Docket No. _____
Filed on behalf of ThermiGen, LLC and ThermiAesthetics, LLC
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THERMIGEN, LLC AND THERMIAESTHETICS, LLC,
Petitioners,

v.

Viveve, Inc.,
Patent Owner.

Case No. Unassigned

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,961,511 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42

Claims 1-42

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I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, Petitioners ThermiGen, LLC, ThermiAesthetics, LLC, and Almirall, S.A.("Petitioner" or "Thermi") requests *inter partes* review of claims 1-42 ("Challenged Claims") of U.S. Patent No. 8,961,511 (the "'511 patent"), and cancellation of those claims as unpatentable. The '511 patent is attached to this petition as Exhibit 1001.

The '511 patent is titled "Vaginal Remodeling Device and Methods." The Challenged Claims of the '511 patent generally recite a method for remodeling female genital tissue by applying heat. The Challenged Claims are unpatentable as anticipated or obvious over the prior art (under the pre-AIA statutory framework), 35 U.S.C. §§ 102 and 103, including prior art that was not before the examiner during prosecution.

There is a reasonable likelihood that Thermi will prevail since the prior art teaches the use of heat through the application of radiant energy to remodel collagen containing tissue, including the use of RF energy to heat and remodel vaginal tissue. It would have been obvious to a person of ordinary skill ("POSITA") in the art that any human tissue containing collagen could be remodeled by the application of heat as taught in the prior art. The limitations in the '511 patent claims recite standard parameters disclosed in the prior art.

II. MANDATORY NOTICES

A. Real Party-in-Interest

The real parties-in-interest are ThermiGen, LLC, ThermiAesthetics, LLC, and Almirall, S.A. ThermiGen is a limited liability company organized under the laws of the State of Texas with its principal place of business at 3131 West Royal Lane, Suite 100, Irving, Texas 75063. ThermiAesthetics is a limited liability company organized under the laws of the State of Texas with its principal place of business at 3131 West Royal Lane, Suite 100, Irving, Texas 75063. Almirall, S.A., a pharmaceutical company headquartered in Barcelona, Spain, acquired ThermiGen, LLC and Thermi Aesthetics, LLC in 2016.

B. Related Matters

Patent Owner filed a patent infringement action against ThermiGen, LLC, ThermiAesthetics, LLC, and an associated physician and consultant to Thermi, Red Alinsod, M.D., asserting infringement of U.S. Patent Nos. 8,961,511 (the "'511 patent") on October 21, 2016 in the Eastern District of Texas, entitled *Viveve Inc. v. ThermiGen, LLC, ThermiAesthetics, LLC, and Red Alinsod, M.D.*, Case No. 16-cv-1189-JRG. Petitioner has filed, or will file, concurrently with the present Petition, a second petition for *inter partes* review of claims 43-58 of the '511 patent.

C. Notice of Counsel and Service Information

Petitioners' counsel is:

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A Power of Attorney is filed herewith under 37 C.F.R. § 42.10(b). Petitioner consents to electronic service. Pursuant to 37 C.F.R. § 42.8(b)(4), all services and communications can be sent to jtrainor@whitecase.com and ddrivas@whitecase.com.

III. FEES

Petitioners authorize the United States Patent and Trademark Office to charge the fees enumerated in 37 C.F.R. § 42.15(a) regarding this Petition and any additional fees that may be due in connection with this Petition from Deposit Account No. 503672.

IV. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify pursuant to Rule 42.104(a) that the patent for which review is sought is available for *inter partes* review and that Petitioners are not barred or estopped from requesting an *inter partes* review on the grounds identified in this Petition.

V. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioners challenge claims 1-42 of the ’511 patent.

A. The ’511 patent describes a method for remodeling female genital tissue

Application No. 11/704,067 was filed on February 7, 2007 and issued as the ’511 patent on February 24, 2015. The ’511 patent claims priority to Provisional Application No. 60/743,247, filed on February 7, 2006. The sole named inventor is Jonathan B. Parmer. However, at least certain claims of the ’511 patent are not supported by the Provisional Application and are thus not entitled to this earlier date. *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015).

For example, the limitations recited in the “wherein” clause in claims 1 and 35 reciting “heating a portion of the vagina extending from the introitus inwardly to a location from 1-3.5cm in from the introitus” and “heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock, wherein the aspect closest to the urethra is at 12 o’clock” respectively, are absent from the Provisional Application. As such, the support for these independent claims and the claims depending therefrom, is not present in the disclosure of the Provisional Application as required by 35 U.S.C. § 112. In addition, the specific limitations recited in claims 17-22 are not supported by the Provisional Application in accordance with § 112. Thus, the effective filing

date for independent claims 1 and 35, as well as their respective dependent claims is February 7, 2007.

The ’511 patent is directed to the “approaches to treating a loose vagina and introitus with a non-invasive procedure.” (EX. 1001, 2:17-21.) The ’511 patent discloses remodeling target tissues by applying heat to surface tissue to denature collagen and deposit new collagen in the tissue underlying the mucosal epithelium of a female genital tissue. (EX. 1001, 2:25-28.)

The remodeling of the target tissues is achieved by “passing energy through the mucosal surface and into the underlying tissue” creating heat in the target tissue and this heat has the effect of denaturing or partially-denaturing collagen in the tissue. (EX. 1001, 8:39-42.) The application of heat to the connective tissue during a treatment procedure is understood to result in a subsequent depositing of new or nascent collagen by cells of the connective tissue, as part of a biological process that may take place over the course of weeks or months following the procedure.” (EX. 1001, 12:44-49.) The applied heat, “[w]hether by denaturation of existing collagen, or by later deposition of new collagen,” causes remodeling of the target tissue, generally in the form of “tissue contraction or tightening.” (EX. 1001, 5:2-5.)

The ’511 patent describes that “[t]he method includes contacting the mucosal epithelium with a treatment tip that has an energy delivering element and a cooling mechanism. By delivering energy to the tissue while cooling the

epithelial surface, a reverse thermal gradient is created. The RF energy penetrates through the cooled epithelium and into the underlying target tissue, and heats the tissue." (EX. 1001, 4:7-13.) This heating causes a zone of tissue called the "therapeutic zone" to heat to a "therapeutic temperature that causes remodeling." (EX. 1001, 4:14-16.) Meanwhile, the cooling of the epithelial surface "protects it from potentially damaging effects of excess heat that would accumulate in the absence of cooling." (EX. 1001, 13:16-19.)

In sum, the '511 patent describes a method which at its core entails a single step: heat is passed through the epithelial surface of a female genital tissue to underlying collagen containing target tissues and, as a result of the application of heat, the natural process of remodeling collagen occurs, which tightens the female genital tissue, *e.g.*, the vagina. (EX. 1001, 5:2-6.)

B. The Challenged Claims recite known techniques and conventional processes

That heat could be used to denature collagen and remodel tissue was well-known before the filing of the application leading to the '511 patent. (EX. 1003, ¶¶ 30-35; EX. 1004, ¶¶10, 38-41.)

The '511 patent itself incorporates by reference several prior art patents and published patent applications that it characterizes as "relevant to" aspects of "collagen denaturation and the exploitation of this for medical or cosmetic purposes." (EX. 1001, 1:35-61.) The '511 patent acknowledges that it "build[s] on those of prior art such as those described by Knowlton, including U.S.

2004/0000316 ("Knowlton '316"), and others cited in the background, all incorporated by this reference." (EX. 1001, 5:65-6:2.) The Knowlton prior art references, and specifically Knowlton '316, disclose methods for remodeling tissue through the delivery of energy and creation of a reverse thermal gradient. (*See e.g.*, EX. 1005, [0003], [0021]; EX. 1006, 3:37-42, 3:65-4:2.) The '511 patent also incorporates by reference U.S. Patent No. 6,350,276 ("Knowlton '276"). (EX. 1001, 1:47-49.)

Knowlton '276 was issued on February 26, 2002, nearly four years before the Provisional Application date. Knowlton '276 discloses the delivery of electromagnetic energy and mechanical energy to "selected body structures" to achieve "both molecular and cellular remodeling of collagen containing tissues." (EX. 1007, 11:40-64.) Knowlton '276 discloses an embodiment where the treated "tissue structure 9 includes any collagen containing tissue structure." (EX. 1007, 6:56-57.) Knowlton '276 specifically describes the treatment of pre-term cervical dilation by applying an energy delivery device to the cervix leading to the tightening of the dilated cervix. (EX. 1007, 13:35-47; *see also* EX. 1003, ¶¶ 66-69, EX. 1004, ¶¶20-21.)

During prosecution of the '511 patent, the Examiner repeatedly rejected the proposed claims of the '511 patent as anticipated and/or obvious in light of Knowlton '276. (EX. 1002, Thermi033903-3910; Thermi033958-3969; Thermi034149-4160.) The applicant attempted to overcome the Examiner's

rejection by arguing that Knowlton ’276 fails to disclose the treatment of “tissue underlying a mucosal epithelium of female genital tissue.” (EX. 1002, Thermi033946-3947.) In response, the Examiner issued a final rejection noting that 1) the cervix is “female genital tissue”, and 2) Knowlton ’276 discloses the treatment of the cervix and the underlying tissues. (EX. 1002, Thermi033969-3970.)

The applicant filed a request for continued examination and amended the independent claims to include an additional limitation of “remodeling a therapeutic zone including at least one of vulva, introitus or vagina” and arguing that Knowlton ’276 does not disclose treating these tissues. (EX. 1002, Thermi033994-3995.) The Examiner once again rejected applicant’s arguments, explaining that even as amended claim 1 fails to “positively require that any of the tissue of the vulva, the introitus or the vagina is actually required to be heated and/or remodeled.” (EX. 1002, Thermi034161.)

Ultimately the Examiner allowed further-revised claims including claims requiring that “the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus,” an area that typically excludes the cervix. (EX. 1002, Thermi034149-4160.) As explained by the Examiner in the Notice of Allowance:

> As set forth in the February 13th, 2014 Non-Final Office Action, Knowlton fails to contemplate the specific areas of treatment set

> forth in independent claims 2 and 27-29. No other reference has been found which discloses, fairly suggests or makes obvious this area of treatment whether taken alone or in combination with the Knowlton reference.

(EX. 1002, Thermi034562.)

While the Examiner determined that Knowlton '276 did not expressly disclose the specific areas of treatment of the above-referenced is added limitation, there is no doubt Knowlton '276 discloses the treatment of female genital tissue (the cervix) by way of an energy delivery device inserted into the vagina causing the remodeling of collagen containing tissues adjacent to or underlying the vagina. Issued independent claim 35, moreover, is not limited to treatment of any particular depth of the vagina. Thus, the core of the Challenged Claims was already known as of June 30, 1999 when the application which issued as Knowlton '276 was filed, and was certainly in the prior art and well-known no later than February 26, 2002 when the Knowlton '276 patent issued. (EX. 1003, ¶¶ 66-69, EX. 1004, ¶¶20-21.)

C. Overview of expert declarations

Roger Dmochowski, M.D., is a board-certified urologist and urogynecologist with almost thirty years of experience treating patients, including using RF and other forms of radiant energy. Since 2002, Dr. Dmochowski has been a Professor of Urology and of Obstetrics and Gynecology at Vanderbilt University, where he is currently the Director of the Section of Female Pelvic Medicine, and program director of the Fellowship in

Pelvic Medicine. Dr. Dmochowski has written and presented on the fields of urology and urogynecology and, more specifically, has authored a number of publications concerning the use of RF technology in the treatment of urogynecological conditions. Dr. Dmochowski has also consulted with companies in the development of treatments for incontinence and other urogynecological conditions, serving, for example, as the lead investigator for SURx in clinical trials for an RF delivery device designed to treat genuine stress incontinence. Dr. Dmochowski will provide background on the state of the art as of February 2006 for RF and radiant energy devices designed to treat female genital tissue and provide his expert opinion as to why, by then, the treatment method to remodel female genital tissue claimed in the '511 patent would have been obvious to a person of ordinary skill. (EX. 1003, ¶¶1-8, 10.)

