020707 01789 U.S. PTO

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11/704067
02/07/2007

PTO/SB/05 (09-04)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))

Attorney Docket No.	10095-701.201
First Inventor	PARMER, JONATHAN B.
Title	VAGINAL REMODELING DEVICE AND METHODS
Express Mail Label No.	EV 955 597 239 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☒ **Fee Transmittal Form (e.g., PTO/SB/17)**
   (Submit an original and a duplicate for fee processing)
2. ☒ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☒ **Specification** [*Total Pages* 26]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. ☒ **Drawing(s)** (*35 U.S.C.113*) [*Total Sheets* 9]
5. **Oath or Declaration** [*Total Sheets* ___]
   a. ☐ Newly executed (original or copy)
   b. ☐ Copy from a prior application (37 CFR 1.63 (d))
   (for a continuation/divisional with Box 18 completed)
   i. ☐ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
   (if applicable, items a.-c. are required)
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents**
P.O. Box 1450
Alexandria VA 22313-1450

ACCOMPANYING APPLICATIONS PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee _____
10. ☐ **37 C.F.R. 3.73(b) Statement** ☐ **Power of Attorney**
    (when there is an assignee)
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☒ **Return Receipt Postcard** (MPEP 503)
    (Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
    (if foreign priority is claimed)
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other: _____

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*
☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No: ____ / ____
Prior application information: *Examiner* ____ *Art Unit:* ____

19. CORRESPONDENCE ADDRESS

☐ *Customer Number* 66854 *OR* ☐ *Correspondence address below*

Name	DAVID C. COHEN				
Address					
City		*State*		*Zip Code*	
Country		*Telephone*		*Fax*	

Signature	David C Cohen	Date	February 7 2007
Name (Print/Type)	DAVID C. COHEN	*Registration No. (Attorney/Agent)*	43,554

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BTL EX1002
IPR2024-00703
U.S. Patent No. 8,961,511

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL for FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 1425.00

Complete If Known	
Application Number	UNASSIGNED
Filing Date	HEREWITH
First Named Inventor	PARMER, Jonathan B.
Examiner Name	UNASSIGNED
Art Unit	UNASSIGNED
Attorney Docket No.	10095-701.201

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify) : _____

☒ Deposit Account Deposit Account Number: 50-4050 Deposit Account Name: SHAY LAW GROUP LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee($)	Fee($)	Fee($)	Fee($)	Fee($)	Fees Paid ($)
Utility	300	150	500	250	200	100	500.00
Design	200	100	100	50	130	65	____
Plant	200	100	300	150	160	80	____
Reissue	300	150	500	250	600	300	____
Provisional	200	100	0	0	0	0	____

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
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Total Claims		Extra Claims		Fee($)		Fee Paid ($)
57	-20 or HP=	37	x	25	=	925

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Indep. Claims		Extra Claims		Fee($)		Fee Paid ($)
2	- 3 or HP=	0	x	0	=	0

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	Fee ($)	Fee Paid ($)
	____	____

3. APPLICATION SIZE FEE

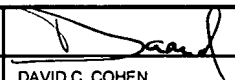
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____	- 100 =	____	/ 50 =	____	(round **up** to a whole number) x		= ____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	____
Other (e.g., late filing surcharge) : _____	____

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 43,554	Telephone 650-212-1700
Name (Print/Type)	DAVID C. COHEN		Date 2/7/07

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SUBMITTED BY

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SLG Docket No.: 10095-701.201

UNITED STATES PATENT APPLICATION

VAGINAL REMODELING DEVICE AND METHODS

Inventor(s): **PARMER**, Jonathan B.
275 Eleanor Drive
Woodside, CA 94062
Citizen of United States of America

Entity: Small Entity

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Express Mail Label: EV 955 597 239 US

VAGINAL REMODELING DEVICE AND METHODS

RELATED APPLICATIONS

[001] This patent application claims priority to U.S. Provisional Application no. 60/743,247, of Parmer, filed on February 7, 2006, entitled "Vaginal rejuvenation treatment device and methods", the disclosure of which is incorporated by reference.

FIELD OF THE INVENTION

[002] This invention relates generally to a method and apparatus for remodeling tissue of the vagina and vulva, such as by the application of radiant energy.

BACKGROUND

[003] The vagina is made up of three layers, a mucosa of stratified squamous epithelial tissue, the submucosa or lamina propria containing vascularized connective tissue and a deeper muscularis, containing smooth muscle. Collagen molecules are produced by cells resident in the these tissues which synthesize three polypeptide chains that wrap around one another to form a triple helix. Collagen is a major type of fibrous protein that is a basic structural element of connective tissue, tendon, cartilage, and bone. Each of the collagen chains is approximately 1000 amino acid units in length, with glycine recurring regularly every third unit, and with proline and hydroxyproline recurring very frequently. Cross-linking occurs between the sides, not the ends, of collagen molecules and is coupled with the amino acid composition to give collagen its great strength. Collagen tissue tightening takes place in a direction parallel to an axis of collagen fibers.

[004] The phenomenon of thermal contraction of collagen begins with a denaturation of the triple helix of the collagen molecule. Partial denaturation of collagen tissue results in a contraction of the collagen-rich spaces and provides a "tightening" effect on the overlaying tissue. Patents relevant to aspects of collagen denaturation and exploitation of this for medical or cosmetic purposes include U.S. Patents 5,919,219 to Knowlton for "Method for Controlled Contraction of Collagen Tissue Using RF Energy" and 5,755,753 to Knowlton for "Method for Controlled Contraction of Collagen Tissue"; and U.S. Patent 5,143,063 to Fellner for "Method of Removing Adipose Tissue".

[005] Further patents and published patent applications include U.S. Patent 6,350,276 to Knowlton for "Tissue Remodeling Apparatus Containing Cooling Fluid"; U.S. Patent 6,387,380

to Knowlton for "Apparatus for Controlled Contraction of Collagen Tissue"; U.S. Patent 6,425,912 to Knowlton for "Method and Apparatus for Modifying Skin Surface and Soft Tissue Structure"; U.S. Patent 6,453,202 to Knowlton for "Apparatus for Tissue Remodeling"; U.S. Pub 2002/0049483 to Knowlton for "Fluid Delivery Apparatus"; U.S. Pub 2003/0212393 to Knowlton for "Handpiece with RD Electrode and Non-Volatile Memory"; U.S. Pub 2003/0236487 to Knowlton for "Method for Treatment of Tissue with Feedback"; and U.S. Pub 2004/0000316 to Knowlton for "Methods for Creating Tissue Effect Utilizing Electromagnetic Energy and a Reverse Thermal Gradient".

[006] The vaginal tissue of women is stretched during vaginal child birth; at least some of the effects of the stretching are permanent and many women have long term medical consequences. Some consequences include physical problems, such as uterine prolapse, cystoceles, urethroceles, enteroceles, rectoceles, stress urinary incontinence, bowel movement problems, for which surgical options are available. Some consequences may include sexual aspects, as may follow from excessive loosening of the vagina and its opening, the introitus. Such loosening typically occurs with the first vaginal delivery, and the loosening tends to increase with subsequent vaginal deliveries. This effective of looseness in this region may include decreased pressure and friction during intercourse, and as a consequence, decreased sexual pleasure for women and their conjugal partners. Some surgical options can be exercised in an attempt to alleviate these problems, but surgical approaches can bring with them a risk of scarring that is entirely counterproductive with regard to the desired result. More generally, these surgical approaches are not highly popular because of the risks associated with an invasive procedure, in a sensitive area, especially when such procedures are considered medically optional.

[007] There is a need for effective approaches to treating a loose vagina and introitus with a non-invasive procedure; accordingly, the object of the present invention to provide apparatus and method for corrective or restorative remodeling of the mucosal surfaces of the vagina, introitus, and vulva.

SUMMARY OF THE INVENTION

[008] Embodiments of the invention include an apparatus for remodeling target tissues, including the lamina propria and the muscularis, underlying the mucosal epithelium of a female genital tissue. The apparatus comprises a hand piece and a treatment tip, the hand piece further supported a by comprehensive upstream electronic system. Embodiments of the treatment tip comprise a connector portion, which connects the tip to the hand piece, a midsection, typically

narrowed, and a distal portion that comprises an energy delivery element. The treatment tip further comprises a housing that defines an internal space. The internal space accommodates a cooling system, with a lumen for conveying a refrigerating fluid, and nozzles, which are adapted to spray refrigerant on to the internal side of the energy delivery element thereby cooling it, such the cooled, in turn, cooling a genital mucosal epithelial surface on contact.

[009] The types of energy delivery element may include a radiofrequency, microwave, or ultrasound delivery embodiments. Some particular embodiments include capacitively coupled RF electrodes, which may by monopolar or bipolar. Monopolar RF electrode-based embodiments may comprise a conductive pad to serve as a return electrode. Bipolar RF-based embodiments may include one or more pairs of electrodes. The electrodes may further comprise thermal sensors that provide feedback control based on local temperature, and may further comprise EEROM chips that identify the treatment tip type or convey configuration parameters of the electrode to the hand piece, or to the larger electronic system.

[010] The energy delivery element and the treatment tip as a whole are adapted to make optimal contact with the genital epithelial surface, when contact and capacitive coupling is occurring between the tip and an epithelial contact site. By optimal contact is meant a contact that best allows a delivery of energy into the target tissue that is broadly uniform across the surface of the contact site, notably without significant distortion along the edges of the contact site. Non-uniform delivery of energy does not serve the remodeling process well, and further may risk damage to the mucosal epithelium. These adaptive configurations include a sidemounted configuration of the energy delivery element, the face of the energy delivery element being substantially parallel with respect to the linear axis of the treatment tip. Other adaptive configurations include a narrowed mid-section of the tip proximal to the distal portion. This configuration allows the energy delivery element at the distal portion of the tip to project outward or forward from its surrounding support structure, thereby allowing the contact between the energy delivery element and the mucosal epithelium to be more accurate, deliberate, and visible, and for the level of contacting pressure to be better controlled by the physician.

[011] Further, the dimensions and configuration of the energy delivery element are adapted to the optimize contact, particularly with the vaginal wall. The width of the energy delivery element is between 0.75 and 1.25 cm. Such a width is sufficient to engage the curved wall of the vagina in a manner that is sufficiently flat and parallel that the quality of contact across the face of the energy delivery element is substantially equal, without increased pressure, closer contact, or

distortion along the edges of the element. Such a close contact allows for a uniform delivery of energy into the underlying target tissue. In some embodiments, the face of the energy delivery element is radially curved (with respect to the longitudinal axis of the tip) within the width of the element so as to create an arc of up to 30 degrees. Such curvature is also adapted to make parallel contact with the vaginal wall. An element of about 1 cm width, per embodiments of the invention, requires about 10 contact sites to radially treat a 300 degree arc inside a vagina, thus a 30 degree arc provides for a good fit against the curve of the vaginal wall and thereby provides a uniform delivery of energy into the target tissue.

[012] In typical embodiments, the length of the energy delivery element is about 1 to about 3 cm in length, in other embodiments it may be as long as about 4 cm. This is a length well adapted to treating the lower aspect of the vagina, wherein treatment by the method comprises contacting the vaginal epithelium in a region that extends from the introitus inward to a position about 3 to 4 cm inward from the introitus. In some embodiments of the invention, the method can by practiced with a single row of parallel contact sites immediately inside the introitus. In other embodiments, the method may include deeper rows, or rows that overlap an intial row, while keeping the contact sites within the lower portion of the vagina.

[013] Embodiments of the invention include methods for remodeling a therapeutic zone of tissue within a target tissue of female genitalia. 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. The target zone of embodiments of the invention does not include deeper tissue, such as endopelvic fascia.

[014] The anatomical areas of the female genitalia treated by embodiment of the invention include the vulva and the vagina, and the introitus, the opening of the vagina. The vulva includes tissue radiating outward from the introitus to Hart's line, where mucosal epithelium gives way to skin on the outer surface of the labia minora. With more specific regard to the vagina, embodiments of the method comprise treating the lower portion of the vagina, a portion extending from the introitus to a location from about 2 cm to about 4 cm inward from the introitus, in other embodiments the location may extends inward as far as about 6 cm. With regard to the circumference of the inner wall of the vagina, a clock-position reference scheme is helpful. The urethra lies next to the anterior wall of the vagina, the location of the vaginal wall nearest the urethra and urethral opening may be considered 12 o'clock. With this reference point,

the target tissue of embodiments of the invention include the approximately 300 degree arc between 1 o'clock and 11 o'clock. Embodiments of the invention do not include treating the approximately 60 degree arc between 11 o'clock and 1 o'clock because the practice of this invention is not directed toward tissue in the vicinity of the urethra.

[015] Embodiments of the method include heating the target zone with radiant energy, typically radiofrequency (RF) energy, but other embodiments may use microwave or ultrasound energy. The 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.

[016] A zone of tissue that is heated within the target tissues to a threshold level, *i.e.*, to a therapeutic temperature that causes remodeling is termed a therapeutic zone. Not all tissue within the target tissue necessarily reaches this threshold level of heat. In some cases, cooling from the treatment tip may penetrate into the target tissue, and in this situation, the presence of cooled tissue may have an effect on the therapeutic zone, by moving it deeper within the target tissue, for example, or by constraining its volume.

[017] Energy delivered from the treatment tip may heat the target tissue to a temperature as high as about 80 degrees C. In some embodiments, therapeutic temperature may range between about 45 degrees C. and about 80 degrees C. In other embodiments, the therapeutic temperature may range between about 50 degrees C. and about 75 degrees C. In still other embodiments, the therapeutic temperature may range between about 55 degrees C. and about 70 degrees C. Heating is a process subject to feedback control during a treatment procedure, so as to keep the temperature within a predetermined temperature range. Feedback may be provided by one or more thermisters (thermal sensors) or impedance monitors. The treatment tip may cool the epithelium to a temperature between about 0 degrees C. and about 10 degrees C. A reverse thermal gradient, accordingly may be represented a low temperature of between about 0 degrees C. and about 10 degrees C. at the mucosal epithelium, and a high temperature of between 45 degrees C. and about 80 degrees C. in the target tissue. During a typical procedure, according to embodiments of the invention, any period of heating is accompanied by cooling; however cooling may also precede heating, and follow heating.

[018] Methods of treatment comprise contacting the treatment tip to a contact site on the mucosal epithelium. The contact site conforms to the dimensions of the treating surface of the

treatment tip. During the course of a single treatment, as for example would occur to a visit to a medical office, typically a plurality of contact sites are treated. During a procedure, a single contact site may be contacted multiple times. The summed total of mucosal contact sites comprises a treatment area. Such an area, comprising multiple contact sites may be recorded on a grid. The method may be applied on more than one occasion; a patient may return to her physician at a later date when the effects of a previous treatment may be evaluated and a treatment repeated. The treatment areas of the separate procedures may be the same, be different, or overlap.

[019] Remodeling genital tissue, per embodiments of the invention may include heat-denaturing collagen within collagen-rich areas in the target tissues. Inasmuch as the overlaying mucosal epithelium is cooled by the method, it does not get heated, and is substantially unaffected by the method. Remodeling of target tissue within the therapeutic zone may occur substantially during the time when the tissue is being heated. Remodeling may also occur substantially after the heating has occurred, for example days or weeks later. Such remodeling comprises biological healing responses to the stress of heating, and such responses may include the deposition of new collagen. Whether by denaturation of existing collagen, or by later deposition of new collagen, the effect of remodeling on the tissue is generally one of tissue contraction or tightening. Thus, embodiments of invention comprise tightening the vagina and the introitus. The effect of vaginal childbirth on the vagina and introitus is a loosening of these tissues. Inasmuch as the method comprises tightening these tissues, the method has a rejuvenating effect in that it remodels the tissue toward the conformation it had prior to having experienced vaginal childbirth.

INCORPORATION BY REFERENCE

[020] All publications and patent applications identified herein are incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[021] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative

embodiments, in which the principles of the invention are utilized, and the accompanying drawings.

[022] **Fig. 1** is a perspective view of an apparatus for applying radiant energy to the target tissue while cooling the epithelium in order to remodel genital tissue, shown are a hand piece and a connected treatment tip.

[023] **Fig. 2** is an exposed perspective view of a treatment tip embodiment.

[024] **Fig. 3** is an exposed side view of a treatment tip embodiment.

[025] **Fig. 4** is frontal cutaway view of the treatment tip, showing cooling nozzles that underlay the energy delivery element that contacts the epithelium

[026] **Fig. 5** shows frontal views of the treatment tip embodiments with (A) a single monopolar electrode, (B) a single bipolar of electrodes, and (C) multiple pairs of bipolar electrodes.

[027] **Fig. 6** shows front perspective views of two embodiments of a treatment tip, treatment side facing up, where **Fig, 6A** shows an electrode with a flat surface, and **Fig. 6B** shows an electrode with a curved surface.

[028] **Fig. 7** is a schematic view of female genitalia depicting the mucosal epithelial surfaces that overlay the target tissue, as well as an orienting clock to provide a circumferential reference scheme for the vagina wall.

[029] **Fig. 8** shows a treatment tip contacting a genital epithelial mucosal surface and the underlying target tissue including the lamina propria and the muscularis.

[030] **Fig. 9** depicts (**Fig. 9A**) a treatment area of a mucosal epithelium comprising multiple contact sites, and (**Fig. 9B**) a representation of the treatment area as a mapping grid.

DETAILED DESCRIPTION OF THE INVENTION

Apparatus

[031] Embodiments of the present invention include an apparatus and method for remodeling female genital tissue by applying heat to a target tissue underlying the surface mucosal epithelium, while cooling the surface epithelium itself. The apparatus and methods build on those of prior art such as those described by Knowlton, including US 2004/0000316, and others cited in

the background, all incorporated by this reference, but include novel features in the apparatus and methods that are configured and adapted to particulars of the female genital treatment site, the mucosal epithelium contacted by the present apparatus, and the underlying target tissue that is remodeled according to aspects of the invention. **Fig. 1** shows an apparatus **1**, which comprises a hand piece **2** and a treatment tip **10**. The hand piece **2** is adapted to be held by an operator, such as a physician, and may include connections to a larger supporting system (not shown), or, in some embodiments, it may be operable as self-sufficient independent device. **Fig. 1** shows the connector portion **15** of the shaft of the treatment tip, the narrow midsection **24**, and the distal portion **28,** which includes the energy delivery element **30**.

[032] **Figs. 2 - 5** provide various views of the treatment tip. **Fig. 2** provides an exposed view from a perspective proximal to the tip, **fig 3** is an exposed view from a side perspective, and **Fig. 4** is a frontal view directed toward the energy delivery element, exposed so as to reveal the nozzles directly below the energy delivery element. **Fig. 5** shows embodiments of the treatment tip that vary with respect to the type of energy delivery element (*i.e.*, radiofrequency electrodes, variously monopolar, a bipolar pair, and multiple biopolar pairs). The treatment tip **10**, depicted in greater detail in **Figs. 2 – 5** includes a housing **26**, a connector portion **15**, and an energy delivery element **30**, which receives input through wire **31 (Fig 3)**. The treatment tip as a whole is designed as a quick connect/disconnect unit with respect to its attachment to the base hand piece **2**. The connection of the treatment tip **10** to the hand piece **2** is by way of the connector portion **15** of the treatment tip. The housing **26** defines an interior space **29** which extends forward from the connector portion **15** to the distal end **28** of the treatment tip. The energy delivery element **30** is side-mounted with respect to the linear axis of the tip, configured to face outward on a side on the distal portion **28** of the tip. By a side-mount, or by mounted so as to face a side of the treatment tip, it is meant that the energy delivery element **30** is configured to be approximately parallel to the linear axis of the shaft **20**.

[033] Between the connector portion **15** and the distal portion **28** of the tip is narrowed mid-section mid-portion **24**, such narrowing or tapering on the same side as that which the energy delivery element **30** faces (narrowing may occur generally in the midsection **24**, but embodiments typically include the narrowing at least on the same side as the energy delivery element). The side-mounted configuration of the energy delivery element **30** and the tapered section **24** of the tip both are adapted to optimize the contact of the energy delivery element to the epithelial surfaces of the female genitalia, in particular to those of the vagina. Details of the female genitalia are described further below. For the purpose of describing the advantage of a side placement **22**

and the tapered section **21** of the shaft, of the canal-like aspect of vagina and entry into it with an instrument that engages the side of the canal are considered. An elongate structure best suited for entry into the vagina, and to make a substantially flat or surface-to-surface parallel contact with the side of the vagina, a side mounted energy delivery unit is advantageous. An advantage conferred by parallel contact is that contact pressure is distributed equally across the contact area, with no pressure biased against any side of the contact site. With such a uniformly pressured contact occurring, so too is energy uniformly directed to underlying target tissue. The narrow mid-section **24** of the shaft further provides a functional advantage to the tip **10** in that it allows the energy delivery element **30** at the distal portion **28** of the tip to project forward from the body of the shaft, such projection allowing the physician operating the apparatus to make contact to epithelium with appropriate pressure, to make the contact more discrete, to make the contacting flat, and to better visualize the contact.

[034] The overall length of the treatment tip **10**, from the base of the connector portion **15** to the foremost point of the distal portion **28** is designed such that the side mounted energy delivery element **30** reaches the innermost region of the vagina that is treated by the tip. Accordingly, embodiments of the tip may have an overall length of between about 2.75 inches and 4.25 inches. Particular embodiments have an overall length of between about 3 inches and about 4 inches. Still more embodiments have an overall length of between about 3.25 inches and about 3.75 inches. This overall length is appropriate for providing the treatment tip access the lower portion of a gently unfolded vagina.

[035] The energy delivery element **30** also has dimensions advantageously adapted to making appropriately flat contact with the vaginal wall. The width of the element, an RF electrode in typical embodiments, in some embodiments is between about 0.7 cm and about 1.3 cm. In other embodiments, the width is between about 0.8 cm and about 1.2 cm. In still other embodiments, the width is between about 0.9 cm and about 1.1 cm. In some embodiments, the length of the energy delivery element **30** is between about 2 and about 3 cm. In other embodiments, the length is between about 2.25 cm and about 2.75 cm. The constraints on the length are related to the advantageous aspect of being able to make contact at particular sites on the mucosal epithelium, to avoid contact with other sites, deeper in the vagina, where it is not desired to make contact, and generally to make contact discretely and efficiently at the desired treatment area. The method of treatment typically comprises treating the vagina at a point no deeper than about 3.5 cm in from the introitus. The constraints on the width of the energy delivery element related, as described above, to the desirability of being able to make a substantially flat contact with the inner aspect of

a curved surface. By constraining the width of the contact site, an increased pressure or closeness of contact that could occur along lengthwise edges is minimized.

[036] In embodiments depicted to this point, the energy delivery element has had a flat configuration. **Fig. 6** shows another embodiment of the treatment tip **10**, where the energy delivery element **30** takes a curvilinear form. In other embodiments the energy delivery element comprises a curved surface such it includes a curvature radially with respect to the linear axis while remaining parallel to the linear axis, the form representing an arc of a cylinder. **Fig. 6A** shows a treatment tip embodiment where the energy delivery element is flat, while the embodiment in **Fig. 6B** has a curved surface, the curve being radial with respect to the linear axis of the tip. The arc of the curvature may be as large as approximately 30 degrees. Some embodiments may include a curvature of about 30 degrees. This 30 degrees of curvature is adapted to fit the curvature of the vaginal wall.

[037] Accordingly, various configurational and dimensional aspects of the treatment tip **10** and the energy delivery element **30** are advantageous for the method of remodeling genital tissue. These features are particularly suited for treating the vaginal wall, but also are appropriate for treating mucosal epithelial surfaces of female genitalia outside the vagina. As described above, these features include (1) the side-facing orientation of the energy delivery element with respect to the linear axis of the treatment tip and its shaft, (2) the overall length of the treatment tip from its proximal end to the distal end, (3) the narrow portion **24** of the tip which allows the energy delivery element to project forward from a background structure, rather than being in contiguous plane with surrounding structure, (4) the surface dimensions of the energy delivery element, particularly the width, which allow for substantially flat contact with the vaginal wall in the case of a flat energy delivery element 30, and (5) in the case of embodiment with a curved energy delivery element, a particularly close fit between the energy delivery element and the vaginal wall is achievable. All such enumerated features contribute to a uniformly-distributed contact between the energy delivery surface and the mucosal epithelium, such uniform fit diminishes the liklihood of edge-biased contact that could harm the epithelium, and affirmatively promotes uniform distribution of energy across the area of site where the energy delivery element contacts the epithelium and through which energy radiates into the underlying target tissue. Uniformity in flux across a surface area promotes an advantageous uniformity, consistency, and predictability in the remodeling response. Further, and equally important, small variation in flux also minimizes occurrence of damage, either to the epithelium or the target tissue, that can occur when large

excursions in energy flux include, as they inevitably do, areas which receive high rates of energy flux.

[038] As seen in **figs. 2 and 3**, the interior space **29** of the tip accommodates a cooling system to cool the energy delivery element, which comprises a cooling lumen **54** for conveying cooling fluid **52** to nozzles **56**. The cooling fluid typically comprises a refrigerant, as exemplified by 1,1,1,2-tetrafluoroethane (R 134A), which is stored in a reservoir (not shown) under pressure, and conveyed through a lumen **54** to nozzles **56**. The nozzles are configured within the interior space **29** in the distal portion **28** or the tip **10** under the inner surface of the energy delivery element **30**. On release of the refrigerant from the nozzles, it sprays onto the interior surface and cools the element as the refrigerant undergoes a liquid to gas transition. The exterior surface of the energy delivery element, when in contact with an epithelial mucosal surface as during the practice of method embodiments of the invention, cools the epithelial surface upon such contact. This surface cooling prevents the build up of heat on the mucosal surface, the energy being delivered by the delivery element passes through the mucosal surface and into the underlying tissue targeted by the invention, which is then heated.

[039] The energy delivery element **30** is may be any of an RF electrode, a microwave emitter, or an ultrasound emitter. Embodiments that include an RF electrode will be described in some detail. The RF electrode, in some embodiments, is a capactive electrode, which capacitively couples to the mucosal epithelium. The RF electrode, without limiting the scope of the invention, may have a thickness in the range of about 0.01 to about 1.0 mm.

