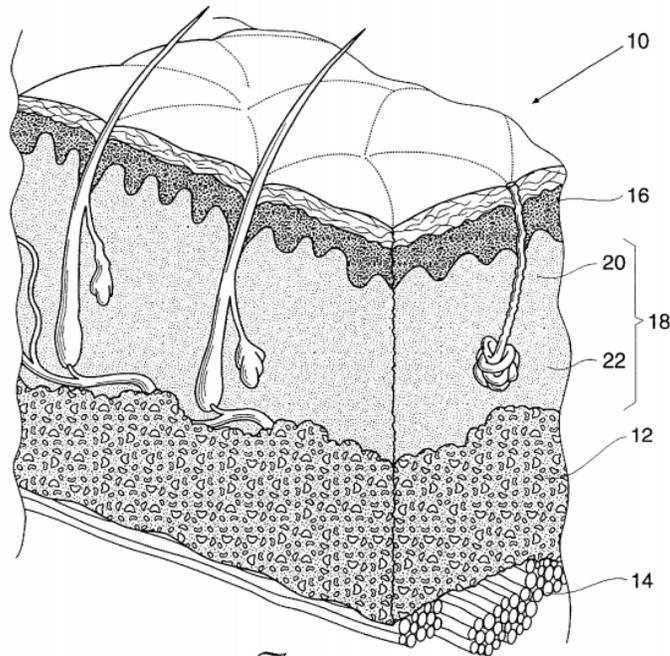


Fig. 1

(Utely, FIG. 1.)

Artisans understood that damaging collagen tissue could improve the outward appearance of the skin. (Grove Decl., ¶45.) Specifically, skin defects, such as those caused by aging, disease, or trauma, can be improved by purposefully wounding the skin to induce the natural wound healing process in the skin. (*Id.*) Artisans knew that inducing “trauma initiates wound healing with consequent formation of connective tissue” that would result in repair of both the induced damage and reduction of previously existing skin defects, such as wrinkles or scars, in its vicinity. (Ex. 1014, “Orentreich,” 543, 548-49; Ex. 1015, “Pozner,” 428; Grove Decl., ¶45.)

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There were various known techniques for inducing damage (or trauma) in the skin. (Grove Decl., ¶46.) 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 induce heat-based damage to the tissue and subsequent generation of collagen. (See, e.g., Pozner, 428; Grove Decl., ¶46.)

B. The prior art used various electromagnetic radiation techniques to induce damage to skin.

Thermal damage treatments in the prior art used various electromagnetic radiation techniques to induce damage to skin. (Altshuler, 1:14-26; Grove Decl., ¶47.) Electromagnetic radiation techniques can be generally categorized into two groups: ablative laser skin resurfacing (“LSR”) and non-ablative collagen remodeling (“NCR”). (Grove Decl., ¶47.) LSR used laser radiation 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.” (Ex. 1012, “Debendictis,” ¶[0002]; Grove Decl., ¶47.)

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. downtime) from the extensive thermal damage to the epidermis and dermis (Utely, 1:48-50), various NCR techniques were developed. (Grove Decl., ¶48.) These techniques rely on thermal damage of only the dermal tissue without

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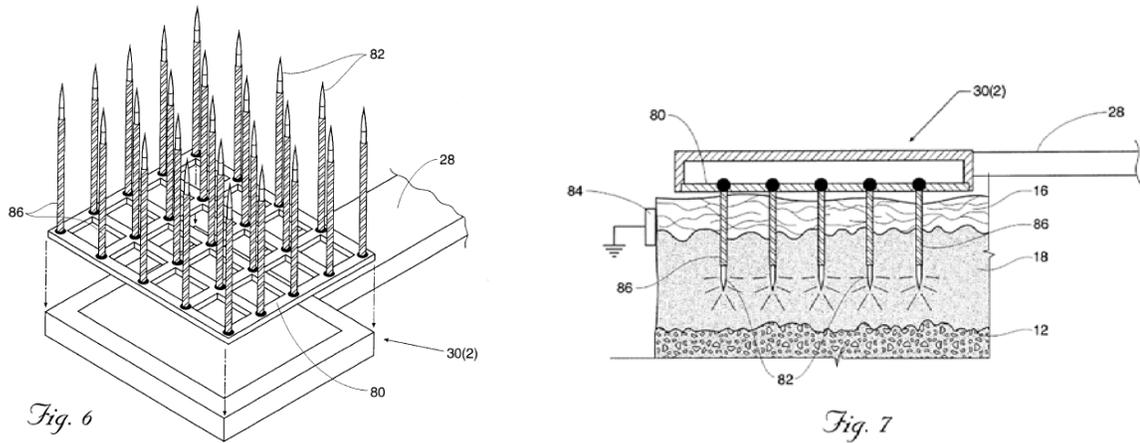
ablation of the epidermis. (*Id.*; Ex. 1017, “Capon,” 8.) The thermal damage to the dermis induces collagen shrinkage and stimulates the body’s natural wound healing processes, which results in biological repair and formation of new dermal collagen. (Pozner, 428; Capon, 8; Grove Decl., ¶48.) The new dermal collagen restores the strength and physical properties of the dermis and ultimately improves the outward appearance of the skin. (Pozner, 428; Grove Decl., ¶48.) NCR treatments utilize electromagnetic radiation at various frequencies, including non-ablative laser frequencies (Capon, 8.) and RF frequencies (Utely, 4:38-41; Altshuler, 10:8-14.). (Grove Decl., ¶48.) Damage to the epidermis during NCR treatments is preferably reduced to a minimum to promote faster recovery time for the patient. (Utely, 1:59-64.)

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

By 2001, it was well-known that RF energy could be used to cause thermal damage to induce collagen shrinkage. (Utely, 1:51-56; Grove Decl., ¶49.) 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,” 120; Ex. 1020, “Narins,” 496; Grove Decl., ¶49.) New collagen forms by such thermal damage. (Hsu, 120.)

Needles were a well-known way to deliver RF energy to skin and other tissue. (Grove Decl., ¶50.) 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, 7:40-63, FIGS. 6-7.) Similarly, Underwood used an array of needle-shaped electrodes advanced into the dermis to deliver RF energy. (Ex. 1011, "Underwood," ¶[0016], FIGS. 5-8.) Edwards is another example of using needles to deliver RF energy into body tissue. (Ex. 1013, "Edwards," 10:10-13, FIG. 6.)



(Utely, FIGS. 6-7.)

In short, collagen shrinkage and regeneration caused by RF needling was well-known, and the formation of new collagen is simply an end result of the natural healing process. (Underwood, ¶[0029]; Grove Decl., ¶51.)

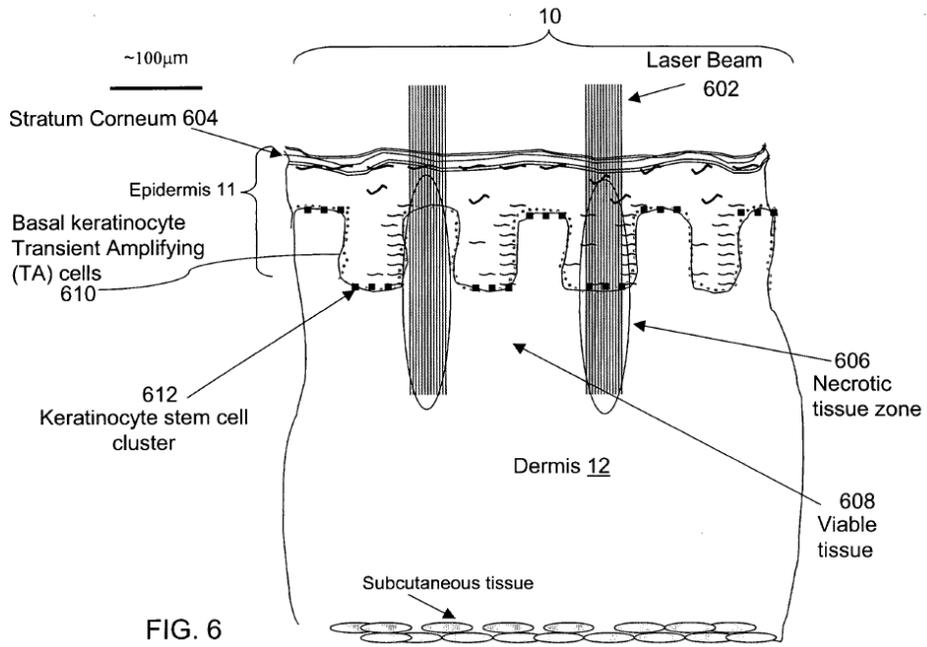
D. The prior art described fractional damage patterns and understood their benefits.

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; Grove Decl., ¶52.) The prior art taught that the controller can govern the

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applied RF energy to produce different energy intensities and application patterns. (Utely, 8:24-33; Grove Decl., ¶53.) And “[t]he precise heat-induced behavior [of collagen] ... [was known to be] dependent on several factors, including the maximum temperature reached and exposure time.” (Ex. 1023, “Thermal Modification,” p. 306.) It was also well-known that “radio-frequency heating ... may easily cause nonhomogeneous heating.” (*Id.*, 307.) For example, “hot spots [were known to] occur around each [RF needle] electrode ...” (Cosman, ¶[0014], [0052]-[0054], FIGS. 3-4; Grove Decl., ¶53.)

Beyond these teachings, the prior art also specifically taught damage patterns (as shown below, for example) from electromagnetic radiation in which small areas of damaged tissue were surrounded by areas of sparing (*i.e.*, undamaged tissue). (Altshuler, 1:8-11; Debendictis, ¶[0014], FIG. 6; Edwards, 10:10-13, 32-35, FIG. 6.)



(Debendictis, Fig. 6.)