Robert D. Tucker, Ph.D., M.D., is a pathologist with a doctorate in biophysics and a professor of Pathology and Biomedical Engineering at the University of Iowa. Dr. Tucker has worked on the development of RF devices for treating various conditions since medical school in 1979, and has served as a principal investigator in pursuit of clinical approval for different RF and thermal devices, including for electrosurgery and the treatment of soft tissue. Dr. Tucker has published extensively on the use of RF energy to treat tissue and is intimately familiar with the technology and its application to epidermal and other dermal tissue. Dr. Tucker, as a physician and researcher using RF prior

art up to February 2006, will provide insight as to what was known about RF technology and its effect on tissue at that time, what temperature was known to be effective in inducing remodeling and how the technology safeguarded against undesired effects resulting from the application of RF energy. Dr. Tucker further details the secondary effects on tissue where RF energy was used to ablate and will offer his expert opinion as to why it would have been obvious to a POSITA as of February 2006 to treat female genital tissue with RF energy with the expectation that remodeling would occur. (EX. 1004, ¶¶1-8, 10.)

D. Prior Art and Printed Publications

The following references are pertinent to the grounds of unpatentability explained below (references identified with a × were not before the examiner and references with a ᵞ are cited on the face of the patent, but were not cited by the examiner):

1. U.S. Patent No. 6,463,331 to Stuart D. Edwards× (EX. 1008, "Edwards"), filed March 30, 2000, and issued October 8, 2002, is prior art to the Challenged Claims of the '511 patent under 35 U.S.C. §§ 102(b) and 102(e).

2. U.S. Published Application 2004/0193238 to Mosher *et al*. (EX. 1009, "Mosher"), filed January 15, 2004, published on September 30, 2004, and ultimately issued as Patent No. 7,315,762 on January 1, 2008. The published application is prior art to the Challenged Claims of the '511 patent under 35 U.S.C. § 102(b) and the issued patent is prior art under 102(e).

3. U.S. Patent No. 6,216,704 to Ingle *et al*. [v] (EX. 1010, "Ingle '704"), filed August 12, 1998, and issued April 17, 2001, is prior art to the Challenged Claims of the '511 patent under 35 U.S.C. § 102(b) and 102(e).

E. Grounds for Challenge

There is a reasonable likelihood that Petitioners will prevail with respect to at least one of the Challenged Claims and that each of the Challenged Claims is not patentable. *See* 35 U.S.C. § 314(a). Petitioners request cancellation of claims 1-42 of the '511 patent under the following statutory grounds:

1. Ground 1: Claims 1-10, 13-14, 17, 23-25, 27-33 are anticipated under 35 U.S.C. § 102 by Edwards.

2. Ground 2: Claims 1-42 are obvious in light of Edwards in combination with Ingle '704 and Mosher under 35 U.S.C. § 103(a).

VI. OVERVIEW OF THE PRIMARY PRIOR ART REFERENCES

A. Overview of Edwards

Edwards discloses a method and system for applying energy to targeted tissues to selectively ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition. (EX. 1008, 2:32-39.) Edwards discloses several different embodiments, including an embodiment directed to vaginal remodeling. (EX. 1008, 3:5-13; 7:14-8:5; 13:12-14:4; Figs. 4 and 9.)

Edwards describes that "the RF energy is delivered to the anterior and posterior regions of the vaginal wall. This has the effect of tightening of vaginal walls so as to increase support of the bladder outlet, proximal and mid-urethra.

Moreover, circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function." (EX. 1008, 3:5-13.) The anterior region of the vagina encompasses the area which is 1cm to 3.5cm in from the introitus. (EX. 1004, ¶62; EX. 1003, ¶¶82, 83.) Edwards describes the vaginal remodeling embodiment in more detail later in the specification disclosing:

> A method 900 is performed to create a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both. Remodeling of the anterior wall treats incontinence based on bladder outlet hypermobility by increasing support for the bladder outlet, as well as the proximal and mid-urethra. Remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function.

(EX. 1008, 13:14-22.)

The text above refers to Figure 9 (below), a process flow diagram showing a method for using a fourth embodiment for vaginal remodeling. (EX. 1008, Fig. 9.)

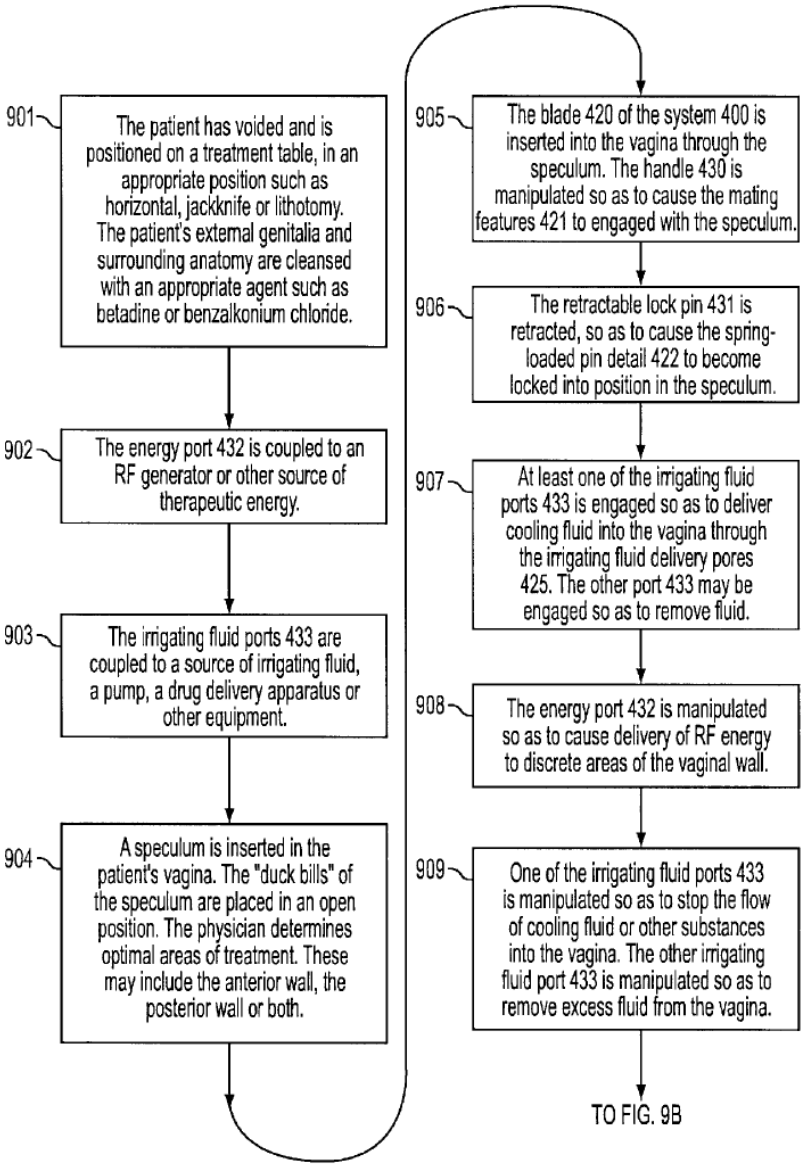

FIG. 9A

As described in Figure 9A, Edwards discloses the use of cooling fluid before, during, and after the heating process as the cooling is started before the application of energy (block 907), and is not stopped until after the RF energy has been delivered to the vaginal wall (block 909). (EX. 1008, Fig. 9.) Edwards also explains that the cooling fluid, "serves to minimize thermal

damage to tissues when the electrodes **225** are deployed." (EX. 1008, 4:59-61; *see generally,* EX. 1003, ¶¶77-86; EX. 1004, ¶¶17-19, 53.)

B. Overview of Mosher

Mosher is entitled "Non-surgical incontinence treatment system and method" and describes its invention as providing:

> [M]ethods, devices, and systems which enhance the structural support provided by a body's tissues, particularly for treatment of incontinence. The techniques of the invention generally involve directing energy from a probe into collagenous tissues of the pelvic support system. The energy will often cause contraction of the collagenous tissue.

(EX. 1009, ¶0045.)

Mosher describes that, in its non-invasive embodiment, "RF current is transmitted between the electrodes of the probe body to heat the endopelvic fascia." (EX. 1009, ¶0058.) Mosher notes that "the techniques of the present invention will be effective for controllably and repeatably enhancing the structural support of a wide variety of fascia and other collagenous tissues throughout the body, they will find applications in a wide variety of therapies." (EX. 1009, ¶0046.) Mosher describes the broad range of tissues that can be treated by its method of "directing energy from a probe into collagenous tissues" including the lamina propria, explaining that:

> [T]he treatment of the present invention may be directed at a variety of tissue structures defining the pelvic floor and/or diaphragm (including: …); structures of the bladder and urethra (including …); structures of the vagina (including: vagino-uterine fascia, lamina propria—the dense connective tissue layer just under

> the epithelium; pubo-urethral or puboprostatic ligaments; pubo-vesicle ligament and posterior pubo-urethral or puboprostatic ligament; pubovesicle muscle, a smooth muscle that is integrated with the pubovesicle ligament; and pubocervical fascia which attaches to the ATFP); structures of the uterus (including…); and structures of the bowel (including: …).

(EX. 1009, ¶0048.)

Figures 6 and 6a of Mosher "illustrate non-invasive vaginal probes and a method for non-invasively treating endopelvic fascia using cooled electrodes." (EX. 1009, ¶0027.) Figures 10A-C and 11 show temperature studies, including studies where the feedback temperature was increased to 85° C, done using the non-invasive treatment probe described in Figures 6 and 6a. (EX. 1009, ¶¶0031-0032; ¶0073.) Mosher also describes that a "non-invasive cooled electrode probe similar to that shown in Figs. 6 and 6A heats tissue until the temperature sensing needle at 4.5mm depth reaches a set point of 75° C. at 185 seconds." (EX. 1009, ¶0085; *see generally,* EX. 1003, ¶¶56-64; EX. 1004, ¶¶31-32, 49-51, 60.)

C. Overview of Ingle '704

Ingle '704 is entitled "Noninvasive devices, methods, and systems for shrinking of tissues" and it discloses the use of directed heating to cause the shrinking of collagenous tissues. (EX. 1010, 2:59-67.) Ingle '704 states:

> This energy heats fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues. The energy will preferably be applied through a large, cooled electrode having a substantially flat electrode surface. Such a cooled plate electrode is capable of directing electrical energy

> through an intermediate tissue and into fascia, while the cooled electrode surface prevents injury to the intermediate tissue.

(EX. 1010, 2:59-67.)

Ingle '704 discloses that "the tissue contraction energy of the present invention can be applied as intermittent pulses of radiofrequency (RF) electrical current transmitted between cooled electrodes." (EX. 1010, 7:1-4) Ingle '704 specifically provides an exemplary embodiment of a vaginal probe that applies energy to the target tissue through the vaginal wall:

> In another aspect, the present invention provides a probe for applying energy to fascia from within the vagina of a patient body. The fascia is separated from the vagina by a vaginal wall. The probe comprises a probe body having a proximal end and a distal end, the probe having a length and a cross-section selected to permit introduction into the vagina. An energy transmitting element is mounted to the probe body. The transmitting element is capable of transmitting sufficient heating energy through the vaginal wall to heat and contract the fascia. A cooling system is disposed adjacent to the transmitting element. The cooling system is capable of maintaining the vaginal wall adjacent the probe below a maximum safe temperature when the fascia is heated by the transmitting element.

(EX. 1010, 3:36-50.)

Ingle '704 describes the breadth of possible applications noting that it can be used to treat "a wide variety of alternative conditions … and may even be used in cosmetic procedures such as abdominoplasty (through selectively shrinking of the abdominal wall), to remove wrinkles by shrinking the collagenated skin tissues, or to lift sagging breasts by shrinking their support

ligaments." (EX. 1010, 17:66-18:7; *see generally* EX. 1003, ¶¶43-55; EX. 1004, ¶¶28-30.)

Ingle '704 includes Figure 12L which shows a cross-sectional view of the treatment head with electrodes (86D), cooling system (89), temperature sensor (95), endopelvic fascia (EF), and vaginal wall (VW). (EX. 1010, 23:40-65.)