[040] The RF electrode **30** has a conductive portion **35** facing the interior space **29** within the treatment tip, and a dielectric portion **36** facing the exterior of the tip. Conductive portion **35** comprises a metal, exemplary metals including copper, gold, silver, and aluminum. Dielectric portion **36** may comprise a variety of different materials including, by way of example, polyimide, Teflon (RTM) and the like, silicon nitride, polysilanes, polysilazanes, polyimides, Kapton and other polymers, antenna dielectrics and other dielectric materials well known in the art. Other exemplary dielectric materials include polymers such as polyester, silicon, sapphire, diamond, zirconium-toughened alumina (ZTA), alumina and the like. Dielectric portion **36** covers the conductive portion **35,** and is disposed between conductive portion **35** and the patient's tissue during treatment. In another embodiment, RF electrode **30** is made of a composite material, including but not limited to gold-plated copper, copper-polyimide, silicon/silicon-nitride and the like. In one embodiment, conductive portion **35** adheres to dielectric portion **36** which can be a

substrate with a thickness, by way of example and without limitation, of about 0.001". This embodiment is similar to a standard flex circuit board material commercially available in the electronics industry. In this embodiment, dielectric portion **36** is in contact with the mucosal epithelium, and the conductive portion **35** is separated from the mucosal epithelium.

[041] Generally, RF electrodes **30** can be either monopolar or bipolar. In the monopolar mode, RF current flows through body tissue from a return electrode which can be in a form of a conductive pad applied to another portion of the patient's body. **Fig. 5** shows various embodiments of electrodes from a facing perspective, for example **Fig. 5A** shows a tip with a monopolar pair of electrodes, **Fig. 5B** shows a bipolar pair, and **Fig. 5C** shows a tip with multiple bipolar pairs. Additionally, the electrode may be equipped with an integrated EEROM (Electrically Erasable Read Only Memory, also known as EEPROM) programmable memory chip at any suitable location within the treatment tip (not shown). Such a chip may provide identifying information or other information about the operational status or configuration parameters of the RF electrode to the system, such parameters may include, by way of example, the type and size of the electrode, the number of times the energy delivery element has been fired, and the like. Additionally, thermisters (thermal sensors) **38** (shown in **Fig. 4**) may be provided at each corner of an RF electrode, or otherwise in close proximity to the electrode, to provide feedback to the system on the temperature at their location.

[042] In some embodiments, the treatment tip as a whole is designed as a single-use disposable component, while the hand piece **2** is typically a reusable instrument. The single-use and disposable aspects of treatment tip **10** are in accord with its designated use in a single procedure, in the context of a female patient having a procedure, per embodiments of the method further described below, in a medical setting. Accordingly, the entirety of construction and components of the treatment tip retain their integrity through sterilization procedures, and the tip is typically packaged singly in a container or a wrap that preserves the sterile integrity of the tip until such time when it is unwrapped and connected to the hand piece **2** in preparation for a treatment procedure. Embodiments of the treatment tip **10** are modular in that they have a common connector portion **12** but may have variations in the shaft portion **20** and energy delivery elements **30** and cooling mechanism components, such as the fluid **52** or nozzles **56**.

Electronic Support System for the Apparatus

[043] The apparatus **1** is included in a larger electronic system (not shown) with features well known in the art. Embodiments comprise a power source, an RF power source in typical

embodiments; it feeds energy to an RF power generator and power flows therefrom to RF electrodes **30.** A multiplexer measures current, voltage and temperature, at the thermal sensors **38** associated with to each RF electrode **30**. The multiplexer is driven by a controller, which can be a digital or analog controller, or a computer with software. When controller is a computer it can include a CPU coupled through a system bus. On the system there may also be a keyboard, disk drive, or other non volatile memory systems, a display, and other peripherals, as are well known in the art. Also coupled to the bus may be a program memory and a data memory.

[044] An operator interface includes operator controls and a display. The controller can be coupled to different types of imaging systems including ultrasonic, thermal sensors **38**, and impedance monitors **39**. Current and voltage are used to calculate impedance. A diagnostic phase can be initially run to determine the level of treatment activity. This can be done through ultrasound as well as other means. Diagnostics can be performed both before and after treatment.

[045] Thermal sensors **38** measure voltage and current as delivered to the desired treatment site; the output for these sensors is used by a controller to control the delivery of RF power, which can also control temperature and power. An operator set level of power and/or temperature may be determined to provide operating limits that will not be exceeded. The controller maintains the set level under changing conditions. The amount of RF energy delivered controls the amount of power. A profile of power delivered can be incorporated in the controller, as well as a preset amount of energy to be delivered. Feedback control can be based on monitoring of impedance, temperature, or other indicators, and occurs either at the controller or at RF generator, if it incorporates a controller. For impedance measurement, this can be achieved by supplying a small amount of non therapeutic RF energy. Voltage and current are then measured to confirm electrical contact.

[046] Circuitry, software and feedback to controller result in full process control and are used to change power, the duty cycle, monopolar or bipolar energy delivery, flow rate and pressure ,and can also determine when the process is completed through time, temperature and/or impedance. These process variables can be controlled and varied in accordance with tissue temperature, as monitored at multiple sites on contacting exterior surface **34**, as well as by monitoring impedance to current flow at each RF electrode **39**, indicating changes in current carrying capability of the tissue during the process. Further, a controller can provide multiplexing, monitor circuit continuity, and determine which RF electrode **30** is activated.

[047] Thermal sensors **38** can be thermistors, which have a resistance that varies with temperature. An analog amplifier can be a conventional differential amplifier circuit for use with thermistors and transducers. The output of the analog amplifier is sequentially connected by an analog multiplexer to the input of an analog digital converter. The output of the amplifier is a voltage, which represents the respective sensed temperatures. The digitized amplifier output voltages are supplied by analog to digital converter to a microprocessor, which calculates the temperature or impedance of the tissue. In some embodiments, the microprocessor can be a type 6800, however, any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature. The microprocessor sequentially receives and stores digital representations of impedance and temperature. Each digital value received by the microprocessor corresponds to different temperatures and impedances.

[048] Calculated temperature and impedance values can be indicated on a display. Alternatively, or in addition to the numerical indication of temperature or impedance, calculated impedance or temperature values can be compared by the microprocessor with temperature and impedance limits. When the values exceed predetermined temperature or impedance values a warning can be given on the display and additionally, the delivery of RF energy to its respective electrode can be decreased or multiplexed to another electrode. A control signal from the microprocessor can reduce the power level by the RF generator, or de-energize the power delivered to any particular electrode. The controller 68 receives and stores the digital values that represent temperatures and impedances sent. Calculated surface temperatures and impedances can be forwarded by the controller to the display. If desired, the calculated surface temperature of the vaginal mucosal tissue layer is compared with a temperature limit and a warning signal can be sent to the display. Similarly, a control signal can be sent to the RF power source when temperature or impedance values exceed a predetermined level.

Methods

[049] Embodiments of the invention provide a non-surgical method and apparatus for remodeling the tissues of the female genitalia by applying heat to a target tissue underlying the surface mucosal epithelium, while cooling the surface epithelium itself. Typically, the tissues are those of women who have had one or more vaginal births, and whose tissues have been stretched by giving birth. 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. Particular features or areas of genital tissue (**Fig. 7**) having an epithelial surface

include the vulva and the vagina **112**, and the introitus **114**, the entrance to the vagina and a demarcation between the internal and external genitalia.

[050] The heating of target tissue, per embodiments of this invention includes raising the temperature of the target tissue to as high as 80 degree C. Temperature is raised to a level that is therapeutic, *i.e.*, to a temperature that causes remodeling, as described herein. That portion of the target tissue which attains the therapeutic temperature, for a sufficient time, is termed the therapeutic zone within the target tissue. The therapeutic temperature, in some cases may be only as high as 45 degrees C, or as high as 80 degrees C. The inventive method, therefore includes heating target tissue to as high as 80 degrees C. Per embodiments of the invention, target tissue may be heated to a temperature between about 45 degrees C and about 80 degrees C. In other embodiments, the target tissue temperature may be heated to a temperature between about 50 degrees C and about 75 degrees C. In still other embodiments, the target tissue may be heated to a temperature between about 55 degrees C and about 70 degrees.

[051] The vagina is a fibromuscular tube, lined with stratified squamous epithelium, that connects the external and internal organs of the female reproductive system. The vagina runs obliquely upwards and backwards at an angle of about 45 degrees between the bladder in front and the rectum and anus behind. In an adult female the anterior wall is about 7.5 cm long and the posterior wall is about 9 cm long. The difference in length is due to the angle of insertion of the cervix through the anterior wall. More particularly with regard to the vagina, embodiments of the invention comprise remodeling the lower portion of the vagina, the lower portion representing, the lower being that portion immediately inward from the introitus. Thus, according to embodiments of the invention, the portion of the vagina to be treated is a region between the introitus and a position located no further than about 3 to about 4 cm inward from the introitus. 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. Using this orientation, embodiments of the invention comprise treating and remodeling the vagina over the 300 degree circumferential arc from about 1 o'clock to about 11 o'clock.

[052] The mucosal epithelium of vulvar tissue outside the vagina and the introitus includes the labia minora, or that portion of the vulva extending outward from the introitus to Hart's line, the boundary where mucosal epithelium and labial skin meet (**Fig. 7**). The mucosal epithelium and the skin, while contiguous, are embryologically and histologically distinct. The portion of the

female genitalia that are covered by epithelium is also substantially defined by the bounds of the vestibule, which extends outward or down from the hymenal ring at the top of the vagina, radially beyond the introitus, including the portion of labia minora located within Hart's line **120**. 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. These described target tissue layers below the epithelium overlay deeper tissues, including endopelvic fascia, which are not a target tissue for embodiments of the present invention.

[053] The remodeling of the connective tissue underlying the mucosal epithelial surfaces does not substantially affect the epithelium itself. The method and apparatus, as provided by embodiments of the invention are non-invasive and substantially non ablative of genital issue. The nature of the engagement between the apparatus and genital tissue is that of contacting a treatment tip to an epithelial surface of the genital tissue. Through such contact, the apparatus delivers heat to underlying tissue, while preventing the heating of the surface epithelium by cooling it.

[054] In a particular embodiment, the invention provides a method and apparatus for remodeling vulvar and vaginal target tissue through the use of a radiofrequency (RF) energy source **30** (see the energy delivery element of **Figs. 1 -5**) through the vaginal or vulvar mucosal epithelial tissue and to the respective underlying layers that are the target tissue of embodiments of the invention. Other embodiments may make use of other forms of energy, such as microwave or ultrasound. Impedance through mucosal epithelium is lower than that of skin, thus less energy is required to cause heating than would be required were skin being treated rather than mucosal epithelium.

[055] The application of energy to the underlying connective tissue creates heat in the targeted tissue, and the heat is understood to have an immediate or nearly immediate effect of denaturing or partially-denaturing collagen in the tissue, this denaturation of collagen being a factor in the tissue remodeling. In other embodiments of the invention, 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.

[056] As provided by embodiments of the invention, remodeling of genital tissue, whether by denaturation of collagen in the tissue, or by subsequent deposition of new collagen in the tissue, results in a tightening of genital tissue, particularly that of the vagina and the introitus. A consequence of the heating of the target tissue may include a melting or denaturing of preexisting collagen in the tissue, which may reduce or compact the volume occupied by the collagen, the effect of which is to tighten surrounding tissue A longer term biological consequence of the heating may include a healing process in which there is an increase in the rate of cellular production and deposition into the extracellular space. Both types of responses, the near-immediate response of pre-existing collagen, and the longer term increased amount of collagen are understood to contribute to an overall tightening of the target tissue.

[057] The tightening of tissue is such that the remodeled genitalia assumes a rejuvenated form, a conformation of the genitalia as they were before having being stretched by vaginal birth. Remodeling of genital tissue, as practiced by embodiments of this invention, may be understood variously as contracting or tightening of tissue, this may apply to the vulva, the vagina, and the introitus. Genitalia rejuvenated by practice of embodiments of the invention, by virtue of the greater tightness of the remodeled vagina and introitus, for example, provide for increased pressure and friction during sexual intercourse, and accordingly may provide greater sexual satisfaction for a woman with such remodeled genitalia and for her sexual partner.

[058] Embodiments of the invention provide a method and apparatus for creating a reverse thermal gradient that utilizes one or more RF electrodes **30**, to convey energy that manifests as heat in the target tissue, and a mechanism to cool the epithelial surface above the targeted underlying layers. A purpose of cooling the epithelial surface is to protect it from potentially damaging effects of excess heat that would accumulate in the absence of cooling. The epithelial surface is thus a conduit for energy passing through to underlying layers, but the energy does not manifest in the form of increased temperature at the epithelial surface. As such, the epithelium itself is not damaged or substantially modified by the method. Such protection from heating may derive both from the heat-sink aspect of a cooled body, as well as an increase in tissue impedance that is associated with cooled tissue.

[059] In some embodiments, the cooling mechanism of the apparatus includes a lumen **54** adapted to accommodate a cooling fluid conveyed to nozzles **56**, which cool the energy delivery

element **30** of treatment tip **10** of the apparatus. Embodiments of the method thus provide for contacting a contact site on a genital epithelial surface, the tip having the capability both to cool the surface epithelium and to heat the underlying tissue. The cooling fluid cools the treatment tip of the apparatus, as provided by embodiments of the invention; in turn, the surface of the cooled treatment tip cools the surface of the mucosal epithelium that the treatment tip contacts. As provided by embodiments of the invention, the epithelial surface may be cooled to a temperature range of about 0 degrees C to about 10 degrees C. As energy from the tip passes through the mucosal epithelial surface, the underlying soft tissue may be heated to a temperature range of about 45 degrees C. to about 80 degrees C. Thus, a reverse thermal gradient is created, with a lower temperature at the mucosal epithelium, and a higher temperature in the underlying tissue.

[060] In some embodiments the method includes feedback control mechanisms to control the heating such that temperature does not exceed a predetermined level. As provided by embodiments of the apparatus, the feedback is provided to RF delivery by thermal or impedance sensors. In other embodiments, the method may be controlled by delivering a predetermined total of amount of energy. In some embodiments the method may be controlled by delivering an amount of energy within a predetermined amount of time.

[061] More specifically within the target tissue of the invention, a treatment zone may be defined, where the heat is particularly focused, or where the heat reaches a threshold temperature sufficient to cause remodeling. Such a treatment zone may be centered at a particular depth below the epithelium, and the treatment zone may have a particular range of depth, it may, for example be broadly distributed across the full range of the lamina propria and muscularis, or it may occupy a relatively flat zone. In some embodiments of the invention, cooling is allowed to proceed into the target tissue itself, below the epithelial surface, to form a cold-protected tissue zone. The cooling of a portion of the target tissue may have an effect on the therapeutic zone, such that the depth and range of the therapeutic zone may be modulated or shifted with respect to where it would be absent such cooling of a portion of the target tissue. If cooling penetrates to a given level in the target tissue to create a cold-protected zone, for example, the therapeutic zone may be pushed deeper into the target tissue. Further, lower temperature in general tends to contain the dissemination of heat, thus focusing the therapeutic zone into a narrower range of depth.

[062] In typical embodiments of the invention, the method provides for surface cooling coincident with the time that heat is being delivered to underlying tissue. In some embodiments,

in addition to cooling the surface while heating the underlying tissue, the method includes a period of cooling before the application of heat. In other embodiments, the method includes a period of cooling after the application of heat. In still other embodiments, the method includes cooling both before and after the application of heat.

[063] As shown in **Fig. 8**, a treatment tip **10** of the apparatus contacts a contact site **102** on the genital epithelium **100**, and such contact creating a site on the epithelium corresponding to the surface area within the outline of the profile of the treatment tip. **Fig. 8** shows the distal end **28** of the tip, with the energy delivery element **30** (shown by dotted lines) facing toward the mucosal epithelium. Also shown below the contact site **102** (with dotted lines) are target tissue layers, the lamina propria **104** and the muscularis **106**. In typical embodiments of the invention, the method includes making contact with the epithelium, delivering energy, and then moving the treatment tip to another contact site, and delivering energy there. A procedure, such as would take place in a visit to a medical office, would typically include a radial sequence of contacting the epithelium within the vagina and/or contacting other sites outside the vagina. During the same procedure, the treatment tip may be returned to the same contact point multiple times. The circumference of the lower portion of an unfolded vagina, gently stretched as it is during the practice of this method, is approximately 12 cm. Accordingly, with a treatment tip of about 1 cm in width, a series of about 10 contact sites allows completion of an 300 degree arc of the circumference, between the 1 o'clock and 11 o'clock positions. These dimensional considerations underlie the rationale for an embodiment of the treatment wherein the surface of the energy delivery element has a curvature of about 30 degrees, each contact site accounting for about 10% of the 300 degree arc.

[064] **Fig. 9A** is a schematic representation of a vagina **122**, with the introitus **124** forming the entrance to the vagina. In a typical procedure, the treatment tip would contact various contact sites in the lower vagina, just inside the introitus. As shown in **Fig. 9A**, an accumulated set of contact sites **102** that have been treated by the treatment tip, and they collectively comprise a treatment area on the vaginal epithelium. In some embodiments of the method, a single radial row of sites is contacted, as shown in **Fig. 9A**. In other embodiments, one or more further rows could be included in a procedure, extending further into the vagina, so long as the treatment area remains in the lower portion of the vagina. Contact sites, per embodiments of the invention may include regions outside of the vagina, but within the bounds of Hart's line. Outside of the vagina, the treatment area will develop with a flatter aspect, in contrast to the inner radial configuration characteristic of the vaginal contact sites. As further provided by embodiments of the method and shown **Fig. 9B**, the contact sites may be recorded on a grid **115**, the completed grid thus being a

mapped representation of the treatment area, which can be referred to during evaluation of the remodeling at some time point following the treatment. As shown, the treatment grid may contain reference points with respect to the circumferential location on the vagina, as provided, for example, by the clock dial scheme.

[065] As summarized above, a given treatment area will be treated during a single procedure during an office visit. The method further includes repetitions of such procedures, typically on another day, when the effects of the previous procedure may be evaluated. From such evaluation, judgment may be made with regard to re-treating a particular previously-treated area, or proceeding to treat other areas. Thus, as provided by embodiments of the method, one or more procedures during follow-up visits may variously include treating the same treatment area, treating an entirely different treatment area, or treating an overlapping treatment area, partially the same as previous area, and partially different.

[066] Other variations of treatment tip design and associated methods can be employed to achieve the objectives of the invention without departing from the scope of the invention, as will be appreciated by those skilled in the art. The shape and dimensions of the tip can also be adjusted, as desired, to enhance the effectiveness of the treatment taking into consideration physiological and anatomical information. While various embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Although the description has offered the theory that collagen denaturation underlies the remodeling of tissue brought about by practicing the invention, and theory has also been offered that tissue remodeling may occur as a result of the deposition of collagen by connective tissue at a time after the inventive procedure has been performed. Some theory has also been offered to explain the nature of the protection afforded to the mucosal epithelium by cooling it. Such theories has been offered to simply as possible theories of how the invention works and as an aid in describing the invention, however, it should be understood that such theories and interpretation do not bind or limit the claims with regard to tissue remodeling brought about by the practice of the invention. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the scope of the invention, methods and structures within the scope of the invention includes equivalents.

Claims

What is claimed is:

1. A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue, the method comprising:

   heating the target tissue, and

   remodeling the therapeutic zone of target tissue.

2. The method of claim 1, wherein heating the target tissue comprises heating it to a temperature between about 45 degrees C. and about 80 degrees C.

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

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

5. The method of claim 1, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

6. The method of claim 5, wherein the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy.

7. The method of claim 1, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

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

9. The method of claim 7, wherein the feedback control is provided by one or more impedance monitors.

10. The method of claim 1, wherein the method further comprises cooling the epithelium.

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

12. The method of claim 10, wherein cooling the epithelium comprises cooling it to a temperature between about 0 degrees C. and about 10 degrees C.

13. The method of claim 10, 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.

14. The method of claim 10, wherein the cooling precedes the heating, and continues during the heating.

15. The method of claim 10, wherein the cooling is during the heating, and continues after heating.

16. The method of claim 10, wherein the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue.

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

18. The method of claim 1, 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.

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

20. The method of claim 18, 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.

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

22. The method of claim 20, the method further comprising repeating the procedure one or more times.

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

24. The method of claim 1, wherein the female genitalia includes the vulva and the vagina.

25. The method of claim 1, wherein the female genitalia includes the introitus.

26. The method of claim 1, wherein the female genitalia includes a portion of the vagina extending from the introitus inwardly to a location from about 1 cm to about 3.5 cm in from the introitus.

27. The method of claim 1, wherein the female genitalia includes a portion of the vagina circumferentially around its wall from about 1 o'clock to about 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock.

28. The method of claim 1, wherein the female genitalia includes a portion radiating outward from the introitus to Hart's line.

29. The method of claim 1, wherein the female genitalia includes the mucosal surfaces of the labia minora.

30. The method of claim 1, wherein the target tissue includes submucosa and muscularis below the mucosal epithelium.

31. The method of claim 1, wherein the heating does not substantially modify the mucosal epithelium of the genital tissue.

32. The method of claim 1, wherein remodeling comprises contracting target tissue.

33. The method of claim 1, wherein remodeling comprises tightening the introitus.

34. The method of claim 1, wherein remodeling comprises tightening the vagina.

35. The method of claim 1, wherein remodeling comprises denaturing collagen.

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

37. The method of claim 1, wherein remodeling comprises rejuvenating the genital tissue toward a conformation like that which the genitalia had prior to experiencing vaginal birth.

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

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

40. The method of claim 39, wherein the remodeling after the heating is by a depositing of collagen in the target tissue.

41. An apparatus for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue, the apparatus comprising:

a treatment tip, the tip comprising:

a shaft comprising a longitudinal axis,

an energy delivery element, and

a cooling mechanism,

wherein the energy delivery element is adapted to contact the epithelium, and

wherein treatment tip is configured to deliver energy from the energy delivery element to the target tissue in a uniform manner.

42. The apparatus of claim 41, wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft.

43. The apparatus of claim 41, wherein the energy delivery element is configured to have a width of about 0.75 cm to about 1.25 cm.

44. The apparatus of claim 41, wherein the energy delivery element is configured to have a length of about 1 cm to about 3 cm.

45. The apparatus of claim 41, wherein the energy delivery element is configured to be flat.

46. The apparatus of claim 41, wherein the energy delivery element is configured to have a radial curvature with respect to the longitudinal axis of the shaft.

47. The apparatus of claim 46, wherein the radial curvature is an arc of up to 30 degrees.

48. The apparatus of claim 46, wherein the radial curvature is an arc of about 30 degrees.

49. The apparatus of claim 41, wherein the shaft is configured to include a narrow portion proximal to the energy delivery element, and wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft, such that the energy delivery element projects forward from the shaft.

50. The apparatus of claim 41, wherein the cooling system is configured to cool the energy delivery element.

51. The apparatus of claim 41, wherein the cooling system comprises cooling fluid and at least one nozzle, the nozzle configured to spray the cooling fluid on the energy delivery element.

52. The apparatus of claim 41, wherein the energy delivery element comprises at least one capacitively coupled electrode.

53. The apparatus of claim 41, wherein the energy delivery element comprises at least one radiofrequency (RF) electrode.

54. The apparatus of claim 53, wherein the RF electrode is a monopolar electrode.

55. The apparatus of claim 53, wherein the at least one RF electrode is a bipolar electrode pair.

56. The apparatus of claim 53, further comprising at least one thermister located in close proximity to the electrode.

57. The apparatus of claim 53, further comprising a programmable memory chip.

VAGINAL REMODELING DEVICE AND METHODS

ABSTRACT

This invention relates generally to apparatus and methods for tightening tissue of the female genitalia by heating targeted connective tissue with radiant energy, while cooling the mucosal epithelial surface over the target tissue to protect it from the heat. Embodiments include a treatment tip that comprises both an energy delivery element and a cooling mechanism. As the treatment tip contacts the epithelial mucosa, the tip cools the mucosa by contact, and delivers energy through the epithelium to the underlying tissue, thereby creating a reverse thermal gradient. The effect of the applied heat is to remodel genital tissue by tightening it. Such remodeling may include a tighter vagina and a tighter introitus. The tightening may be a consequence of thermal denaturation of collagen as well as a longer term healing response in the tissue that includes an increased deposition of collagen.

SHAY LAW GROUP LLP - Express Mail Label: EV 955 597 239 US
SLG Docket No.: 10095-701.201
Inventor(s): PARMER, Jonathan B.