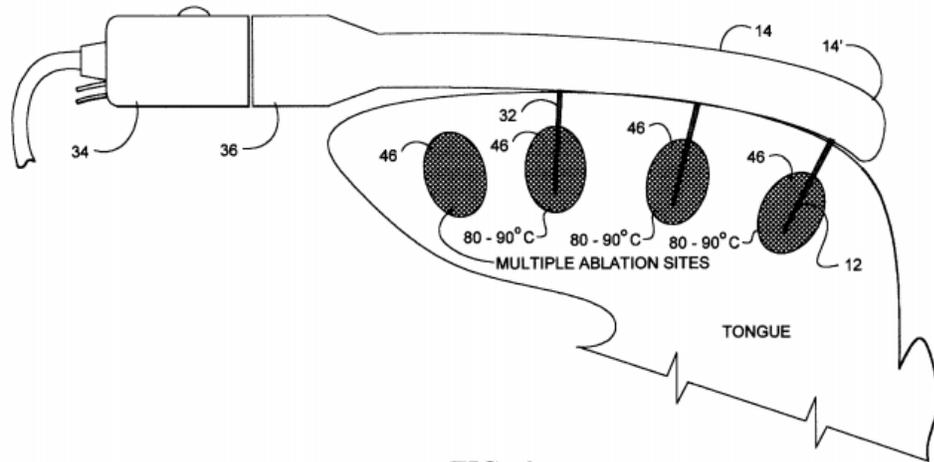


FIG. 6

(Edwards, Fig. 6.)

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This type of damage pattern is sometimes referred to as fractional damage because a portion or a fraction of the tissue is damaged while another portion is spared. (Debendictis, ¶[0044]; Grove Decl., ¶54.) 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, these treatments caused “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. (Grove Decl., ¶55.)

III. THE '899 PATENT

The '899 patent issued on December 6, 2016, from U.S. Application No. 14/458,644, filed on August 13, 2014 and claiming priority to Provisional Application No. 60/558,476, filed on April 1, 2004. (Ex. 1001, “'899 patent,” (22), (60).) The '899 patent's background section described various prior art LSR and NCR techniques. (*Id.*, 1:61-3:52.) However, although the '899 patent referenced the U.S. counterpart to Altshuler as providing “[e]xamples of NCR techniques” (*id.*, 3:6-8), the '899 patent failed to note that this reference specifically disclosed fractional damage patterns and specifically mentioned an RF system.¹ (Grove

¹ Indeed, the '899 patent's sole inventor is also an inventor in Altshuler, and the '899 patent's provisional application gives a description that is quite similar to

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Decl., ¶¶56-61.) Similarly, although the '899 patent discussed the application of RF energy “at the surface of the skin” ('899 patent, 3:31-34), the '899 patent failed to note the known application of RF energy to the dermis through needles. (Grove Decl., ¶62.)

With these omissions in its background section, the '899 patent then disclosed nothing more than these well-known concepts. (*Id.*, ¶58.) As shown in Figure 3 (reproduced below), the '899 patent's device includes “a plurality of needles 350 attached to a base 310.” ('899 patent, 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.)

Altshuler. (Grove Decl., ¶61.) For example, both specifications describe electromagnetic radiation (EMR), including optical and radio frequencies, as the energy source to induce damage. (Ex. 1005, “'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).)

“Optionally, energy source 320 and/or control module 330 may be located outside of the housing.” (*Id.*, 5:49-51.)

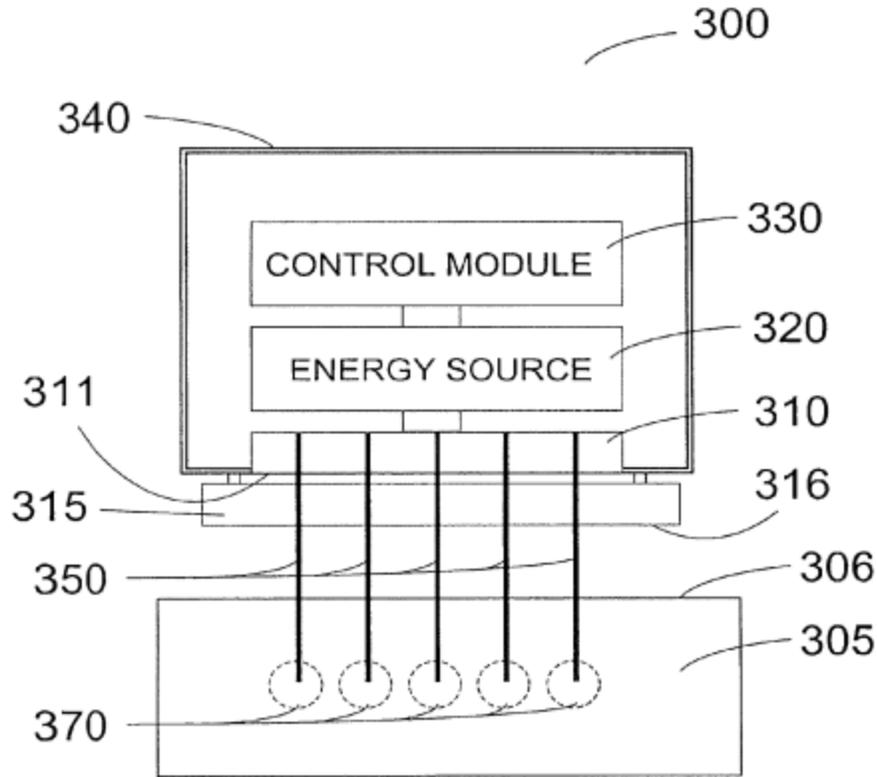


FIG. 3

(’899 Patent, FIG. 3.)

For treatment, the needles are inserted into the skin to a desired depth. (*Id.*, 6:7-17.) RF energy is 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.)

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In short, the '899 patent does not claim anything that goes beyond what was well-known in the art. (Grove Decl., ¶¶63-68.) Indeed, Patent Owner admitted during prosecution that the claimed components were disclosed in the prior art: “The Utely Patent relates to a *tissue reshaping apparatus* that includes a *plurality of shafts attached to a base*, where *the base is attached to housing, an energy source* in communication with one or more of the needles, and *a control module.*” (Ex. 1003, “357 PH,” 141 (emphases added).) To argue patentability over Utely alone, Patent Owner relied on forming new collagen and a pattern of fractional damage. (*Id.*, 142-143.) But these features were also known in the art.

IV. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSA”) in the technical field 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 2004. (Grove Decl., ¶¶40-41.) A POSA at the relevant time would typically 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 engineering graduate degree. (*Id.*)

V. CLAIM CONSTRUCTION

Lumenis discusses terms in need of express construction under the *Phillips* standard below.² For claim terms that are not discussed, Lumenis has applied the ordinary and customary meaning. (*Id.*, ¶69.) The parties submitted other terms for construction at the ITC.³ (*Id.*, ¶73.) 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.

A. “a pattern of fractional damage”

The Board should construe “a pattern of fractional damage” to mean “the pattern of damage caused by non-uniform heating.” This construction was adopted by the ITC in the related ITC proceeding, and the Board should adopt the same meaning.

Although the ’899 patent specification does not include the term “a pattern of fractional damage,” the specification uses the term “fractional wounding” three

² Lumenis’ proposed constructions for the purpose of this proceeding are not an admission that the claims are valid under 35 U.S.C. § 112. Lumenis reserves the right to challenge the validity of the claims under 35 U.S.C. § 112 in other proceedings and forums.

³ Other than “a pattern of fractional damage,” the ITC has not yet construed the claims.

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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”. (Grove Decl., ¶¶70-71.)

Lumenis notes 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.” The Grounds below render the claims obvious under either construction.

B. “a control module”

The Board should construe “a control module” to mean “a controller.” At the ITC, Lumenis took the position that this term invoked 35 U.S.C. § 112, ¶6, and that the claim was indefinite for lack of corresponding structure.⁴ However, during the

⁴ Although the ALJ granted a motion for summary determination that the '899 patent's claims were indefinite based on this reasoning, the Commission remanded the Initial Determination to the ALJ for relevant factual findings on the extrinsic evidence.

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ITC proceeding, Patent Owner asserted that § 112, ¶6 does not apply because “persons of ordinary skill in the art use the term ‘control module’ to refer to a known structure in the medical device field.” (Petition for Review, 2.) Indeed, Patent Owner admitted 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.)

Given the Patent Owner’s admissions that the control module is a standard controller or off-the-shelf product, and that a POSA would consider “a control module or controller to be a well-recognized name for a known structural element in these sorts of systems” (*id.*, 17), for this proceeding Lumenis adopts Patent Owner’s position that § 112, ¶6 does not apply to the term “control module” because it connotes structure to a POSA. *See Caterpillar Inc. v. Wirtgen America, Inc.*, IPR2017-02185, Paper 7 at 11-12 (P.T.A.B May 3, 2018) (“Our rules do not require positions consistent with related cases in different fora. ... Various reasons may justify inconsistencies.”) Accordingly, the Board should construe “a control module” to mean “a controller.” (Grove Decl., ¶72.)

VI. SUMMARY OF GROUNDS

A. Prior Art Applied

Utely issued on August 21, 2001 and is Section 102(b) prior art.

Altshuler published on July 11, 2002 and is Section 102(b).

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Underwood published on July 4, 2002 and is Section 102(b) prior art.

Debendictis published in English on January 27, 2005 from a PCT application that was filed on July 9, 2004 and that designated the US. If the '899 patent is not entitled to the April 1, 2004 filing date of its provisional application, Debendictis is Section 102(b) prior art. Even if the '899 patent is entitled to its earliest possible priority date, Debendictis is at least Section 102(e) prior art. Specifically, Debendictis claimed priority to U.S. Provisional Application No. 60/486,304, which was filed on July 11, 2003. And the '304 application provides § 112 support for at least claims 1 and 2 of Debendictis. (Ex. 1026, “'304 Provisional,” 11:16-22, 12:14-23, 13:7-9, 16:6-22, claims 1, 3; Grove Decl., ¶82.) *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1382-83 (Fed. Cir. 2015).

Brown published on August 19, 2004 and was filed on February 2, 2004. Thus, Brown is at least Section 102(e) prior art.