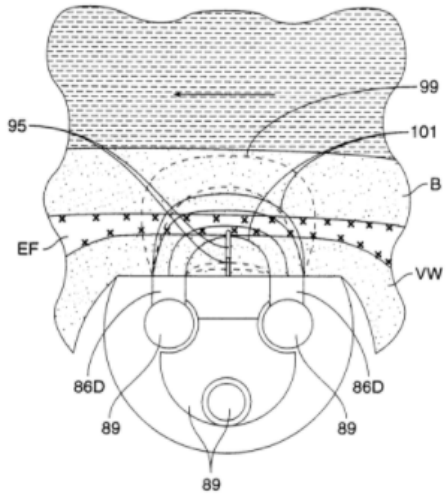

FIG. 12L

Ingle '704 also discloses the use of an ultrasonic heating probe as shown in Figure 13. (EX. 1010, 24:41-58; Fig. 13.)

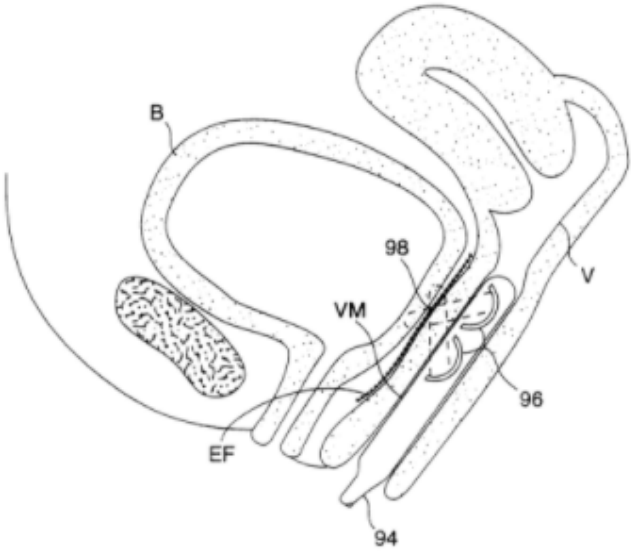

FIG. 13

VII. PERSON HAVING ORDINARY SKILL IN THE ART

The level of skill of a POSITA of the ’511 patent is a medical doctor practicing in the field of plastic surgery and in particular, in urogynecology or a similar field. In the absence of practicing in these fields, a POSITA is a medical doctor who has at least ten years of knowledge and experience in the treatment or research regarding treatment of tissue with radiant energy.

VIII. CLAIM CONSTRUCTION

A claim in *inter partes* review is given the “broadest reasonable construction in light of the specification.” (37 C.F.R. § 42.100(b).) This standard requires that the challenged claims be read in light of the specification as interpreted by a POSITA. *In re Suitco Surface, Inc*., 603 F.3d 1255, 1260 (Fed. Cir. 2010). In *Microsoft Corp. v. Proxyconn, Inc*., the Federal Circuit explained that the broadest reasonable interpretation does not mean that the

Board can construe the claim terms "so broadly that its constructions are unreasonable under general claim constructions principles," and that the construction must not be "divorced from the specification and the record evidence" and consistent with "the [construction] that those skilled in the art would reach." 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011); *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999). Consistent with 37 C.F.R. § 42.100(b), Petitioner submits the following claim term constructions. Any claim terms not included in the following discussion are to be given their broadest reasonable construction in light of the specification as commonly understood by a POSITA.

A. Target Tissue

Term (Claims 1, 35, 43, and 51)	Proposed Construction
"target tissue"	tissue underlying the epithelium

In accordance with the broadest reasonable interpretation standard, the term "target tissue" means "tissue underlying the epithelium."

The '511 patent repeatedly describes the "target tissue" as the tissue "underlying the mucosal epithelium." (EX. 1001, 2:25-28, 3:41-47 ("The target tissue lies immediately beneath the mucosal epithelium of genital tissues, and includes the lamina propria, a connective tissue that includes collagen in the extracellular space, and the muscularis, which includes smooth muscle."); 11:11-14 ("In particular, the target tissues (Fig. 8) are the connective tissue

layers such as the lamina propria or submocosa 102 and the muscularis 104 underlying the mucosal epithelium 100 of genital tissues.").) The '511 patent further states:

> The target tissue of embodiments of this invention include the connective tissue underlying these mucosal epithelial surfaces of the genitalia which, progressing down from the epithelial surface, are known as the lamina propria 102 and the muscularis 104 (FIG. 8), respectively (see, for example, Netter, Atlas of Human Anatomy, 4th edition, Saunders, 2006). The lamina propria includes a mixture of cells types that populate connective tissue, such as fibroblasts, and the muscularis is a layer of smooth muscle. Collagen is secreted or deposited into the extracellular space in these tissues by cells such as fibroblasts.

(EX. 1001, 12:2-13.)

B. Heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock

Term (Claim 35)	Proposed Construction
"heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock"	Heating at least one point of the vaginal wall between 1 o'clock to 11 o'clock positions in a circumferential view with the urethra at 12 o'clock

The broadest reasonable interpretation of the phrase "heating a portion of the vagina" is heating at least one point of the vagina. The later portion of the phrase "circumferentially around its wall from 1 o'clock to 11 o'clock" is an orienting reference based on the '511's circumferential reference scheme:

"With regard to the circumferential aspects of the vagina, locations along the circumference of the vaginal wall may be assigned a clock position (*see* reference clock dial 136, in FIG. 7) such that the circumferential point closest to the urethra is at 12 o'clock." (EX. 1001, 11:51-55.) This effort to carve out the portion of the clock from 11 o'clock to 1 o'clock appears to have been an effort by the patentee to differentiate its claimed invention from prior art references such as Knowlton '276 which were directed to the non-invasive treatment of various issues including "preterm delivery due to an incompetent cervix" and "pelvic prolapse and stress incontinence." (EX. 1007, 14:46-50.)

Claim 35 should not be interpreted to require a series of contact points as described in an embodiment of the invention (EX. 1001, 14:37-45), this is improper as it imports limitations from the specification into the claim and ignores the principal of claim differentiation based on claim 40's added requirement that "contacting the epithelium with a treatment tip at a one or more contact sites during a procedure" which would be redundant if claim 35, from which it depends, already contained this limitation.

IX. SPECIFIC GROUNDS FOR PETITION

Pursuant to Rule 42.104(b)(4)-(5), the below sections demonstrate in detail how the prior art discloses each and every limitation of claims 1-42 of the '511 patent, and how those claims are rendered obvious by the prior art.

A. Ground I: CLAIMS 1-10, 13-14, 17, 23-25, and 27-33 are anticipated by Edwards

1. Claim 1

a. (preamble) A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:

Edwards discloses a method and system for applying energy to targeted tissues to selectively ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition. (EX. 1008, 2:32-39; EX. 1003, ¶79; EX. 1004, ¶¶18-19.) Edwards describes that radiofrequency (RF) energy can be applied to "target tissue" such as uro-genital tissues so as to cause shrinkage and remodeling, reshaping, bulking and other treatment effects. (*See e.g.* EX. 1008, 2:26-30.) Specifically, Edwards describes that it "provides a method and system for the curative treatment of female uro-genital disorders by application of radiofrequency (RF) energy to targeted tissues … so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition." (*See e.g.* EX. 1008, 2:33-39.)

Edwards includes a process flow diagram describing an application of its disclosed method for vaginal remodeling noting that remodeling "both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual

function." (EX. 1008, 13:12-23, Fig. 9.) Thus Edwards discloses this limitation.

b. Heating the target issue

With respect to the vaginal remodeling embodiment, Edwards describes that:

> The RF energy is delivered to the anterior and posterior regions of the vaginal wall. This has the effect of tightening of vaginal walls so as to increase support of the bladder outlet, proximal and mid-urethra. Moreover, circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function.

(EX. 1008, 3:5-13.)

As described in Figure 9a of Edwards, the "energy port 432 is manipulated so as to cause delivery of RF energy to discrete areas of the vaginal wall." (*See e.g.* EX. 1008, 13:54-56.) A POSITA would understand that Edwards' "delivery of RF energy to discrete areas of the vaginal wall" causes the heating of the tissues below the epithelium and thus discloses heating the target tissue. (EX. 1003, ¶81; EX. 1004, ¶18.) The fact that the RF electrodes put off a significant amount of heat is confirmed by the inclusion of a cooling system in Edwards as described below.

Edwards includes a process flow diagram showing a method for vaginal remodeling. (EX. 1008, Fig. 9.) As described in block 907 of Figure 9a, the vaginal remodeling process disclosed in Edwards includes the use of cooling fluid during the treatment process. (EX. 1008, Fig. 9) ("At least one of the

irrigating fluid ports 433 is engaged so as to deliver cooling fluid into the vagina through the irrigating fluid delivery pores 425.") Edwards also explains that the cooling fluid, "serves to minimize thermal damage to tissues when the electrodes **225** are deployed." (EX. 1008, 4:59-61.) Edwards discloses that "Each electrode 423 includes at least one thermocouple 424 that is used to monitor the temperature of each electrode 423. This constant temperature monitoring, combined with a computerized control algorithm, is utilized to independently control the electrodes 423. If one of the electrodes 423 exceeds temperature safety limits, that particular one of the electrodes 423 can be disengaged without aborting the entire procedure." (EX. 1008, 7:43-50.)

Thus Edwards discloses this limitation.

c. Remodeling the therapeutic zone of target tissue

Edwards discloses the selective heating of targeted tissues by application of RF energy to remodel the underlying tissue thereby correcting an unwanted condition. (EX. 1008, 2:26-30 (describing the application of RF energy to "uro-genital tissues so as to cause shrinkage and remodeling, reshaping, bulking and other treatment effects"); (EX. 1008, 2:33-40) (describing the use of RF energy to "ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition").) Edwards discloses that "[t]he tiny cites of treated muscle resorb, remodel and shrink in the weeks that follow treatment …." (EX. 1008, 2:53-56.)

Edwards discloses "vaginal remodeling." (EX. 1008, 3:26-28 ("FIG. 4 is a block diagram showing a fourth embodiment of the distal end of a system that can be used for vaginal remodeling"; s*ee also* EX. 1008, 3:38-39 ("FIG. 9 is a process flow diagram showing a method for using a fourth embodiment for vaginal remodeling"); EX. 1008, 7:14-15 ("FIG. 4 is a block diagram showing a fourth embodiment of a device that can be used for vaginal remodeling."); EX. 1008, 13:13-23 ("FIG. 9 is a process flow diagram showing a method for using a fourth embodiment for vaginal remodeling.").) A detailed description of this fourth embodiment explains that the remodeling of "both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function." (EX. 1008, 13:14-23; EX. 1003, ¶¶82-86; EX. 1004, ¶19.)

The remodeling, as admitted in the '511 patent and taught in the cited references, is a natural phenomenon that results from the heating of the tissue.

Edwards anticipates the method of treatment claimed in the '511 patent, *i.e.*, the application of RF energy to cause the remodeling of vaginal tissue. The claims are the same method of treatment described in Edwards, and are necessarily met as the "remodeling" is the *result* caused when heated tissue reaches a sufficient temperature (*see* EX. 1001, 4:15-16, 5:2-5, 11:22), not an independent active step carried out by the person administering the claimed method.

d. Wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1cm to 3.5cm in from the introitus.

Edwards discloses the remodeling of the vagina wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1cm to 3.5cm in from the introitus. As described earlier in Section V.B., this element was added during the prosecution of the '511 to overcome the Knowlton '276 reference which specifically describes the treatment of pre-term cervical dilation by applying an energy delivery device to the cervix leading to the tightening of the dilated cervix. (EX 1007, 13:35-47.) Given that the cervix, the passage between the lower end of the uterus and the vagina, is located at the posterior end of the vagina, the examiner apparently determined that Knowlton '276 did not disclose this revised claim limitation directed to the treatment of the anterior portion of the vagina. Edwards is expressly directed to "vaginal remodeling" by the treatment of the vaginal wall. (EX. 1008, 3:25-28.) Edwards explains that remodeling "both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting [in] physical and psychological improvement in the area of sexual function. (EX. 1008, 13:14-23.)