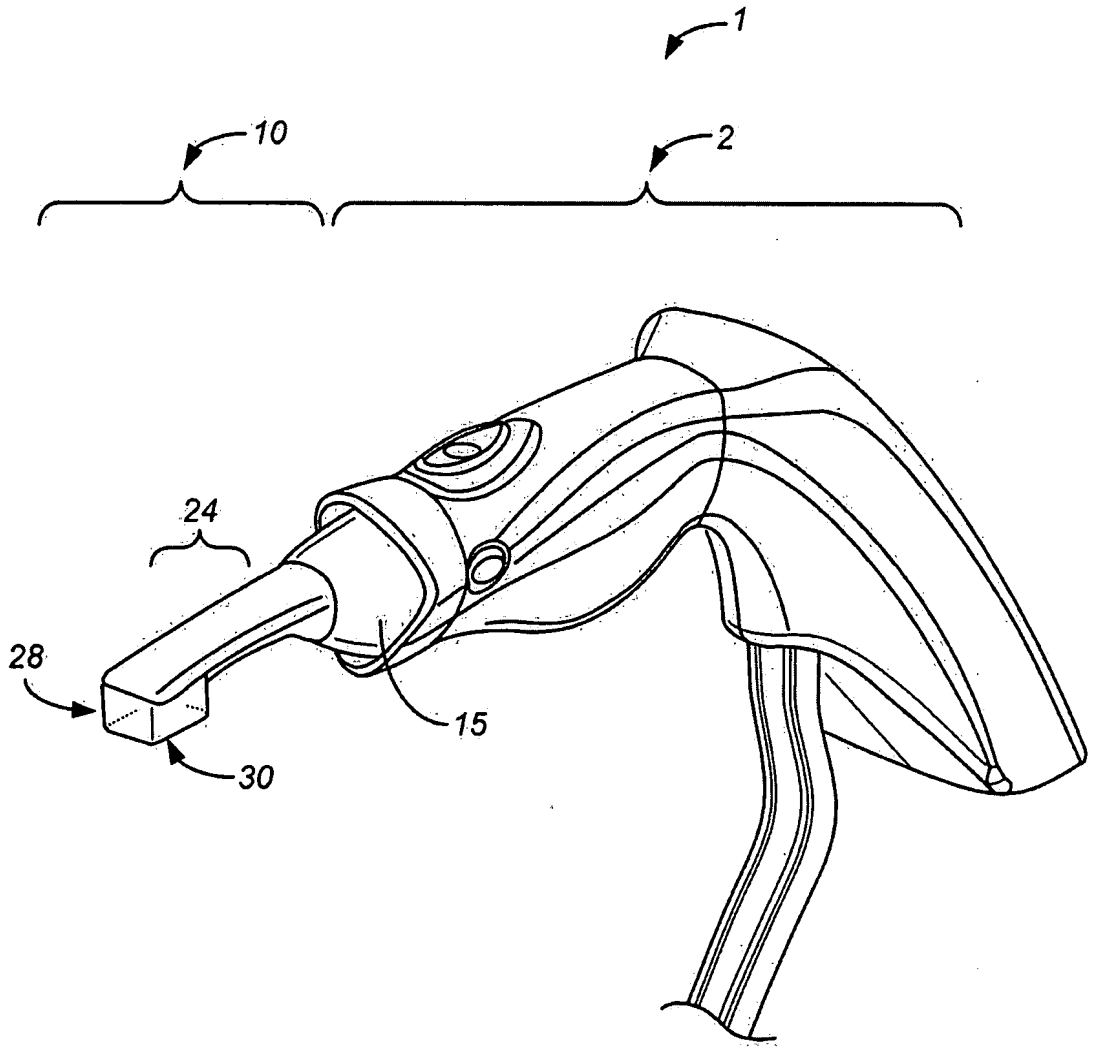


FIG. 1

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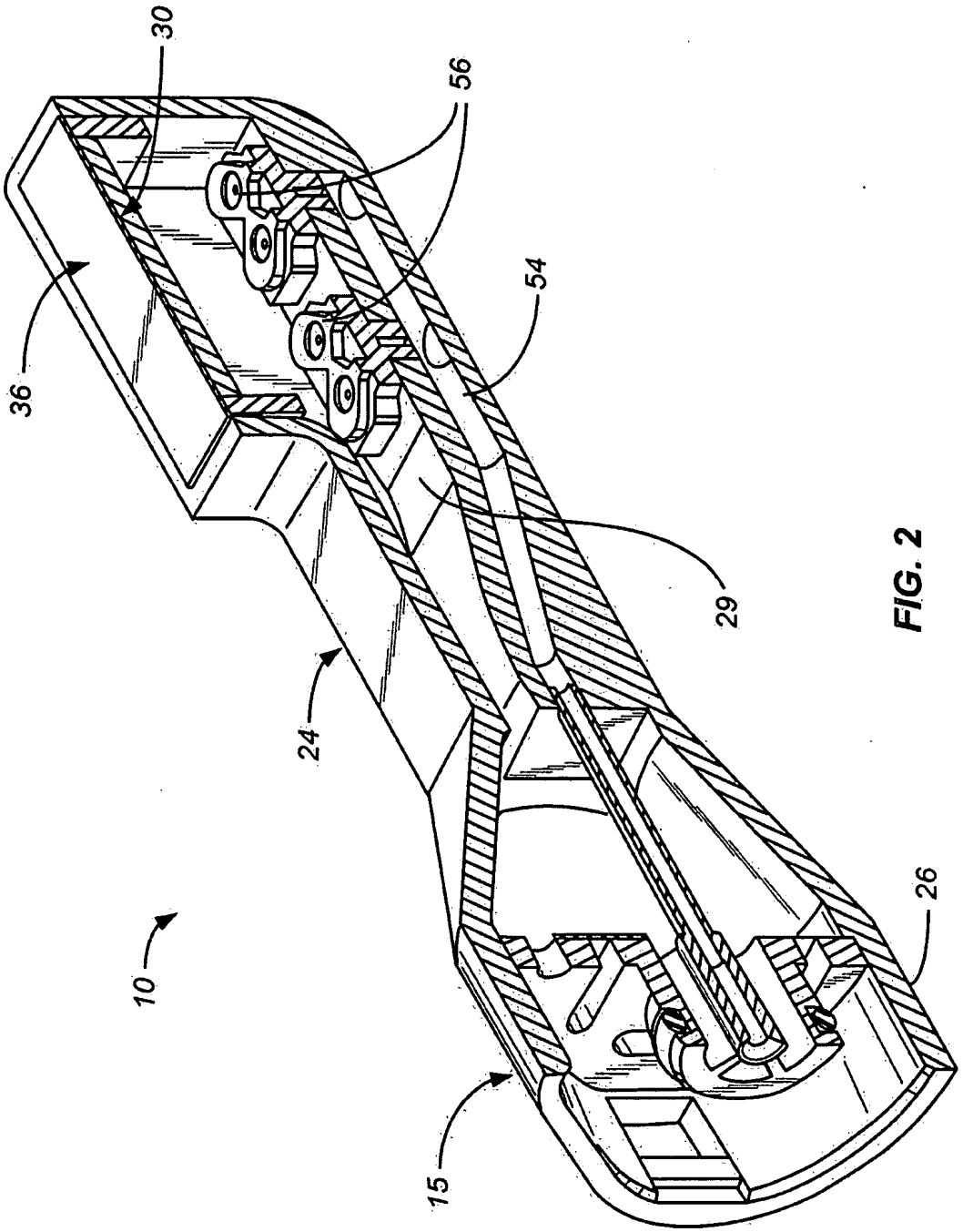


FIG. 2

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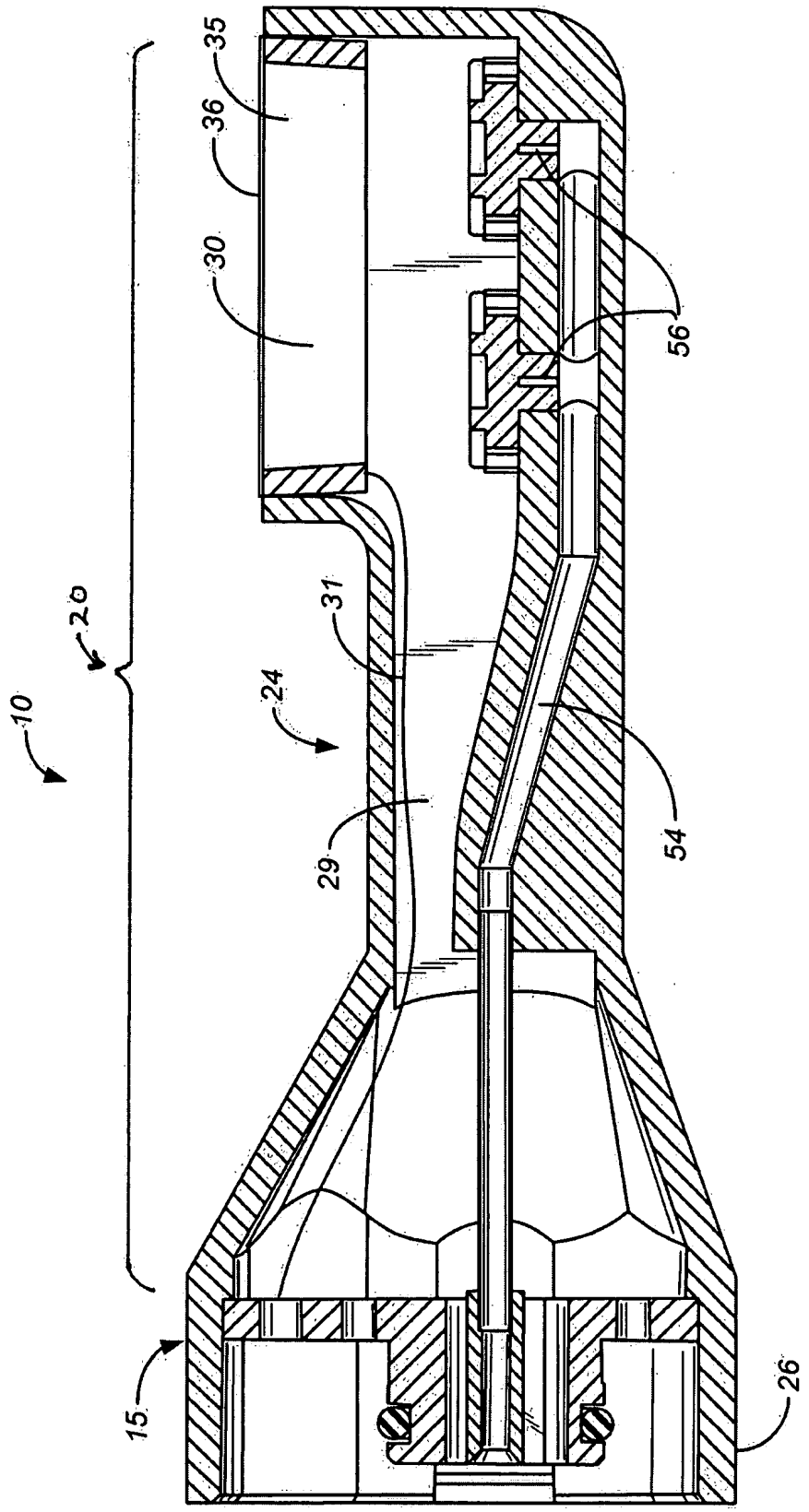


FIG. 3

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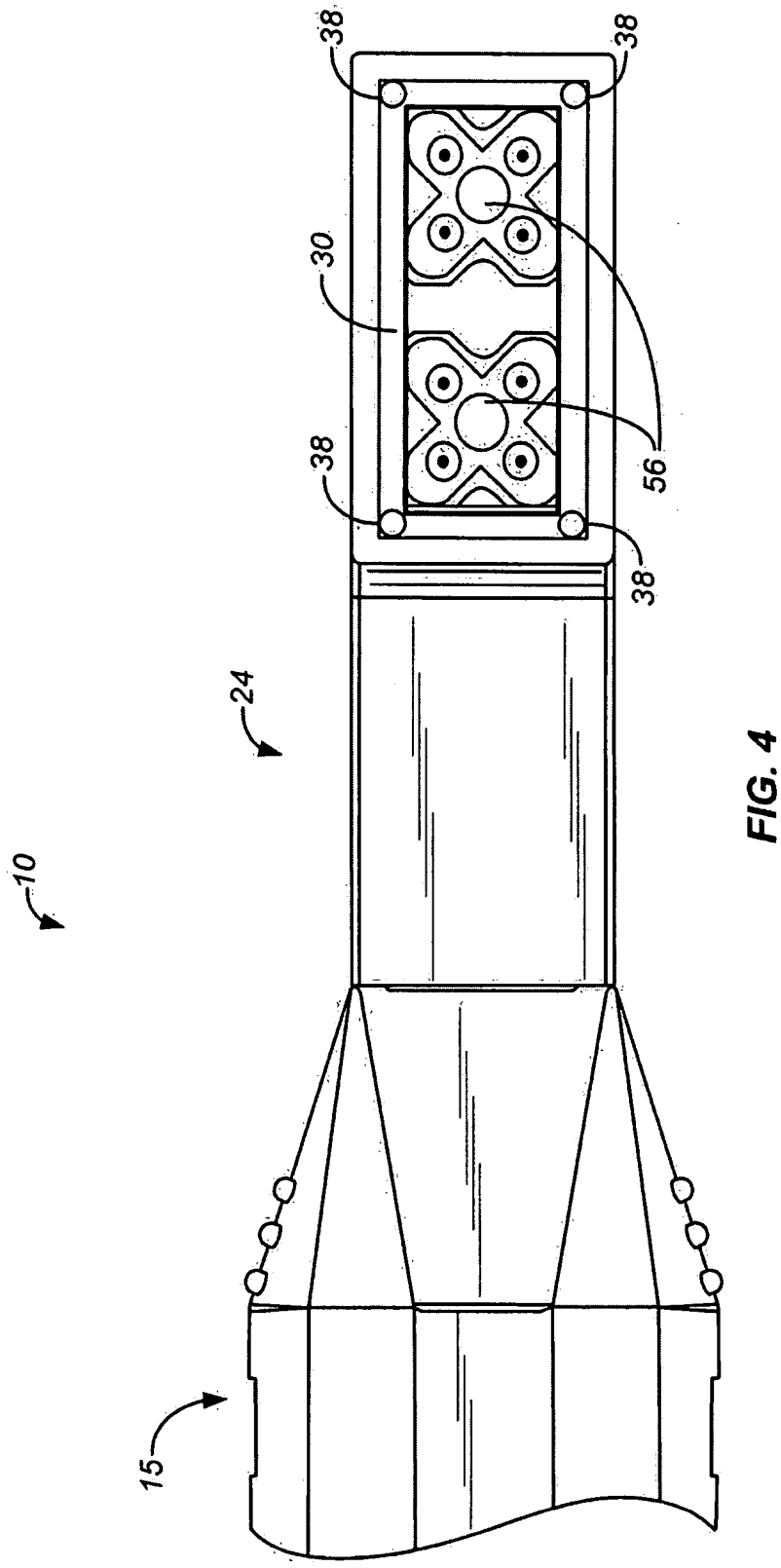


FIG. 4

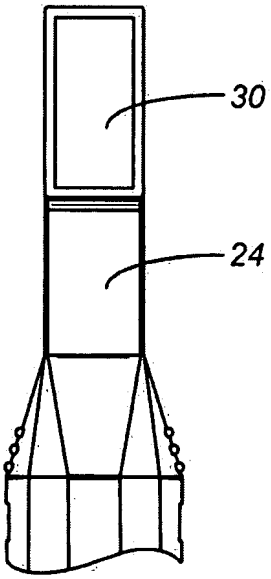


FIG. 5A

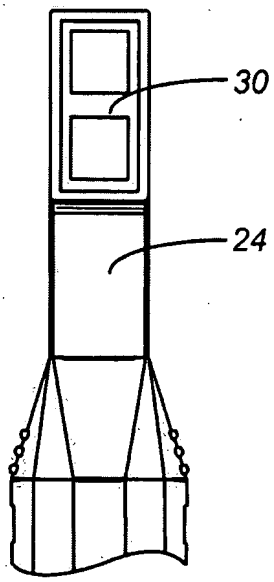


FIG. 5B

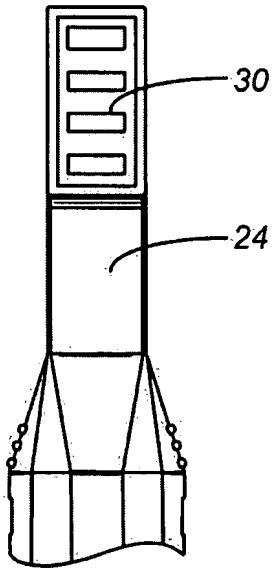


FIG. 5C

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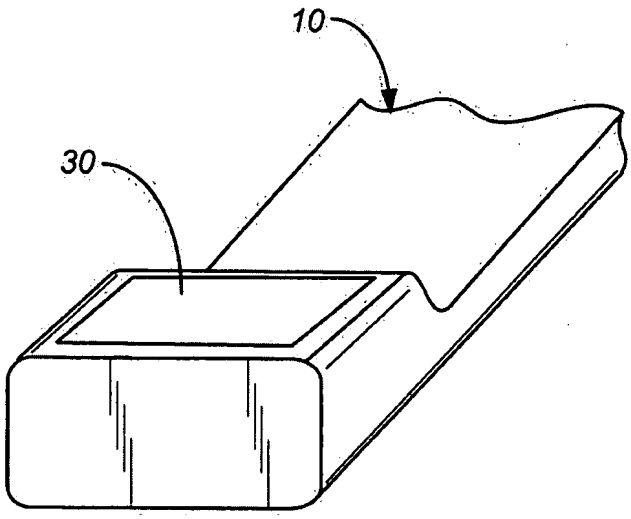


FIG. 6A

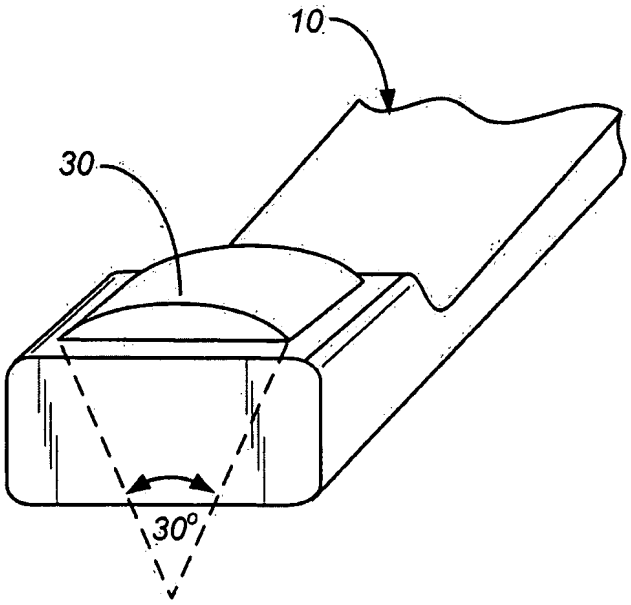


FIG. 6B

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SLG Docket No.: 10095-701.201
Inventor(s): PARMER, Jonathan B.

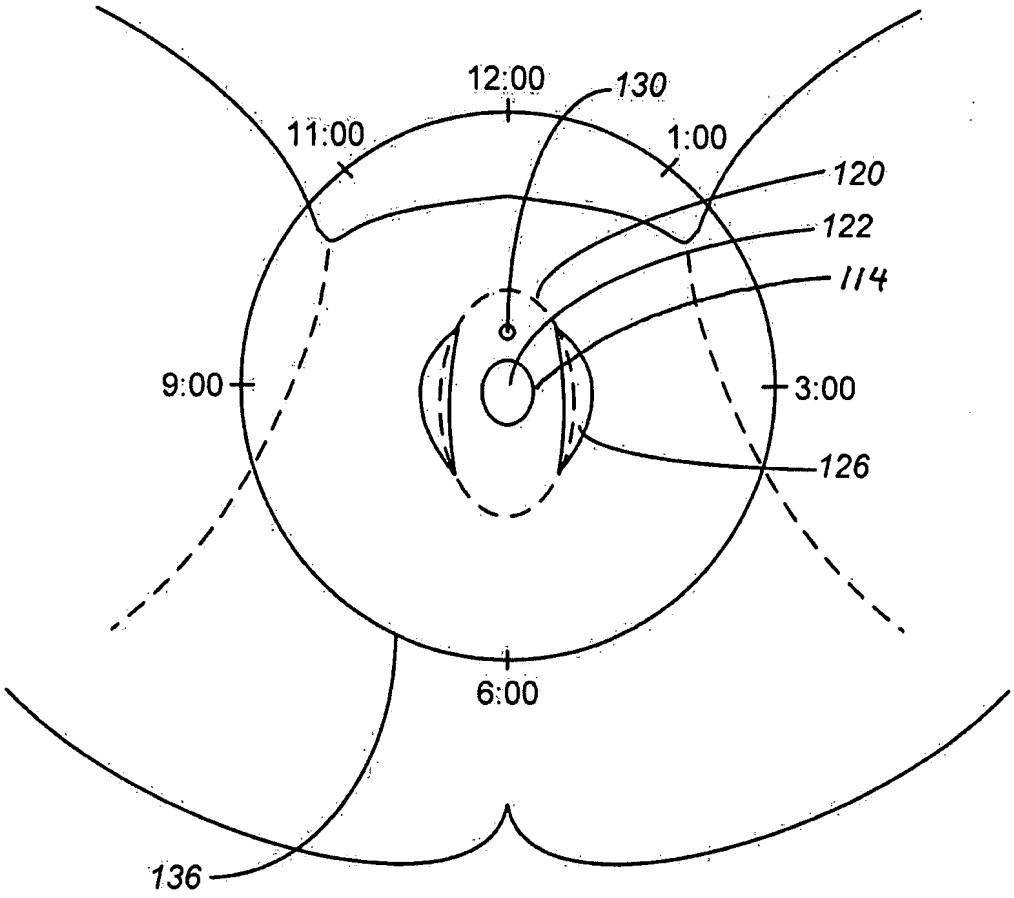


FIG. 7

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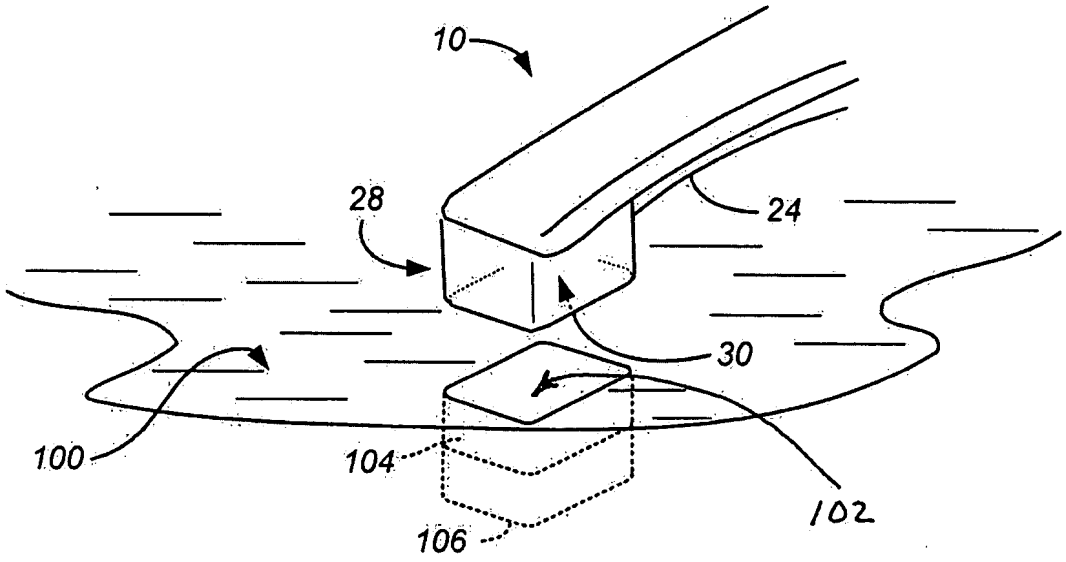


FIG. 8

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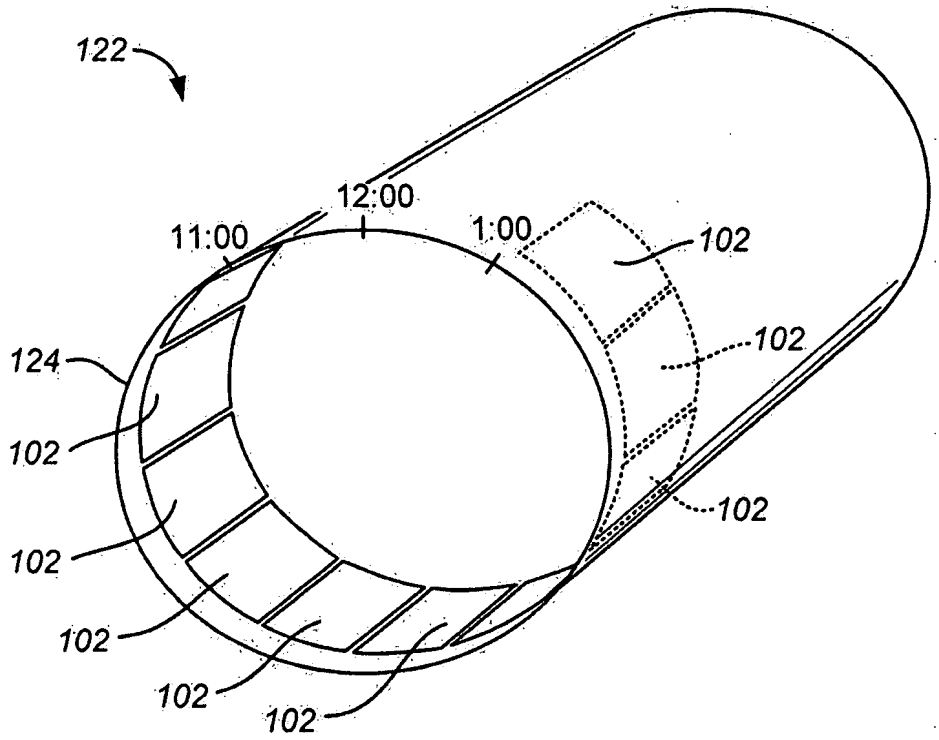


FIG. 9A

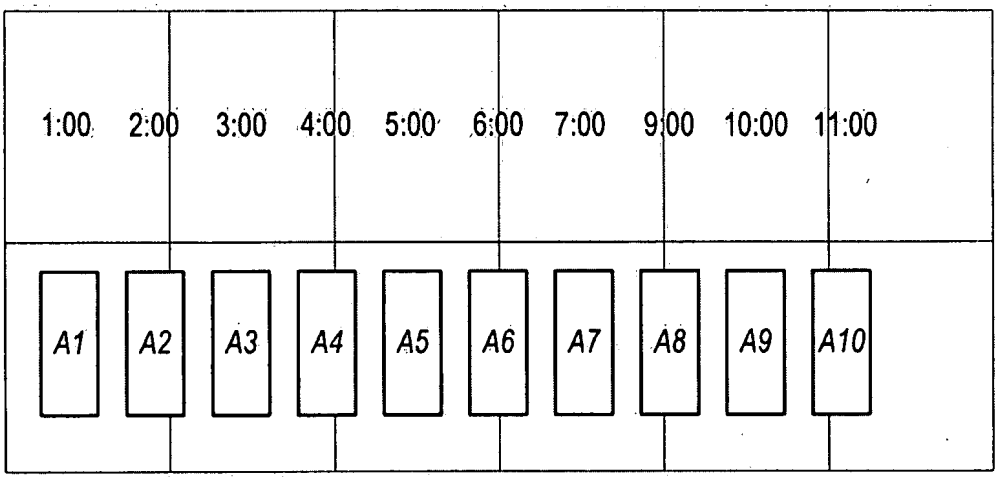


FIG. 9B

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

02/14/2007 CNGUYEN2 00000029 504050 11704067

01 FC:2011	150.00	DA
02 FC:2111	250.00	DA
03 FC:2311	100.00	DA
04 FC:2202	925.00	DA

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*U.S. Government Printing Office: 2002 — 466-267/60013

PTO/SB/06 (12-04)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number: 11704 067

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	150.00		N/A	300.00
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	$250		N/A	$500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	$100		N/A	$200
TOTAL CLAIMS (37 CFR 1.16(i))	57 minus 20 =	* 37	X$ 25 =	925	OR	X$50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	* 0	X100 =			X200 =	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			+180=			+360=	
			TOTAL	500		TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

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APPLICATION AS AMENDED – PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
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Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
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Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
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* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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page 1

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

SERIAL NO. 11704067 | FILING DATE

APPLICANT(S)

CLAIMS

	AS FILED		AFTER 1ST AMENDMENT		AFTER 2ND AMENDMENT	
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MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

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CLAIMS

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TOTAL IND.	2					
TOTAL DEP.	55					
TOTAL CLAIMS	57					

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TOTAL CLAIMS						

PTO-1360 (Rejection only) (3/03)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201

CONFIRMATION NO. 4378

66854
SHAY LAW GROUP, LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

FORMALITIES LETTER

Date Mailed: 03/13/2007

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$65** for a small entity

- **$65** Surcharge.