Utely, Altshuler, Underwood, Debendictis, and Brown are analogous art to the '899 patent because they are from the same field of endeavor: treatment systems for delivery of electromagnetic radiation energy to skin or other tissues. (Grove Decl., ¶83.)

B. Grounds

This Petition presents four grounds of unpatentability:

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Ground	References	Basis	Claims Challenged
1	Utely, Altshuler	§103(a)	1-2, 4, 6-7, 10-11, 15, 20-21
2	Utely, Altshuler, Brown	§ 103(a)	9, 12, 17, 23
3	Underwood, Debendictis	§103(a)	1-2, 4, 6, 10-11, 15- 16, 20-22
4	Underwood, Debendictis, Brown	§ 103(a)	9, 12, 17, 23

Grounds 1-4 are substantially different than the art and arguments previously considered by the Office.

First, there were no prior art rejections during prosecution of the '899 patent. (Ex. 1002, “'899 PH,” 230-232.) Although the Examiner rejected pending claims in parent applications of the '899 patent as anticipated by or obvious over Utely, those rejections always relied on Utely as disclosing a pattern of fractional damage (or a pattern of localized regions of thermal damage). ('357 PH, 117, 163; Ex. 1004, “'394 PH,” 150-151, 387.) The Examiner never relied on Utely in combination with any other references as disclosing the “pattern of fractional damage” feature. ('357 PH, 117, 163.) Instead, the Examiner eventually agreed with Patent Owner that Utely did not disclose inducing fractional damage with RF energy.⁵ (*Id.*, 176, 190.) In doing so, the Examiner took an improperly narrow view

⁵ In allowing the '899 patent, the Office again emphasized this feature, finding that the claims of the '899 patent were allowable because they claimed a

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of Utely's teachings based on Patent Owner's misguided arguments that Utely's statements of achieving or maintaining a temperature indicate that Utely's system was only for uniformity of heating. (*Id.*, 178, 190.)

Although a U.S. equivalent of Altshuler was cited in an IDS ('899 PH, 25), the Examiner never applied Altshuler, let alone in combination with Utely. This is particularly important where Altshuler teaches both (1) the exact claim limitations alleged during prosecution to be missing from Utely, and (2) an express motivation for modifying Utely with these limitations. Altshuler disclosed the creation of fractional damage patterns using RF energy and explained the benefits of doing so. (Altshuler, 13:11-23, 18:23-19:2.)

Second, although a family member of Underwood and a U.S. equivalent of Debendictis were cited in an IDS ('899 PH, 25), the Examiner never applied Underwood or Debendictis. Like Altshuler, Debendictis disclosed fractional damage patterns, which the Patent Owner argued was missing from Utely, as well as the benefits of using fractional damage patterns. (Debendictis, ¶¶[0014], [0041], [0044].)

Moreover, during prosecution, Patent Owner (mistakenly) argued that Utely was only about shrinking collagen and taught away from forming new collagen.

system that is configured “*to induce fractional damage by RF energy.*” ('899 PH, 267 (emphasis in original).)

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(’357 PH, 142-143.) Thus, Underwood is also different than Utely because it specifically describes “generat[ing] the growth of new collagen in” a patient’s dermis. (Underwood, Abstract.)

Third, although a family member of Brown was cited in an IDS (’899 PH, 24), the Examiner never applied Brown.

Thus, the combinations of references in each of Grounds 1-4 are substantially different than the prior art examined during prosecution and the arguments presented below are substantially different than the Examiner’s rejection based on Utely alone. (Grove Decl., ¶¶85-86.)

Finally, the ’899 patent has never been challenged in a post-grant proceeding before the Office. Because this Petition is not a follow-on petition, the *General Plastic* factors are generally not applicable here, and despite the current disposition of the ITC investigation involving the ’899 patent, the Board should still institute this proceeding. *Expedia, Inc. v. Int’l Business Machines Corp.*, IPR2018-01354, Paper 8 at 36-37 (P.T.A.B. Jan. 15, 2019).

Although the Board has found that “the advanced state of [a] district court proceeding is an additional factor that weighs in favor of denying” institution, *NHK Spring Co., Ltd. v. Intri-Plex Technologies, Inc.*, IPR2018-00752, Paper 8 at 19-20 (P.T.A.B. Sept. 12, 2018) (precedential) , the co-pending litigation here is an ITC investigation, not district court litigation. This difference is crucial because,

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unlike *NHK Spring*, this IPR will not be “duplicative or amount to a waste of the Board’s resources.” *Wirtgen America, Inc. v. Caterpillar Paving Products Inc.*, IPR2018-01201, Paper 13 at 11-12 (P.T.A.B. Jan. 8, 2019).

An ITC Investigation cannot resolve a challenge to patent validity in any other forum—including the PTAB—because *the ITC does not have authority to invalidate a patent. Am. Hosp. Supply Corp. v. Travenol Lab.*, 745 F.2d 1, 5 (Fed. Cir. 1984); *Texas Inst. Inc. v. Cypress Semi. Corp.*, 90 F.3d 1558, 1568-69 (Fed. Cir. 1996).

Additionally, ITC decisions do not necessarily inform issues raised in IPR petitions due to the different evidentiary standards and burdens. *Instradent USA, Inc. v. Nobel Biocare Services AG*, IPR2015-01786, Paper 106 at 3-4 (P.T.A.B. Feb. 15, 2017)) (instituting review despite a prior ITC decision resolving the same question of patentability). In addition to the different evidentiary standards and burdens, this Petition challenges additional claims that are not at issue in the ITC investigation. *Intel Corp. v. Qualcomm, Inc.*, IPR2018-01295, Paper 8 at 16-17 (P.T.A.B. Jan. 15, 2019).

In short, the Board should not exercise its discretion to deny institution of this IPR.

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE UNDER § 103

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

Claims 1-2, 4, 6-7, 10-11, 15, and 20-21 would have been obvious over the combination of Utely and Altshuler. (Grove Decl., ¶¶6-8.) As discussed above, Patent Owner admitted that “Utely ... relates to a tissue reshaping apparatus that includes a plurality of shafts attached to a base, where the base is attached to housing, an energy source in communication with one or more of the needles, and a control module.” (’357 PH, 141.) Indeed, Utely disclosed a skin treatment device that uses needles to transmit RF energy “to the dermis in a targeted, selective fashion, to dissociate and contract collagen tissue.” (Utely, 4:27-28, 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.*, 8:27-29.)

To the extent Utely did not expressly use the term “a pattern of fractional damage,” it was known before the ’899 patent’s earliest priority date that a pattern of fractional damage was desirable. (Grove Decl., ¶110.) Altshuler, which shares an inventor with the ’899 patent, expressly disclosed applying electromagnetic radiation to the dermis so that areas of treatment or damage were surrounded by

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areas of sparing. (Altshuler, 1:10-11.) And Altshuler taught that its fractional damage pattern from heating “selective portions” instead of a large area (*i.e.*, bulk damage) “result[ed] in *significant collagen regeneration with less trauma and pain to the patient.*” (Altshuler, 18:29-19:2 (emphasis added); Grove Decl., ¶¶111-115.)

Thus, a POSA would have been motivated to use Utely’s controller to control the energy so that it achieved areas of treatment or damage surrounded by areas of sparing, as taught by Altshuler, to achieve significant collagen generation and less trauma and pain to the patient. (Grove Decl., ¶¶114-117.) A POSA would have had a reasonable expectation of success in combining the teachings of Utely and Altshuler to arrive at the claimed invention. (*Id.*, ¶¶118-119.) Therefore, claims 1-2, 4, 6-7, 10-11, 15, and 20-21 would have been obvious over Utely in view of Altshuler, notwithstanding any objective indicia of nonobviousness (*see* Section VII.E). (Grove Decl., ¶87.)

1. Independent claim 1

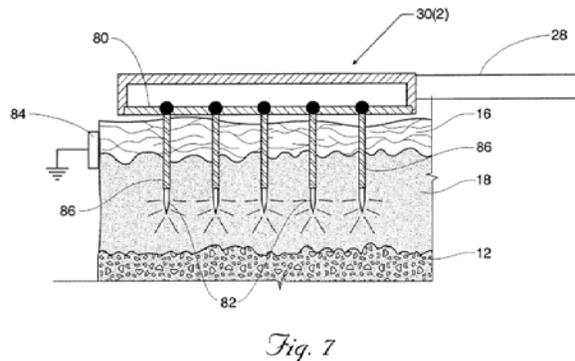
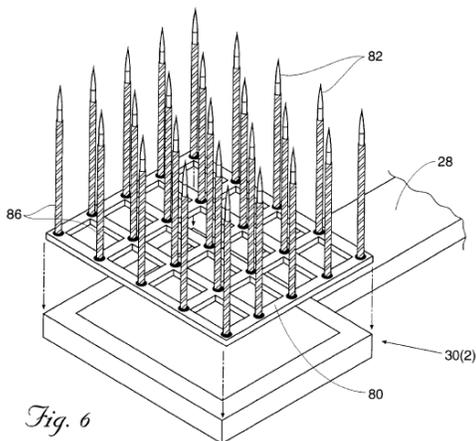
Utely and Altshuler disclosed each element of independent claim 1. (*Id.*, ¶¶95-96.)

a. Preamble

Utely disclosed “[a] *skin treatment device.*” (*Id.*, ¶97.) Specifically, Utely “provide[d] systems and methods of treating cosmetic conditions affecting the

30 that “transmits energy internally directly into the dermis” through a plurality of needles. (Utely, 5:25-27, FIGS. 6-7.)

Intradermal treatment energy applicator 30(2) “includes a carrier 80 on the distal end of handle 28.” (*Id.*, 7:40-42.) Utely expressly taught that “carrier 80 supports an array of spaced-apart needle electrodes 82,” as shown in Figures 6 and 7 (reproduced below). (Utely, 7:42-43, FIGS. 6-7.) Thus, 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.” (Grove Decl., ¶199.)



(Utely, FIGS. 6-7.)