A POSITA would understand that Edwards' description of physical improvement in the area of sexual function is caused by a tightening of the anterior vaginal wall, and that the anterior vaginal wall includes the portion of

the vagina extending from the introitus inwardly to a location from 1cm to 3.5cm in from the introitus. (EX. 1004, ¶71; EX. 1003, ¶¶87-88, 116-17.) A POSITA would know that the mean length from cervix to introitus along the anterior wall in an unaroused vagina of a woman of child-bearing age is approximately 6.5cm. (EX. 1003, ¶¶29, 83.) Therefore, the treatment of the anterior wall of the vagina, as contemplated by Edwards would necessarily entail the treatment of the portion of the vagina from the introitus to at least an inward position of 2cm. (EX. 1003, ¶¶88).)

2. Claim 2: The method of claim [] wherein heating the target tissue comprises heating it to a temperature between 45 degrees C and 80 degrees C.

The ’511patent itself incorporates by reference several prior art patents and published patent applications that it characterizes as “relevant to” aspects of “collagen denaturation and the exploitation of this for medical or cosmetic purposes.” (EX. 1001, 1:35-61.) In addition, a POSITA would have had an understanding of the temperatures necessary to effectuate changes to collagen, including denaturation. (*See* EX. 1004, ¶¶57-62; EX. 1003, ¶¶90, 125.)

Because the optimal conditions for the denaturation of collagen were already known to those in the field, a POSITA would understand that the descriptions in Edwards calling for “the curative treatment of female uro-genital disorders by application of radiofrequency (RF) energy to targeted tissues … so as to ablate, tighten, shrink or reshape the tissue and thereby correct an

unwanted condition" to entail that the target tissue be heated to a temperature between 45° C and 80° C. (EX. 1008, 2:33-40; *see also* EX. 1004, ¶¶57-62; EX. 1003, ¶¶90, 125.)

Further, as noted by the Examiner during prosecution of the '511 patent:

> It would have been obvious to one of ordinary skill in the art at the time of the invention was made to heat the target tissue to the claimed temperature ranges since the claims temperature ranges are well known and commonly utilized temperature ranges in the art to provide the desired remodeling and thermal treatment disclosed in Knowlton. Additionally it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the disclosed ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art."

(EX. 1002, Thermi033911.)

Thus Edwards discloses this limitation.

3. Claim 3: The method of claim [] wherein heating the target tissue comprises heating it to a temperature between 50 degrees C and 75 degrees C.

See claim 2 *supra*.

4. Claim 4: The method of claim [] wherein heating the target tissue comprises heating it to a temperature between 55 degrees C and 70 degrees C.

See claim 2 *supra*.

5. Claim 5: The method of claim [], wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

Figure 4 of Edwards (below) depicts the distal end of the treatment

system for vaginal remodeling.

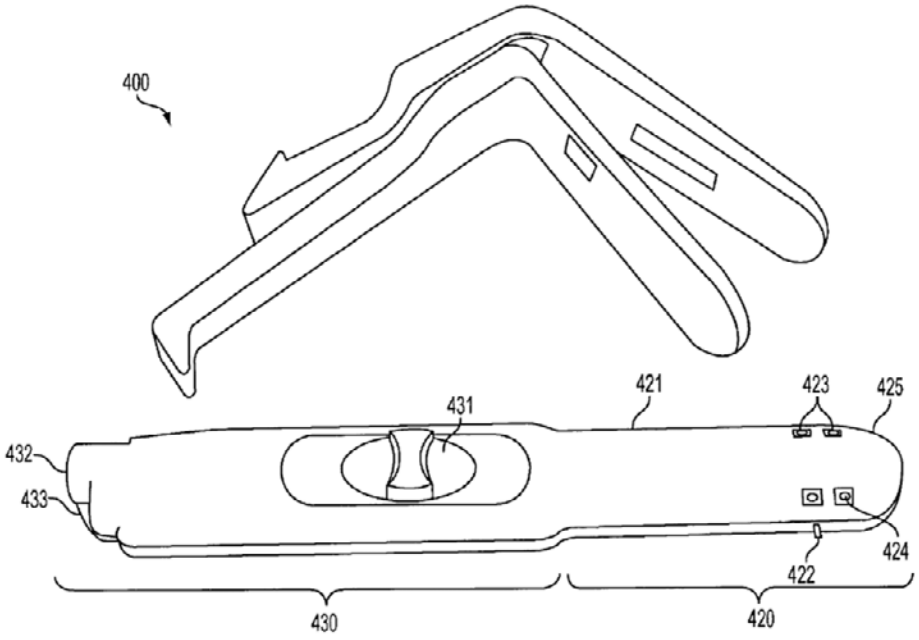

FIG. 4

Edwards describes that the "system 400 includes a treatment element 410. The proximal end of the treatment element 410 is coupled to an RF generator. The distal end of the treatment element 410 is inserted into a vagina using a speculum." (EX. 1008, 7:14-19.) Edwards describes that "In a preferred embodiment, these electrodes 423 are disposed to deliver RF energy. However, in other embodiments the electrodes 423 may also deliver microwave energy, ELF (extremely low frequency energy), laser and other forms of therapeutic energy." (EX. 1008, 7:37-42.) Edwards also discloses that the vaginal probe is "manipulated so as to cause delivery of RF energy to discrete areas of the vaginal wall." (EX. 1008, 13:54-56.) Edwards discloses that its method creates a "series of lesions in either the anterior vaginal wall, the posterior vaginal wall

or both." (EX. 1008, 13:14-16.) A POSITA would understand that the "delivery of RF energy to discrete areas of the vaginal wall" along with the "presence of lesions" language discloses that the vaginal wall is contacted by the treatment tip. (EX. 1004, ¶53.) Thus Edwards discloses this limitation.

6. Claims 6 and 33: The method of claim [], wherein the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy.

Edwards describes that "In a preferred embodiment, these electrodes 423 are disposed to deliver RF energy. However, in other embodiments the electrodes 423 may also deliver microwave energy, ELF (extremely low frequency energy), laser and other forms of therapeutic energy." (EX. 1008, 7:37-42.) Ingle '704 noted that focused ultrasound energy is particularly well suited for heating and shrinking the pelvic support tissues from a vaginal probe." (EX 1008, 8:45-52; Fig. 13.) Mosher describes a vaginal probe utilizing "bipolar RF energy between alternating pairs of electrodes." (EX 1007, ¶58; *see also* EX. 1003, ¶ ¶40, 84; EX. 1004, ¶ ¶42-45.)

7. Claim 7: The method of claim [], wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature

Edwards discloses that "[e]ach electrode 423 includes at least one thermocouple 424 that is used to monitor the temperature of each electrode 423. This constant temperature monitoring, combined with a computerized control algorithm, is utilized to independently control the electrodes 423. If one of the electrodes 423 exceeds temperature safety limits, that particular one of the

electrodes 423 can be disengaged without aborting the entire procedure." (EX. 1008, 7:43-50; EX. 1004, ¶¶63-65.)

8. Claim 8: The method of claim 7, wherein the feedback control is provided by one or more thermal sensors.

As described above with respect to claim 7, feedback control is provided by "thermocouple 424" which is a thermal sensor "used to monitor the temperature of each electrode 423." (EX. 1008, 7:43-45; EX. 1004, ¶¶63-65.) Therefore it also satisfies the requirement of claim 8 that "the feedback control is provided by one or more thermal sensors."

9. Claim 9: The method of claim [], wherein the method further comprises cooling the epithelium.

Element 907 of Figure 9a of Edwards describes its vaginal remodeling method and includes a description of the use of cooling fluid during the treatment process. (EX. 1008, Fig. 9 ("At least one of the irrigating fluid ports 433 is engaged so as to deliver cooling fluid into the vagina through the irrigating fluid delivery pores 425."). Edwards also explains that the cooling fluid, "serves to minimize thermal damage to tissues when the electrodes **225** are deployed." (EX. 1008, 4:59-61; EX. 1003, ¶86; EX. 1004, ¶53.) Therefore, Edwards discloses the cooling of the epithelium.

10. Claim 10: The method of claim 1, wherein cooling is by contacting the epithelium with a treatment tip, the tip including a cooling mechanism.

As described above with respect to claim 5, Edwards discloses contacting the epithelium with a treatment tip, the tip including an energy delivery element.

(*See supra* IX.A.5.) Figure 4 of Edwards shows that the treatment tip includes a cooling mechanism as element 425 depicts "fluid delivery pores." (EX. 1008, Fig. 4; EX. 1003, ¶86; EX. 1004, ¶53.) Edwards discloses that at least one of the "irrigating fluid ports 433 is engaged so as to deliver cooling fluid into the vagina through the irrigating fluid delivery pores 425." (EX. 1008, Fig. 9, step 907.) Thus Edwards discloses this limitation.

11. Claim 13: The method of claim 9, wherein the cooling precedes the heating, and continues during the heating.

Figure 9 of Edwards describes that the cooling fluid is delivered in the step before the RF energy is delivered, and is not turned off until after the RF energy has been delivered. (EX. 1008, Fig. 9; EX. 1003, ¶86; EX. 1004, ¶53.) Therefore Edwards discloses this limitation.

12. Claim 14: The method of claim 9, wherein the cooling is during the heating, and continues after heating.

Figure 9 of Edwards describes that the cooling fluid is delivered in the step before the RF energy is delivered, and is not turned off until after the RF energy has been delivered. (EX. 1008, Fig. 9; EX. 1003, ¶86; EX. 1004, ¶53.) Therefore Edwards discloses this limitation.

13. Claim 17: The method of claim [], wherein the method comprises contacting the epithelium with a treatment tip at a one or more contact sites during a procedure, the tip comprising an energy delivery element adapted to heat the target tissue.

As described in association with claim 5, Edwards discloses that energy is delivered by contacting the epithelium with a treatment tip, the tip including an energy delivery element. *See* Section IX.A.5 *supra*.

Edwards also discloses that the energy can be applied at one or more contact sites stating that "[t]he physician determines optimal areas of treatment. These may include the anterior wall, the posterior wall or both." (EX. 1008, 13:38-42; EX. 1003, ¶130; EX. 1004, ¶¶66-67.) Edwards further discloses that "In a preferred embodiment, the blade 420 may be disengaged and relocked into another position in the speculum, so as to delivery [sic] energy to another area of the vagina." (EX. 1008, 13:60-62.)

14. Claim 23: The method of claim 1, wherein the target tissue heating includes heating submucosa and muscularis below a mucosal epithelium.

Edwards discloses wherein the target tissue heating includes heating submucosa and muscularis below a mucosal epithelium. Edwards describes that it is directed to the treatment of "uro-genital tissues" by way of RF energy and that the application of the energy can "cause shrinkage and remodeling, reshaping, bulking and other treatment effects" and "ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition." (EX. 1008, 2:26-30; 2:33-40.) Edwards also discloses a vaginal probe and describes that it

is "manipulated so as to cause delivery of RF energy to discrete areas of the vaginal wall." (EX. 1008, 13:54-56.) Because the vaginal wall is covered by mucosal epithelium, the treatment described in Edwards, where RF energy is applied to the vaginal wall so as to "cause shrinkage and remodeling, reshaping, bulking and other treatment effects" necessarily requires the heating of the submucosa and muscularis below the mucosal epithelium. (EX. 1004, ¶¶69, 76; EX. 1003, ¶¶24, 50, 89, 96, 97.)

15. Claim 25: The method of claim 1, wherein remodeling comprises contracting target tissue.

Edwards discloses the remodeling of target tissue by way of contraction as it describes the use of RF energy to "ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition." (EX. 1008, 2:33-40; *see also* EX. 1003, ¶¶34-37, 77-90, 130; EX. 1004, ¶¶18-19.) As described above with respect to claim element 1(c), the remodeling of the target tissue is a natural phenomenon that necessarily occurs based on the application of RF energy to the target tissue. (*See* Section IX.A.1.c, *supra*.)

16. Claim 26: The method of claim 1, wherein remodeling comprises tightening the introitus.

Edwards discloses the remodeling comprises tightening the introitus as "remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function." (EX. 1008, 13:14-23; s*ee also* 3:5-14.) A POSITA

would understand that tightening the anterior of the vagina would tighten the introitus. (EX. 1003, ¶¶34-37, 77-90, 130; EX. 1004, ¶¶18-19, 71.)