Replies should be mailed to: Mail Stop Missing Parts

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199
PART 3 - OFFICE COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
11/704,067	02/07/2007	1615	1425	10095-701.201	57	2

CONFIRMATION NO. 4378

66854
SHAY LAW GROUP, LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA94403

FILING RECEIPT

Date Mailed: 03/13/2007

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Jonathan B. Parmer, Residence Not Provided;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This appln claims benefit of 60/743,247 02/07/2006

Foreign Applications

If Required, Foreign Filing License Granted: 03/13/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US11/704,067**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Vaginal remodeling device and methods

Preliminary Class

424

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of

Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at Fax No. 571.273.8300 on June 13, 2007

L Rodriguez 6/13/07

Lola Rodriquez June 13, 2007

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CENTRAL FAX CENTER
JUN 13 2007

Attorney Docket No. 10095-701.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)
)
Inventors: Jonathan B. Parmer)
)
Application No.:11/704,067)
)
Filed: February 7, 2007)
)
Title: ***VAGINAL REMODELING DEVICE AND METHODS***)

Confirmation No.: 4378

Art Unit: UNASSIGNED

Examiner: UNASSIGNED

Customer No. 66854

06/14/2007 WASFAW1 00000039 504050 11704067
01 FC:2051 65.00 DA

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

RESPONSE TO NOTICE TO FILE MISSING PARTS
AND REQUEST FOR EXTENSION OF TIME TO FILE SAME

Sir:

In response to the Notice to File Missing Parts of Nonprovisional Application dated March 13, 2007, please find the following:

1. Copy of Notice to File Missing Parts;
2. Declaration, executed by inventor;

06/14/2007 WASFAW1 00000039 504050 11704067
02 FC:2251 60.00 DA

► Request is hereby made for a One (1) month extension of time to file these documents, up to and including **June 13, 2007**.

☒ Please charge the extension fee (ONE months/small entity) of $60, and the surcharge of $65 to Deposit Account No. 50-4050. Please also deduct from or credit to said Deposit Account any other fees attendant with this matter.

Respectfully submitted,

Date: June 13, 2007

By: _____
James R Shay
Reg. No. 32,062

PAGE 1/4 * RCVD AT 6/13/2007 7:39:00 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/22 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-16

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JUN 13 2007

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below adjacent to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of subject matter (process, machine, manufacture, or composition of matter, or an improvement thereof) which is claimed and for which a patent is sought by way of the application entitled:

"VAGINAL REMODELING DEVICE AND METHODS"

which (check)
- ☐ is attached hereto.
- ☐ and is amended by the Preliminary Amendment attached hereto.
- ☒ was filed on **February 7, 2007** as Application Serial No. **11/704,067**
- ☐ and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
Number	Country	Day/Month/Year Filed	Yes	No
			☐	☐

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application Number	Filing Date
N/A	

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or PCT international application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information, which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, which became available between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PAGE 2/4 * RCVD AT 6/13/2007 7:39:00 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/22 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-16

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JUN 13 2007

Application Serial No.	Filing Date	Status (patented, pending, abandoned)
N/A		

I declare that all statements made herein of my own knowledge are true, all statements made herein on information and belief are believed to be true, and all statements made herein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be subject to the penalties including fine or imprisonment or both as set forth under 18 U.S.C. 1001, and that violations of this paragraph may jeopardize the validity of the application or this document, or the validity or enforceability of any patent, trademark registration, or certificate resulting therefrom.

Full name of sole (or joint) inventor: **PARMER, Jonathan B.**
Inventor's Signature: _____ Date: 5/24/07
Residence: **275 Eleanor Drive, Woodside CA 94062**
Post Office Address: **275 Eleanor Drive, Woodside CA 94062** Citizenship: **USA**

Full name of sole (or joint) inventor:
Inventor's Signature: _____ Date: _____
Residence:
Post Office Address: Citizenship:

Full name of sole (or joint) inventor:
Inventor's Signature: _____ Date: _____
Residence:
Post Office Address: Citizenship:

Full name of sole (or joint) inventor:
Inventor's Signature: _____ Date: _____
Residence:
Post Office Address: Citizenship:

PAGE 3/4 * RCVD AT 6/13/2007 7:39:00 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/22 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-16

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JUN 13 2007

37 C.F.R. §1.56
Duty to disclose information material to patentability

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1,97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
(2) It refutes, or is inconsistent with, a position the applicant takes in:
    (i) Opposing an argument of unpatentability relied on by the Office, or
    (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;
(2) Each attorney or agent who prepares or prosecutes the application; and
(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

PAGE 4/4 * RCVD AT 6/13/2007 7:39:00 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/22 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-16

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
11/704,067	02/07/2007	1615	1490	10095-701.201	57	2

CONFIRMATION NO. 4378

66854
SHAY LAW GROUP LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA94403

UPDATED FILING RECEIPT

Date Mailed: 06/22/2007

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Jonathan B. Parmer, Woodside, CA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This appln claims benefit of 60/743,247 02/07/2006

Foreign Applications

If Required, Foreign Filing License Granted: 03/13/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US11/704,067**

Projected Publication Date: 10/04/2007

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Vaginal remodeling device and methods

Preliminary Class

424

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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POWER OF ATTORNEY BY ASSIGNEE TO EXCLUSION OF INVENTOR UNDER 37 C.F.R. § 3.71 WITH REVOCATION OF PRIOR POWERS

The undersigned ASSIGNEE of the entire interest in:

☐ U.S. Patent No.

☒ U.S. Application No. 11/704,067, filed on February 7, 2007

hereby appoints all Shay Law Group LLP attorneys registered to practice before the United States Patent and Trademark Office, as associated with:

Customer No. 66854

to prosecute this application and transact all business in the United States Patent and Trademark Office in connection therewith and hereby revokes all prior powers of attorney; said appointment to be to the exclusion of the inventors and the inventors' attorneys in accordance with the provisions of 37 C.F.R. § 3.71.

The following evidentiary documents establish a chain of title from the original owner to the Assignee:

(complete one of the following)

☐ a copy of an Assignment attached hereto, which Assignment has been (or is herewith) forwarded to the Patent and Trademark Office for recording; or

☒ the Assignment recorded on June 13, 2007 at reel 019431, beginning at frame 0739.

Pursuant to 37 C.F.R. § 3.73(b) the undersigned Assignee hereby states that evidentiary documents have been reviewed and hereby certifies that, to the best of ASSIGNEE's knowledge and belief, title is in the identified ASSIGNEE.

CHANGE OF CORRESPONDENCE ADDRESS

Direct all correspondence and telephone calls to:

Name	James R. Shay					
Address	Shay Law Group LLP					
Address	2755 Campus Drive, Suite 210					
City	San Mateo	State	CA	Zip	94403	Customer No.: 66854
Country	USA	Telephone	650.212.1700	Fax	650.212.7562	

ASSIGNEE: TiVaMed Inc.

By: _____
Jonathan B. Parmer, President and CEO

Date: 6/17/07

Electronic Acknowledgement Receipt

EFS ID:	2132264
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	James R. Shay/Sue Bromaghim
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10095-701.201
Receipt Date:	28-AUG-2007
Filing Date:	07-FEB-2007
Time Stamp:	15:12:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		10095-701-201-SupDecl-POA-by-Assignee.pdf	491980 cec9bbec2a9e3829636542e5c980704eef08b209	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Oath or Declaration filed	1	3
	Power of Attorney	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	491980	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

SUPPLEMENTAL DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below adjacent to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of subject matter (process, machine, manufacture, or composition of matter, or an improvement thereof) which is claimed and for which a patent is sought by way of the application entitled:

VAGINAL REMODELING DEVICE AND METHODS

which (check)
- ☐ is attached hereto.
- ☐ and is amended by the Preliminary Amendment attached hereto.
- ☒ was filed on February 7, 2007 as Application No. 11/704,067
- ☐ and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
Number	Country	Day/Month/Year Filed	Yes	No
			☐	☐

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application Number	Filing Date
60/743,247	February 7, 2006

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or PCT international application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information, which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, which became available between the filing date of the prior application(s) and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status (patented, pending, abandoned)
N/A		

I declare that all statements made herein of my own knowledge are true, all statements made herein on information and belief are believed to be true, and all statements made herein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be subject to the penalties including fine or imprisonment or both as set forth under 18 U.S.C. 1001, and that violations of this paragraph may jeopardize the validity of the application or this document, or the validity or enforceability of any patent, trademark registration, or certificate resulting therefrom.

Full name of sole (or joint) inventor: **Jonathan B. PARMER**

Inventor's Signature: _____ Date: 8/17/07

Residence:
275 Eleanor Drive
Woodside, CA 94062

Post Office Address: Same Citizenship: USA

Attorney Docket No. 10095-701.201

r37 C.F.R. §1.56
Duty to disclose information material to patentability

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1,97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
(2) It refutes, or is inconsistent with, a position the applicant takes in:
    (i) Opposing an argument of unpatentability relied on by the Office, or
    (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;
(2) Each attorney or agent who prepares or prosecutes the application; and
(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201

CONFIRMATION NO. 4378

OC000000025705856

66854
SHAYGLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

Date Mailed: 09/06/2007

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 08/28/2007.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199
OFFICE COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201

CONFIRMATION NO. 4378

66854
SHAYGLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA94403

Title: Vaginal remodeling device and methods

Publication No. US-2007-0233191-A1
Publication Date: 10/04/2007

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Pre-Grant Publication Division, 703-605-4283

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	11/704,067	Confirmation No.: 4378
Applicant(s):	Jonathan Parmer	
Filed:	February 7, 2007	
Art Unit:	3739	
Examiner:	PEFFLEY, MICHAEL F	
Title:	VAGINAL REMODELING DEVICE AND METHODS	
Customer No.:	66854	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☒ **3).** Before the mail date of a first Office Action on the merits, or

☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 11/19/08

By: _____
James R. Shay Reg. #32062

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08a (09-08)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US- 4,326,529	4/27/1982	Doss et al.	
	2	US- 4,381,007	4/26/1983	Doss	
	3	US- 4,785,807	11/22/1988	Blanch	
	4	US- 4,785,828	11/22/1988	Maurer	
	5	US- 4,907,589	3/13/1990	Cosman	
	6	US- 4,920,978	5/1/1990	Colvin	
	7	US- 4,976,709	12/11/1990	Sand	
	8	US- 5,046,511	9/10/1991	Maurer et al.	
	9	US- 5,143,063	9/1/1992	Fellner	
	10	US- 5,230,349	7/27/1993	Langberg	
	11	US- 5,301,692	4/12/1994	Knowlton	
	12	US- 5,334,193	8/2/1994	Nardella	
	13	US- 5,348,554	9/20/1994	Imran et al.	
	14	US- 5,458,596	10/17/1995	Lax et al.	
	15	US- 5,569,242	10/29/1996	Lax et al.	
	16	US- 5,660,836	8/26/1997	Knowlton	
	17	US- 5,755,753	5/26/1998	Knowlton	
	18	US- 5,765,567	6/16/1998	Knowlton	
	19	US- 5,824,076	10/20/1998	Knowlton	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	148	WO1995/010981A1	4/27/1995	KRESCH et al.		
	149	WO1997/034534A1	9/25/1997	Femrx, Inc.		
	150	WO1998/019613A1	5/14/1998	Surx, Inc.		
	151	WO1999/008614A1	2/25/1999	Surx, Inc.		
	152	WO1999/053853A1	10/28/1999	Vidacare, Inc.		
	153	WO2001/080723A2	11/1/2001	Curon Medical, Inc.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08a (09-08)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	20	US- 5,871,524	2/16/1999	Knowlton	
	21	US- 5,919,219	7/6/1999	Knowlton	
	22	US- 5,937,863	8/17/1999	Knowlton	
	23	US- 5,947,891	9/7/1999	Morrison	
	24	US- 5,948,011	9/7/1999	Knowlton	
	25	US- 5,951,550	9/14/1999	Shirley et al.	
	26	US- 5,954,717	9/21/1999	Behl et al.	
	27	US- 6,002,968	12/14/1999	Edwards	
	28	US- 6,024,743	2/15/2000	Edwards	
	29	US- 6,035,238	3/7/2000	Ingle et al.	
	30	US- 6,044,847	4/4/2000	Carter et al.	
	31	US- 6,081,749	6/27/2000	Ingle et al.	
	32	US- 6,091,995	7/18/2000	Ingle et al.	
	33	US- 6,139,569	10/31/2000	Ingle et al.	
	34	US- 6,156,060	12/5/2000	Roy et al.	
	35	US- 6,216,704	4/17/2001	Ingle et al.	
	36	US- 6,236,891	5/22/2001	Ingle et al.	
	37	US- 6,241,753	6/5/2001	Knowlton	
	38	US- 6,277,116	8/21/2001	Utley et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	154	WO2003/011158A1	2/13/2003	FRANCO, Nicholas		
	155	WO2003/053355A2	7/3/2003	Surx, Inc.		
	156	WO2006/033067A2	3/30/2006	Spine Solutions Inc.		
	157	WO2006/034357A2	3/30/2006	Advanced Cardiovascular Sys		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08a (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	39	US- 6,283,987	9/4/2001	Laird et al.	
	40	US- 6,292,700	9/18/2001	Morrison et al.	
	41	US- 6,311,090	10/30/2001	Knowlton	
	42	US- 6,322,584	11/27/2001	Ingle et al.	
	43	US- 6,350,276	2/26/2002	Knowlton	
	44	US- 6,377,854	4/23/2002	Knowlton	
	45	US- 6,377,855	4/23/2002	Knowlton	
	46	US- 6,381,497	4/30/2002	Knowlton	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

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Sheet 5 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

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	77	US- 6,836,688	12/28/2004	Ingle et al.	
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Sheet 6 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

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Sheet 7 of 8

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Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

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EFS ID:	4320986
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	James R. Shay/Angelica Zuniga
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10095-701.201
Receipt Date:	19-NOV-2008
Filing Date:	07-FEB-2007
Time Stamp:	19:18:20
Application Type:	Utility under 35 USC 111(a)

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10095-701201.pdf	828888 951ea41cce95e59ac77f5f190e70a8157a8758a8	yes	11

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	Document Description		Start	End	
	Information Disclosure Statement Letter		1	3	
	Information Disclosure Statement (IDS) Filed (SB/08)		4	11	
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2	Foreign Reference	WO1995010981A1.pdf	8203932 619def76c744fa7c58ab4113b66fdf1025cb4424	no	50
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3	Foreign Reference	WO1997034534A1.pdf	19149057 52a71dd18d289656aaef4f1626b6856f4664c858	no	42
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4	Foreign Reference	WO1998019613A1.pdf	13245541 9c97d6286c0e46a378215a8e5a61f065baac43fa	no	81
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5	Foreign Reference	WO1999008614A1.pdf	17123525 d56ed87860495fcc8c06f087f28fffe7f5e24db1	no	100
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6	Foreign Reference	WO1999053853A1.pdf	5546537 53ddeb00571cf8e162c67d88ee58497f93c3fb20	no	50
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7	Foreign Reference	WO2001080723A2.pdf	5487580 f43ac0e43726ed4eee65492bf2ff1052b419a63a	no	45
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Warnings:					
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9	Foreign Reference	WO2003053355A2.pdf	4770356 a6f933aceb34766c4cf036ad980035b92ebca780	no	29
Warnings:					
Information:					
10	Foreign Reference	WO2006033067A2.pdf	13930748 71b33ada1573efcdc014befd90e0b497ceeabca0	no	126
Warnings:					
Information:					
11	Foreign Reference	WO2006034357A2.pdf	8414956 f9cba3d7a01bcc1dbc96aac14757b265c6679d67	no	62
Warnings:					
Information:					
			Total Files Size (in bytes):	100256621	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201	4378

66854 7590 08/13/2010

SHAY GLENN LLP
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SAN MATEO, CA 94403

EXAMINER	
HUPCZEY, JR, RONALD JAMES	

ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
08/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/704,067	PARMER, JONATHAN B.	
	Examiner	Art Unit	
	RONALD HUPCZEY, JR	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the impedance monitors "39" as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the impedance monitors "39" of paragraph [0044] must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: in paragraph [0046] the electrode has been referred to as the reference character "39". The Examiner believes that this is in error since the remainder of the specification states that the electrode is reference character "30". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5-11, 13, 16, 18, 20, 22-42, 45-46 and 49-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton et al (US Pat. No. 6,350,276).

Regarding claim 1, Knowlton discloses a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue (as in the embodiment of figures 13-14 describing the treatment of cervix, see col. 13; 35-37), the method comprising heating the target tissue and remodeling the therapeutic zone of target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 5, Knowlton discloses that the heating comprises delivering energy by contacting the epithelium with a treatment tip (contact by template **12** and force application **14**

contacting tissue surface **21**), the tip including an energy delivery element (energy delivery device **18** contained therein).

Regarding claim 6, Knowlton the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy (see col. 7; 52 – col. 8; 3).

Regarding claim 7, Knowlton discloses that the heating is controlled by a feedback control such that temperature does not go higher than a predetermined temperature (see at least col. 20; 66 though col. 21; 26).

Regarding claim 8, Knowlton discloses that the feedback control is provided by one or more thermal sensors (see at least col. 20; 66 though col. 21; 26.

Regarding claim 9, Knowlton discloses that the feedback control is provided by one or more impedance monitors (see at least col. 19; 20 though col. 21; 26.

Regarding claim 10, Knowlton discloses that the method further comprises cooling the epithelium (cooling of contact tissue **21** by the fluid **15** as in col. 5; 16 through col. 6; 4).

Regarding claim 11, Knowlton discloses that the cooling is by contacting the epithelium with a treatment tip wherein the tip includes a cooling mechanism (fluid **15** contacting tissue surfaces as in col. 5; 4-15 through the delivery of the fluid through device **10** to the contacting tip as would be in figures 13-14).

Regarding claim 13, Knowlton discloses that 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 (see col. 5; 16 – col. 6; 48 disclosing the extent and effect of the cooling provided by fluid **15**).

Regarding claim 16, Knowlton discloses that the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue (see col. 5; 52-59).

Regarding claim 18, Knowlton discloses that the method comprises contacting the epithelium with a treatment tip at a one or more contact sites during a procedure (see figure 3 showing the template **12** and surface **14** contacting the tissue surface **21** at a plurality of points during treatment), the tip comprising an energy delivery element adapted to heat the target tissue (energy delivery device within the template/surface).

Regarding claim 20, Knowlton discloses that the method includes contacting the tip to the epithelium at a plurality of contact sites (template **12** and surface **14** contacting multiple sites) during a procedure and moving the tip from site to site wherein the combined contact sites comprising a treatment area (movement of the tip into contact with each of the sites contacted by template **12** and surface **14** containing energy device **18** to form a combined treatment area).

Regarding claim 22, Knowlton discloses that the method further comprising repeating the procedure one or more times (see col. 11; 65 – col. 12; 1 discussing the retreating and refining by using the procedure again).

Regarding claim 23, Knowlton discloses that the treatment areas of the one or more procedures, respectively, may be any of the same treatment area, different treatment areas, or overlapping treatment areas (refining of a previous treatment as in col. 11; 65 – col. 12; 1 would required the retreating of substantially the same area).

Regarding claim 24, Knowlton discloses that the female genitalia includes the vulva and the vagina (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female does also include the vulva and the vagina).

Regarding claim 25, Knowlton disclose that the genitalia includes the introitus (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female does also include the introitus).

Regarding claim 26, Knowlton discloses that the female genitalia includes a portion of the vagina extending from the introitus inwardly to a location from about 1 cm to about 3.5 cm in from the introitus (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female includes the portion of anatomy recited in the claim).

Regarding claim 27, Knowlton discloses that the female genitalia includes a portion of the vagina circumferentially around its wall from about 1 o'clock to about 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female includes the portion of anatomy recited in the claim).

Regarding claim 28, Knowlton discloses that the female genitalia includes a portion radiating outward from the introitus to Hart's line (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female includes the portion of anatomy recited in the claim).

Regarding claim 29, Knowlton discloses that the female genitalia includes the mucosal surfaces of the labia minora (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female includes the portion of anatomy recited in the claim).

Regarding claim 30, Knowlton discloses that the target tissue includes submucosa and muscularis below the mucosal epithelium (see at least col. 3; 66 – col. 4; 14).

31. The method of claim 1, wherein the heating does not substantially modify the mucosal epithelium of the genital tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64; it is noted that the without better defining what "substantially" means in the claim, the Examiner is interpreted the effects of the method of Knowlton to not be substantial).

Regarding claim 32, Knowlton discloses that remodeling comprises contracting target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claims 33 and 34, Knowlton discloses that the method described in claim 1 would include tightening the vagina and/or introitus (as displayed in figures 13 and 14 by the treatment of pre-term cervical dilation wherein the template **12** with energy device **18** treats the cervix such that tightening occurs and the entire cervix is strengthened, see at least col. 13; 37-43).

Regarding claim 35, Knowlton discloses that the remodeling comprises denaturing collagen (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 36, Knowlton discloses that the remodeling comprises tightening collagen-rich sites in the target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 37, Knowlton discloses that the remodeling comprises rejuvenating the genital tissue toward a conformation like that which the genitalia had prior to experiencing vaginal birth (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64 and col. 13; 36-47).

Regarding claim 38, Knowlton discloses that at least some of the remodeling occurs during the heating (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 39, Knowlton discloses that at least some of the remodeling occurs after the heating (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 40, Knowlton discloses that the remodeling after the heating is by a depositing of collagen in the target tissue (see at least col. 14; 19-36 which discloses the induction of collagen formation due to heating).

Regarding claim 41, Knowlton discloses an apparatus for remodeling a therapeutic zone within a target tissue comprising tissue underlying a mucosal epithelium of female genital tissue, the apparatus comprising a treatment tip (distal end of device **10**, see figures 1 and 2A), the tip comprising a shaft comprising a longitudinal axis (see figures 1 and 2a), an energy delivery element, (element **18**) and a cooling mechanism (fluid **15** supplied to the distal end of device **10** via a lumen **13'**), wherein the energy delivery element is capable of contacting the epithelium (as

shown and disclosed throughout as contacting tissue surface **21**) and wherein the treatment tip is configured to deliver energy from the energy delivery element to the target tissue in a uniform manner (see at least col. 7; 30- col. 8; 3 disclosing the application of energy).

Regarding claim 42, Knowlton discloses that the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft (see the structural arrangement of the energy elements **18** relative to the longitudinal axis of the shaft in figure 2A).

Regarding claim 45, Knowlton discloses that the energy delivery element is configured to be fiat (see the flat shape of the energy device **18** in figure 18B).

Regarding claim 46, Knowlton discloses that wherein the energy delivery element is configured to have a radial curvature with respect to the longitudinal axis of the shaft (see curved shape of energy device **18** as in figure 1).

Regarding claim 49, the shaft is configured to include a narrow portion proximal to the energy delivery element (narrow portion of the shaft of the device indicated at **10** distal to **10'** in figure 2A) wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft (see the structural arrangement of each of energy devices **18**), such that the energy delivery element projects forward from the shaft (energy devices **18** extending distally in figure 2A).

Regarding claim 50, Knowlton discloses that the cooling system is configured to cool the energy delivery element (fluid **15** being provided to energy element **18** via lumen **13'**).

Regarding claim 51, Knowlton discloses the cooling system comprises cooling fluid (fluid **15**) and at least one nozzle (opening of lumen **13'** spraying fluid onto device **18** as in col. 5; 10-15) the nozzle configured to spray the cooling fluid on the energy delivery element.

Regarding claim 52, Knowlton discloses that the energy delivery element comprises at least one capacitively coupled electrode (see col. 19; 28-29 discussing capacitive coupling).

Regarding claim 53, Knowlton discloses that the energy delivery element comprises at least one radiofrequency (RF) electrode (energy device **18** functioning to receive RF energy as in at least col. 7; 52 – col. 8; 10).

Regarding claims 54 and 55, Knowlton discloses that the RF electrodes function in either a monopolar or bipolar manner (see col. 15; 25- col. 16; 67)

Regarding claim 56, Knowlton discloses that at least one thermistor located in close proximity to the electrode (see col. 8; 31-50).

Regarding claim 57, Knowlton discloses that the system comprises a programmable memory chip (see col. 21; 15-25).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-4, 12, 14-15, 17, 19, 21, 43-44 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton et al (US Pat. No. 6,350,276).

Regarding claims 2-4, While Knowlton discloses various temperature ranges and energy density/delivery Knowlton fails to specifically recite the tissue to be heated the claimed ranges. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the target tissue to the claimed temperature ranges since the claimed 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. *In re Aller*, 105 USPQ 233.

Regarding claim 12, Knowlton discloses that the cooling fluid applied to the epithelium is cooled to the temperature of -100 degrees Fahrenheit (see col. 5; 41-42) but fails to specifically recite that the epithelium comprises cooling it to a temperature between about 0 degrees C. and

about 10 degrees C. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to cool the tissue to the temperature range claimed 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. *In re Aller*, 105 USPQ 233. Additionally, in view of the disclosed cooling ranges and control system of Knowlton, one of ordinary skill in the art would readily appreciate the capability of the system to cool the epithelial surface to the claim temperature.

Regarding claims 14 and 15, Knowlton discloses a plurality of different heating and cooling algorithms (see col. 6; 5-7) but fails to specifically recite the cooling schemes of each of the claims. However, it would have been obvious to one of ordinary skill in the art in light of the disclosure in column 6 of Knowlton to provide cooling before, during and after the heating of the tissue in order to successfully effectuate the desired treatment. In looking at the feedback system, temperature sensors and cooling system, one of ordinary skill would readily appreciate the desire to cool the tissue at each time to ensure that the tissue surface is never overheated thereby charring or burning the contact surface.