Moreover, Utely 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).) Thus, Utely’s needles are “*arranged for insertion into a dermal layer of skin.*” (Grove Decl., ¶100.)

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Finally, a POSA would have understood Utely's carrier 80 to be a "base" as claimed. (*Id.*, ¶101.) 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 Utely's Figure 6 shows that carrier 80 is attached to intradermal treatment energy applicator 30(2). (Utely, FIG. 6.) 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, 48-49.) Thus, Utely's needles are "*attached to a base.*" (Grove Decl. ¶101.)

c. Element 1.2: the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source

Utely also disclosed this element. (*Id.*, ¶¶103-104.) Utely's "system 24 further includes a device 32 to generate treatment energy." (Utely, 4:38-39.) And 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.) A POSA would have understood generator 32 to be an "*RF energy source.*" (Grove Decl. ¶103.)

Moreover, Utely taught how this energy was applied to the skin in its intradermal treatment energy applicator 30(2). (*Id.* ¶104.) Specifically, "[e]ach electrode 82 comprises a discrete transmission source of radio frequency energy,

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which the controller 48 governs.” (Utely, 7:45-47.) 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). (Grove Decl., ¶104.)

d. Element 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

The combination of Utely and Altshuler disclosed this element. (*Id.*, ¶¶105-121.)

Utely disclosed “*a control module for controlling delivery of the RF energy from the RF energy source.*” (*Id.* ¶105.) Specifically, Utely’s “system 24 also includes a controller 48” that “is linked to the generator 32.” (Utely, 4:61-63.) “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.*” (Grove Decl. ¶105.)

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*

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needles are inserted therein.” (*Id.*, ¶¶106-107.) Utely taught that its “system applies energy to the dermis in a targeted, selective fashion, to dissociate and contract collagen tissue.” (Utely, 4:26-30.) A POSA would have understood dissociation and contraction of collagen tissue to be damage. (Grove Decl., ¶106.) 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.*, 7:58-67.) Further, Utely disclosed that “electrodes 82 can be operated individually or in groups to form defined energy 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.*” (Grove Decl., ¶107.)

While 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” (Utely, 8:27-29, 4:64-5:1), it did not expressly use the term fractional damage. However, fractional damage to the dermis was known, and so were the resulting beneficial collagen regeneration and other benefits. (Grove Decl., ¶¶108-110.) Accordingly, it would have been

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obvious to use Utely's controller 48 to control RF energy delivery to the needles to induce a pattern of fractional damage. (*Id.*, ¶110.)

Altshuler disclosed "*induc[ing] a pattern of fractional damage.*" (*Id.*, ¶111.)

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.*) Altshuler's "apparatus for 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.)

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.*, 1:10-11; Grove Decl., ¶112.) As discussed above, the proper construction of "a pattern of fractional damage" is "the pattern of damage caused

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by non-uniform heating.” (*Supra* Section V.A.) Altshuler’s description falls squarely within this construction, as well as the other proposed constructions at the ITC. (Grove Decl., ¶112.)

Altshuler further disclosed that this pattern of fractional damage could be induced “*by the RF energy in the dermal layer.*” (*Id.*, ¶113.) Specifically, although Altshuler focuses on optical EMR sources, Altshuler taught that other frequencies of EMR radiation may be used: “RF or other EM[R] sources may also be employed in suitable applications.” (Altshuler, 10:8.) And Altshuler explained 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.) Altshuler also taught that “where the treatment is skin remodeling 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.*” (Grove Decl., ¶113.)

The reasons for creating Altshuler’s pattern of fractional damage are expressly set forth in Altshuler: “significant collagen regeneration with less trauma and pain to the patient.” (Altshuler, 18:29-19:2; Grove Decl., ¶114.) Altshuler recognized that “treatments which are performed over a relatively large area, such as skin rejuvenation and hair removal, ... can cause varying degrees of skin

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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.*, 2:1-5.)

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.*, 18:30-19:2 (emphasis added).) 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.* 13:20-22 (emphasis added); Grove Decl., ¶115.)

Thus, a POSA would have been motivated to combine Altshuler’s teachings with Utely’s apparatus, for example, by using Utely’s controller 48 to control the RF energy delivered to needle electrodes 82 so that it induced a pattern of fractional damage to rejuvenate the skin by achieving significant collagen

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regeneration with less trauma and pain to the patient. (Altshuler, 13:11-23, 18:21-19:2; Grove Decl., ¶116.) Indeed, using Utely’s controller to implement Altshuler’s fractional damage pattern in Utely’s system would be nothing more than the use of a known technique to improve similar devices in the same way. (Grove Decl., ¶116.)

Further, a POSA would have been motivated to use Utely’s RF needles to achieve the pattern of fractional damage because of known limitations of laser skin treatments. (Grove Decl., ¶117.) For example, darker skin tones absorb too much laser energy, making it difficult or impossible to effectively use laser energy. (Altshuler, 3:14-21.) Delivering RF 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; Grove Decl., ¶117.) Thus, a POSA would have been motivated to use Utely’s RF needles to achieve Altshuler’s pattern of fractional damage. (Grove Decl., ¶117.)

Moreover, a POSA would have had a reasonable expectation of success in using Utely’s controller 48 to implement Altshuler’s fractional damage pattern. (Grove Decl., ¶118.) Altshuler taught that the radiation source of its treatment system may be an “RF ... source.” (Altshuler, 10:11-23.) 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. (Grove Decl.,

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¶118.) Moreover, 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.*, 4:27-28, 8:27-29.) Thus, 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; Grove Decl., ¶118.) Indeed, 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. (*Id.*, ¶119.)

It would have been simple for a POSA to use Utely’s controller to achieve Altshuler’s damage pattern (e.g., by modifying parameters that affect tissue damage). (*Id.*) Because Altshuler made known the goal of multiple small micro-wounds, a POSA would have been able to control Utely’s RF energy to accomplish fractional damage. (*Id.*, ¶124.). According to Patent Owner, all that was needed was for the control module to “cause the RF generator to apply a lower amount of

energy,” which “simply required plugging in new set points into a standard control module to deliver less energy.” (Petition for Review, 1-2.) As further evidence that a POSA would have had a reasonable expectation of success, RF needles had already been used to create a pattern of fractional damage in body tissue. (Grove Decl., ¶120.) For example, Edwards disclosed a device that “creat[ed] different ablation zones 46” that could be “non-connecting,” as shown in Edwards’ Figure 6 (reproduced below). (Edwards, 10:10-22, 34-35; FIG. 6.)

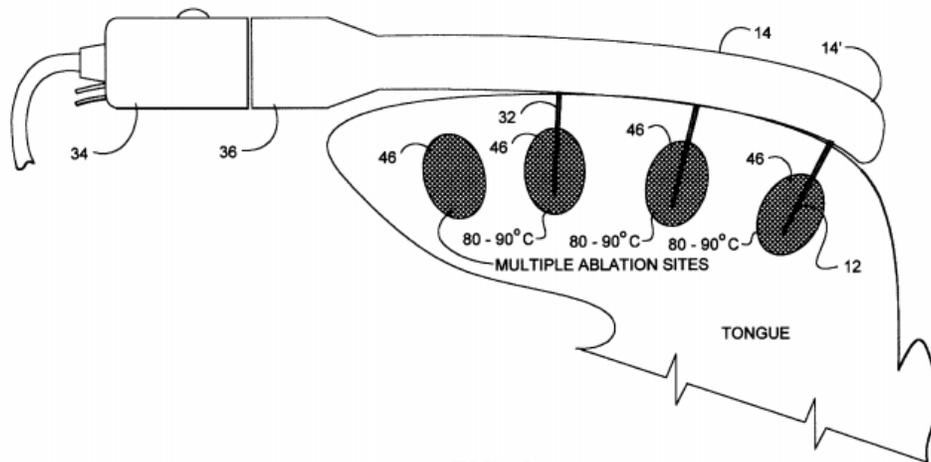


FIG. 6

(Edwards, FIG. 6.)

Thus, 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.” (Grove Decl., ¶121.)

e. Element 1.4: wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin

The combination of Utely and Altshuler disclosed this element. (Grove Decl., ¶122.) As discussed above, the formation of new collagen is the body's natural response to collagen damage. (*Id.*) Thus, both Utely's and Altshuler's controlled delivery of RF energy are configured to stimulate formation of new collagen in the skin. (*Id.*) Setting aside any question of doubt, Altshuler expressly taught that "causing selective damage or destruction [of collagen] results in collagen regeneration." (Altshuler, 18:22-25.) A POSA would have understood collagen regeneration to mean the formation of new collagen. (Grove Decl., ¶122.) Moreover, Altshuler further 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*." (Altshuler, 18:30-19:2 (emphasis added).) 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*." (Grove Decl., ¶122.)

* * *

Thus, the combination of Utely and Altshuler disclosed each limitation of claim 1. (*Id.*, ¶¶123-125) And a POSA would have had a reason to combine these

references to arrive at the claimed invention, with a reasonable expectation of success. (*Id.*) Accordingly, claim 1 would have been obvious over Utely in view of Altshuler, notwithstanding any objective indicia of nonobviousness, which is discussed with respect to all challenged claims in Section VII.E. (*Id.*)

2. Claim 2

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.*” Utely disclosed these limitations. (Grove Decl., ¶¶126-130.) 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.) Utely’s bipolar mode would cause areas of non-ablative damage associated with each bipolar pair because the electrodes “ohmically heat adjacent dermal tissue.” (*Id.*, 8:25-27) The adjacent dermal tissue in this mode would be along the path of the RF energy between needles of the bipolar pairs of electrodes. (Grove Decl., ¶129-130.)

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Using Utely's controller to achieve Altshuler's fractional damage pattern would not have affected Utely's bipolar mode. (*Id.*, ¶131.) The areas of treatment or damage along the paths the RF energy travels would be surrounded by areas of sparing. (*Id.*) Accordingly, claim 2 would have been obvious over Utely in view of Altshuler. (*Id.*)

3. Claim 4

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.*” Utely disclosed this limitation. (*Id.*, ¶¶132-135.) Specifically, Utely disclosed that “controller 48 includes an input/output (I/O) device 50” that “allows the physician to input control and 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. (Grove Decl., ¶134.)