17. Claim 27: The method of claim 1, wherein remodeling comprises tightening the vagina.

Edwards discloses the application of RF energy to the "anterior and posterior regions of the vaginal wall" which "has the effect of tightening of vaginal walls" and noting that the "circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function." (EX. 1008, 3:5-14; EX. 1003, ¶¶34-37, 77-90, 130; EX. 1004, ¶¶18-19, 72.)

18. Claim 28: The method of claim 1, wherein remodeling comprises denaturing collagen.

As described above with respect to claim element 1(c), the mechanism of the remodeling of the target tissue is a natural phenomenon that necessarily occurs based on the application of energy to the target tissue and this element is necessarily met by the method taught by Edwards. (Section IX.A.1.c, *supra*.)

19. Claim 29: The method of claim 1, wherein remodeling comprises tightening collagen-rich sites in the target tissue.

See claim 28 *supra*.

20. Claim 30: The method of claim 1, wherein at least some of the remodeling occurs during the heating.

See claim 28 *supra*.

21. Claim 31: The method of claim 1, wherein at least some of the remodeling occurs after the heating.

See claim 28 *supra*.

22. Claim 32: The method of claim 31, wherein the remodeling after the heating is by a depositing of collagen in the target tissue.

See claim 28 *supra*.

23. Claim 35

a. Claim 35a–c:

Claims 35a-c are identical to claims 11a, and thus for the reasons described above, Edwards discloses these limitations.

b. Claim 35d: wherein the heating includes heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock.

Edwards describes treatment of both the anterior and posterior vaginal wall. (EX. 1008, 13:14-23.) The treatment of both the anterior and posterior wall in Edwards necessarily entails heating a portion of the vagina circumferentially around its wall within the range from 1 o'clock to 11 o'clock, as the dividing line between the anterior and posterior walls would be the 3 o'clock and 9 o'clock positions and Edwards is treating at least one position within the 3 o'clock and the 9 o'clock positions. (EX. 1003, ¶¶89, 119-120; EX. 1004, ¶¶70, 72.)

B. Ground II: claims 1-42 Are invalid as obvious in light OF EDWARDS IN COMBINATION WITH INGLE AND MOSHER UNDER 35 U.S.C. § 103(A)

1. Claim 1 (preamble)

a. A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:

As discussed above in Section IX.A.1.a., Edwards discloses this limitation. However, to the extent it is determined that it did not anticipate this limitation, Mosher and Ingle also disclose this limitation.

Mosher states the techniques of its invention "generally involve directing energy from a probe into collagenous tissues of the pelvic support system" to "cause contraction of the collagenous tissue." (EX. 1009, ¶0045.)

Mosher describes the broad range of tissues that can be treated by its method of "directing energy from a probe into collagenous tissues" including the "lamina propria—the dense connective tissue layer just under the epithelium." (EX. 1009, ¶0048; *see also* EX. 1003, ¶¶41, 56-64; EX. 1004, ¶¶31-32, 69, 87.)

Ingle describes that it utilizes energy to "heats fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues." (EX. 1010, 2:59-67.) Further, Ingle specifically provides an exemplary embodiment of a non-invasive transvaginal delivery

device that applies energy to the target tissue through the vaginal wall. (EX. 1010, 3:36-50; EX. 1003, ¶¶48-55.)

Thus Edwards, Mosher, and Ingle all this limitation.

b. Heating the target issue

As discussed above in Section IX.A.1.b., Edwards discloses this limitation. However, to the extent it is determined that it did not anticipate this limitation, Mosher and Ingle also disclose this limitation.

Mosher describes the broad range of tissues that can be targeted by its method of "directing energy from a probe into collagenous tissues" including the "lamina propria—the dense connective tissue layer just under the epithelium." (EX. 1009, ¶0048; EX. 1003, ¶57.) Figures 6 and 6a of Mosher "illustrate non-invasive vaginal probes and a method for non-invasively treating endopelvic fascia using cooled electrodes." (EX. 1009, ¶0027; EX. 1003, ¶¶59, 63.) Mosher describes that a "non-invasive cooled electrode probe similar to that shown in FIGS. 6 and 6A heats tissue until the temperature sensing needle at 4.5mm depth reaches a set point of 75° C. at 185 seconds." (EX. 1009, ¶0085; *see also* EX. 1003, ¶¶41, 56-64; EX. 1004, ¶¶31-32, 49-51.)

Ingle '704 similarly discloses that it provides a method for "therapeutically heating a target zone of a tissue" where the "target zone is heated by directing energy from the probe, through the pre-cooled adjacent tissue, and into the target zone." (EX. 1010, 4:4-10.) Ingle '704 also describes

that "energy heats the target tissue so that the target tissue contracts" while cooling the intermediate tissue. (EX. 1010, 3:51-58; EX. 1003, ¶¶46-55; EX. 1004, ¶¶28-30.)

Thus the combination of discloses this limitation.

c. Remodeling the therapeutic zone of target tissue

As discussed above in Section IX.A.1.c., Edwards discloses this limitation. However, to the extent it is determined that it did not anticipate this limitation, Mosher and Ingle also disclose this limitation.

Mosher notes that the "techniques of the invention generally involve directing energy from a probe into collagenous tissues of the pelvic support system. The energy will often cause contraction of the collagenous tissue." (EX. 1009, ¶0045; EX. 1003, ¶56.) Mosher describes the broad range of tissues that can be treated by its method of "directing energy from a probe into collagenous tissues" including the "propria—the dense connective tissue layer just under the epithelium." (EX. 1009, ¶0048; EX. 1003, ¶56-64; EX. 1004, ¶32.)

Ingle '704 similarly discloses that it provides a method for "therapeutically heating a target zone of a tissue" where the "target zone is heated by directing energy from the probe, through the pre-cooled adjacent tissue, and into the target zone." (EX. 1010, 4:4-10.) Ingle notes that its methods can be used to heat "target zones" to "a significantly higher

temperature than intermediate tissue **36**." (EX. 1010, 15:65-16:4; *see also* EX. 1003, ¶¶46-55; EX. 1004, ¶52.)

Ingle '704 discloses an exemplary embodiment of a vaginal probe that applies energy to the target tissue through the vaginal wall to cause contraction of the underlying collagen tissue. (EX. 1010, 8:53-65.) Ingle '704 also discloses that the heating energy remodels the targeted collagenated tissue. (EX. 1010, 3:51-58; EX. 1003, ¶¶46, 49-50; EX. 1004, ¶69.)

As described above, Edwards, Mosher, and Ingle '704 all disclose the tightening or contracting the collagen tissue underlying the epithelium of female genital tissue and thus disclose remodeling of the therapeutic zone of target tissue as construed by Petitioners.

d. Wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1cm to 3.5cm in from the introitus.

As discussed above in Section IX.A.1.d., Edwards discloses this limitation. However, to the extent it is determined that it did not anticipate this limitation, Mosher and Ingle '704 also disclose this limitation.

Mosher discloses that "the techniques of the present invention will be effective for controllably and repeatably enhancing the structural support of a wide variety of fascia and other collagenous tissues throughout the body, they will find applications in a wide variety of therapies." (EX. 1009, ¶0045; EX. 1003, ¶59.) Mosher describes the broad range of tissues that can be treated by

its method of "directing energy from a probe into collagenous tissues" including the lamina propria and other "tissue structures defining the pelvic floor." (EX. 1009, ¶0048.)

Mosher further discloses a "laterally elongate treatment region of the endopelvic fascia … ideally having a width of about 25mm and a length of about 15mm. Treatment depths will preferably be at least about 2mm, optionally being as much as 6mm." (EX. 1009, ¶0074; EX. 1003, ¶¶59- 61.)

A POSITA would understand Mosher's direction to "tissue structures defining the pelvic floor" to mean that Mosher was directing its treatment to the bottom portion of the vagina. (EX. 1003, ¶¶29-30, 59-62.) Further, Mosher's description of a treatment region with a "width of about 25mm and a length of about 15mm" means that even if the bottom of the treatment area was exactly at the introitus, the treatment area would necessarily extend 1.5cm inward and thus necessarily heat a portion of the vagina at least 1.5cm inward from the introitus. (EX. 1003, ¶¶29-30, 59-62.)

Additionally, a POSITA would understand that Mosher's described treatment depth of between 2mm and as much as 6mm, would include remodeling of the muscularis, as the distance from the vaginal wall to the muscularis is typically about 3mm in depth. (EX. 1003, ¶¶29-30, 59-62.)

Ingle describes a probe for the treatment of various tissue structures to treat urinary incontinence including treatment of "the urethral wall, the bladder

neck, the bladder, the urethra, bladder suspension ligaments, the sphincter, pelvic ligaments, pelvic floor muscles, fascia, and the like." (EX. 1010, 11:8-24.)

A POSITA would understand that given the nature and location of the tissues described in Ingle '704, treatment of these tissues by way of a vaginal probe would necessarily include the application of energy to a portion of the vagina extending from the introitus inwardly to a location from 1cm to 3.5cm in from the introitus. (EX. 1004, ¶30; EX. 1003, ¶51.)

e. Reasons to combine Edwards, Mosher, and Ingle '704

Further to Sections IX.B.1(a)-(d) above, it would have been obvious to a POSITA to combine the treatment methods of Edwards, Mosher, and Ingle '704. (EX. 1003, ¶36; EX. 1004, ¶15.) Edwards, Mosher, and Ingle '704 all disclose non-invasive treatment probes that can be used to provide RF energy to and through the vaginal wall to denature the underlying collagen containing tissue to tighten it. (*See e.g*. EX. 1008 (Edwards), 2:26-40, 3:5-14, 7:14-19, 13:14-23, 13:54-56; EX 1009 (Mosher), ¶¶0027, 0045, 0048, 0066, 0074, Figs. 6 and 6A; EX 1010 (Ingle '704) at 3:36-50, 23:40-65, Fig. 12L.) Edwards, Mosher, and Ingle '704 all describe methods of cooling the intermediate tissue while heating the underlying tissue. (*See e.g*. EX. 1008 (Edwards), 4:59-61, Fig. 9; EX 1009 (Mosher), ¶¶0058, 0069; EX 1010 (Ingle '704), 2:59-67, 3:36-50, 4:4-10, 20:59-63.) All three references relate to the same field as they all

disclose non-invasive treatments that can be used to treat urinary incontinence as well as other uro-genital disorders and Ingle '704 specifically teaches application of the same treatment methods for non-medical cosmetic uses in other parts of the body, *i.e.*, in extra genital tissue. (*See e.g.* EX. 1008 (Edwards), 13:12-23; EX 1009 (Mosher), ¶0045; EX 1010 (Ingle '704), 8:53-65.)

A POSITA would have been motivated to combine the treatment tips of Ingle and Mosher, including their cooling mechanisms, with the teaching of Edwards because Edwards explains that its cooling fluid, "serves to minimize thermal damage" to the mucosal epithelium "when the electrodes **225** are deployed." (EX. 1006, 4:59-61, 7:51-53.) Ingle describes that "heat should be removed from the housing adjacent the transducer so as to prevent the surface of the transducer housing from rising above about 45 nC. As described above, it will often be desirable to chill the intermediate tissue engaged by the probes of the present invention to temperatures significantly lower than this. It should at least be possible to maintain the housing below a maximum safe tissue temperature by using an adequate flow a cooling liquid such as water, and still further cooling may be possible." (EX 1010, 26:28-37.) Mosher describes that its probe "makes use of cooling prior to and during RF energy application, and all measurement locations were maintained at or below standard tissue temperatures at the offset locations. Hence, these studies indicate there is no

tissue heating beyond the footprint of probe 54, and lateral heat dispersion can be well controlled for the non-invasive application of RF energy using a cooled electrode non-invasive applicator." (EX 1009, 12:44-51.) Given Edwards' stated goal of minimizing thermal damage to the mucosal epithelium, it would have been obvious to combine the more robust cooling mechanisms described in Ingle '704 and Mosher with the treatment probe in Edwards to better meet this stated goal. (EX. 1004, ¶54; EX. 1003, ¶36.) Edwards notes that with respect to its non-invasive vaginal probe embodiment, the electrodes may deliver other forms of therapeutic energy. (EX. 1006, 7:39-42.) A POSITA would understand that ultrasound is one such "other form of therapeutic energy" and thus a POSITA would be motivated to combine the ultrasound vaginal probe embodiment described in Ingle '704 with Edwards.