Regarding claim 17, Knowlton fails to specifically recite the temperature gradients produced in the various levels of tissue when utilizing a reverse thermal gradient cooling device. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reverse thermal gradient ranges from a low temperature of about 0 degrees C. to about 10 degrees C. at the epithelium to a high temperature of about 45 degrees C. to about 80 degrees C. in the underlying target tissue 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. *In re Aller*, 105 USPQ 233. Knowlton discloses in col. 5; 52-59, the use of reverse thermal gradient devices which are known in the art and as such, one of ordinary skill, given the disclosed control system, temperature monitoring devices and feedback system would readily appreciate operating the system of Knowlton at the claimed ranges to effectuate the disclosed treatments to the tissue **9**.

Regarding claims 19 and 21, Knowlton discloses the monitoring of contact between the treatment tip of the device and the treatment surface **21** with a sensor to ensure that adequate contact is maintained during treatment (see at least cols. 19-20 discussing the monitoring of contact and impedance at the electrode sites) and the repeated treatment which is needed along with the use of multiple modalities of treatment to a target site (see col. 11; 65 – col. 12; 1). Knowlton fails to specifically recite the limitations of claims 19 and 21. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to contact one or more sites one or more times or contact any one site more than once during treatment in order to effectively provide the desired treatment to the tissue **9**. Repeated application of energy to a target portion of tissue is well known in the art and providing such a treatment step to the method of Knowlton would be a matter of mere routine experimentation by one of ordinary skill in order to obtain the desired result at the target area.

Regarding claims 43 and 44, Knowlton fails to recite the claimed sizes of the energy delivery element. However, one of ordinary skill in the art at the time the invention was made would readily appreciate providing an energy delivery device of the claimed size 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. *In re Aller*,

105 USPQ 233. Additionally, Knowlton discloses for the energy device **18** to have a plurality of different intended target sites and to work within a plurality of different energy density ranges which would require one of ordinary skill in the art to adjust the size of the energy device to a suitable size based on the desired treatment and energy density.

Regarding claims 47 and 48, while Knowlton in the embodiments of figures 1 and 2B show that the energy device **18** has a radius of curvature, Knowlton fails to disclose that the radius of curvature is up to or about 30 degrees. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a radius of curvature of up to or about 30 degrees in order to provide an energy device, template and surface which all conform to a desired treatment area. Additionally, in providing such a range, 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. *In re Aller*, 105 USPQ 233. It has also been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Edwards (US 2002/0183735 A1), Mosher (US 2004/0193238 A1), Roy (US 2004/0249425 A1), Maurer (US 5010895), Stern (US 5443470).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH

Notice of References Cited	Application/Control No. 11/704,067	Applicant(s)/Patent Under Reexamination PARMER, JONATHAN B.	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0183735	12-2002	Edwards et al.	606/32
*	B	US-2004/0193238	09-2004	Mosher et al.	607/099
*	C	US-2004/0249425	12-2004	Roy et al.	607/099
*	D	US-5,010,895	04-1991	Maurer et al.	607/138
*	E	US-5,443,470	08-1995	Stern et al.	607/98
*	F	US-6,350,276	02-2002	Knowlton, Edward W.	607/104
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	Art Unit
	RONALD HUPCZEY, JR	3739

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/10/2010								
	1	✓								
	2	✓								
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	4	✓								
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	36	✓								

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	Art Unit
	RONALD HUPCZEY, JR	3739

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/10/2010								
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	Art Unit
	RONALD HUPCZEY, JR	3739

SEARCHED

Class	Subclass	Date	Examiner
606	1-52	08/06/2010	RJH
607	50, 115, 138	08/06/2010	RJH

SEARCH NOTES

Search Notes	Date	Examiner
East Search	08/06/2010	RJH
Inventor Search	08/06/2010	RJH

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S2	0	("2007/0233191").URPN.	USPAT	OR	ON	2010/08/06 14:45
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EAST Search History (Interference)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US- 4,326,529	4/27/1982	Doss et al.	
	2	US- 4,381,007	4/26/1983	Doss	
	3	US- 4,785,807	11/22/1988	Blanch	
	4	US- 4,785,828	11/22/1988	Maurer	
	5	US- 4,907,589	3/13/1990	Cosman	
	6	US- 4,920,978	5/1/1990	Colvin	
	7	US- 4,976,709	12/11/1990	Sand	
	8	US- 5,046,511	9/10/1991	Maurer et al.	
	9	US- 5,143,063	9/1/1992	Fellner	
	10	US- 5,230,349	7/27/1993	Langberg	
	11	US- 5,301,692	4/12/1994	Knowlton	
	12	US- 5,334,193	8/2/1994	Nardella	
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	15	US- 5,569,242	10/29/1996	Lax et al.	
	16	US- 5,660,836	8/26/1997	Knowlton	
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	18	US- 5,765,567	6/16/1998	Knowlton	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	148	WO1995/010981A1	4/27/1995	KRESCH et al.		
	149	WO1997/034534A1	9/25/1997	Femrx, Inc.		
	150	WO1998/019613A1	5/14/1998	Surx, Inc.		
	151	WO1999/008614A1	2/25/1999	Surx, Inc.		
	152	WO1999/053853A1	10/28/1999	Vidacare, Inc.		
	153	WO2001/080723A2	11/1/2001	Curon Medical, Inc.		

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	08/06/2010

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	20	US- 5,871,524	2/16/1999	Knowlton	
	21	US- 5,919,219	7/6/1999	Knowlton	
	22	US- 5,937,863	8/17/1999	Knowlton	
	23	US- 5,947,891	9/7/1999	Morrison	
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	25	US- 5,951,550	9/14/1999	Shirley et al.	
	26	US- 5,954,717	9/21/1999	Behl et al.	
	27	US- 6,002,968	12/14/1999	Edwards	
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	29	US- 6,035,238	3/7/2000	Ingle et al.	
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	34	US- 6,156,060	12/5/2000	Roy et al.	
	35	US- 6,216,704	4/17/2001	Ingle et al.	
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	37	US- 6,241,753	6/5/2001	Knowlton	
	38	US- 6,277,116	8/21/2001	Utley et al.	

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	154	WO2003/011158A1	2/13/2003	FRANCO, Nicholas		
	155	WO2003/053355A2	7/3/2003	Surx, Inc.		
	156	WO2006/033067A2	3/30/2006	Spine Solutions Inc.		
	157	WO2006/034357A2	3/30/2006	Advanced Cardiovascular Sys		

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	08/06/2010

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	39	US- 6,283,987	9/4/2001	Laird et al.	
	40	US- 6,292,700	9/18/2001	Morrison et al.	
	41	US- 6,311,090	10/30/2001	Knowlton	
	42	US- 6,322,584	11/27/2001	Ingle et al.	
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	45	US- 6,377,855	4/23/2002	Knowlton	
	46	US- 6,381,497	4/30/2002	Knowlton	
	47	US- 6,381,498	4/30/2002	Knowlton	
	48	US- 6,387,380	5/14/2002	Knowlton	
	49	US- 6,405,090	6/11/2002	Knowlton	
	50	US- 6,413,255	7/2/2002	Stern	
	51	US- 6,416,504	7/9/2002	Mosel et al.	
	52	US- 6,425,912	7/30/2002	Knowlton	
	53	US- 6,427,089	7/30/2002	Knowlton	
	54	US- 6,430,446	8/6/2002	Knowlton	
	55	US- 6,438,424	8/20/2002	Knowlton	
	56	US- 6,453,202	9/17/2002	Knowlton	
	57	US- 6,461,332	10/8/2002	Mosel et al.	

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	08/06/2010

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

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	58	US- 6,461,378	10/8/2002	Knowlton	
	59	US- 6,470,216	10/22/2002	Knowlton	
	60	US- 6,478,791	11/12/2002	Carter et al.	
	61	US- 6,480,746	11/12/2002	Ingle et al.	
	62	US- 6,482,204	11/19/2002	Lax et al.	
	63	US- 6,533,780	3/18/2003	Laird et al.	
	64	US- 6,546,934	4/15/2003	Ingle et al.	
	65	US- 6,558,381	5/6/2003	Ingle	
	66	US- 6,572,639	6/3/2003	Ingle et al.	
	67	US- 6,579,266	6/17/2003	Mosel et al.	
	68	US- 6,587,731	7/1/2003	Ingle et al.	
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	73	US- 6,751,507	6/15/2004	Morrison et al.	
	74	US- 6,772,013	8/3/2004	Ingle et al.	
	75	US- 6,776,779	8/17/2004	Roy et al.	
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Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	08/06/2010

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

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	77	US- 6,836,688	12/28/2004	Ingle et al.	
	78	US- 6,840,954	1/11/2005	Dietz et al.	
	79	US- 6,852,110	2/8/2005	Roy et al.	
	80	US- 6,879,858	4/12/2005	Adams	
	81	US- 6,882,885	4/19/2005	Levy et al.	
	82	US- 6,889,090	5/3/2005	Kreindel	
	83	US- 6,976,492	12/20/2005	Ingle et al.	
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	88	US- 2002/0032441A1	3/14/2002	Ingle et al.	
	89	US- 2002/0049483A1	4/25/2002	Knowlton	
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	91	US- 2002/0120260A1	8/29/2002	Morris et al.	
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Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	08/06/2010

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Sheet 6 of 8

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

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	96	US- 2003/0097162A1	5/22/2003	Kreindel	
	97	US- 2003/0120326A1	6/26/2003	Dietz et al.	
	98	US- 2003/0130575A1	7/10/2003	Desai	
	99	US- 2003/0139740A1	7/24/2003	Kreindel	
	100	US- 2003/0139790A1	7/24/2003	Ingle et al.	
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	102	US- 2003/0178032A1	9/25/2003	Ingle et al.	
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	106	US- 2003/0212393A1	11/13/2003	Knowlton et al.	
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	111	US- 2004/0000316A1	1/1/2004	Knowlton et al.	
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Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	08/06/2010

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Sheet 7 of 8

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Filing Date	February 7, 2007
First Named Inventor	Jonathan Parmer
Art Unit	3739
Examiner Name	PEFFLEY, MICHAEL F
Attorney Docket Number	10095-701.201

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	118	US- 2004/0102824A1	5/27/2004	Sharkey et al.	
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	122	US- 2004/0127895A1	7/1/2004	Flock et al.	
	123	US- 2004/0172291A1	9/2/2004	Knowlton	
	124	US- 2004/0186535A1	9/23/2004	Knowlton	
	125	US- 2004/0193238A1	9/30/2004	Mosher et al.	
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	129	US- 2004/0236177A1	11/25/2004	Matlock	
	130	US- 2004/0236393A1	11/25/2004	Ingle et al.	
	131	US- 2004/0249425A1	12/9/2004	Roy et al.	
	132	US- 2004/0260368A1	12/23/2004	Ingle et al.	
	133	US- 2004/0267336A1	12/30/2004	Morrison et al.	

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	134	US- 2005/0154433A1	7/14/2005	Levy Jr. et al.	
	135	US- 2005/0171582A1	8/4/2005	Matlock	
	136	US- 2005/0171583A1	8/4/2005	Mosher et al.	
	137	US- 2005/0187599A1	8/25/2005	Sharkey et al.	
	138	US- 2005/0203399A1	9/15/2005	Vaezy et al.	
	139	US- 2005/0288544A9	12/29/2005	Matlock	
	140	US- 2005/0288680A1	12/29/2005	Ingle et al.	
	141	US- 2006/0025837A1	2/2/2006	Stern et al.	
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	145	US- 2007/0083247A1	4/12/2007	Wyeth et al.	
	146	US- 2007/0088413A1	4/19/2007	Weber et al.	
	147	US- 2007/0106349A1	5/10/2007	Karni et al.	
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FILED VIA EFS ON NOVEMBER 15, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	11/704,067	Confirmation No.:	4378
Applicant	:	Jonathan B. PARMER		
Filing Date	:	February 7, 2007		
Title	:	Vaginal Remodeling Device and Methods		
Group Art Unit	:	3739		
Examiner	:	Ronald James HUPCZEY, Jr.		
Docket No.	:	10095-701.201		
Customer No.	:	66854		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

AMENDMENT IN RESPONSE TO OFFICE ACTION

Introductory Comments:

This Amendment responds to the non-final Office Action dated August 13, 2010, for which a response is due November 13, 2010 (Saturday) or November 15, 2010 (Monday).

Please enter the amendments and consider the remarks as follows.

Amendments to the Specification begin on page 2.

Amendments to the Claims begin on page 4.

Remarks / Arguments begin on page 11 of this paper.

Amendments to the Specification:

Please amend Paragraph **[0012]** of the application as follows:

[0012] In typical embodiments, the length of the energy delivery element is about 1 to about 3 cm in length, in other embodiments it may be as long as about 4 cm. This is a length well adapted to treating the lower aspect of the vagina, wherein treatment by the method comprises contacting the vaginal epithelium in a region that extends from the introitus inward to a position about 3 to 4 cm inward from the introitus. In some embodiments of the invention, the method can by practiced with a single row of parallel contact sites immediately inside the introitus. In other embodiments, the method may include deeper rows, or rows that overlap an ~~intial~~ initial row, while keeping the contact sites within the lower portion of the vagina.

Please amend Paragraph **[0037]** of the application as follows:

[0037] Accordingly, various configurational and dimensional aspects of the treatment tip **10** and the energy delivery element **30** are advantageous for the method of remodeling genital tissue. These features are particularly suited for treating the vaginal wall, but also are appropriate for treating mucosal epithelial surfaces of female genitalia outside the vagina. As described above, these features include (1) the side-facing orientation of the energy delivery element with respect to the linear axis of the treatment tip and its shaft, (2) the overall length of the treatment tip from its proximal end to the distal end, (3) the narrow portion **24** of the tip which allows the energy delivery element to project forward from a background structure, rather than being in contiguous plane with surrounding structure, (4) the surface dimensions of the energy delivery element, particularly the width, which allow for substantially flat contact with the vaginal wall in the case of a flat energy delivery element 30, and (5) in the case of embodiment with a curved energy delivery element, a particularly close fit between the energy delivery element and the vaginal wall is achievable. All such enumerated features contribute to a uniformly-distributed contact between the energy delivery surface and the mucosal epithelium, such uniform fit diminishes the ~~liklihood~~ likelihood of edge-biased contact that could harm the

epithelium, and affirmatively promotes uniform distribution of energy across the area of site where the energy delivery element contacts the epithelium and through which energy radiates into the underlying target tissue. Uniformity in flux across a surface area promotes an advantageous uniformity, consistency, and predictability in the remodeling response. Further, and equally important, small variation in flux also minimizes occurrence of damage, either to the epithelium or the target tissue, that can occur when large excursions in energy flux include, as they inevitably do, areas which receive high rates of energy flux.

Please amend Paragraph **[0039]** of the application as follows:

[0039] The energy delivery element **30** [[is]] may be any of an RF electrode, a microwave emitter, or an ultrasound emitter. Embodiments that include an RF electrode will be described in some detail. The RF electrode, in some embodiments, is a ~~capactive~~ capacitive electrode, which capacitively couples to the mucosal epithelium. The RF electrode, without limiting the scope of the invention, may have a thickness in the range of about 0.01 to about 1.0 mm.

Please amend Paragraph **[0046]** of the application as follows:

[0046] Circuitry, software and feedback to controller result in full process control and are used to change power, the duty cycle, monopolar or bipolar energy delivery, flow rate and ~~pressure ,and~~ pressure, and can also determine when the process is completed through time, temperature and/or impedance. These process variables can be controlled and varied in accordance with tissue temperature, as monitored at multiple sites on contacting exterior surface **34**, as well as by monitoring impedance to current flow at each RF electrode [[**39**,]] **30,** indicating changes in current carrying capability of the tissue during the process. Further, a controller can provide multiplexing, monitor circuit continuity, and determine which RF electrode **30** is activated.

Amendments to the Claims:

Please make the amendments as shown. A complete listing of the claims follows:

1. (Original) A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue, the method comprising:

heating the target tissue, and

remodeling the therapeutic zone of target tissue.

2. (Original) The method of claim 1, wherein heating the target tissue comprises heating it to a temperature between about 45 degrees C. and about 80 degrees C.

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

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

5. (Original) The method of claim 1, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

6. (Original) The method of claim 5, wherein the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy.

7. (Original) The method of claim 1, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

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

9. (Canceled)

10. (Original) The method of claim 1, wherein the method further comprises cooling the epithelium.

11. (Original) The method of claim 10, wherein cooling is by contacting the epithelium with a treatment tip, the tip including a cooling mechanism.

12. (Original) The method of claim 10, wherein cooling the epithelium comprises cooling it to a temperature between about 0 degrees C. and about 10 degrees C.

13. (Original) The method of claim 10, 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.

14. (Original) The method of claim 10, wherein the cooling precedes the heating, and continues during the heating.

15. (Original) The method of claim 10, wherein the cooling is during the heating, and continues after heating.

16. (Original) The method of claim 10, wherein the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue.

17. (Original) The method of claim 16, wherein the reverse thermal gradient ranges from a low temperature of about 0 degrees C. to about 10 degrees C. at the epithelium to a high temperature of about 45 degrees C. to about 80 degrees C. in the underlying target tissue.

18. (Original) The method of claim 1, 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.

19. (Original) The method of claim 18, wherein the method is performed during a procedure, and wherein the contacting of any one of more contact sites is repeated one or more times during a procedure.

20. (Original) The method of claim 18, 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.

21. (Original) The method claim 20, wherein any one of the contact sites is contacted one or more times during a procedure.

22. (Original) The method of claim 20, the method further comprising repeating the procedure one or more times.

23. (Original) The method of claim 22, wherein the treatment areas of the one or more procedures, respectively, may be any of the same treatment area, different treatment areas, or overlapping treatment areas.

24. (Original) The method of claim 1, wherein the female genitalia includes the vulva and the vagina.

25. (Original) The method of claim 1, wherein the female genitalia includes the introitus.

26. (Original) The method of claim 1, wherein the female genitalia includes a portion of the vagina extending from the introitus inwardly to a location from about 1 cm to about 3.5 cm in from the introitus.

27. (Original) The method of claim 1, wherein the female genitalia includes a portion of the vagina circumferentially around its wall from about 1 o'clock to about 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock.

28. (Original) The method of claim 1, wherein the female genitalia includes a portion radiating outward from the introitus to Hart's line.

29. (Original) The method of claim 1, wherein the female genitalia includes the mucosal surfaces of the labia minora.

30. (Original) The method of claim 1, wherein the target tissue includes submucosa and muscularis below the mucosal epithelium.

31. (Original) The method of claim 1, wherein the heating does not substantially modify the mucosal epithelium of the genital tissue.

32. (Original) The method of claim 1, wherein remodeling comprises contracting target tissue.

33. (Original) The method of claim 1, wherein remodeling comprises tightening the introitus.

34. (Original) The method of claim 1, wherein remodeling comprises tightening the vagina.

35. (Original) The method of claim 1, wherein remodeling comprises denaturing collagen.

36. (Original) The method of claim 1, wherein remodeling comprises tightening collagen-rich sites in the target tissue.

37. (Original) The method of claim 1, wherein remodeling comprises rejuvenating the genital tissue toward a conformation like that which the genitalia had prior to experiencing vaginal birth.

38. (Original) The method of claim 1, wherein at least some of the remodeling occurs during the heating.

39. (Original) The method of claim 1, wherein at least some of the remodeling occurs after the heating.

40. (Original) The method of claim 39, wherein the remodeling after the heating is by a depositing of collagen in the target tissue.

41. (Original) An apparatus for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue, the apparatus comprising:

a treatment tip, the tip comprising:

a shaft comprising a longitudinal axis,

an energy delivery element, and

a cooling mechanism,

wherein the energy delivery element is adapted to contact the epithelium, and wherein treatment tip is configured to deliver energy from the energy delivery element to the target tissue in a uniform manner.

42. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft.

43. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to have a width of about 0.75 cm to about 1.25 cm.

44. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to have a length of about 1 cm to about 3 cm.

45. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to be flat.

46. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to have a radial curvature with respect to the longitudinal axis of the shaft.

47. (Original) The apparatus of claim 46, wherein the radial curvature is an arc of up to 30 degrees.

48. (Original) The apparatus of claim 46, wherein the radial curvature is an arc of about 30 degrees.

49. (Original) The apparatus of claim 41, wherein the shaft is configured to include a narrow portion proximal to the energy delivery element, and wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft, such that the energy delivery element projects forward from the shaft.

50. (Original) The apparatus of claim 41, wherein the cooling system is configured to cool the energy delivery element.

51. (Original) The apparatus of claim 41, wherein the cooling system comprises cooling fluid and at least one nozzle, the nozzle configured to spray the cooling fluid on the energy delivery element.

52. (Original) The apparatus of claim 41, wherein the energy delivery element comprises at least one capacitively coupled electrode.

53. (Original) The apparatus of claim 41, wherein the energy delivery element comprises at least one radiofrequency (RF) electrode.

54. (Original) The apparatus of claim 53, wherein the RF electrode is a monopolar electrode.

55. (Original) The apparatus of claim 53, wherein the at least one RF electrode is a bipolar electrode pair.

56. (Currently Amended) The apparatus of claim 53, further comprising at least one ~~thermister~~ thermistor located in close proximity to the electrode.

57. (Original) The apparatus of claim 53, further comprising a programmable memory chip.

REMARKS

Claim Summary

Claims 1-8 and 10-57 are pending. Claim 9 has been canceled. Claim 56 has been amended to correct a typographical error. Cancellation or amendment of any claim is not to be considered a dedication to the public of any subject matter.

Information Disclosure Statement

Applicant notes with thanks that the Examiner has considered all references submitted in an Information Disclosure Statement dated 11/19/2008.

Drawings

The Examiner objected to the drawings under 37 C.F.R. § 1.83(a) because they fail to show the impedance monitors recited in claim 9. Claim 9 has been canceled.

Specification

The Examiner objected to the disclosure because of a typographical error in paragraph [0046]. Applicant has amended that paragraph to change "39" to "30."

Claim Rejections Under 35 U.S.C. § 102

The Examiner rejected claims 1, 5-11, 13, 16, 18, 20, 22-42, 45, 46 and 49-57 under 35 U.S.C. § 102(b) as being anticipated by Knowlton US 6,350,276 ("Knowlton"). Claim 1 recites a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue, the method comprising: heating the target tissue, and remodeling the therapeutic zone of target tissue. Knowlton, on the other hand, discloses application of energy to a cervix, not to tissue beneath mucosal epithelium of female genital tissue as recited by claim 1. Knowlton therefore cannot anticipate claim 1 or claims 2-8 and 10-40 depending from claim 1.

Likewise, claim 41 recites an apparatus for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue, the apparatus comprising: a treatment tip, the tip comprising: a shaft comprising a longitudinal axis, an energy delivery element, and a cooling mechanism, wherein the energy

delivery element is adapted to contact the epithelium, and wherein treatment tip is configured to deliver energy from the energy delivery element to the target tissue in a uniform manner. Knowlton, on the other hand, describes a device adapted to treat a cervix, not tissue beneath mucosal epithelium of female genital tissue as recited by claim 41. Knowlton therefore cannot anticipate claim 41 or claims 42-57 depending from it.

Claim Rejections Under 35 U.S.C. § 103

The Examiner rejected claims 2-4, 12, 14, 15, 17, 19, 21, 43, 44, 47 and 48 under 35 U.S.C. § 103(a) as being unpatentable over Knowlton. The Examiner has not provided a rationale for the obviousness of modifying the Knowlton method to perform the method recited in claim 1, nor has the Examiner provided a rationale for the obviousness of modifying the Knowlton device to achieve the device recited by claim 41. The Examiner has therefore not established a *prima facie* case for the obviousness over Knowlton of claims 1 and 41, from which claims 2-4, 12, 14, 15, 17, 19, 21, 43, 44, 47 and 48 depend. Claims 2-4, 12, 14, 15, 17, 19, 21, 43, 44, 47 and 48 are patentable over Knowlton under § 103(a).

CONCLUSION

Applicant requests reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Date: November 15, 2010

By: 
James R. Shay, Reg. No. 32,062

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VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	11/704,067	Confirmation No.: 4378
Applicant(s):	Jonathan B. Parmer	
Filed:	February 7, 2007	
Art Unit:	3739	
Examiner:	HUPCZEY, JR, RONALD JAMES	
Title:	VAGINAL REMODELING DEVICE AND METHODS	
Customer No.:	66854	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☒ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☐ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☐ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: November 15, 2010

By: _____
James R. Shay Reg. #32062

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PTO/SB/08b (07-09)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	HUPCZEY, JR, RONALD JAMES
Attorney Docket Number	10095-701.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	159	PARMER et al.; U.S. Pat. App. # 12/884,108 entitled "Vaginal remodeling device and methods," filed 9/16/2010	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	11704067
Filing Date:	07-Feb-2007
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Filer:	James R. Shay/Sue Bromaghim
Attorney Docket Number:	10095-701.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	8841632
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	James R. Shay/Sue Bromaghim
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10095-701.201
Receipt Date:	15-NOV-2010
Filing Date:	07-FEB-2007
Time Stamp:	18:53:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	6037
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		10095-701-201-Amend-IDS.pdf	1484073 f091e8409bf3c722cfd1ff6c7379d228da457205	yes	16

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Specification	2	3
Claims	4	10
Applicant Arguments/Remarks Made in an Amendment	11	12
Transmittal Letter	13	15
Information Disclosure Statement (IDS) Filed (SB/08)	16	16

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	29775 a46b54ea926a0d3ac262cbb3c80d604a7ece57e8	no	2

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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201	4378

66854 7590 01/27/2011

SHAY GLENN LLP
2755 CAMPUS DRIVE
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EXAMINER	
HUPCZEY, JR, RONALD JAMES	
ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
01/27/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/704,067	PARMER, JONATHAN B.	
	Examiner	Art Unit	
	RONALD HUPCZEY, JR	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/15/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and Remarks, filed November 15th, 2010, are acknowledged by the Examiner. Currently, claims 1-8 and 10-57 are pending with claim 9 cancelled and claim 56 amended. Applicant's cancellation of claim 9 has obviated the previously filed objection to the drawings. Applicant's amendment to the specification obviates the previously filed objection. The following is a complete response to the November 15th, 2010 communication.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5-8, 10-11, 13, 16, 18, 20, 22-42, 45-46 and 49-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton et al (US Pat. No. 6,350,276).