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.” (Utely, 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. (Grove Decl., ¶135.)

Using Utely’s controller to achieve Altshuler’s fractional damage pattern would not have changed this feature of Utely. (*Id.*, ¶136.) Accordingly, claim 4 would have been obvious over Utely in view of Altshuler. (*Id.*)

4. Claim 6

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.*” The combination of Utely and Altshuler disclosed this limitation. (Grove Decl., ¶¶137-140.) Altshuler disclosed a “cooling element 215 ... to cool the surface of skin 200 over treatment volume V.” (Altshuler, 11:6-7.) Altshuler used cooling element 215 to precool the patient’s skin to a depth 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.*, 15:4-11.) Altshuler also taught that cooling “also block[s] pain signals from being transmitted to the brain, thus permitting treatments to be effected with greater

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patient comfort.” (*Id.*, 15:14-17.) Thus, Altshuler disclosed “*a cooler for cooling a surface of the skin.*” (Grove Decl., ¶139.)

Thus, a POSA would have been 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. (Altshuler, 15:4-17; Grove Decl., ¶140.) Because Altshuler taught precooling and “cooling [that] continue[d] after the application of radiation begins” (Altshuler, 15:7-10), 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.*” (Grove Decl., ¶140.)

It would have been simple and straightforward to modify Utely to include Altshuler’s cooling element. (*Id.*, ¶141.) For example, a POSA would have easily implemented a thermoelectric element in Utely’s treatment device 26. (*Id.*) Thus, a POSA would have had a reasonable expectation of success in arriving at claim 6’s device. Accordingly, claim 6 would have been obvious over Utely in view of Altshuler. (*Id.*)

5. Claim 7

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*

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mechanism for delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.” The combination of Utely and Altshuler disclosed these limitations. (*Id.*, ¶¶142-145.) Utely disclosed embodiments where “at least some, and preferably all, of the needle electrodes 90 include interior fluid passages 94 ... in communication with the fluid delivery apparatus 38” to deliver a fluid to tissue at the end of the needles (Utely, 9:12-17.)

Moreover, Altshuler disclosed that “pain may be controlled by the use of a local anesthetic” during treatment. (Altshuler, 3:26-29.) Although there are some risks with anesthetics (*id.*), medical practitioners frequently administer pain medications during a dermatologic treatment such as RF microneedling. (Grove Decl., ¶145.) Thus, 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” (Altshuler, 3:26-29) would have led a POSA to use Utely’s already existing needles (by making them hollow) rather than using a separate needle. (Grove Decl., ¶145.)

Thus, 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. (*Id.*, ¶146.) 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. (*Id.*) Accordingly, claim 7 would have been obvious over Utely in view of Altshuler. (*Id.*)

6. Claim 10

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.*” The combination of Utely and Altshuler disclosed this limitation. (*Id.*, ¶¶147-151.) Utely disclosed that “[e]ach electrode 82 comprises a discrete transmission source of radio frequency energy, which the controller governs” “to ohmically heat adjacent dermal tissue.” (Utely, 7:45-47, 8:24-26.) 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,*” which is a tip of the needle electrodes 82. (*Id.*, 8:12-15, FIG. 7 (emphasis added).) 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). (Grove Decl., ¶¶149-150.)

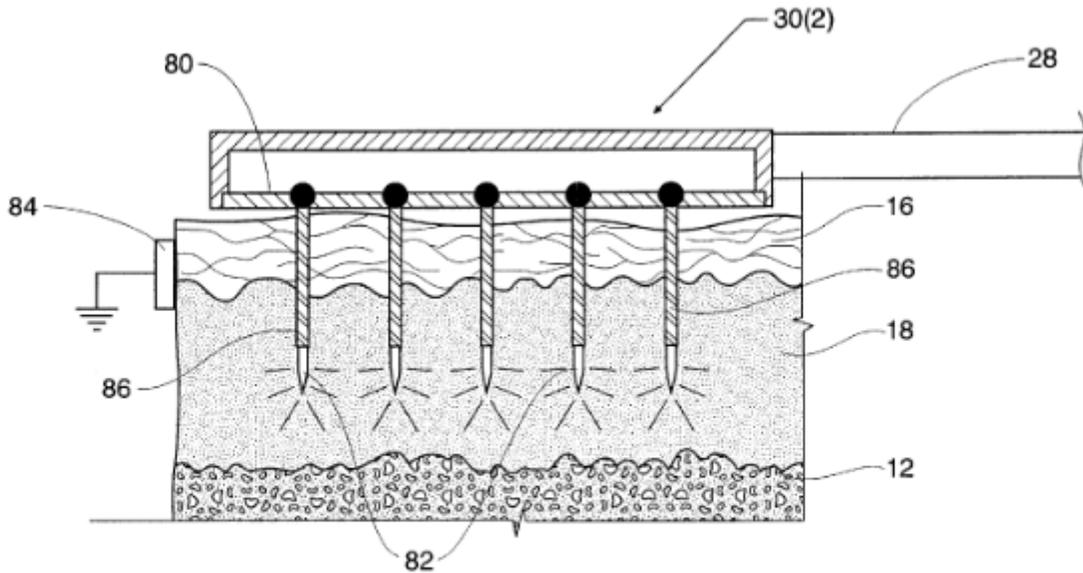


Fig. 7

(Utely, Fig. 7.)

Moreover, Altshuler disclosed a treatment pattern that comprises “some area of sparing around each of the islands or areas of treatment/damage 214.” (Altshuler, 13:19-23.) Using Utely’s controller to achieve Altshuler’s fractional damage pattern would have resulted in “*undamaged regions between the damaged regions,*” as expressly taught by Altshuler. (Grove Decl., ¶151.)

Thus, in combining Utely and Altshuler as set forth above, a POSA would have arrived at claim 10’s device. (*Id.*, ¶152.) Accordingly, claim 10 would have been obvious over Utely in view of Altshuler. (*Id.*)

7. Claim 11

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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.*” The combination of Utely and Altshuler disclosed this limitation. (*Id.*, ¶¶153-156.) Each of Utely’s needle electrodes 82 has a tip that heats adjacent dermal tissue. (Utely, FIG. 7, 8:12-15, 7:45-47, 8:24-26.) A POSA would have understood that the damaged areas would be centered around (*i.e.*, localized) each of the electrodes and adjacent to each other, as shown in Utely’s Figure 7 (reproduced below). (Grove Decl., ¶155.)

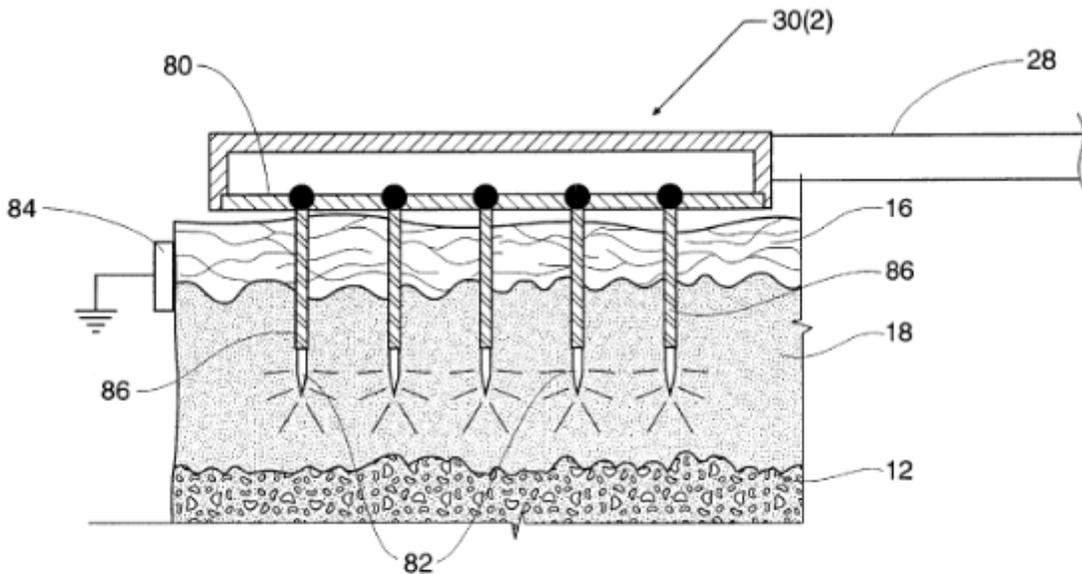


Fig. 7

(Utely, Fig. 7.)

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Moreover, Altshuler disclosed a treatment pattern that comprises “some area of sparing around each of the islands or areas of treatment/damage 214.” (Altshuler, 13:19-23.) Using Utely’s controller to achieve Altshuler’s fractional damage pattern would have resulted in “*small localized area of thermal damage surrounding each tip.*” (*Id.*, 2:1-5; Grove Decl., ¶156.)

Thus, in combining Utely and Altshuler as set forth above, a POSA would have arrived at claim 11’s device. (*Id.*, ¶157.) Accordingly, claim 11 would have been obvious over Utely in view of Altshuler. (*Id.*)

8. Independent claim 15

Claim 15 is substantively similar to claims 1 and 10. (*Id.*, ¶¶158-162; ’899 patent, 12:34-47, 13:13-17, 13:30-45.) Thus, Utely’s and Altshuler’s teachings discussed above with respect to claims 1 and 10 are equally applicable to the same features in claim 15. (Grove Decl., ¶159.)