2. Claims 2 and 36: The method of claim [] wherein heating the target tissue comprises heating it to a temperature between 45 degrees C and 80 degrees C.

As discussed above in Section IX.A.2, and acknowledged by the '511 patent, the temperature ranges necessary for the remodeling of collagen tissue were well known prior to '511 patent. (*See* section IX.A.2 *supra*.)

Mosher and Ingle '704 also expressly disclose this limitation. Ingle '704 discloses that "[p]referably, the target tissue will be raised to a temperature of about 60 nC or more, while the intermediate tissue remains at or below a maximum safe temperature of about 45 nC." (EX. 1010, 8:39-44; *see also* 7:7-

15; 8:66-9:11.) Ingle further notes that "[p]reliminary work in connection with the present invention has shown that fascia and other collagenated tissues which are heated to a temperature range of between about 60 nC and 140 nC, often being in a range from about 60 nC to about 110 nC, and preferably between about 60 nC and 80 nC, will contract." (EX. 1010, 12:64-13:2.) Mosher states that "to effect significant, repeatable tissue shrinkage, it is generally desirable to subject the treatment volume to temperatures of at least 70° C. for a time of about 30 seconds or more." (EX. 1009, ¶0065.)

Thus the combination discloses this limitation. (EX. 1004, ¶¶57-62; EX. 1003, ¶¶32, 46, 49-50, 52, 57-58, 115, 127.)

3. Claim 3: The method of claim 1, wherein heating the target tissue comprises heating it to a temperature between 50 degrees C. and 75 degrees C.

See claim 2 above.

4. Claim 4: The method of claim 1, wherein heating the target tissue comprises heating it to a temperature between 55 degrees C. and 70 degrees C.

See claim 2 above.

5. Claims 5 and 37: The method of claim [], wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

As discussed above in Section IX.A.5, Edwards discloses this limitation. Mosher and Ingle also disclose this limitation.

Mosher depicts its non-invasive treatment probe in Figures 6 and 6A where elements 56 are the electrodes.

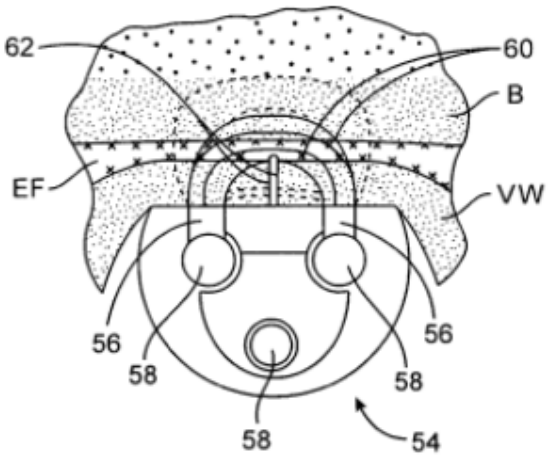

FIG. 6

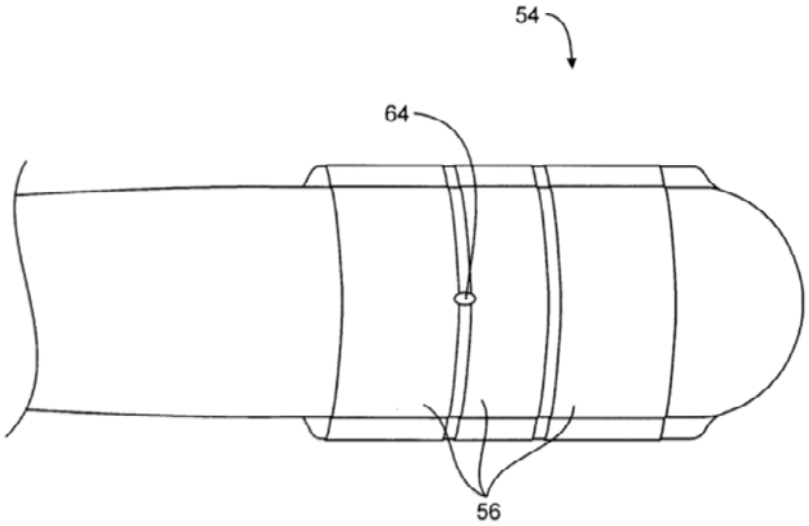

FIG. 6A

Mosher describes that pre-cooling can "inhibit heating of the intervening tissue to a temperature causing surface lesions within the vagina" and that "a relatively

flat tissue-engaging electrode surface helps direct electrical current flux." (EX. 1009, ¶0058; *see also* EX. 1004, ¶¶55-56.) The use of the phrase tissue engaging electrode makes clear that the electrodes described in Mosher deliver energy by contacting the epithelium. Ingle discloses that its "probe for therapeutically heating a target tissue of a patient body through an intermediate tissue" includes "an electrode with an electrode surface which is engagable against the intermediate tissue." (EX. 1010, 3:11-20.)

6. Claims 6, 33 and 41: The method of claim [], wherein the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy.

As discussed above in Section IX.A.6, Edwards discloses this limitation.

7. Claims 7 and 38: The method of claim [], wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature

As discussed above in Section IX.A.7, Edwards discloses this limitation. Ingle and Mosher also disclose this limitation.

Ingle discloses that a "control system will often selectively energize the electrode and/or cooling system in response to the monitored temperature." (EX. 1010, 3:32-35.) Ingle also discloses that "needle mounted temperature sensors will ideally provide direct feedback of the tissue temperature so that selected treatment zone is heated to about 60 nC or more, while heating of the tissues adjacent the electrodes is limited to about 45 nC or less." (EX. 1010, 7:7-15.)

Mosher describes that "[f]eedback on the pre-cooling and heating temperatures may be provided by needle-mounted temperature sensors 62" and that its "feedback loop from the probe-supported temperature sensing needle" can set a "probe feedback temperature." (EX. 1009, ¶0073; *see also* EX. 1004, ¶¶63-65.)

8. Claim 8: The method of claim 7, wherein the feedback control is provided by one or more thermal sensors.

As discussed above in Section IX.A.8, Edwards discloses this limitation. Ingle '704 and Mosher disclose that "the feedback control is provided by one or more thermal sensors." (*See* EX. 1010, 7:7-15 ("needle mounted temperature sensors"); and Mosher, ¶0073 ("needle-mounted temperature sensors 62"); *see also* EX. 1004, ¶¶63-65.)

9. Claims 9 and 39: The method of claim [], wherein the method further comprises cooling the epithelium.

As discussed above in Section IX.A.9, Edwards discloses this limitation. Ingle '704 discloses the use of a "controlled regimen of timed pre-cooling and then heating" to selectively raise the temperature of endopelvic fascia EF (or any other target tissue), while the vaginal mucosa adjacent probe **84** is protected by the cooled probe." (EX. 1010, 20:59-63.) Ingle '704 also describes that the "tissue will preferably be pre-cooled by the surfaces of electrodes 12, 14, generally using an electrode surface temperature of at or above 0 nC." (EX. 1010, 15:27-39.)

Mosher describes its non-invasive probe 54 "makes use of cooling prior

to and during RF energy application." (EX. 1009, ¶0069.)

Therefore, the combination discloses the cooling of the epithelium. (EX. 1003, ¶¶41, 48-49, 58, 63-64, 130; EX. 1004, ¶¶46-54, 56.)

10. Claim 10: The method of claim 1, wherein cooling is by contacting the epithelium with a treatment tip, the tip including a cooling mechanism.

As discussed above in Section IX.A.10, Edwards discloses this limitation. Ingle '704 and Mosher also disclose this limitation.

Ingle includes Figure 12L which shows a cross-sectional view of the treatment head with electrodes (86D), cooling system (89), temperature sensor (95), endopelvic fascia (EF), and vaginal wall (VW). (EX. 1010, 23:40-65.)

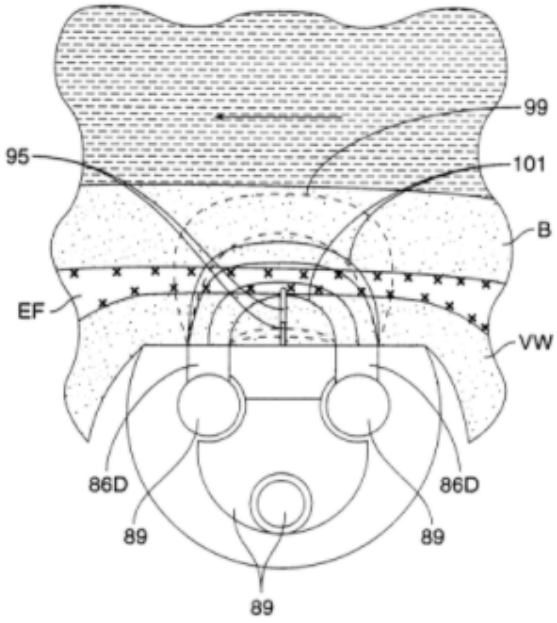

FIG. 12L

Ingle '704 also discloses a vaginal probe where the "cooling system is disposed adjacent to the transmitting element. The cooling system is capable of

maintaining the vaginal wall adjacent the probe below a maximum safe temperature when the fascia is heated by the transmitting element." (EX. 1010, 3:36-50.) Ingle '704 also discloses that the tissue "will preferably be pre-cooled by the surfaces of electrodes 12, 14." (EX. 1010, 15:27-39.) Mosher similarly discloses a cooled electrode vaginal probe including a plurality of cooled electrodes. (EX. 1009, ¶0058; Fig. 6; *see also* EX. 1003, ¶¶55-56.)

11. Claim 11: The method of claim 1, wherein cooling the epithelium comprises cooling it to a temperature between 0 degrees C. and 10 degrees C.

As described above with respect to claim 10, Ingle discloses that the "tissue will preferably be pre-cooled by the surfaces of electrodes 12, 14, generally using an electrode surface temperature of at or above 0 nC. Pre-cooling will substantially decrease the temperature of intermediate tissues 36…. (EX. 1010, 15:27-39.) A POSITA would understand that the use of "an electrode surface temperature of at or above 0 nC" to "substantially decrease the temperature of intermediate tissues" as described in Ingle '704 would lead to the cooling of the epithelium to a temperature between 0 and 10 degrees C. (EX. 1004, ¶¶46-54.)

12. Claim 12: The method of claim 1, wherein the method further comprises cooling of at least some of the target tissue, the cooling of the target tissue having an effect on the therapeutic zone.

Mosher discloses a cooled electrode vaginal probe where the "fluid conduits cool the intervening or intermediate tissue between probe body 54 and

the endopelvic fascia EF, such as the vaginal wall VW as seen in FIG. 6 …. Advantageously, the pre-cooling can inhibit heating of the intervening tissue to a temperature causing surface lesions within the vagina." (EX. 1009, ¶0058; Fig. 6.) In describing it non-invasive treatment probe shown in Figures 6 and 6A, Mosher describes that

> Referring now to FIG. 11, the temperature profile along the center line of a non-invasive, cooled electrode vaginal probe is graphically illustrated at varying depths from the probe/tissue interface. While potentially effective for some patients, the quantity of tissue heated above 70° C. is somewhat limited, being about 12 cubic millimeters in this study. This volume was a result of a treatment method which ends heating as soon as tissue temperature reached 70° C. This limited treatment volume nonetheless provided a cured/improved effectiveness rate, at six months after treatment, of over 50%.

(EX. 1009, ¶0070.)