Regarding claim 1, Knowlton discloses a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue (as in the embodiment of figures 13-14 describing the treatment of cervix, see col. 13; 35-37), the method comprising heating the target tissue and remodeling the therapeutic zone of target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 5, Knowlton discloses that the heating comprises delivering energy by contacting the epithelium with a treatment tip (contact by template **12** and force application **14**

contacting tissue surface **21**), the tip including an energy delivery element (energy delivery device **18** contained therein).

Regarding claim 6, Knowlton the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy (see col. 7; 52 – col. 8; 3).

Regarding claim 7, Knowlton discloses that the heating is controlled by a feedback control such that temperature does not go higher than a predetermined temperature (see at least col. 20; 66 though col. 21; 26).

Regarding claim 8, Knowlton discloses that the feedback control is provided by one or more thermal sensors (see at least col. 20; 66 though col. 21; 26.

Regarding claim 10, Knowlton discloses that the method further comprises cooling the epithelium (cooling of contact tissue **21** by the fluid **15** as in col. 5; 16 through col. 6; 4).

Regarding claim 11, Knowlton discloses that the cooling is by contacting the epithelium with a treatment tip wherein the tip includes a cooling mechanism (fluid **15** contacting tissue surfaces as in col. 5; 4-15 through the delivery of the fluid through device **10** to the contacting tip as would be in figures 13-14).

Regarding claim 13, Knowlton discloses that 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 (see col. 5; 16 – col. 6; 48 disclosing the extent and effect of the cooling provided by fluid **15**).

Regarding claim 16, Knowlton discloses that the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue (see col. 5; 52-59).

Regarding claim 18, Knowlton discloses that the method comprises contacting the epithelium with a treatment tip at a one or more contact sites during a procedure (see figure 3 showing the template **12** and surface **14** contacting the tissue surface **21** at a plurality of points during treatment), the tip comprising an energy delivery element adapted to heat the target tissue (energy delivery device within the template/surface).

Regarding claim 20, Knowlton discloses that the method includes contacting the tip to the epithelium at a plurality of contact sites (template **12** and surface **14** contacting multiple sites) during a procedure and moving the tip from site to site wherein the combined contact sites comprising a treatment area (movement of the tip into contact with each of the sites contacted by template **12** and surface **14** containing energy device **18** to form a combined treatment area).

Regarding claim 22, Knowlton discloses that the method further comprising repeating the procedure one or more times (see col. 11; 65 – col. 12; 1 discussing the retreating and refining by using the procedure again).

Regarding claim 23, Knowlton discloses that the treatment areas of the one or more procedures, respectively, may be any of the same treatment area, different treatment areas, or overlapping treatment areas (refining of a previous treatment as in col. 11; 65 – col. 12; 1 would required the retreating of substantially the same area).

Regarding claim 24, Knowlton discloses that the female genitalia includes the vulva and the vagina (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female does also include the vulva and the vagina).

Regarding claim 25, Knowlton disclose that the genitalia includes the introitus (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female does also include the introitus).

Regarding claim 26, Knowlton discloses that the female genitalia includes a portion of the vagina extending from the introitus inwardly to a location from about 1 cm to about 3.5 cm in from the introitus (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female includes the portion of anatomy recited in the claim).

Regarding claim 27, Knowlton discloses that the female genitalia includes a portion of the vagina circumferentially around its wall from about 1 o'clock to about 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female includes the portion of anatomy recited in the claim).

Regarding claim 28, Knowlton discloses that the female genitalia includes a portion radiating outward from the introitus to Hart's line (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female includes the portion of anatomy recited in the claim).

Regarding claim 29, Knowlton discloses that the female genitalia includes the mucosal surfaces of the labia minora (It is noted that with respect to the embodiment in figures 13 and 14, Knowlton specifically discloses treating the cervix but it is well known that the genitalia of a female includes the portion of anatomy recited in the claim).

Regarding claim 30, Knowlton discloses that the target tissue includes submucosa and muscularis below the mucosal epithelium (see at least col. 3; 66 – col. 4; 14).

31. The method of claim 1, wherein the heating does not substantially modify the mucosal epithelium of the genital tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64; it is noted that the without better defining what "substantially" means in the claim, the Examiner is interpreted the effects of the method of Knowlton to not be substantial).

Regarding claim 32, Knowlton discloses that remodeling comprises contracting target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claims 33 and 34, Knowlton discloses that the method described in claim 1 would include tightening the vagina and/or introitus (as displayed in figures 13 and 14 by the treatment of pre-term cervical dilation wherein the template **12** with energy device **18** treats the cervix such that tightening occurs and the entire cervix is strengthened, see at least col. 13; 37-43).

Regarding claim 35, Knowlton discloses that the remodeling comprises denaturing collagen (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 36, Knowlton discloses that the remodeling comprises tightening collagen-rich sites in the target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 37, Knowlton discloses that the remodeling comprises rejuvenating the genital tissue toward a conformation like that which the genitalia had prior to experiencing

vaginal birth (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64 and col. 13; 36-47).

Regarding claim 38, Knowlton discloses that at least some of the remodeling occurs during the heating (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 39, Knowlton discloses that at least some of the remodeling occurs after the heating (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 40, Knowlton discloses that the remodeling after the heating is by a depositing of collagen in the target tissue (see at least col. 14; 19-36 which discloses the induction of collagen formation due to heating).

Regarding claim 41, Knowlton discloses an apparatus for remodeling a therapeutic zone within a target tissue comprising tissue underlying a mucosal epithelium of female genital tissue, the apparatus comprising a treatment tip (distal end of device **10**, see figures 1 and 2A), the tip comprising a shaft comprising a longitudinal axis (see figures 1 and 2a), an energy delivery element, (element **18**) and a cooling mechanism (fluid **15** supplied to the distal end of device **10** via a lumen **13'**), wherein the energy delivery element is capable of contacting the epithelium (as shown and disclosed throughout as contacting tissue surface **21**) and wherein the treatment tip is configured to deliver energy from the energy delivery element to the target tissue in a uniform manner (see at least col. 7; 30- col. 8; 3 disclosing the application of energy).

Regarding claim 42, Knowlton discloses that the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft (see the structural arrangement of the energy elements **18** relative to the longitudinal axis of the shaft in figure 2A).

Regarding claim 45, Knowlton discloses that the energy delivery element is configured to be fiat (see the flat shape of the energy device **18** in figure 18B).

Regarding claim 46, Knowlton discloses that wherein the energy delivery element is configured to have a radial curvature with respect to the longitudinal axis of the shaft (see curved shape of energy device **18** as in figure 1).

Regarding claim 49, the shaft is configured to include a narrow portion proximal to the energy delivery element (narrow portion of the shaft of the device indicated at **10** distal to **10'** in figure 2A) wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft (see the structural arrangement of each of energy devices **18**), such that the energy delivery element projects forward from the shaft (energy devices **18** extending distally in figure 2A).

Regarding claim 50, Knowlton discloses that the cooling system is configured to cool the energy delivery element (fluid **15** being provided to energy element **18** via lumen **13'**).

Regarding claim 51, Knowlton discloses the cooling system comprises cooling fluid (fluid **15**) and at least one nozzle (opening of lumen **13'** spraying fluid onto device **18** as in col. 5; 10-15) the nozzle configured to spray the cooling fluid on the energy delivery element.

Regarding claim 52, Knowlton discloses that the energy delivery element comprises at least one capacitively coupled electrode (see col. 19; 28-29 discussing capacitive coupling).

Regarding claim 53, Knowlton discloses that the energy delivery element comprises at least one radiofrequency (RF) electrode (energy device **18** functioning to receive RF energy as in at least col. 7; 52 – col. 8; 10).

Regarding claims 54 and 55, Knowlton discloses that the RF electrodes function in either a monopolar or bipolar manner (see col. 15; 25- col. 16; 67)

Regarding claim 56, Knowlton discloses that at least one thermistor located in close proximity to the electrode (see col. 8; 31-50).

Regarding claim 57, Knowlton discloses that the system comprises a programmable memory chip (see col. 21; 15-25).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2-4, 12, 14-15, 17, 19, 21, 43-44 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton et al (US Pat. No. 6,350,276).

Regarding claims 2-4, While Knowlton discloses various temperature ranges and energy density/delivery Knowlton fails to specifically recite the tissue to be heated the claimed ranges. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the target tissue to the claimed temperature ranges since the claimed 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. In re Aller, 105 USPQ 233.

Regarding claim 12, Knowlton discloses that the cooling fluid applied to the epithelium is cooled to the temperature of -100 degrees Fahrenheit (see col. 5; 41-42) but fails to specifically recite that the epithelium comprises cooling it to a temperature between about 0 degrees C. and about 10 degrees C. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to cool the tissue to the temperature range claimed 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. In re Aller, 105 USPQ 233. Additionally, in view of the disclosed cooling ranges and control system of Knowlton, one of ordinary skill in the art would readily appreciate the capability of the system to cool the epithelial surface to the claim temperature.

Regarding claims 14 and 15, Knowlton discloses a plurality of different heating and cooling algorithms (see col. 6; 5-7) but fails to specifically recite the cooling schemes of each of the claims. However, it would have been obvious to one of ordinary skill in the art in light of the disclosure in column 6 of Knowlton to provide cooling before, during and after the heating of the tissue in order to successfully effectuate the desired treatment. In looking at the feedback system, temperature sensors and cooling system, one of ordinary skill would readily appreciate the desire to cool the tissue at each time to ensure that the tissue surface is never overheated thereby charring or burning the contact surface.

Regarding claim 17, Knowlton fails to specifically recite the temperature gradients produced in the various levels of tissue when utilizing a reverse thermal gradient cooling device. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reverse thermal gradient ranges from a low temperature of about 0 degrees C. to about 10 degrees C. at the epithelium to a high temperature of about 45 degrees C. to about 80 degrees C. in the underlying target tissue 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. In re Aller, 105 USPQ 233. Knowlton discloses in col. 5; 52-59, the use of reverse thermal gradient devices which are known in the art and as such,

one of ordinary skill, given the disclosed control system, temperature monitoring devices and feedback system would readily appreciate operating the system of Knowlton at the claimed ranges to effectuate the disclosed treatments to the tissue **9**.

Regarding claims 19 and 21, Knowlton discloses the monitoring of contact between the treatment tip of the device and the treatment surface **21** with a sensor to ensure that adequate contact is maintained during treatment (see at least cols. 19-20 discussing the monitoring of contact and impedance at the electrode sites) and the repeated treatment which is needed along with the use of multiple modalities of treatment to a target site (see col. 11; 65 – col. 12; 1). Knowlton fails to specifically recite the limitations of claims 19 and 21. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to contact one or more sites one or more times or contact any one site more than once during treatment in order to effectively provide the desired treatment to the tissue **9**. Repeated application of energy to a target portion of tissue is well known in the art and providing such a treatment step to the method of Knowlton would be a matter of mere routine experimentation by one of ordinary skill in order to obtain the desired result at the target area.

Regarding claims 43 and 44, Knowlton fails to recite the claimed sizes of the energy delivery element. However, one of ordinary skill in the art at the time the invention was made would readily appreciate providing an energy delivery device of the claimed size 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. In re Aller, 105 USPQ 233. Additionally, Knowlton discloses for the energy device **18** to have a plurality of different intended target sites and to work within a plurality of different energy density ranges

which would require one of ordinary skill in the art to adjust the size of the energy device to a suitable size based on the desired treatment and energy density.

Regarding claims 47 and 48, while Knowlton in the embodiments of figures 1 and 2B show that the energy device **18** has a radius of curvature, Knowlton fails to disclose that the radius of curvature is up to or about 30 degrees. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a radius of curvature of up to or about 30 degrees in order to provide an energy device, template and surface which all conform to a desired treatment area. Additionally, in providing such a range, 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. In re Aller, 105 USPQ 233. It has also been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

8. Applicant's arguments filed November 15th, 2010 have been fully considered but they are not persuasive.

Applicant argues on pages 11-12 of the Remarks that Knowlton fails to disclose the treatment of "tissue underlying a mucosal epithelium of female genital tissue" as recited in claims 1 and 41 since Knowlton discloses the application of energy to a cervix. The Examiner respectfully disagrees with Applicant's characterization of the Knowlton reference with specific regard given to what is considered "female genital tissue". It is first noted that claim 1 requires "the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue". Like claim 1, claim 41 describes the same desired target tissue. In order to determine where the

"therapeutic zone within a target tissue" may be contained within a patient, it is first necessary to determine what can be considered and recognized as "female genital tissue" by one of ordinary skill in the art. It is the Examiner's position that one of ordinary skill in the art would readily recognize the cervix as a portion of female genitalia thereby qualifying such a structure as "female genital tissue". Next, it is essential to determine if the "female genital tissue" comprises tissue which underlies mucosal epithelium. The cervix is known to be comprised of an epithelium and for the epithelium to be composed of stratified squamous epithelium and simple columnar epithelium. In light of this known structure of the cervix and its consideration by the Examiner as "female genital tissue", it is finally essential to determine if the heating and remodeling in Knowlton occurs in the "tissue underlying a mucosal epithelium of female genital tissue". Knowlton clearly discusses in at least col. 4; 1-13 that the treatment area can include tissue and underlying tissue. In the remainder of col. 3; 66 through col. 11; 64 it is clear to the Examiner that Knowlton discloses the treatment of tissue underlying a tissue layer and, in the case of the embodiment of figures 13 and 14, that would include "tissue underlying a mucosal epithelium of female genital tissue" as required by claim 1. Similarly, it is clear that the treatment tip of the device would, due to the contact of the device with the cervix, be capable of contacting the epithelium and, as disclosed throughout col. 3; 66 - col. 11; 64, be capable of treating tissue underlying the epithelium. As such, it remains the Examiner position that the rejection of claims 1, 5-11, 13, 16, 18, 20, 22-42, 45-46 and 49-57 under 35 U.S.C. 102(b) as being anticipated by Knowlton et al (US Pat. No. 6,350,276) remains tenable. Additionally, since it is the Examiner's position that the rejection of claims 1 and 41 as being anticipated by Knowlton et al (US Pat. No. 6,350,276) is proper, the Examiner further believes that the rejection

of claims 2-4, 12, 14-15, 17, 19, 21, 43-44 and 47-48 under 35 U.S.C. 103(a) as being unpatentable over Knowlton et al (US Pat. No. 6,350,276) remain tenable. Applicant is invited to contact the Examiner to discuss the above response if clarification of the Examiner's position or further explanation is needed.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	**Art Unit**
	RONALD HUPCZEY, JR	3739

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/10/2010	01/20/2011							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	-							
	10	✓	✓							
	11	✓	✓							
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	29	✓	✓							
	30	✓	✓							
	31	✓	✓							
	32	✓	✓							
	33	✓	✓							
	34	✓	✓							
	35	✓	✓							
	36	✓	✓							

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	**Art Unit**
	RONALD HUPCZEY, JR	3739

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/10/2010	01/20/2011							
	37	✓	✓							
	38	✓	✓							
	39	✓	✓							
	40	✓	✓							
	41	✓	✓							
	42	✓	✓							
	43	✓	✓							
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	45	✓	✓							
	46	✓	✓							
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	53	✓	✓							
	54	✓	✓							
	55	✓	✓							
	56	✓	✓							
	57	✓	✓							

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	HUPCZEY, JR, RONALD JAMES
Attorney Docket Number	10095-701.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	159	PARMER et al.; U.S. Pat. App. # 12/884,108 entitled "Vaginal remodeling device and methods," filed 9/16/2010	

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	01/20/2011

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.H./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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EAST Search History (Interference)

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	Art Unit
	RONALD HUPCZEY, JR	3739

SEARCHED

Class	Subclass	Date	Examiner
606	1-52	08/06/2010	RJH
607	50, 115, 138	08/06/2010	RJH

SEARCH NOTES

Search Notes	Date	Examiner
East Search	08/06/2010	RJH
Inventor Search	08/06/2010	RJH
Updated Search	1/20/2011	RJH

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

Approved for use through 03/31/2007. OMB 0651-0031
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Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. PARMER
Art Unit	3739
Examiner Name	Ronald James HUPCZEY, JR.
Attorney Docket Number	10095-701.201

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☑ Other Amendment Accompanying RCE, filed herewith

   b. ☑ Enclosed

      i. ☑ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☐ Information Disclosure Statement (IDS)

      iv. ☐ Other _____

2. Miscellaneous

   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 50-4050.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	Linda Gont	Date	APRIL 15, 2011
Name (Print/Type)	LINDA GONT	Registration No.	67,715

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature	FILED VIA EFS		
Name (Print/Type)	SUE BROMAGHIM	Date	APRIL 15, 2011

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

FILED VIA EFS ON APRIL 15, 2011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	11/704,067	Confirmation No.:	4378
Applicant	:	Jonathan B. PARMER		
Filing Date	:	February 7, 2007		
Title	:	Vaginal Remodeling Device and Methods		
Group Art Unit	:	3739		
Examiner	:	Ronald James HUPCZEY, JR.		
Docket No.	:	10095-701.201		
Customer No.	:	66854		

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

AMENDMENT ACCOMPANYING RCE

Introductory Comments:

This Amendment accompanies a Request for Continued Examination and is responsive to the final Office Action dated January 27, 2011, for which a response is due **April 27, 2011**.

Please enter the amendments and consider the remarks as follows.

Amendments to the Specification are not being made at this time.

Amendments to the Claims begin on page 2.

Remarks / Arguments begin on page 9 of this paper.

Amendments to the Claims:

Please make the amendments as shown. A complete listing of the claims follows:

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

heating the target tissue, and

remodeling the therapeutic zone of target tissue.

2. (Original) The method of claim 1, wherein heating the target tissue comprises heating it to a temperature between about 45 degrees C. and about 80 degrees C.

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

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

5. (Original) The method of claim 1, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

6. (Original) The method of claim 5, wherein the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy.

7. (Original) The method of claim 1, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

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

9. (Canceled)

10. (Original) The method of claim 1, wherein the method further comprises cooling the epithelium.

11. (Original) The method of claim 10, wherein cooling is by contacting the epithelium with a treatment tip, the tip including a cooling mechanism.

12. (Original) The method of claim 10, wherein cooling the epithelium comprises cooling it to a temperature between about 0 degrees C. and about 10 degrees C.

13. (Original) The method of claim 10, 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.

14. (Original) The method of claim 10, wherein the cooling precedes the heating, and continues during the heating.

15. (Original) The method of claim 10, wherein the cooling is during the heating, and continues after heating.

16. (Original) The method of claim 10, wherein the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue.

17. (Original) The method of claim 16, wherein the reverse thermal gradient ranges from a low temperature of about 0 degrees C. to about 10 degrees C. at the epithelium to a high temperature of about 45 degrees C. to about 80 degrees C. in the underlying target tissue.

18. (Original) The method of claim 1, 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.

19. (Currently amended) The method of claim 18, wherein the method is performed during a procedure, and wherein the contacting of any one [[of]] or more contact sites is repeated one or more times during a procedure.

20. (Original) The method of claim 18, 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.

21. (Currently amended) The method of claim 20, wherein any one of the contact sites is contacted one or more times during a procedure.

22. (Original) The method of claim 20, the method further comprising repeating the procedure one or more times.

23. (Currently amended) The method of claim 22, wherein the treatment areas of the one or more procedures~~, respectively,~~ may be any of the same treatment area, different treatment areas, or overlapping treatment areas.

24. – 25. (Canceled)

26. (Currently amended) The method of claim 1, wherein the ~~female genitalia~~ heating includes heating a portion of the vagina extending from the introitus inwardly to a location from about 1 cm to about 3.5 cm in from the introitus.

27. (Currently amended) The method of claim 1, wherein the ~~female genitalia~~ heating includes heating a portion of the vagina circumferentially around its wall from about 1 o'clock to about 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock.

28. (Currently amended) The method of claim 1, wherein the ~~female genitalia~~ heating includes heating a portion radiating outward from the introitus to Hart's line.

29. (Currently amended) The method of claim 1, wherein the ~~female genitalia~~ heating includes heating a ~~the~~ mucosal ~~surfaces~~ surface of the labia minora.

30. (Currently amended) The method of claim 1, wherein the target tissue heating includes heating submucosa and muscularis below ~~the~~ a mucosal epithelium.

31. (Currently amended) The method of claim 1, wherein the heating does not substantially modify ~~the~~ a mucosal epithelium of the genital tissue.

32. (Original) The method of claim 1, wherein remodeling comprises contracting target tissue.

33. (Original) The method of claim 1, wherein remodeling comprises tightening the introitus.

34. (Original) The method of claim 1, wherein remodeling comprises tightening the vagina.

35. (Original) The method of claim 1, wherein remodeling comprises denaturing collagen.

36. (Original) The method of claim 1, wherein remodeling comprises tightening collagen-rich sites in the target tissue.

37. (Original) The method of claim 1, wherein remodeling comprises rejuvenating the genital tissue toward a conformation like that which the genitalia had prior to experiencing vaginal birth.

38. (Original) The method of claim 1, wherein at least some of the remodeling occurs during the heating.

39. (Original) The method of claim 1, wherein at least some of the remodeling occurs after the heating.

40. (Original) The method of claim 39, wherein the remodeling after the heating is by a depositing of collagen in the target tissue.

41. (Currently amended) An apparatus for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying ~~a mucosal~~ an epithelium of female genital tissue comprising at least one of vulva, introitus, and vagina tissue, the apparatus comprising:

a treatment tip, the tip comprising:

a shaft comprising a longitudinal axis,

an energy delivery element, and

a cooling ~~mechanism~~ system,

wherein the energy delivery element is adapted to contact the epithelium, and wherein the treatment tip is configured to deliver energy from the energy delivery element to the target tissue in a uniform manner.

42. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft.

43. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to have a width of about 0.75 cm to about 1.25 cm.

44. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to have a length of about 1 cm to about 3 cm.

45. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to be flat.

46. (Original) The apparatus of claim 41, wherein the energy delivery element is configured to have a radial curvature with respect to the longitudinal axis of the shaft.

47. (Original) The apparatus of claim 46, wherein the radial curvature is an arc of up to 30 degrees.

48. (Original) The apparatus of claim 46, wherein the radial curvature is an arc of about 30 degrees.

49. (Original) The apparatus of claim 41, wherein the shaft is configured to include a narrow portion proximal to the energy delivery element, and wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft, such that the energy delivery element projects forward from the shaft.

50. (Original) The apparatus of claim 41, wherein the cooling system is configured to cool the energy delivery element.

51. (Original) The apparatus of claim 41, wherein the cooling system comprises cooling fluid and at least one nozzle, the nozzle configured to spray the cooling fluid on the energy delivery element.

52. (Original) The apparatus of claim 41, wherein the energy delivery element comprises at least one capacitively coupled electrode.

53. (Original) The apparatus of claim 41, wherein the energy delivery element comprises at least one radiofrequency (RF) electrode.

54. (Original) The apparatus of claim 53, wherein the RF electrode is a monopolar electrode.

55. (Original) The apparatus of claim 53, wherein the at least one RF electrode is a bipolar electrode pair.

56. (Previously Presented) The apparatus of claim 53, further comprising at least one thermistor located in close proximity to the electrode.

57. (Original) The apparatus of claim 53, further comprising a programmable memory chip.

REMARKS

Claim Summary

Claims 1, 19, 21, 23, 26-31 and 41 are currently amended. Claims 24 and 25 are canceled. Claim 9 was previously canceled. No claims are withdrawn from consideration. Claims 1-8, 10-23, and 26-57 are currently pending. Cancellation or amendment of any claim is not to be considered a dedication to the public of any subject matter.

Information Disclosure Statements

Applicant notes with thanks that the Examiner has considered all references submitted in an Information Disclosure Statement dated 11/15/2010.

Claim Rejections Under 35 U.S.C. § 102

The Examiner rejected claims 1, 5-8, 10, 11, 13, 16, 18, 20, 22-42, 45, 46, and 49-57 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. 6,350,276 to Edward Knowlton ("Knowlton").

Claim 1, as amended, recites a method for remodeling a therapeutic zone within a target tissue, the tissue including at least one of vulva, introitus, and vagina tissue. Knowlton does not disclose a method for remodeling a therapeutic zone including at least one of vulva, introitus or vagina. As Knowlton does not disclose a method for remodeling a therapeutic zone including at least one of vulva, introitus or vagina, Knowlton cannot anticipate claim 1. Claim 1 and claims 5-8, 10, 11, 13, 16, 18, 20, 22, 23, 26-40 depending from it, are patentable over Knowlton under § 102(b).

Independent claim 41 as amended, recites an apparatus for remodeling a therapeutic zone within a target tissue, the target tissue including tissue underlying a mucosal epithelium of female genital tissue, the female genital tissue being at least one of vulva, introitus, and vagina tissue. Knowlton does not disclose an apparatus for remodeling a therapeutic zone underlying a mucosal epithelium of at least one member of the group vulva, introitus, and vagina. As Knowlton does not disclose an apparatus for remodeling a therapeutic zone underlying a mucosal epithelium of at least one member of the group vulva, introitus, and vagina, Knowlton cannot anticipate claim 41. Claim 41 and claims 42, 45, 46, and 49-57 depending from it, are patentable over Knowlton under § 102(b).

Claim Rejections Under 35 U.S.C. § 103

The Examiner rejected claims 2-4, 12, 14, 15, 17, 19, 21, 43, 44, 47 and 48 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Knowlton. Claims 2-4, 12, 14, 15, 17, 19, and 21 depend from independent claim 1. As discussed above, Knowlton does not disclose a method for remodeling a therapeutic zone including at least one of vulva, introitus or vagina as required by claim 1. The Examiner has not provided a rational basis for the obviousness of modifying Knowlton's method to include remodeling these specific tissue sites. Claim 1, and claims 2-4, 12, 14, 15, 17, 19, and 21 depending from it, are patentable over Knowlton under § 103(a).

Claims 43, 44, 47 and 48 depend from independent claim 41. As discussed above, Knowlton does not disclose a method for remodeling a therapeutic zone including at least one of vulva, introitus or vagina as required by claim 41. The Examiner has not provided a rational basis for the obviousness of modifying Knowlton's method to include remodeling these specific tissue sites. Claim 41, and claims 43, 44, 47 and 48 depending from it, are patentable over Knowlton under § 103(a).