In claim 15, the control module is configured “to *cause* a pattern of fractional damage *to be produced* in the dermal layer *in a vicinity of the tips of the needles.*” Causing a pattern of fractional damage to be produced is the same as inducing a pattern of fractional damage. (*Id.*, ¶160.) Moreover, this pattern would be in a vicinity of the tips of the needles, as shown in Utely’s Figure 7, for the reasons discussed above with respect to claims 10 and 11. (*Id.*)

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Claim 15's final limitation is similar to the limitations of claims 1 and 10: "*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.*" Thus, Utely's and Altshuler's teachings discussed above with respect to claims 1 and 10 are equally applicable to this claim 15 limitation. (*Id.*, ¶161.)

Thus, the combination of Utely and Altshuler disclosed each limitation of claim 15. (*Id.*, ¶162.) 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. (*Id.*) Accordingly, claim 15 would have been obvious over Utely in view of Altshuler. (*Id.*)

9. Independent claim 20

Claim 20 is substantively similar to claims 1, 2, and 10. (*Id.*, ¶¶163-167; '899 patent, 12:34-54, 13:13-17, 14:1-16.) Thus, Utely's and Altshuler's teachings discussed above with respect to claims 1, 2, and 10 are equally applicable to the same features in claim 20. (Grove Decl., ¶164.)

As discussed above with respect to claim 2, Utely disclosed that the needles may be arranged in a group of bipolar pairs. (Utely, 7:64-67; Grove Decl., ¶165.) And there would be damage between the tips of the needles of the bipolar pairs

along the path the RF energy flows. (Grove Decl., ¶166.) These damaged regions would be surrounded by undamaged regions to achieve fractional damage. (*Id.*)

Thus, the combination of Utely and Altshuler disclosed each limitation of claim 20. (*Id.*, ¶167.) 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. (*Id.*) Accordingly, claim 20 would have been obvious over Utely in view of Altshuler. (*Id.*)

10. Claim 21

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.*” The combination of Utely and Altshuler disclosed this limitation. (*Id.*, ¶¶168-171.) 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, the damaged regions would be elongated between the needles of the bipolar pairs when using Utely’s controller 48 to implement Altshuler’s fractional damage pattern. (Grove Decl., ¶170.)

Thus, using Utely’s controller to achieve Altshuler’s fractional damage pattern with bipolar needles would have resulted in claim 21’s device. (*Id.*, ¶172.) Accordingly, claim 21 would have been obvious over Utely in view of Altshuler. (*Id.*)

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

Claims 9, 12, 17, and 23 would have been obvious over the combination of Utely, Altshuler, and Brown, notwithstanding any objective indicia of nonobviousness (*see* Section VII.E). (*Id.*, ¶¶9-10, 173-174.)

1. Claim 9

Claim 9 depends from claim 1 and further recites “*further comprising a spacer having holes through which the needles are configured to move.*” Brown disclosed this limitation. (*Id.*, ¶¶178-180.) Brown disclosed “an RF treatment device for creating transmural lesions in tissue” with “a plurality of tissue penetrating RF needle electrodes.” (Ex. 1010, “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.) A POSA would have understood Brown’s device with its openings 142 to operate as a spacer having holes through which the needles are configured to move. (Grove Decl., ¶180.) The needles 134 can be inserted into the tissue when they are in the extended position. (Brown, FIG. 9.)

A POSA would have been motivated to include a spacer, as taught by Brown, on Utely’s device to improve safety. (*Id.*, ¶181.) 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. (*Id.*) A POSA would have had a reasonable expectation of success in including such a spacer. (*Id.*) Accordingly, claim 9 would have been obvious over Utely in view of Altshuler and Brown. (*Id.*)

2. Claims 12, 17, and 23

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.*” Brown disclosed this limitation. (*Id.*, ¶¶182-184.) 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. (Grove Decl., ¶184.)

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. (*Id.*, ¶185.) A POSA would have had a reasonable expectation of success in including a vibrator. (*Id.*) Accordingly, claims 12, 17, and 23 would have been obvious over Utely in view of Altshuler and Brown. (*Id.*)

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

Claims 1-2, 4, 6, 10-11, 15-16, and 20-22 would have been obvious over the combination of Underwood and Debendictis. (*Id.*, ¶¶11-13.) Underwood disclosed a skin treatment device that uses needles 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.” (Underwood, ¶¶[0011], [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].)

To the extent Underwood did not expressly use the term “a fractional pattern of damage,” it was known before the ’899 patent’s earliest priority date that fractional damage was desirable. (Grove Decl., ¶206.) Debendictis expressly taught “intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue.” (Debendictis, ¶[0014].) And 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.*; Grove Decl., ¶¶207-209.)

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Thus, a POSA would have been motivated to use Underwood's controller to control the energy so that it "spar[ed] healthy tissue around the thermally altered tissue," as taught by Debendictis, to make "the repair process [] more robust" and to minimize side effects. (Debendictis, ¶[0014]; Grove Decl., ¶¶209-211.) A POSA would have had a reasonable expectation of success in combining the teachings of Underwood and Debendictis to arrive at the claimed invention. (Grove Decl., ¶¶212-213.) Therefore, claims 1-2, 4, 6, 10-11, 15-16, and 20-22 would have been obvious over Underwood in view of Debendictis, notwithstanding any objective indicia of nonobviousness (*see* Section VII.E). (*Id.*, ¶186.)

1. Independent claim 1

Underwood and Debendictis disclosed each element of independent claim 1. (*Id.*, ¶¶193-194.)

a. Preamble

Underwood disclosed "[a] skin treatment device." (*Id.*, ¶¶195-196.) Specifically, Underwood disclosed "surgical devices and methods which employ high frequency electrical energy to treat a patient's skin." (Underwood, ¶¶[0003], [0029].) For example, Underwood's Figure 1 (reproduced below) illustrates "an electrosurgical system 2 generally compris[ing] an electrosurgical handpiece or probe 10." (*Id.*, ¶[0035], FIG. 1.) A POSA would have considered electrosurgical system 2 to be a skin treatment device. (Grove Decl., ¶196.)

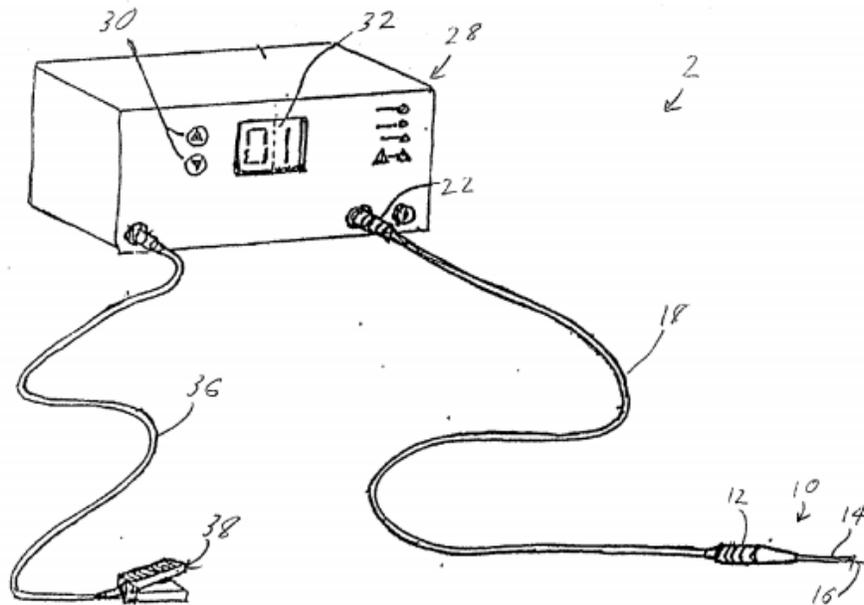


FIG. 1

(Underwood, Fig. 1.)

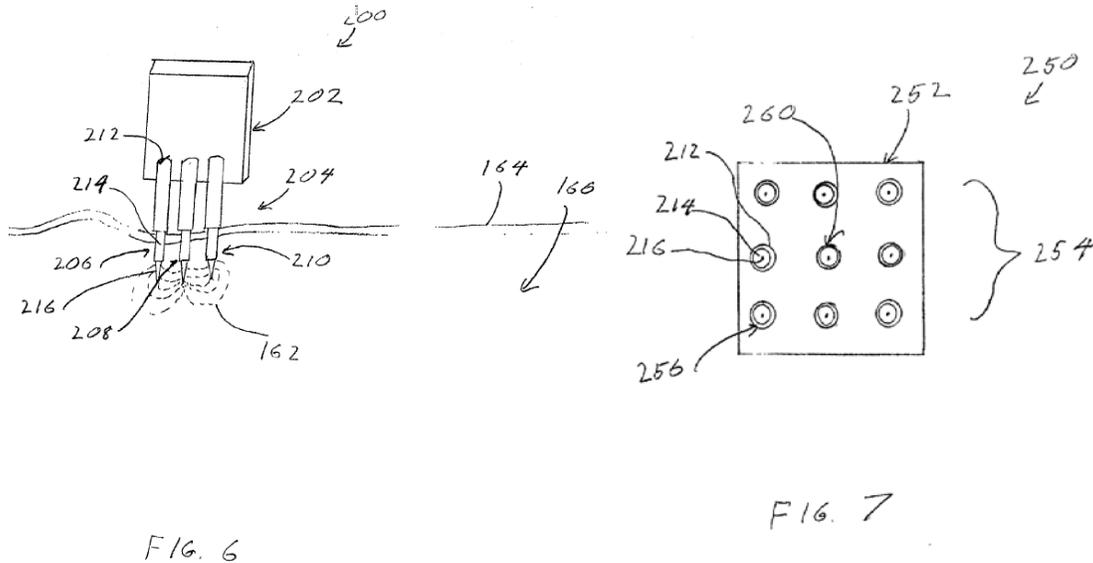
b. Element 1.1

Underwood disclosed element 1.1. (*Id.*, ¶¶197-201.) In particular, Underwood’s probe 10, including its handle 12 and elongate shaft 14 is a “housing” as claimed. (Underwood, ¶¶0035; Grove Decl., ¶197.)

The “primary purpose” of probe 10 is “to mechanically support the electrode(s).” (Underwood, ¶¶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.*) And Underwood disclosed

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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.” (Grove Decl., ¶[198].)