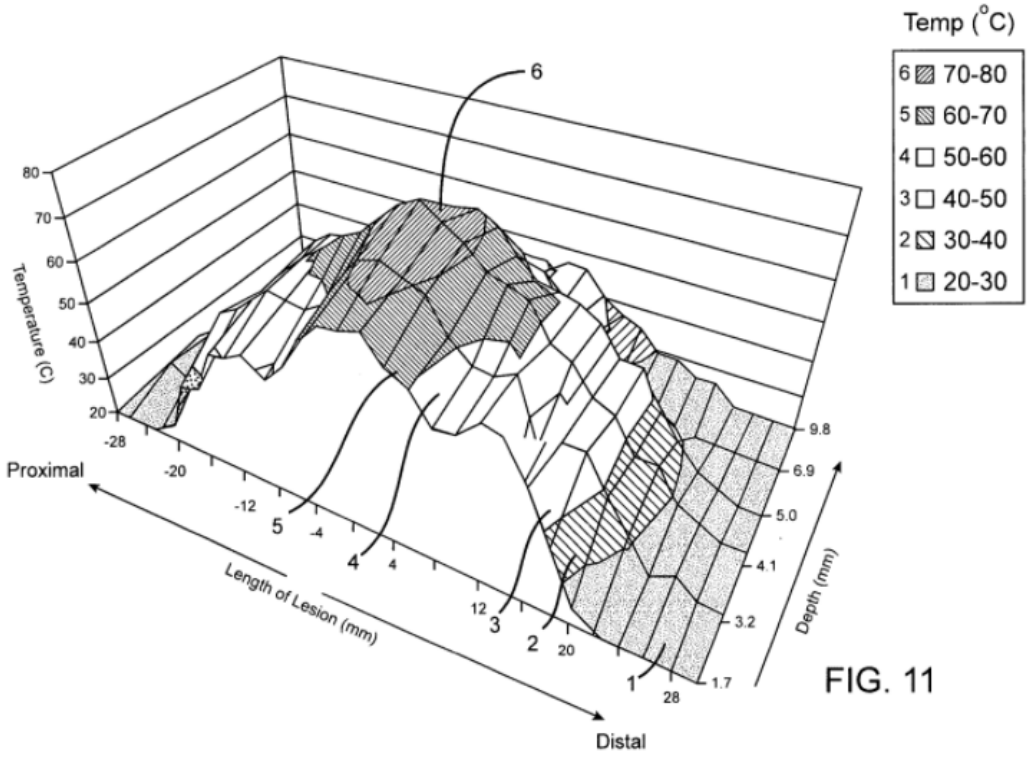

FIG. 11

A POSITA would understand that the precooling cools at least some of the target tissue and affects the therapeutic zone. Additionally, a POSITA would understand that the lower temperature at the shallower depth showing in Figure 11 of Mosher shows the cooling of at least some of the target tissue affecting the therapeutic zone as the temperature would, in the absence of cooling, be higher closer to the contact point with the delivery mechanism at the surface. (EX. 1004, ¶¶46-54.)

Ingle ’704 discloses precooling and describes that the pre-cooling will “substantially decrease the temperature of intermediate tissues 36” and that “[a]t

least a portion of the target zone remains at or near the initial body temperature, as illustrated in FIG. 3B." (EX. 1010, 15:27-39.)

Ingle '704's disclosure that "at least a portion of the target zone remains at or near the initial body temperature" during the pre-cooling acknowledges that at least a portion of the target tissue is cooled, and a POSITA would understand that this cooling would have an effect on the therapeutic zone. Thus the combination of Edwards, Ingle '704, and Mosher discloses this limitation.

13. Claim 13: The method of claim 1, wherein the cooling precedes the heating, and continues during the heating.

As discussed above in Section IX.A.11, Edwards discloses this limitation. Ingle discloses that "[o]nce the tissue has been pre-cooled, the RF current is directed through the tissue between the electrodes to heat the tissue … the electrode surfaces are often cooled throughout the heating process." (EX. 1010, 15:58-65; Figs. 3A-C.) In describing its non-invasive treatment probe shown in figures 6 and 6A, Mosher describes that "Probe 54 makes use of cooling prior to and during RF energy application." (EX. 1009, ¶0069; ¶0058; EX. 1004, ¶49.)

14. Claim 14: The method of claim 1, wherein the cooling is during the heating, and continues after heating.

As discussed above in Section IX.A.12, Edwards discloses this limitation. Ingle '704 describes that "[t]o minimize collateral damage to the adjacent tissues 36 and stunned tissue 38, the cooling system continues to circulate cold fluid through the electrode, and to remove heat from the tissue, after the heating

radiofrequency energy is halted." (EX. 1010, 16:7-12, Figs. 3C-E; EX. 1004, ¶49.)

15. Claim 15: The method of claim 1, wherein the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue.

Ingle '704 discloses that the electrodes will "generally be actively cooled while the electrodes are energized by a RF potential, and between RF pulses. Cooling will preferably also be provided both before and after the heating cycles, and needle mounted temperature sensors will ideally provide direct feedback of the tissue temperature so that selected treatment zone is heated to about 60 nC or more, while heating of the tissues adjacent the electrodes is limited to about 45 nC or less." (EX. 1010, 7:7-15) Thus Ingle expressly discloses a reverse thermal gradient as the temperature adjacent to the electrode is limited to about or less than 45° C while the temperature of the target tissue is heated to about 60° C or more.

Additionally, a POSITA would understand that because Edwards, Mosher, and Ingle all disclose cooling of the epithelium before heating, they necessarily disclose the creation of a reverse thermal gradient from the epithelium to the target tissue. (EX. 1004, ¶¶46-54.) A portion of this reverse thermal gradient can be seen in Figure 11 of Mosher shown below.

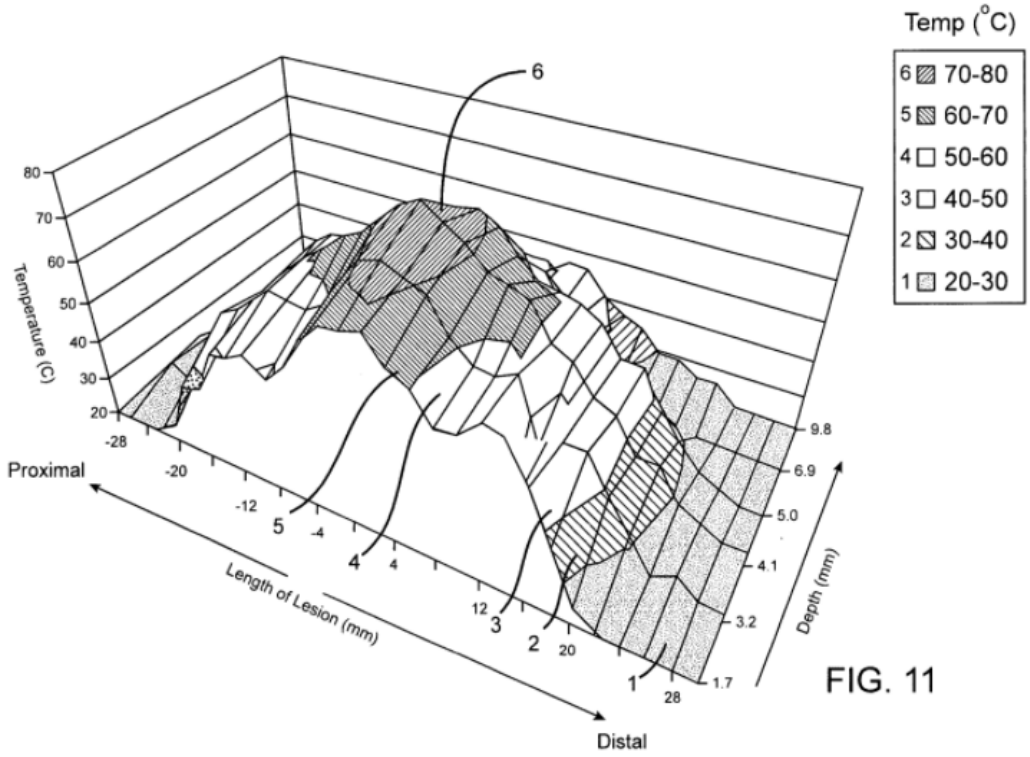

FIG. 11

(EX. 1009, Fig 11.)

16. Claim 16: The method of claim 1, wherein the reverse thermal gradient ranges from a low temperature of 0 degrees C. to 10 degrees C. at the epithelium to a high temperature of 45 degrees C. to 80 degrees C. in the underlying target tissue.

As described above with respect to claim 11, Ingle discloses pre-cooling using an electrode surface temperature of at or above 0 nC. (EX. 1010, 15:27-39.) A POSITA would understand that the use of pre-cooling and "an electrode surface temperature of at or above 0 nC" to "substantially decrease the temperature of intermediate tissues" as described in Ingle would lead to the

cooling of the epithelium to a temperature between 0 and 10 degrees C. (EX. 1004, ¶52; EX. 1003, ¶¶49-52.)

Ingle '704 discloses preferably heating the target tissue to between about 60 nC and 80 nC to cause contraction." (EX. 1010, 12:64-13:2.) Because Ingle '704 discloses a surface temperature of between 0 and 10 degrees Celsius and heating the target tissue to between 60-80 degrees Celsius as described above, it discloses the "reverse thermal gradient ranges from a low temperature of 0 degrees C. to 10 degrees C. at the epithelium to a high temperature of 45 degrees C. to 80 degrees C. in the underlying target tissue" limitation.

Even if this limitation was not expressly disclosed by Ingle '704, it would have been obvious for a POSITA to use the heating and cooling systems described in Ingle to create this specific thermal gradient which falls within the thermal gradient expressly disclosed in Ingle of "at or above 0nc" at the electrode surface" to the preferred temperature of the target tissue of "between 60nc and 80nc" as discussed above. (EX. 1004, ¶¶49, 52.)

17. Claims 17 and 40: The method of claim [], wherein the method comprises contacting the epithelium with a treatment tip at a one or more contact sites during a procedure, the tip comprising an energy delivery element adapted to heat the target tissue.

See discussion of claim 5 above. Section IX.B.5.

18. Claim 18: The method of claim 17, wherein the method is performed during a procedure, and wherein the contacting of any one or more contact sites is repeated one or more times during a procedure.

Mosher describes that the "techniques of the present invention will be effective for controllably and repeatably enhancing the structural support of a wide variety of fascia and other collagenous tissues throughout the body...." (EX. 1009, ¶0046.)

Ingle describes that "the electrode may be energized for 15 secs. and turned off for 15 secs. repeatedly during a heating session so that current is driven from the electrode for about 50% of the duty cycle." (EX. 1010, 7:25-29.) Therefore Ingle is describing the repeated treatment of the contact site during a procedure. Further, even if Ingle, Mosher, and Edwards did not expressly disclose this limitation, it would be obvious to a POSITA to use the treatment methods disclosed in Ingle, Mosher, and Edwards to contact "one or more contact sites is repeated one or more times during a procedure" and therefore, this limitation is obvious in light of the combination of Ingle, Mosher, and Edwards. (EX. 1003, ¶130; EX. 1004, ¶¶66-67.)

19. Claim 19: The method of claim 17, wherein the method includes contacting the tip to the epithelium at a plurality of contact sites during a procedure, moving the tip from site to site, the combined contact sites comprising a treatment area.

As discussed above in Section IX.A.13, Edwards discloses this limitation. Mosher disclosed that "heating may be performed by tip movement of at least a

pair of electrodes supported by the probe body. In such an embodiment, the treatment volume may increase as the tip movement speed decreases." (EX. 1009, ¶0013.) Ingle discloses that "computer feedback may be used to guide the user in the application of ultrasound energy using ultrasound probe" to "help the user dynamically guide the probe to the desired treatment area" to allow the user to "selectively activate the probe so as to treat the target tissues, either manually by the user or automatically under computer control." (EX. 1010, 26:1-17.)

Ingle also describes that stabilizing structures can be used with its vaginal probe to "provide heating to the deep tissues above and to the sides of the vagina." (EX. 1010, 31:30-38.) A POSITA would understand Ingle's description of treating tissue "above and to the sides of the vagina" to entail treatment of a plurality of contact sites. (EX. 1003, ¶130; EX. 1004, ¶¶66-67.)

20. Claim 20: The method of claim 19, wherein any one of the contact sites is contacted one or more times during a procedure.

As described above with respect to claim 18, Edwards, Ingle, and Mosher all disclose the repeated contact of any one or more contact sites during a procedure. Further, even if Ingle, Mosher, and Edwards did not expressly disclose this limitation, it would be obvious to a POSITA to use the treatment methods disclosed in Ingle, Mosher, and Edwards to satisfy the "any one of the contact sites is contacted one or more times during a procedure" limitation in

light of the disclosures of the references and the knowledge of a POSITA. (EX. 1003, ¶130; EX. 1004, ¶¶66-67.)