CONCLUSION

Applicant requests reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Date: April 15, 2011

By: Linda Gont
Linda Gont, Reg. No. 67,715

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

Electronic Patent Application Fee Transmittal

Application Number:	11704067
Filing Date:	07-Feb-2007
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Filer:	James R. Shay/Sue Bromaghim (LG)
Attorney Docket Number:	10095-701.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**405**

Electronic Acknowledgement Receipt

EFS ID:	9894278
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	James R. Shay/Sue Bromaghim (LG)
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10095-701.201
Receipt Date:	15-APR-2011
Filing Date:	07-FEB-2007
Time Stamp:	18:14:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$405
RAM confirmation Number	4986
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		10095-701-201-RCE-Amend.pdf	1017598 1dace0629ed153a12a4cfe1c1daeee084e8c5e47	yes	11

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Request for Continued Examination (RCE)	1	1
Amendment Submitted/Entered with Filing of CPA/RCE	2	2
Claims	3	9
Applicant Arguments/Remarks Made in an Amendment	10	11

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	30009 f1ef7a2f6d40dfa2d0f5c2abd4aa45b962e4b28b	no	2

Warnings:

Information:

Total Files Size (in bytes):	1047607

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/704,067	02/07/2007	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	04/15/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 54	Minus	** 57	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/LYNNELL JOHNSON/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
		US-			
		US-			
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	160	WO96/22739A1	8/1/1996	Vidamed, Inc.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	15898315
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	James R. Shay/Brian Flick
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10095-701.201
Receipt Date:	29-MAY-2013
Filing Date:	07-FEB-2007
Time Stamp:	16:56:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10095-701-201_IDS_Filing_5-29-2013.pdf	265509 5db3c49d96d577059f13a3fa36f53206d8c27587	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	4
Warnings:			
Information:			

2	Foreign Reference	WO1996022739A1.pdf	1855256 cad9cdfb6df8e5c64f225e9cfbc5b7894fa31eac	no	37

Warnings:	
Information:	
Total Files Size (in bytes):	2120765

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 11/704,067	Confirmation No.: 4378
First Named Inventor	: Jonathan B. Parmer	
Filed	: February 7, 2007	
Art Unit	: 3739	
Examiner	: Hupczey, Jr, Ronald James	
Title	: VAGINAL REMODELING DEVICE AND METHODS	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☒ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☒ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☐ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☐ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☒ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

STATEMENT UNDER 37 CFR § 1.704(d)

☒ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 5/29/13

By: _____

James R. Shay, Reg. No. 32,062

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	163	US- 5,242,440	9/7/1993	Shippert	
	165	US- 5,450,293	9/12/1995	Hoffman	
	162	US- 7,294,127	11/13/2007	Leung et al.	
	167	US- 7,998,137	8/5/2010	Elkins et al.	
	164	US- 2007/0093807	4/26/2007	Baxter et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	168	WO2006/105121A2	10/5/2010	Minnow Medical LLC		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	16962384
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	James R. Shay/Brian Flick
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10095-701.201
Receipt Date:	26-SEP-2013
Filing Date:	07-FEB-2007
Time Stamp:	11:59:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10095-701-201_IDS_Filing_9-26-2013.pdf	274126 22821dd6fc0ce2cabc3699bf6a22cc58503c063a	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	4
Warnings:			
Information:			

2	Foreign Reference	WO2006105121A2.pdf	4991954 17fd80fe5b6a51cbf6dd01b90cb33576f1cfd754	no	91

Warnings:	
Information:	
Total Files Size (in bytes):	5266080

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on 9/26/2013.

Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 11/704,067	Confirmation No.: 4378
First Named Inventor	: Jonathan B. Parmer	
Filed	: February 7, 2007	
Art Unit	: 3739	
Examiner	: Hupczey, Jr, Ronald James	
Title	: VAGINAL REMODELING DEVICE AND METHODS	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☒ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Cite no(s):

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. Cite no(s):

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 9/26/13

By: _____
James R. Shay, Reg. No. 32,062

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	170	US- 5,160,334	11/3/1992	Billings et al.	
	169	US- 5,330,469	7/19/1994	Fleenor	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	17328639
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	James R. Shay/Brian Flick
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10095-701.201
Receipt Date:	06-NOV-2013
Filing Date:	07-FEB-2007
Time Stamp:	13:18:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10095-701-201_IDS_Filing_11-6-2013.pdf	269207 1e6d3142e96aacb436a5330eca63060989c383db	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	269207	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
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New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on 11-6-2013.

Brian Flatt
Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 11/704,067	Confirmation No.: 4378
First Named Inventor	: Jonathan B. Parmer	
Filed	: February 7, 2007	
Art Unit	: 3739	
Examiner	: Hupczey, Jr, Ronald James	
Title	: VAGINAL REMODELING DEVICE AND METHODS	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☒ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☒ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

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☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☒ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

STATEMENT UNDER 37 CFR § 1.704(d)

☒ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 11/6/13

By: _____

James R. Shay, Reg. No. 32,062

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201	4378

66854 7590 02/13/2014

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
HUPCZEY, JR, RONALD JAMES	

ART UNIT	PAPER NUMBER
3739	

NOTIFICATION DATE	DELIVERY MODE
02/13/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@shayglenn.com

Office Action Summary	Application No. 11/704,067	Applicant(s) PARMER, JONATHAN B.	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/15/2011*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-8,10-23 and 26-57* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-8,10-23 and 30-57* is/are rejected.

8)☒ Claim(s) *26-29* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *02/07/07* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *5/29/13, 9/26/13, 11/6/13*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 15th, 2011 has been entered. Currently, claims 1-8, 10-23, and 26-57 are pending with claims 1, 19, 21, 23, 26-31, and 41 amended, and claims 9, 24, and 25 cancelled. The following is a complete response to the April 15th, 2011 communication.

Notice of Pre-AIA or AIA Status

2. The present application is being examined under the pre-AIA first to invent provisions.

3. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5-8, 10-11, 13, 16, 18, 20, 22-23, 30-42, 45-46 and 49-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton et al (US Pat. No. 6,350,276).

Regarding claim 1, Knowlton discloses 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 the vulva, introitus and vagina tissue (as in the embodiment of figures 13-14 describing the treatment of cervix, see col. 13; 35-37; the Examiner notes that while Knowlton discusses the specific treatment of the cervix, the other tissues recited in the claim are also considered as part of the female genital tissue with the claim failing to specifically require that those portions comprising the target tissue are actually heat and/or remodeled), the method comprising heating the target tissue and remodeling the therapeutic zone of target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 5, Knowlton discloses that the heating comprises delivering energy by contacting the epithelium with a treatment tip (contact by template **12** and force application **14** contacting tissue surface **21**), the tip including an energy delivery element (energy delivery device **18** contained therein).

Regarding claim 6, Knowlton the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy (see col. 7; 52 – col. 8; 3).

Regarding claim 7, Knowlton discloses that the heating is controlled by a feedback control such that temperature does not go higher than a predetermined temperature (see at least col. 20; 66 though col. 21; 26).

Regarding claim 8, Knowlton discloses that the feedback control is provided by one or more thermal sensors (see at least col. 20; 66 though col. 21; 26.

Regarding claim 10, Knowlton discloses that the method further comprises cooling the epithelium (cooling of contact tissue **21** by the fluid **15** as in col. 5; 16 through col. 6; 4).

Regarding claim 11, Knowlton discloses that the cooling is by contacting the epithelium with a treatment tip wherein the tip includes a cooling mechanism (fluid **15** contacting tissue surfaces as in col. 5; 4-15 through the delivery of the fluid through device **10** to the contacting tip as would be in figures 13-14).

Regarding claim 13, Knowlton discloses that 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 (see col. 5; 16 – col. 6; 48 disclosing the extent and effect of the cooling provided by fluid **15**).

Regarding claim 16, Knowlton discloses that the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue (see col. 5; 52-59).

Regarding claim 18, Knowlton discloses that the method comprises contacting the epithelium with a treatment tip at a one or more contact sites during a procedure (see figure 3 showing the template **12** and surface **14** contacting the tissue surface **21** at a plurality of points during treatment), the tip comprising an energy delivery element adapted to heat the target tissue (energy delivery device within the template/surface).

Regarding claim 20, Knowlton discloses that the method includes contacting the tip to the epithelium at a plurality of contact sites (template **12** and surface **14** contacting multiple sites)

during a procedure and moving the tip from site to site wherein the combined contact sites comprising a treatment area (movement of the tip into contact with each of the sites contacted by template **12** and surface **14** containing energy device **18** to form a combined treatment area).

Regarding claim 22, Knowlton discloses that the method further comprising repeating the procedure one or more times (see col. 11; 65 – col. 12; 1 discussing the retreating and refining by using the procedure again).

Regarding claim 23, Knowlton discloses that the treatment areas of the one or more procedures, may be any of the same treatment area, different treatment areas, or overlapping treatment areas (refining of a previous treatment as in col. 11; 65 – col. 12; 1 would require the retreating of substantially the same area).

Regarding claim 30, Knowlton discloses that the target tissue includes submucosa and muscularis below the mucosal epithelium (see at least col. 3; 66 – col. 4; 14).

Regarding claim 31, Knowlton discloses that the heating does not substantially modify the mucosal epithelium of the genital tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64; it is noted that the without better defining what "substantially" means in the claim, the Examiner is interpreted the effects of the method of Knowlton to not be substantial).

Regarding claim 32, Knowlton discloses that remodeling comprises contracting target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claims 33 and 34, Knowlton discloses that the method described in claim 1 would include tightening the vagina and/or introitus (as displayed in figures 13 and 14 by the treatment of pre-term cervical dilation wherein the template **12** with energy device **18** treats the

cervix such that tightening occurs and the entire cervix is strengthened, see at least col. 13; 37-43).

Regarding claim 35, Knowlton discloses that the remodeling comprises denaturing collagen (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 36, Knowlton discloses that the remodeling comprises tightening collagen-rich sites in the target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 37, Knowlton discloses that the remodeling comprises rejuvenating the genital tissue toward a conformation like that which the genitalia had prior to experiencing vaginal birth (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64 and col. 13; 36-47).

Regarding claim 38, Knowlton discloses that at least some of the remodeling occurs during the heating (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 39, Knowlton discloses that at least some of the remodeling occurs after the heating (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).

Regarding claim 40, Knowlton discloses that the remodeling after the heating is by a depositing of collagen in the target tissue (see at least col. 14; 19-36 which discloses the induction of collagen formation due to heating).

Regarding claim 41, Knowlton discloses an apparatus for remodeling a therapeutic zone within a target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus, and vagina tissue (as in the embodiment of figures 13-14 describing the treatment of cervix, see col. 13; 35-37; the Examiner notes that while Knowlton discusses the specific treatment of the cervix, the other tissues recited in the claim are also considered as part of the female genital tissue with the claim failing to specifically require that those portions comprising the target tissue are actually heat and/or remodeled), the apparatus comprising a treatment tip (distal end of device **10**, see figures 1 and 2A), the tip comprising a shaft comprising a longitudinal axis (see figures 1 and 2a), an energy delivery element, (element **18**) and a cooling system (fluid **15** supplied to the distal end of device **10** via a lumen **13'**), wherein the energy delivery element is capable of contacting the epithelium (as shown and disclosed throughout as contacting tissue surface **21**) and wherein the treatment tip is configured to deliver energy from the energy delivery element to the target tissue in a uniform manner (see at least col. 7; 30- col. 8; 3 disclosing the application of energy).

Regarding claim 42, Knowlton discloses that the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft (see the structural arrangement of the energy elements **18** relative to the longitudinal axis of the shaft in figure 2A).

Regarding claim 45, Knowlton discloses that the energy delivery element is configured to be fiat (see the flat shape of the energy device **18** in figure 18B).

Regarding claim 46, Knowlton discloses that wherein the energy delivery element is configured to have a radial curvature with respect to the longitudinal axis of the shaft (see curved shape of energy device **18** as in figure 1).

Regarding claim 49, the shaft is configured to include a narrow portion proximal to the energy delivery element (narrow portion of the shaft of the device indicated at **10** distal to **10'** in figure 2A) wherein the energy delivery element is configured to be substantially parallel to the longitudinal axis of the shaft (see the structural arrangement of each of energy devices **18**), such that the energy delivery element projects forward from the shaft (energy devices **18** extending distally in figure 2A).

Regarding claim 50, Knowlton discloses that the cooling system is configured to cool the energy delivery element (fluid **15** being provided to energy element **18** via lumen **13'**).

Regarding claim 51, Knowlton discloses the cooling system comprises cooling fluid (fluid **15**) and at least one nozzle (opening of lumen **13'** spraying fluid onto device **18** as in col. 5; 10-15) the nozzle configured to spray the cooling fluid on the energy delivery element.

Regarding claim 52, Knowlton discloses that the energy delivery element comprises at least one capacitively coupled electrode (see col. 19; 28-29 discussing capacitive coupling).

Regarding claim 53, Knowlton discloses that the energy delivery element comprises at least one radiofrequency (RF) electrode (energy device **18** functioning to receive RF energy as in at least col. 7; 52 – col. 8; 10).

Regarding claims 54 and 55, Knowlton discloses that the RF electrodes function in either a monopolar or bipolar manner (see col. 15; 25- col. 16; 67)

Regarding claim 56, Knowlton discloses that at least one thermistor located in close proximity to the electrode (see col. 8; 31-50).

Regarding claim 57, Knowlton discloses that the system comprises a programmable memory chip (see col. 21; 15-25).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-4, 12, 14-15, 17, 19, 21, 43-44 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton et al (US Pat. No. 6,350,276).

Regarding claims 2-4, While Knowlton discloses various temperature ranges and energy density/delivery Knowlton fails to specifically recite the tissue to be heated the claimed ranges.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the target tissue to the claimed temperature ranges since the claimed 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. *In re Aller*, 105 USPQ 233.

Regarding claim 12, Knowlton discloses that the cooling fluid applied to the epithelium is cooled to the temperature of -100 degrees Fahrenheit (see col. 5; 41-42) but fails to specifically recite that the epithelium comprises cooling it to a temperature between about 0 degrees C. and about 10 degrees C. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to cool the tissue to the temperature range claimed 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. *In re Aller*, 105 USPQ 233. Additionally, in view of the disclosed cooling ranges and control system of Knowlton, one of ordinary skill in the art would readily appreciate the capability of the system to cool the epithelial surface to the claim temperature.

Regarding claims 14 and 15, Knowlton discloses a plurality of different heating and cooling algorithms (see col. 6; 5-7) but fails to specifically recite the cooling schemes of each of the claims. However, it would have been obvious to one of ordinary skill in the art in light of the disclosure in column 6 of Knowlton to provide cooling before, during and after the heating of the

tissue in order to successfully effectuate the desired treatment. In looking at the feedback system, temperature sensors and cooling system, one of ordinary skill would readily appreciate the desire to cool the tissue at each time to ensure that the tissue surface is never overheated thereby charring or burning the contact surface.

Regarding claim 17, Knowlton fails to specifically recite the temperature gradients produced in the various levels of tissue when utilizing a reverse thermal gradient cooling device. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reverse thermal gradient ranges from a low temperature of about 0 degrees C. to about 10 degrees C. at the epithelium to a high temperature of about 45 degrees C. to about 80 degrees C. in the underlying target tissue 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. *In re Aller*, 105 USPQ 233. Knowlton discloses in col. 5; 52-59, the use of reverse thermal gradient devices which are known in the art and as such, one of ordinary skill, given the disclosed control system, temperature monitoring devices and feedback system would readily appreciate operating the system of Knowlton at the claimed ranges to effectuate the disclosed treatments to the tissue **9**.

Regarding claims 19 and 21, Knowlton discloses the monitoring of contact between the treatment tip of the device and the treatment surface **21** with a sensor to ensure that adequate contact is maintained during treatment (see at least cols. 19-20 discussing the monitoring of contact and impedance at the electrode sites) and the repeated treatment which is needed along with the use of multiple modalities of treatment to a target site (see col. 11; 65 – col. 12; 1). Knowlton fails to specifically recite the limitations of claims 19 and 21. However, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to contact one or more sites one or more times or contact any one site more than once during treatment in order to effectively provide the desired treatment to the tissue **9**. Repeated application of energy to a target portion of tissue is well known in the art and providing such a treatment step to the method of Knowlton would be a matter of mere routine experimentation by one of ordinary skill in order to obtain the desired result at the target area.

Regarding claims 43 and 44, Knowlton fails to recite the claimed sizes of the energy delivery element. However, one of ordinary skill in the art at the time the invention was made would readily appreciate providing an energy delivery device of the claimed size 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. *In re Aller*, 105 USPQ 233. Additionally, Knowlton discloses for the energy device **18** to have a plurality of different intended target sites and to work within a plurality of different energy density ranges which would require one of ordinary skill in the art to adjust the size of the energy device to a suitable size based on the desired treatment and energy density.

Regarding claims 47 and 48, while Knowlton in the embodiments of figures 1 and 2B show that the energy device **18** has a radius of curvature, Knowlton fails to disclose that the radius of curvature is up to or about 30 degrees. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a radius of curvature of up to or about 30 degrees in order to provide an energy device, template and surface which all conform to a desired treatment area. Additionally, in providing such a range, 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. *In re Aller*, 105 USPQ 233. It has also been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Allowable Subject Matter

10. Claims 26-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: With regard to each of claim 26-29, the Examiner has taken the position with respect to amended claim 1, that while the claim may recite at least one of a vagina, introitus or vulva tissue are part of the target tissue, the other tissue treated in Knowlton are also considered as part of the female genital tissue. The Examiner is also of the position that claim 1, as presently recited, fails to specifically require that those portions (vulva, vagina or introitus tissue) comprising the target tissue are actually required to be either heated or remodeled by the claim. Turning to the recitations in claims 26-29, each claim as amended presently requires that a portion of tissue not taught by Knowlton is heated in the method. That is, a specific portion of the vagina is required to be heated in each of claims 26 and 27, a portion of the genital tissue radiating outward from the introitus to Hart's line is required to be heated in claim 28, and a muscosal surface of the labia minora is required to be heated in claim 29. Knowlton has only ever set forth in col. 13, 35-37 that the circumference of the cervix is treated so as to contract a dilated cervical OS. This limitation fails to provide for the specific locations of heating recited in each of claims 26-29.

Furthermore, the Examiner has failed to find any other piece of prior art that fairly discloses, suggests, or makes obvious the treatment of those areas.

Response to Arguments

12. Applicant's arguments filed April 15th, 2011 have been fully considered but they are not persuasive.

13. Applicant has proffered arguments against the previously-filed rejection of claims 1, 5-8, 10, 11, 13, 16, 18, 20, 22-42, 45, 46, and 49-57 under 35 U.S.C. 102(b) as anticipated by Knowlton (US Pat. No. 6,350,276) on page 9 of the Remarks. Applicant argues with respect to each of independent claims 1 and 41 that Knowlton does not disclose a method for "remodeling a therapeutic zone including at least one of vulva, introitus or vagina" as presently recited in claim 1, or an apparatus "for remodeling a therapeutic zone underlying a mucosal epithelium of at least one member of the group vulva, introitus, and vagina". The Examiner, however, respectfully disagrees with Applicant.

It is the Examiner's position that the Applicant's amendments to each of claims 1 and 41 to which attempt further specify the type of tissue forming at least a part of the therapeutic zone fail 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 per claim 1. Similarly, the Examiner does not believe that the apparatus of claim 41 need to treat any of the tissue of the vulva, the introitus or the vagina. That is, the Examiner is of the position that the embodiment of figures 13-14 with the description of the treatment of cervix in col. 13; 35-37, fairly provides for the claimed method and apparatus. As has been noted above, it is the Examiner's position that while Knowlton discusses the specific treatment of the cervix, the other tissues recited in the claim are also

considered as part of the female genital tissue with each claim failing to specifically require that those portions comprising the target tissue are actually heat and/or remodeled. This lack of a positive requirement of the treatment of the presently-recited areas in claims 1 and 41 is due in part to each limitation's positioning within the preamble of each, claim, to the claiming that it is the female genital tissue which is comprising the tissue of the vagina, introitus or vulva, and to the lack of a close end to the tissue which can comprise the therapeutic zone.

In contrast, the Examiner points to the indication that claims 26-29 are allowable above. These claims have been indicated as allowable due to the fact that each actually requires the treatment of a portion of the female genital tissue (via heating a specific portion) which is not taught by Knowlton (i.e. not the cervix). Such positive claiming can be used as a guideline when drafting subsequent language.

As such, it is for at least the reasoning set forth above that the Examiner believes that the rejection of claims 1, 5-8, 10-11, 13, 16, 18, 20, 22-23, 30-42, 45-46 and 49-57 under 35 U.S.C 102(b) as unpatentable over Knowlton remains tenable. The Examiner further believes that these remarks above fully address Applicant's arguments on page 10 of the Remarks directed towards the previously proffered rejections of claims 2-4, 12, 14-15, 17, 19, 21, 43-44 and 47-48 under 35 U.S.C. 103(a). These arguments are only based on the alleged allowability of claims 1 and 41 as amended, these arguments having been addressed by the Examiner in the response above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD HUPCZEY, JR/
Primary Examiner, Art Unit 3739

RJH

PTO/SB/08a (07-09)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	170	US- 5,160,334	11/3/1992	Billings et al.	
	169	US- 5,330,469	7/19/1994	Fleenor	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	02/09/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	Art Unit
	RONALD HUPCZEY, JR	3739

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	1-52	08/06/2010	RJH
607	50, 115, 138	08/06/2010	RJH

SEARCH NOTES		
Search Notes	Date	Examiner
East Search	08/06/2010	RJH
Inventor Search	08/06/2010	RJH
Updated Search	1/20/2011	RJH
Updated Search	2/9/14	RJH

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

PTO/SB/08a (07-09)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	163	US- 5,242,440	9/7/1993	Shippert	
	165	US- 5,450,293	9/12/1995	Hoffman	
	162	US- 7,294,127	11/13/2007	Leung et al.	
	167	US- 7,998,137	8/5/2010	Elkins et al.	
	164	US- 2007/0093807	4/26/2007	Baxter et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	168	WO2006/105121A2	10/5/2010	Minnow Medical LLC		

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	02/09/2014

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	160	WO96/22739A1	8/1/1996	Vidamed, Inc.		

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	02/09/2014

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EAST Search History

EAST Search History (Prior Art)

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S40	2	"6350276".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/12/14 19:11
S41	71	"606".clas. and introitus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/25 14:28
S42	66	"606".clas. and vulva	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/25 14:36
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S46	6	11/295204 and vulva	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:48
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S54	2	"6350276".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:05
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EAST Search History (Interference)

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	**Art Unit**
	RONALD HUPCZEY, JR	3739

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	**Art Unit**
	RONALD HUPCZEY, JR	3739

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

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CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on June 9, 2014.
/Mary Buggie/ 6/9/2014
Mary Buggie **Date**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	11/704,067	Confirmation No.	: 4378
First Named Inventor	:	Jonathan B. Parmer		
Filing Date	:	February 7, 2007		
Art Unit	:	3739		
Examiner	:	Hupczey, Jr., Ronald James		
Title	:	VAGINAL REMODELING DEVICE AND METHODS		
Customer No.	:	66854		

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

This reply is in response to the non-final Office Action mailed February 13, 2014 for which a response was due May 13, 2014. A one-month Petition for Extension of Time is filed herewith, extending the due date up to and including June 13, 2014. Thus, this response is timely filed. The Commissioner is authorized to charge any fees to make this filing timely to Deposit Account number 50-4050 and to credit any over payments to Deposit Account number 50-4050.

Amendments to the Claims are shown in the listing of claims that begins on page 2.

Remarks begin on page 9.

Reconsideration and allowance of the pending claims, in light of the amendments and remarks presented herein is respectfully requested.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) 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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from about 1 cm to about 3.5 cm in from the introitus.

2. (Original) The method of claim 1, wherein heating the target tissue comprises heating it to a temperature between about 45 degrees C. and about 80 degrees C.

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

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

5. (Original) The method of claim 1, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

6. (Original) The method of claim 5, wherein the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy.

7. (Original) The method of claim 1, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

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

9. (Canceled)

10. (Original) The method of claim 1, wherein the method further comprises cooling the epithelium.

11. (Original) The method of claim 10, wherein cooling is by contacting the epithelium with a treatment tip, the tip including a cooling mechanism.

12. (Original) The method of claim 10, wherein cooling the epithelium comprises cooling it to a temperature between about 0 degrees C. and about 10 degrees C.

13. (Original) The method of claim 10, 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.

14. (Original) The method of claim 10, wherein the cooling precedes the heating, and continues during the heating.

15. (Original) The method of claim 10, wherein the cooling is during the heating, and continues after heating.

16. (Original) The method of claim 10, wherein the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue.

17. (Original) The method of claim 16, wherein the reverse thermal gradient ranges from a low temperature of about 0 degrees C. to about 10 degrees C. at the epithelium to a high temperature of about 45 degrees C. to about 80 degrees C. in the underlying target tissue.

18. (Original) The method of claim 1, 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.

19. (Previously presented) The method of claim 18, 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.

20. (Original) The method of claim 18, 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.

21. (Previously presented) The method of claim 20, wherein any one of the contact sites is contacted one or more times during a procedure.

22. (Original) The method of claim 20, the method further comprising repeating the procedure one or more times.

23. (Previously presented) The method of claim 22, 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.

24. – 25. (Canceled)

26. (Canceled)

27. (Currently amended) ~~The method of claim 1~~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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion of the vagina circumferentially around its wall from about 1 o'clock to about 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock.

28. (Currently amended) ~~The method of claim 1~~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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion radiating outward from the introitus to Hart's line.

29. (Currently amended) ~~The method of claim 1~~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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a mucosal surface of the labia minora.

30. (Previously presented) The method of claim 1, wherein the target tissue heating includes heating submucosa and muscularis below a mucosal epithelium.

31. (Previously presented) The method of claim 1, wherein the heating does not substantially modify a mucosal epithelium of the genital tissue.

32. (Original) The method of claim 1, wherein remodeling comprises contracting target tissue.

33. (Original) The method of claim 1, wherein remodeling comprises tightening the introitus.

34. (Original) The method of claim 1, wherein remodeling comprises tightening the vagina.

35. (Original) The method of claim 1, wherein remodeling comprises denaturing collagen.

36. (Original) The method of claim 1, wherein remodeling comprises tightening collagen-rich sites in the target tissue.