(Underwood, FIGS. 6-7.)

Furthermore, 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.” (Grove Decl., ¶[199].)

Finally, a POSA would have understood electrode support 202 to be a “base” as claimed. (*Id.*, ¶[200].) The ’899 patent explains that the base can be either

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“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 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.*” (Grove Decl. ¶200.)

c. Element 1.2

Underwood disclosed element 1.2. (*Id.*, ¶¶202-203.) 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” with “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.*” (Grove Decl., ¶202.)

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

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applying electric current to the patient,” particularly to “the dermis 166 at a selected depth.” (Underwood, ¶¶[0051]-[0052].) Accordingly, a POSA would have understood that Underwood’s needles “*are further configured for application of radio frequency (RF) energy from a RF energy source.*” (Grove Decl., ¶203.)

d. *Element 1.3*

The combination of Underwood and Debendictis disclosed element 1.3. (*Id.*, ¶¶204-214.)

Underwood disclosed “*a control module for controlling delivery of the RF energy from the RF energy source.*” (*Id.* ¶204.) Specifically, Underwood disclosed “[a] controller ... is connected to a control input of the switching power supply for adjusting the generator output power by supply voltage variation.” (Underwood, ¶[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. (Grove Decl. ¶204.)

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.*” (*Id.*, ¶205) For example, Underwood disclosed that the application of RF energy through the electrodes is configured “to create a heat injury to a target tissue within the patient’s dermis layer.” (Underwood, ¶[0011].)

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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.*) 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.*” (Grove Decl., ¶205.)

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 fractional damage. However, fractional damage to the dermis was known, and so were its benefits. (Grove Decl., ¶206.) And these benefits 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

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RF energy delivery to the needles to induce a pattern of fractional damage. (Grove Decl., ¶206.)

Debendictis disclosed “*induc[ing] a pattern of fractional damage.*” (*Id.*, ¶207.) Like Underwood, Debendictis disclosed “a method for ... improving the appearance of tissue (*e.g.*, skin).” (Debendictis, ¶[0014]; *see also* ’304 Provisional, 12:18-20.) Debendictis further taught that its “method and apparatus [was] for providing fractional treatment of tissue (*e.g.*, skin).” (*Id.*, ¶[0001] ; *see also* ’304 Provisional, 1:5-7.) Specifically, Debendictis disclosed “intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue.” (*Id.*, ¶[0014]; *see also* ’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.” (*Id.*, ¶[0041]; *see also* ’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 regeneration to produce ‘micro-thermal wound repair fields’.” (*Id.*, ¶[0044]; *see also* ’304 Provisional, 11:16-12:5.)

A POSA would have understood Debendictis’s “pattern of thermally altered tissue surrounded by unaltered tissue” to be “*a pattern of fractional damage.*” (*Id.*,

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¶[0014]; *see also* '304 Provisional, 12:18-13:6; Grove Decl., ¶208.) As discussed above, the proper construction of “a pattern of fractional damage” is “the pattern of damage caused by non-uniform heating.” (*Supra* Section V.) Debendictis’s description falls squarely within this construction, as well as the other proposed constructions at the ITC. (*Id.*, ¶208.)

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 also* '304 Provisional, 12:18-13:6; Grove Decl., ¶209.) Debendictis recognized that treatments that “leave no tissue untreated in the targeted region of the skin,” “result[] in undesirable side effects,” including intolerable pain and extended healing times. (Debendictis, ¶[0003] *see also* '304 Provisional, 2:11-12.) Indeed, “a direct correlation exists between the size of the injury and the time required for complete repair.” (*Id.*, ¶[0007]; *see also* '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.” (*Id.*, ¶[0007]; *see also* '304 Provisional, 4:11-14.) Accordingly, a “primary mechanism”

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of Debendictis “is the sparing of volumes of tissue within a larger tissue treatment area.” (*Id.*, ¶[0039]; *see also* ’304 Provisional, 13:19-22.)

Thus, a POSA would have been motivated to combine Debendictis’s teachings with Underwood’s apparatus by using Underwood’s controller to control the RF energy delivered to its needles so that it induced 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. (Debendictis, ¶[0014]; *see also* ’304 Provisional, 12:18-13:6; Grove Decl., ¶210.) Indeed, using Underwood’s controller to implement Debendictis’s fractional damage pattern in Underwood’s system would be nothing more than the use of a known technique to improve similar devices in the same way. (*Id.*)

Further, a POSA would have been motivated to use Underwood’s RF needles to achieve the pattern of fractional damage because of known limitations of laser skin treatments, as discussed above. (*Id.*, ¶211.)

Moreover, a POSA would have had a reasonable expectation of success in using Underwood’s controller to implement Debendictis’s fractional damage pattern. (*Id.*, ¶212.) Underwood disclosed that its controller “adjust[s] the generator output power by supply voltage variation” and that its system 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

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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. (Grove Decl., ¶212.)

A 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. (*Id.*) As discussed above, RF needles had already been used to create a pattern of fractional damage in body tissue. (*Id.*, ¶213.) It would have been simple for a POSA to use Underwood’s controller to achieve Debendictis’s damage pattern (e.g., by governing the power level). (*Id.*, ¶212.) Because Debendictis made known the goal of multiple small micro-wounds, a POSA would have been able to control Underwood’s RF energy to accomplish fractional damage. (*Id.*, ¶219.) According to Patent Owner, all that was needed was for the control module to “cause the RF generator to apply a lower amount of energy,” which “simply required plugging in new set points into a standard control module to deliver less energy.” (Petition for Review, 1-2.)

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.” (Grove Decl., ¶214XX.)

e. Element 1.4

Underwood disclosed element 1.4. (*Id.*, ¶¶215-216.) As discussed above, the formation of new collagen is the body’s natural response to collagen damage. (*Id.*, ¶215.) Thus, both Underwood’s and Debendictis’s controlled delivery of RF energy is configured to stimulate formation of new collagen in the skin. (*Id.*)

Setting aside any question of doubt, Underwood disclosed that “the voltage applied to the first and second electrodes is sufficient to induce heating of the dermis” 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 connective fibers to enhance or stimulate regrowth of new collagen fibers in the underlying tissue.” (*Id.*, ¶[0045].)

Debendictis likewise disclosed “stimulating the generation of ... collagen” or “collagen remodeling.” (Debendictis, ¶¶[0002], [0038]; *see also* ’304

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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 also* ’304 Provisional, 12:18-13:6; Grove Decl., ¶[217].) 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.*” (Grove Decl., ¶[217].)

* * *

The combination of Underwood and Debendictis disclosed each limitation of claim 1. (*Id.*, ¶¶[218-220].) A POSA would have had a reason to combine these references to arrive at the claimed invention, with a reasonable expectation of success. (*Id.*) Accordingly, claim 1 would have been obvious over Underwood in view of Debendictis, notwithstanding any objective indicia of nonobviousness (*see* Section VII.E). (*Id.*)

2. Claim 2

Underwood disclosed claims 2’s limitations. (*Id.*, ¶¶[221-225].) 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. (Grove Decl., ¶[223].) For example, Underwood taught

“providing the middle row or column of electrodes with the same polarity such that current flows between the two outer rows or columns and the middle row/or column.” (Underwood, ¶[0055].) Underwood’s bipolar mode would cause areas of non-ablative damage associated with each bipolar pair because the damage would be along the path of the RF energy between needles of bipolar pairs of electrodes. (Grove Decl., ¶¶224-225.)

Using Underwood’s controller to achieve Debendictis’s fractional damage pattern would not have affected Underwood’s bipolar mode. (*Id.*, ¶226.) The areas of treatment or damage along the paths the RF energy travels would be surrounded by untreated areas of sparing. (*Id.*) Accordingly, claim 2 would have been obvious over Underwood in view of Debendictis. (*Id.*)

3. Claim 4

Underwood disclosed claim 4’s limitation (*Id.*, ¶¶227-229.) 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 application-specific setting*”

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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. (Grove Decl., ¶229.) Moreover, adjusting the supply voltage, energy level, or output power is adjusting the “intensity” of the RF energy as claimed. (*Id.*)

Using Underwood’s controller to achieve Debendictis’s fractional damage pattern would not have changed this feature of Underwood. (*Id.*, ¶230.) Accordingly, claim 4 would have been obvious over Underwood in view of Debendictis. (*Id.*)

4. Claim 6

The combination of Underwood and Debendictis disclosed claim 6’s limitation. (*Id.*, ¶¶231-234.) 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 described a system that cools 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 also* ’304 Provisional, 4:19-5:15, 16:15-17, 17:21-18:10.) Debendictis further taught that a “cooling mechanism may be placed within the handpiece.” (Debendictis, ¶[0097].) Thus,

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Underwood and Debendictis disclosed “*a cooler for cooling a surface of the skin.*” (Grove Decl., ¶233.)

Furthermore, a POSA would have been 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 also* ’304 Provisional, 4:19-5:15; Grove Decl., ¶234.) This would have been most effective when cooling began prior to transmitting RF energy (e.g., when inserting the needles into the skin). (Grove Decl., ¶234.) 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.*” (*Id.*)

It would have been simple and straightforward to modify Underwood to include Debendictis’s cooling mechanism. (*Id.*, ¶235.) Thus, a POSA would have had a reasonable expectation of success in arriving at claim 6’s device. (*Id.*) Accordingly, claim 6 would have been obvious over Underwood in view of Debendictis. (*Id.*)

5. Claim 10

The combination of Underwood and Debendictis disclosed claim 10’s limitation. (*Id.*, ¶¶236-240.) Underwood disclosed that “the temperature of the electrode terminal(s) are carefully controlled such that sufficient thermal energy is

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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; Grove Decl., ¶238.) Because “the current is generally confined to the immediate region around the electrodes” (Underwood, ¶[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.*” (Grove Decl., ¶239.)