21. Claim 21: The method of claim 19, the method further comprising repeating the procedure one or more times.

Mosher describes that the "techniques of the present invention will be effective for controllably and repeatably enhancing the structural support of a wide variety of fascia and other collagenous tissues throughout the body….." (EX. 1009, ¶0046.) Therefore, Mosher expressly disclosed the repeatability of the procedure. Thus this limitation is obvious. (EX. 1003, ¶130; EX. 1004, ¶¶66-67.)

22. Claim 22: The method of claim 21, wherein the treatment areas of the one or more procedures may be any of the same treatment area, different treatment areas, or overlapping treatment areas.

Mosher describes that the "techniques of the present invention will be effective for controllably and repeatably enhancing the structural support of a wide variety of fascia and other collagenous tissues throughout the body….." (EX. 1009, ¶0046.) Therefore Mosher discloses that its treatments may be repeated in multiple procedures and thus Mosher expressly disclosed this limitation. (EX. 1003, ¶130; EX. 1004, ¶¶66-67.)

23. Claim 23: The method of claim 1, wherein the target tissue heating includes heating submucosa and muscularis below a mucosal epithelium.

As discussed above in Section IX.A.14, Edwards discloses this limitation. Mosher also describes that its method can be used to heat a variety of tissues

including the submucosa and muscularis below a mucosal epithelium, including the "lamina propria—the dense connective tissue layer just under the epithelium." (EX. 1009, ¶0048.) Ingle discloses a method utilizing a vaginal probe where "the target tissue will be raised to a temperature of about 60 nC or more, while the intermediate tissue remains at or below a maximum safe temperature of about 45 nC." (EX. 1010, 8:39-44) Figure 11 of Mosher shows heating of the tissue at a depth of 1.7 -5mm to a temperature of at least 60 degrees Celsius. A POSITA would understand that because at least a portion of the submucosa and muscularis fall within this range, Mosher discloses this limitation. Therefore, Edwards, Mosher, and Ingle '704 all disclose the heating of submucosa and muscularis below a mucosal epithelium. (EX. 1003, ¶¶48-54 (Ingle '704), ¶¶56-58, 64 (Mosher), ¶81 (Edwards); EX. 1004, ¶69.)

Even if it is determined that Edwards, Mosher, and Ingle '704 did not explicitly disclose this limitation, it would be obvious in light of the knowledge of a POSITA. Each of the references discloses a vaginal probe for heating the target tissue underlying mucosal epithelium. Given the nature of heat transfer, the heating of the target tissue to correct urinary incontinence also includes the heating of the submucosa and muscularis below a mucosal epithelium, which are closer to the probes that are providing the heating than the target tissue. (EX. 1003, ¶¶118, 120.)

24. Claim 24: The method of claim 1, wherein the heating does not modify a mucosal epithelium of the genital tissue.

As described with respect to claim 23, Ingle '704 discloses that the "vaginal mucosa" is protected by the cooled probe and that it remains at or below a maximum safe temperature of about 45 nC. (EX. 1010, 20:59-63.) A POSITA would understand that protecting the vaginal mucosa and keeping it below 45 degrees Celsius means that the method does not modify a mucosal epithelium of the genital tissue. Thus this limitation is obvious. (EX. 1004, ¶¶49-50; EX. 1003, ¶¶36, 49, 129.)

25. Claim 25: The method of claim 1, wherein remodeling comprises contracting target tissue.

As described above with respect to claim element 1(c), the remodeling of the target tissue is a natural phenomenon that necessarily occurs based on the application of RF energy to the target tissue and therefore Edwards, Ingle '704, and Mosher necessarily disclose this limitation. (*See* IX.A.1.c *supra*.)

Mosher describes that its technique "will often cause contraction of the collagenous tissue." EX. 1009, ¶0045; ¶0066. Ingle describes that its method "relies on inducing controlled shrinkage or contraction of a support tissue of the body, typically being a collagenated tissue such as fascia, ligament, or the like. (EX. 1010, 11:8-24.) Thus this limitation is obvious. (EX. 1003, ¶¶34, 38, 48, 55, 57; EX. 1004, ¶¶32, 39-41, 69.)

26. Claim 26: The method of claim 1, wherein remodeling comprises tightening the introitus.

As discussed above in Section IX.A.16, Edwards discloses this limitation. Ingle '704 describes the treatment of various tissue structures to treat urinary incontinence including treatment of "the urethral wall, the bladder neck, the bladder, the urethra, bladder suspension ligaments, the sphincter, pelvic ligaments, pelvic floor muscles, fascia, and the like." (EX. 1010, 11:8-24.)

In light of Ingle's disclosure of the heating of the vaginal wall to treat urinary incontinence, and given what was known of the dimensions and spatial relationship of the urethra and vaginal tissues, a POSITA would have understood that Ingle '704's method could be used to tighten the introitus. (EX. 1010, 30:66-31:4; EX. 1003, ¶51; EX. 1004, ¶30.) Mosher also describes that its method can be used to heat a variety of tissues including the submucosa and muscularis below a mucosal epithelium. (EX. ¶1009, ¶0048; EX. 1003, ¶59, 68.)

It was well known that tissue underlying non-mucosal epithelial layers was also susceptible to RF remodeling. A POSITA would understand that the method of treatment to tighten underlying tissue through the internal tissue of the vagina described in Edwards, Mosher, and Ingle '704 could similarly be applied to tighten the tissue under the "introitus" and thus this claim is obvious in light of Edwards, Mosher, and Ingle '704. (EX. 1004, ¶70-71, 74; EX. 1003, ¶68.)

27. Claim 27: The method of claim 1, wherein remodeling comprises tightening the vagina.

Edwards explicitly discloses this limitation. *See* section IX.A.17 *supra*.

28. Claim 28: The method of claim 1, wherein remodeling comprises denaturing collagen.

As described above with respect to claim element 1(c), the mechanism of the remodeling of the target tissue is a natural phenomenon that necessarily occurs based on the application of energy to the target tissue and this element is necessarily met by the method taught by Edwards. (*See* Section IX.A.1.c *supra*.)

Mosher explicitly describes that "RF heating will typically induce collagen shrinkage … [o]ver about two weeks, type III collagen will replace the **denatured collagen….**" (EX. 1009, ¶0066.)

Ingle '704 describes that its disclosed methods lead to "tissue contraction" by way of "controlled heating of the tissue by affecting the collagen molecules of the tissue. Contraction occurs as a result of heat-induced uncoiling and repositioning of the collagen β-pleated structure. By maintaining the times and temperatures set forth below, significant tissue contraction can be achieved without substantial collateral tissue damage." (EX. 1010, 11:25-32; EX. 1003, ¶¶ 32-33, 50-51, 69; EX. 1004, ¶¶24, 27, 29, 39-41.)

29. Claim 29: The method of claim 1, wherein remodeling comprises tightening collagen-rich sites in the target tissue.

See claim 28 above. *See supra* at section IX.B.28.

30. Claim 30: The method of claim 1, wherein at least some of the remodeling occurs during the heating.

See claim 28 above. *See supra* at section IX.B.28.

31. Claim 31: The method of claim 1, wherein at least some of the remodeling occurs after the heating.

See claim 28 above. *See supra* at section IX.B.28.

32. Claim 32: The method of claim 31, wherein the remodeling after the heating is by a depositing of collagen in the target tissue.

See claim 28 above. *See supra* at section IX.B.28.

33. Claims 34 and 42: The method of claim [], wherein heating comprises delivering energy by ultrasound energy.

Edwards describes the use of various energy sources including ultrasound. (EX. 1006, 5:29-33.) Ingle '704 also describes the delivery of ultrasound energy. (EX. 1010, 10:36-38; 24:48-58; EX. 1003, ¶40; EX. 1004, ¶¶43-44.)

34. Claim 35

a. Claim 35a –c:

Claims 35a-c are identical to claims 1a-c, and thus for the reasons described above in Section IX.A.23.a-c., Edwards, Mosher, and Ingle disclose these limitations.

b. Claim 35d: wherein the heating includes heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock.

As discussed above in Section IX.A.23.b., Edwards discloses this limitation. Mosher describes that "it may be advantageous to distribute the treatment volume along the patient's lateral orientation while limiting the length of treatment along the axis of the patient's urethra." (EX. 1009, ¶0074.) Mosher describes a treatment region with a "width of about 25mm and a length of about 15mm" (EX. 1009, ¶0074.) According to the '511, "an element of about 1cm width requires about 10 contact sites to treat a 300 degree arc." (EX. 1001, 3:22-27.) Thus the 60 degree portion between 11 o'clock and 1 o'clock is approximately 2cm wide. Therefore, Mosher's description of a treatment area with a width of about 2.5cm would necessarily treat tissue within the 1 o'clock to 11 o'clock portion of the vagina. (EX. 1003, ¶¶60-62.)

Ingle '704 describes that stabilizing structures can be used with its vaginal probe to "provide heating to the deep tissues above and to the sides of the vagina." (EX. 1010, 31:33-39.) Ingle '704's description of tissue "to the sides of the vagina" would necessarily treat tissue within the 1 o'clock to 11 o'clock portion of the vagina as the sides of the vagina would fall at the 3 o'clock and 9 o'clock positions. (EX. 1003, ¶53.)

X. CONCLUSION

Based on the foregoing, claims 1-42 of the ’511 recite subject matter that is unpatentable. The Petitioner requests institution of an *inter partes* review to cancel these claims.

Respectfully Submitted,

/James Trainor/

Lead Counsel
James Trainor, Reg. No. 52,297

Back-up Counsel
Dimitrios Drivas, Reg. 32,218

CERTIFICATION OF WORD COUNT UNDER 37 CFR § 42.24(d)

Pursuant to 37 C.F.R. §§ 42.24(d) and 42.24(a)(1), I hereby certify that the number of words in this Petition is 13,965 excluding the table of contents, table of authorities, mandatory notices under § 42.8, certificate of service, certificate of word count, and the listing of exhibits.

Respectfully Submitted,

/James Trainor/
Lead Counsel
James Trainor, Reg. No. 52,297

CERTIFICATE OF SERVICE

I, Tammy Miller, hereby certify that I am a resident of the State of California and over the age of eighteen years, and not a party to the within action; my business address is 3000 El Camino Real, 5 Palo Alto Square, 9th Floor, Palo Alto, California, 94306. On October 20, 2017, I caused the within documents:

- Petition for *Inter Partes* Review of U.S. Patent No. 8,961,511 and accompanying exhibits referenced therein

to be served via Federal Express on the following attorney of record for Patent Owner as listed on PAIR:

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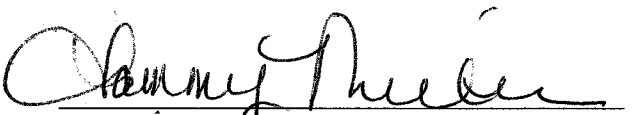
I declare that I am employed in the office of the above captioned attorney at whose direction the service was made.



Tammy Miller

Table of Exhibits for U.S. Patent 8,961,511 Petition for *Inter Partes* Review

Exhibit	Description
1001	U.S. Patent No. 8,961,511 ("'511")
1002	File History of U.S. Patent No. 8,961,511 ("'511FH")
1003	Declaration of Roger Dmochowski, M.D. ("Dmochowski Decl.")
1004	Declaration of Robert D. Tucker, M.D. ("Tucker Decl.")
1005	U.S. Published Application 2004/0000316 ("Knowlton '316)
1006	U.S. Patent No. 6,241,753 (Knowlton '753)
1007	U.S. Patent No. 6,350,276 ("'Knowlton '276")
1008	U.S. Patent No. 6,463,331 ("Edwards")
1009	U.S. Published Application 2004/0193238 ("Mosher").
1010	U.S. Patent No. 6,216,704 ("Ingle '704").
1011	D. Ollivier, "Designer Vaginas," SALON (Nov. 14, 2000), available at http://www.salon.com/2000/11/14/vagina_3/ (last visited March 9, 2017) ("Ollivier").
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