Moreover, Debendictis disclosed “intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue.” (Debendictis, ¶0014; *see also* ’304 Provisional, 12:18-13:6.) Using Underwood’s controller to achieve Debendictis’s fractional damage pattern. would have resulted in “*undamaged regions between the damaged regions,*” as expressly taught by Debendictis. (Grove Decl., ¶240.)

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In combining Underwood and Debendictis, a POSA would have arrived at a claim 10's device. (*Id.*, ¶241.) Accordingly, claim 10 would have been obvious over Underwood in view of Debendictis. (*Id.*)

6. Claim 11

The combination of Underwood and Debendictis disclosed claim 11's limitation. (*Id.*, ¶¶242-246.) Each of Underwood's electrodes 206, 208, 210 has a tip that is "for applying electric current to the patient" that is "generally confined to the immediate region around the electrodes" to cause damage to the dermal tissue. (Underwood, ¶¶[0051], [0054] FIG. 6.) A POSA would have understood that the damaged areas would be centered around (*i.e.*, localized) each of the electrodes and adjacent to each other, as these are the sources of the current. (Grove Decl., ¶245.)

Moreover, Debendictis disclosed "intentionally generating a pattern of thermally altered tissue surrounded by unaltered tissue." (Debendictis, ¶[0014]; *see also* '304 Provisional, 12:18-13:6.) Using Underwood's controller to achieve Debendictis's fractional damage pattern would have resulted in "*small localized area of thermal damage surrounding each tip.*" (*Id.*, ¶[0015]; Grove Decl., ¶246.)

In combining Underwood and Debendictis, a POSA would have arrived at a claim 11's device. (Grove Decl., ¶247.) Accordingly, claim 11 would have been obvious over Underwood in view of Debendictis. (*Id.*)

7. Independent claim 15

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Claim 15 is substantively similar to claims 1 and 10. (*Id.*, ¶¶248-252; '899 patent, 12:34-47, 13:13-17, 13:30-45.) Thus, Underwood's teachings discussed above with respect to claims 1 and 10 are equally applicable to the same features in claim 15. (Grove Decl., ¶249.)

In claim 15, the control module is configured "to *cause* a pattern of fractional damage *to be produced* in the dermal layer *in a vicinity of the tips of the needles.*" Causing a pattern of fractional damage to be produced is the same as inducing a pattern of fractional damage. (*Id.*, ¶250.) Moreover, this pattern would be in a vicinity of the tips of the needles, as shown in Underwood's Figure 6, for the reasons discussed above with respect to claims 10 and 11. (*Id.*)

Claim 15's final limitation is similar to the limitations of claims 1 and 10: "*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.*" Thus, Underwood's and Debendictis's teachings discussed above with respect to claims 1 and 10 are equally applicable to this claim 15 limitation. (*Id.*, ¶251.)

The combination of Underwood and Debendictis disclosed each limitation of claim 15. (*Id.*, ¶252.) 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. (*Id.*) Accordingly, claim 15 would have been obvious over Underwood in view of Debendictis. (*Id.*)

8. Independent claim 20

Claim 20 is substantively similar to claims 1, 2, and 10. (*Id.*, ¶¶253-257; '899 patent, 12:34-54, 13:13-17, 14:1-16.) Thus, Underwood's and Debendictis's teachings discussed above with respect to claims 1, 2, and 10 are equally applicable to the same features in claim 20. (Grove Decl., ¶254.)

As discussed above with respect to claim 2, Underwood disclosed that the needles may be arranged in bipolar pairs. (Underwood, ¶[0055; Grove Decl., ¶255.) And there would be damage between the tips of the needles of the bipolar pairs along the path the RF energy flows. (Grove Decl., ¶256.) These damaged regions would be surrounded by undamaged regions to achieve fractional damage. (*Id.*)

The combination of Underwood and Debendictis disclosed each limitation of claim 20. (*Id.*, ¶257) 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. (*Id.*) Accordingly, claim 20 would have been obvious over Underwood and Debendictis. (*Id.*)

9. Claim 21

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The combination of Underwood and Debendictis disclosed claim 21's limitation. (*Id.*, ¶¶258-261.) Underwood showed that energy passing between two electrodes provides an elongated shape. (Underwood, FIG. 6; Grove Decl., ¶260.) Accordingly, the damaged regions would be elongated between the needles of the bipolar pairs when using Underwood's controller to implement Debendictis's fractional damage pattern. (*Id.*)

Using Underwood's controller to achieve Debendictis's fractional damage pattern with bipolar needles would have resulted in claim 21's device. (*Id.*, ¶¶261-262.) Accordingly, claim 21 would have been obvious over Underwood in view of Debendictis. (*Id.*)

10. Claims 16 and 22

Claims 16 and 22 depend from claims 1 and 20, respectively, and further recite “*wherein the control module is configured to cause necrosis in the dermal layer.*” Debendictis disclosed this limitation. (*Id.*, ¶¶263-265.) As discussed above, Debendictis disclosed “generating a pattern of thermally altered tissue surrounded by unaltered tissue.” (Debendictis, ¶[0014]; *see also* '304 Provisional, 12:18-13:6.) Debendictis taught that the “thermally altered tissue may include a necrotic zone.” (*Debendictis*, ¶[0014]; *see also id.*, ¶¶[0038], [0041], [0044]; '304 Provisional, 6:12-14, 8:3-6, 11:16-18, 16:15-17.)

Using Underwood's controller to achieve Debendictis's fractional damage pattern would have resulted in causing necrosis in the dermal layer. (Grove, ¶265.) Accordingly, claims 16 and 22 would have been obvious over Underwood in view of Debendictis. (*Id.*)

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

Claims 9, 12, 17, and 23 would have been obvious over the combination of Underwood, Debendictis, and Brown, notwithstanding any objective indicia of nonobviousness (*see* Section VII.E). (*Id.*, ¶¶14-15, 266-267.)

1. Claim 9

Brown disclosed claim 9's limitation for the reasons set forth above in Ground 2. (*Id.*, ¶¶268-270.) A POSA would have been motivated to include a spacer, as taught by Brown, on Underwood's device to improve safety and would have had a reasonable expectation of success in doing so, as discussed above. (*Id.*, ¶271) Accordingly, claim 9 would have been obvious over Underwood in view of Debendictis and Brown. (*Id.*)

2. Claims 12, 17, and 23

Brown disclosed the limitation of claims 12, 17, and 23 for the reasons set forth above in Ground 2. (*Id.*, ¶¶272-274.) 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 and would have had a reasonable

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expectation of success in doing so, as discussed above. (*Id.*, ¶275.) Accordingly, claims 12, 17, and 23 would have been obvious over Underwood in view of Debendictis and Brown. (*Id.*)

E. Objective indicia do not support patentability.

Lumenis is not aware of any publically available evidence of objective indicia of nonobviousness with a nexus to the '899 patent claims that weighs against obviousness. (Grove Decl., ¶¶276-280.) Although Patent Owner attempted to rely on objective indicia of nonobviousness at the ITC, the ITC has yet to rule on this issue and Patent Owner failed to submit persuasive *objective evidence* to support its case. If Patent Owner relies on alleged evidence of objective indicia in this proceeding, Lumenis requests an opportunity to rebut such evidence. *Anneal Pharma., LLC v. Supernus Pharma., Inc.*, IPR2013-00368, Paper 8 at 13 (P.T.A.B. Dec. 17, 2013); *Taylor Made Golf Company, Inc. v. Parsons Xtreme Golf, LLC*, IPR2018-00702, Paper 19 at 10-11 (P.T.A.B. Aug. 20, 2018).

VIII. MANDATORY NOTICES

A. Real Parties-in-Interest

Petitioners Lumenis Ltd. and Pollogen Ltd. are the real parties-in-interest.

B. Related matters

The '899 patent is involved in the following litigations:

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Case Name	Case No.	Filed
<i>Certain Radio Frequency Micro-Needle Dermatological Treatment Devices and Components Thereof</i>	337-TA-1112 (ITC)	April 9, 2018
<i>Syneron Medical Ltd. et al. v. EndyMed Medical Ltd. et al.</i>	1-18-cv-10678 (MAD)	April 9, 2018
<i>Syneron Medical Ltd. et al. v. Illooda Co., Ltd. et al.</i>	1-18-cv-10679 (MAD)	April 9, 2018
<i>Syneron Medical Ltd. et al. v. Invasix, Inc. et al.</i>	1-18-cv-10680 (MAD)	April 9, 2018
<i>Syneron Medical Ltd. et al. v. Jeisys Medical Inc. et al.</i>	1-18-cv-10681 (MAD)	April 9, 2018
<i>Syneron Medical Ltd. et al. v. Lumenis Ltd. et al.</i>	1-18-cv-10682 (MAD)	April 9, 2018
<i>Syneron Medical Ltd. et al. v. Lutronic Corp. et al.</i>	1-18-cv-10683 (MAD)	April 9, 2018
<i>Syneron Medical Ltd. et al. v. Sung Hwan E&B Co., Ltd. d/b/a SHENB Co. Ltd. et al.</i>	1-18-cv-10684 (MAD)	April 9, 2018

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IX. GROUNDS FOR STANDING

Lumenis certifies that the '899 patent is available for IPR and that Lumenis is not barred or estopped from requesting IPR of the '899 patent challenging the patent claims on the grounds identified in this Petition. Lumenis has not yet been served with a district court complaint alleging infringement of the '899 patent, and therefore, this Petition is not barred under § 315(b).

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X. STATEMENT OF PRECISE RELIEF REQUESTED FOR EACH CLAIM CHALLENGED

For the reasons provided above, Lumenis requests IPR and cancellation of claims 1-2, 4, 6-7, 9-12, 15-17, and 20-23 of the '899 patent.

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the portions of the above-captioned Petition for *Inter Partes* Review of U.S. Patent No. 9,510,899 specified in 37 C.F.R. § 42.24 have 13,992 words, in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24(a)(1)(i). This word count was prepared using Microsoft Word 2010.

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,510,899**, Petitioner's Power of Attorney, and all accompanying exhibits were served via FedEx® Express on June 6, 2019, in their entireties on the following:

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