37. (Original) The method of claim 1, wherein remodeling comprises rejuvenating the genital tissue toward a conformation like that which the genitalia had prior to experiencing vaginal birth.

38. (Original) The method of claim 1, wherein at least some of the remodeling occurs during the heating.

39. (Original) The method of claim 1, wherein at least some of the remodeling occurs after the heating.

40. (Original) The method of claim 39, wherein the remodeling after the heating is by a depositing of collagen in the target tissue.

41. – 57. (Canceled)

58. (New) The method of claim 27, wherein heating the target tissue comprises heating it to a temperature between about 45 degrees C. and about 80 degrees C.

59. (New) The method of claim 28, wherein heating the target tissue comprises heating it to a temperature between about 45 degrees C. and about 80 degrees C.

60. (New) The method of claim 29, wherein heating the target tissue comprises heating it to a temperature between about 45 degrees C. and about 80 degrees C.

61. (New) The method of claim 27, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

62. (New) The method of claim 28, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

63. (New) The method of claim 29, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

64. (New) The method of claim 27, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

65. (New) The method of claim 28, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

66. (New) The method of claim 29, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

67. (New) The method of claim 27, wherein the method further comprises cooling the epithelium.

68. (New) The method of claim 28, wherein the method further comprises cooling the epithelium.

69. (New) The method of claim 29, wherein the method further comprises cooling the epithelium.

70. (New) The method of claim 27, 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.

71. (New) The method of claim 28, 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.

72. (New) The method of claim 29, 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.

REMARKS

Claims 1-8, 10-23, and 26-57 were pending. Claims 9 and 24-25 were previously cancelled. By this response, claims 1 and 27-29 have been amended, claims 41-57 have been cancelled, and new claims 58-72 have been added. Support for these amendments, and for any new claims, may be found throughout the specification, including original claims 2, 5, 7, 10, and 18. Cancellation or amendment of any claim is not to be considered a dedication to the public of any subject matter.

Thus, claims 1-8, 10-23, 27-40 and 58-72 are currently under consideration.

INFORMATION DISCLOSURE STATEMENT

Applicants note with thanks that the Examiner has considered all references submitted in Information Disclosure Statements dated 05/29/2013, 09/26/2013, and 11/6/2013. A Supplemental Information Disclosure Statement is filed herewith. It is respectfully requested that this Supplemental Information Disclosure Statement be considered and the PTO Form 1449/SB08 be initialed and returned with the next Action.

ALLOWABLE SUBJECT MATTER

Claims 26-29 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

By this response, claim 1 has been amended to incorporate the allowable subject matter of claim 26, including all of the limitations of the base claim and any intervening claims. Further, claims 27, 28 and 29 have all been re-written as independent claims, including all of the limitations of the base claim and any intervening claims. In addition any claims that do not depend from now-allowable claims 1, 27, 28 or 29 have been cancelled, including claims 41-57. Thus, all of the currently pending claims should be in condition for allowance.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 1, 5-8, 10-11, 13, 16, 18, 20, 22-23, 30-42, 45-46, and 49-57

Claims 1, 5-8, 10-11, 13, 16, 18, 20, 22-23, 30-42, 45-46, and 49-57 currently stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,350,276 to Knowlton et al. ("Knowlton").

Without conceding to or agreeing with this rejection, and solely to expedite prosecution, Applicant have herein amended claim 1 to recite all of the element of allowed claim 26, which depended from claim 1. Thus, claim 1 and its dependent claims (claims 1, 5-8, 10-11, 13, 16, 18, 20, 22-23, 30-40) are allowable. Claims 41-42, 45-46, and 49-57 have been cancelled to expedite prosecution. Thus this rejection is moot. Applicants respectfully request withdrawal of the 35 U.S.C. § 102 rejection of the claims, and allowance of all of the currently pending claims.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Claims 2-4, 12, 14-15, 17, 19, 21, 43-44, and 47-48

Claims 2-4, 12, 14-15, 17, 19, 21, 43-44, and 47-48 currently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Knowlton.

Without conceding to or agreeing with this rejection, and solely to expedite prosecution, Applicant have herein amended claim 1 to recite all of the element of allowed claim 26, which depended from claim 1. Thus, claim 1 and its dependent claims (claims 2-4, 12, 14-15, 17, 19, and 21) are allowable. Claims 43-44, and 47-48 have been cancelled to expedite prosecution. Thus this rejection is moot. Applicants respectfully request withdrawal of the 35 U.S.C. § 103 rejection of the claims, and allowance of all of the currently pending claims.

CONCLUSION

Applicants respectfully request that the Examiner expedite the prosecution of this patent application to issuance. If the Patent Office determines that an extension of time and/or other relief is required, Applicants petition for any required relief including extension of time, and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-4050**, referencing 10095-701.201. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: June 9, 2014 By: _____

Richard D. Shoop
Registration No. 45,763

SHAY GLENN LLP
2755 CAMPUS DRIVE, SUITE 210
SAN MATEO, CA 94403
TELEPHONE: 650.287.2164
FACSIMILE: 650.212.7562

PTO/AIA/22 (03-13)
Approved for use through 7/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 10095-701.201

Application Number: 11/704,067

Filed: February 7, 2007

For: VAGINAL REMODELING DEVICE AND METHODS

Art Unit: 3739

Examiner: Hupczey, Jr., Ronald James

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	Micro Entity Fee	
☑	One month (37 CFR 1.17(a)(1))	$200	$100	$50	$ 100
☐	Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☐	Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$
☐	Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐	Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☑ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-4050.

☐ Payment made via EFS-Web.

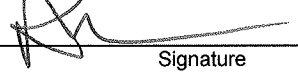
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 45,763.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.



Signature

June 9, 2014
Date

Richard D. Shoop
Typed or printed name

(650) 212-1700
Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Electronic Patent Application Fee Transmittal

Application Number:	11704067
Filing Date:	07-Feb-2007
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Filer:	Richard Douglas Shoop/Mary Buggie
Attorney Docket Number:	10095-701.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Independent Claims in Excess of 3	2201	1	210	210
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	2251	1	100	100
Miscellaneous:				
			Total in USD ($)	**310**

Electronic Acknowledgement Receipt

EFS ID:	19252734
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	Richard Douglas Shoop/Mary Buggie
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	10095-701.201
Receipt Date:	09-JUN-2014
Filing Date:	07-FEB-2007
Time Stamp:	18:03:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$310
RAM confirmation Number	5018
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10095-701-201_Response_6-9-2014.pdf	508139 b672ddf01d741136bd8f78613709cd00250b2bdc	yes	12

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	8
Applicant Arguments/Remarks Made in an Amendment	9	11
Extension of Time	12	12

Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31872 ec71afcf34dd84831ac18cf43c5cfcdbdea384a9	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	540011		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (07-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	171	US- 6,875,209	4/5/2005	Zvuloni et al.	
		US-			
		US-			
		US-			
		US-			
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	177	JPH05-269144A(w/Eng Abs)	10/19/1993	Kuramoto Kogyo		
	176	JPH09-122141A(w/Eng Abs)	5/13/1997	Semuko		
	175	JPH11-504828A(EqWO96/34568A)	5/11/1999	Knowlton		
	174	JP2002-238919A(Corr US6679875)	8/27/2002	Honda et al.		
	173	JP2003503118wEqWO01-00269	1/28/2003	Thermage Inc.		
	172	JP2006-187668A(w/Eng Abs)	7/20/2006	Olympus Corp.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	11704067
Filing Date:	07-Feb-2007
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Filer:	Richard Douglas Shoop/Brian Flick
Attorney Docket Number:	10095-701.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt

EFS ID:	19252898
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	Richard Douglas Shoop/Brian Flick
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	10095-701.201
Receipt Date:	09-JUN-2014
Filing Date:	07-FEB-2007
Time Stamp:	18:13:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$90
RAM confirmation Number	5160
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		10095-701-201_IDS_Filing_6-9-2014.pdf	279368 1891e9f96783fe94891464a82e31517c2f39198d	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	4

Warnings:					
Information:					
2	Foreign Reference	JPH5269144wEngAbs.pdf	628265 ef0d452fb792a05927b77aadc6f1484a2daf8e91	no	10
Warnings:					
Information:					
3	Foreign Reference	JPH9122141wEngAbs.pdf	652769 ec84d02175ce4ae114309bb4002cbc32de018aa9	no	10
Warnings:					
Information:					
4	Foreign Reference	JPH11504828wEq.pdf	3763231 d20538f28232a4987421944210a73446afb23d95	no	82
Warnings:					
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5	Foreign Reference	JP2002238919wCorrUS6679875.pdf	2527303 4f41140a8319601ff09e1300a61567e2d20e6309	no	36
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6	Foreign Reference	JP2003503118wEq.pdf	5682442 30d4ea19a9f17c40f8da2c3061960c44ea8d633b	no	142
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7	Foreign Reference	JP2006187668wEngAbs.pdf	822855 f257448f5cafda00d41b40f55c6c8fee7821b879	no	16
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	29913 ef289f25c2d887b4be30bc8caf7cffbbf67911ba	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	14386146

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on 6-9-2014.

Brian Flank
Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 11/704,067	Confirmation No.: 4378
First Named Inventor	: Jonathan B. Parmer	
Filed	: February 7, 2007	
Art Unit	: 3739	
Examiner	: Hupczey, Jr, Ronald James	
Title	: VAGINAL REMODELING DEVICE AND METHODS	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**
This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☒ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☒ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached

--AND—

☒ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s): 172-177

--AND/OR--

☒ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s): 173-175

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Cite no(s):

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. Cite no(s):

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $90.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 6/9/2014

By: _____

Richard D. Shoop, Reg. No. 45,763

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/704,067	Filing Date 02/07/2007	☒ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 06/09/2014

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 51	Minus	** 57	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 4	Minus	***3	= 1	X $210 =	210
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	**210**

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/LISA THOMAS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201	4378

66854 7590 08/08/2014

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
HUPCZEY, JR, RONALD JAMES	
ART UNIT	PAPER NUMBER
3739	

NOTIFICATION DATE	DELIVERY MODE
08/08/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@shayglenn.com

Office Action Summary	Application No. 11/704,067	Applicant(s) PARMER, JONATHAN B.	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/09/2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-8,10-23,27-40 and 58-72* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☒ Claim(s) *28,29,62,63,65,66,68,69,71 and 72* is/are allowed.

7)☒ Claim(s) *1-8,10-23,27,30-40,58-61,64,67 and 70* is/are rejected.

8)☒ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *02/07/2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *06/09/2014*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and remarks, filed June 9th, 2014, are fully acknowledged by the Examiner. Currently, claims 1-8, 10-23, 27-40 and 58-72 are pending with claims 9, 24-26 and 41-57 cancelled, claims 58-72 newly added, and claims 1 and 27-29 amended. The following is a complete response to the June 9th, 2014 communication.

Notice of Pre-AIA or AIA Status

2. The present application is being examined under the pre-AIA first to invent provisions.

3. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

4. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8, 10-23, 27, 30-40, 58-61, 64, 67 and 70 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Regarding claims 1-4, 12, 17, 27 and 58-60, each claim recites at least one instance of the term of degree of "about" therein. When such a term of degree is used in a claim, there must be some standard set forth in the disclosure or known in the art for measuring the degree. In the

instant case, the Examiner has failed to find any such standard disclosed in the Specification nor is the Examiner aware of any standard set forth in the art for determining the various degrees associated with the recitations of "about" in each of claims 1-4, 12, 17 and 58-60. Since no such standard is provided, it is the Examiner's position that the metes and bounds of each claim cannot be accurately determined. That is, it is unclear to the Examiner how near or far a temperature would necessary need to be to qualify as any of "about 45 degrees C", "about 50 degrees C", "about 55 degrees C", "about 80 degrees C", "about 75 degrees C", "about 10 degrees C", "about 0 degrees C" and "about 70 degrees C" as recited respectively in claims 2-4, 12, 17 and 58-60. Similarly, it is unclear to the Examiner how near or far the desired location about necessary need to be from either of “about 1 cm” or “about 3.5 cm” to meet the limitations set forth in claim 1. Furthermore, it is unclear to the Examiner how near or far from the clock-face arrangement of 1 o'clock and 11 o'clock in claim 27 the heating would need to occur in order to be considered "about 1 o'clock" and "about 11 o’clock”. Claims 2-8, 10-23 and 30-40 are rejected due to their dependency on claim 1. Claims 58, 61, 64, 67 and 70 are rejected due to their dependency on parent claim 27. Appropriate correction is required. See MPEP 2173.05(b).

Regarding claim 31, the claim presently recites the term of degree of “substantially” therein. When such a term of degree is used in a claim, there must be some standard set forth in the disclosure or known in the art for measuring the degree. In the instant case, the Examiner has failed to find any such standard disclosed in the Specification nor is the Examiner aware of any standard set forth in the art for determining the degree associated with the recitation of "substantially" the claim. Since no such standard is provided, it is the Examiner's position that the metes and bounds of each claim cannot be accurately determined. That is, it is unclear to the

Examiner to what degree tissue would not be treated or, alternatively, would be allowed to be treated in order to qualify as "not substantially modified". Appropriate correction is required. See MPEP 2173.05(b)

Regarding claim 37, the claim presently recites “a confirmation like that which the genitalia had prior to experiencing vaginal birth” therein. It is the Examiner's position that the term "like" as used in claim 37 is a term of degree. Since the Examiner has failed to find any standard for determining the degree required by the use of "like” in the claim, it is the Examiner’s position that the scope of the claim is indefinite. That is, it is at most unclear to what degree the confirmation caused by the rejuvenation would necessary need to resemble the pre-birth genitalia confirmation in order to qualify as “like” the pre-birth confirmation. Furthermore, the Examiner is uncertain, per the limitations of the claim how one of ordinary skill in the art would even be capable of ascertaining such an arrival at such a confirmation unless some standard of comparison for each patient undergoing the treatment was established. Appropriate correction is required.

Allowable Subject Matter

6. Claims 28, 29, 62, 63, 65, 66, 68, 69, 71 and 72 are allowed.

7. Claims 1-8, 10-23, 27, 30-40, 58-61, 64, 67 and 70 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), 2nd paragraph, set forth in this Office action. The Examiner maintains the reasons for the indication of allowable subject matter set forth in the February 13th, 2014 Non-Final Office Action.

Response to Arguments

8. Applicant's arguments, see page 10 of the Remarks filed June 9th, 2014, with respect to previously-filed rejections under each of 35 U.S.C. 102(b) and 35 U.S.C. 103(a) based on the Knowlton et al. (US Pat. No. 6,350,276) reference have been fully considered and are persuasive. Therefore, these rejections set forth in the February 13th, 2014 office action has been withdrawn.

9. The Examiner notes that upon further consideration of the claims as presented and the disclosure, the Examiner has issued a number of new rejections under 35 U.S.C. 112 (pre-AIA) second paragraph above. The Examiner believes that these rejections are necessary to address issues of indefiniteness of scope with a number of the claims. Given that these new grounds are based on previously presented claim language, this action is being made **NON-FINAL**. Applicant is invited to contact the Examiner if any clarification of these rejections is needed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD HUPCZEY, JR/
Primary Examiner, Art Unit 3739

RJH

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	171	US- 6,875,209	4/5/2005	Zvuloni et al.	
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	177	JPH05-269144A(w/Eng Abs)	10/19/1993	Kuramoto Kogyo		
	176	JPH09-122141A(w/Eng Abs)	5/13/1997	Semuko		
	175	JPH11-504828A(EqWO96/34568A)	5/11/1999	Knowlton		
	174	JP2002-238919A(Corr US6679875)	8/27/2002	Honda et al.		
	173	JP2003503118wEqWO01-00269	1/28/2003	Thermage Inc.		
	172	JP2006-187668A(w/Eng Abs)	7/20/2006	Olympus Corp.		

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	06/25/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.H./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	Art Unit
	RONALD HUPCZEY, JR	3739

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	1-52	08/06/2010	RJH
607	50, 115, 138	08/06/2010	RJH

SEARCH NOTES		
Search Notes	Date	Examiner
East Search	08/06/2010	RJH
Inventor Search	08/06/2010	RJH
Updated Search	1/20/2011	RJH
Updated Search	2/9/14	RJH
Updated Search	8/4/2014	RJH

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	SEE ATTACHED EAST SEARCH	8/4/14	RJH

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	Art Unit
	RONALD HUPCZEY, JR	3739

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/10/2010	01/20/2011	02/09/2014	08/04/2014					
	1	✓	✓	✓	✓					
	2	✓	✓	✓	✓					
	3	✓	✓	✓	✓					
	4	✓	✓	✓	✓					
	5	✓	✓	✓	✓					
	6	✓	✓	✓	✓					
	7	✓	✓	✓	✓					
	8	✓	✓	✓	✓					
	9	✓	-	-	-					
	10	✓	✓	✓	✓					
	11	✓	✓	✓	✓					
	12	✓	✓	✓	✓					
	13	✓	✓	✓	✓					
	14	✓	✓	✓	✓					
	15	✓	✓	✓	✓					
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	26	✓	✓	O	-					
	27	✓	✓	O	✓					
	28	✓	✓	O	=					
	29	✓	✓	O	=					
	30	✓	✓	✓	✓					
	31	✓	✓	✓	✓					
	32	✓	✓	✓	✓					
	33	✓	✓	✓	✓					
	34	✓	✓	✓	✓					
	35	✓	✓	✓	✓					
	36	✓	✓	✓	✓					

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	**Art Unit**
	RONALD HUPCZEY, JR	3739

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/10/2010	01/20/2011	02/09/2014	08/04/2014					
	37	✓	✓	✓	✓					
	38	✓	✓	✓	✓					
	39	✓	✓	✓	✓					
	40	✓	✓	✓	✓					
	41	✓	✓	✓	-					
	42	✓	✓	✓	-					
	43	✓	✓	✓	-					
	44	✓	✓	✓	-					
	45	✓	✓	✓	-					
	46	✓	✓	✓	-					
	47	✓	✓	✓	-					
	48	✓	✓	✓	-					
	49	✓	✓	✓	-					
	50	✓	✓	✓	-					
	51	✓	✓	✓	-					
	52	✓	✓	✓	-					
	53	✓	✓	✓	-					
	54	✓	✓	✓	-					
	55	✓	✓	✓	-					
	56	✓	✓	✓	-					
	57	✓	✓	✓	-					
	58				✓					
	59				✓					
	60				✓					
	61				✓					
	62				=					
	63				=					
	64				✓					
	65				=					
	66				=					
	67				✓					
	68				=					
	69				=					
	70				✓					
	71				=					
	72				=					

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3	(heat$3 and genital and introitus).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/08/04 11:34
L2	2	(heat$3 and genital and urethra and o'clock).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/08/04 11:34
L3	2	(heat$3 and genital and hart's).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/08/04 11:34
S1	1	11/704067	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 14:45
S2	0	("2007/0233191").URPN.	USPAT	OR	ON	2010/08/06 14:45
S3	1	((JONATHAN) near2 (PARMER)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/06 14:45
S4	7	("5919219" "5755753" "5143063" "6350276" "6387380" "6425912" "6453202").pn.	USPAT	OR	ON	2010/08/06 15:00
S5	0	us-2002004983-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:00
S6	2	us-20020004983-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:00

S7	0	us-200300212393-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:00
S8	2	us-20030212393-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:00
S9	0	us-200400003163-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:01
S10	2	us-20040000316-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:01
S11	236	("20020032441" | "20020049483" | "20020062142" | "20020120260" | "20020151887" | "20020156471" | "20020183735" | "20020195593" | "20030028180" | "20030097162" | "20030120326" | "20030120575" | "20030130575" | "20030139790" | "20030144576" | "20030178032" | "20030195604" | "20030199866" | "20030212393" | "20030216728" | "20030216729" | "20030220635" | "20030236487" | "20040000316" | "20040002704" | "20040002705" | "20040030332" | "20040034346" | "20040034400" | "20040049251" | "20040102824" | "20040111087" | "20040111136" | "20040111137" | "20040127895" | "20040172291" | "20040186535" | "20040193238" | "20040206365" | "20040210214" | "20040210282" | "20040236177" | "20040236393" | "20040249425" | "20040260368" | "20040267336" | "20050154433" | "20050171582" | "20050171583" | "20050187599" | "20050203399" | "20050288544" | "20050288680" | "20060025837" | "20060047331" | "20060167533" | "20070078502" | "20070083247" | "20070088413" | "20070106349" | "4326529" | "4381007" | "4785807" | "4785828" | "4907589" | "4920978" | "4976709" | "5046511" | "5143063" | "5230349" | "5301692" | "5334193" | "5348554" | "5458596" | "5569242" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:13

		"5660836" | "5755753" | "5765567" | "5824076" | "5871524" | "5919219" | "5937863" | "5947891" | "5948011" | "6002968" | "6024743" | "6035238" | "6044847" | "6081749" | "6091995" | "6139569" | "6156060" | "6216704" | "6236891" | "6241753" | "6277116" | "6283987" | "6292700" | "6311090" | "6322584" | "6350276" | "6377854" | "6377855" | "6381498" | "6387380" | "6405090" | "6413255" | "6416504" | "6425912" | "6427089" | "6430446" | "6453202" | "6461332" | "6461378" | "6470216" | "6478791" | "6480746" | "6482204" | "6533780" | "6546934" | "6558381" | "6572639" | "6579266" | "6579566" | "6587731" | "6629535" | "6685623" | "6743165" | "6749624" | "6751507" | "6772013" | "6776779" | "6830052" | "6836688" | "6840954" | "6852110" | "6879858" | "6882885" | "6889090" | "6976492" | "7004942" | "7022121" | "7141049" | "7238183").PN.				
S12	3046	606/32-40.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:14
S13	4154	606/41.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:15
S14	1565	606/50-52.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:15
S15	260	607/50.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:21
S16	705	607/115.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:21
S17	287	607/138.ccls.	US-PGPUB; USPAT; USOCR;	OR	ON	2010/08/06 15:21

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S18	1236	S15 S16 S17	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:27
S19	17	S18 and (mucosal)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:28
S20	555	("1827306" | "3324847" | "3369549" | "3750653" | "3789829" | "3840016" | "3901224" | "3924628" | "3934580" | "4014988" | "4016270" | "4072147" | "4102342" | "4160455" | "4198981" | "4292960" | "4296760" | "4311154" | "4349033" | "4375220" | "4377168" | "4409993" | "4469103" | "4491131" | "4494539" | "4549533" | "4552127" | "4572190" | "4622972" | "4638436" | "4658836" | "4662383" | "4674481" | "4676258" | "4692452" | "4700701" | "4754752" | "4754757" | "4758592" | "4771778" | "4773899" | "4776349" | "4818954" | "4823812" | "4836189" | "4852579" | "4860752" | "4865047" | "4927413" | "4935003" | "4938217" | "4946440" | "4949718" | "4955377" | "4960109" | "4961435" | "4967765" | "4974587" | "4979948" | "4985027" | "4993430" | "4997653" | "4998930" | "5003991" | "5006119" | "5026959" | "5032124" | "5035694" | "5041089" | "5045056" | "5050597" | "5057106" | "5059191" | "5084044" | "5092841" | "5098429" | "5100388" | "5188122").PN. OR ("5277201").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/06 15:28
S21	131	("3831604" | "4074718" | "4140130" | "4164226" | "4290435" | "4343301" | "4346715" | "4375220" | "4381007" | "4441486" | "4545368" | "4556070" | "4633875" | "4676258" | "4709701" | "4756310" | "4881543" | "4887614" | "4889122" | "4944302" | "4957480" | "4962761" | "4976709" | "5003991" | "5133351" | "5143063" | "5186181" | "5190517" | "5230334" | "5231997" | "5249575" | "5282797" | "5304169" | "5315994" | "5334193" | "5342357" | "5348554" | "5366443" | "5370642" | "5374265" | "5423807" | "5423811" | "5437662" | "5458596" | "5462521" | "5464436" | "5496312" | "5507790" | "5569242" | "5660836" | "5681282"	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/06 15:36

		"5683366" | "5692058" | "5693045" | "5697281" | "5697536" | "5697882" | "5697909" | "5755753" | "5769879" | "5775338" | "6139569" | "RE32849").PN. OR ("6350276").URPN.				
S22	0	coad and introitus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 16:38
S23	254	coad.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 16:38
S24	0	coad.in. and cryoablation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 16:38
S25	14	vaginal near3 laxity	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 16:41
S26	19	vaginoplasty	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 09:50
S27	4154	606/41.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:00
S28	1565	606/50-52.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:00
S29	23832792	s "12" S27 S28	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	ON	2010/08/09 10:00

			IBM_TDB			
S30	3046	606/32-40.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:01
S31	7361	S30 S27 S28	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:01
S32	160	S31 and (vagina or vaginoplasty or labiaplasty or introitus or genital)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:02
S33	10187	606/1-31.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:24
S34	222	606/1-31.ccls. and (vagina or vaginoplasty or labiaplasty or introitus or genital)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:24
S35	32	("3626931" | "3800800" | "4396019" | "4541439" | "4616640" | "4757823" | "4869258" | "4909263" | "4911149" | "4972839" | "5007437" | "5046511" | "5388583" | "5499631" | "5562717" | "5573499" | "5662699" | "5690604" | "5699805" | "5725473" | "5782778" | "5833611" | "5851175" | "5875778" | "5881731" | "5916173" | "6169914").PN. OR ("6741895").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/09 13:13
S36	74	(electrode and ablation and (revers$3 near3 thermal near3 gradient))	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/09 13:18
S37	74	(electrode and ablation and (revers$3 near3 thermal near3 gradient))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 13:18
S38	1	((JONATHAN) near2 (PARMER)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2011/01/20 17:12

S39	0	12/884108	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/01/20 17:12
S40	2	"6350276".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/12/14 19:11
S41	71	"606".clas. and introitus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/25 14:28
S42	66	"606".clas. and vulva	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/25 14:36
S43	24	("3278738" | "4616631" | "5026368" | "5125925" | "5179937" | "5242437" | "5242438").PN. OR ("5458595").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:37
S44	21	("4090517" | "5009655" | "5376087" | "5500009").PN. OR ("5830211").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:40
S45	14	11/295204	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:48
S46	6	11/295204 and vulva	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:48
S47	0	11/295204 and vagina$3	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:48
S48	0	11/295204 and introitus	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:48
S49	1	"7153133".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 15:31
S50	4	("5348473" | "6168433").PN. OR ("7153133").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 15:36
S51	45	("0118237" | "1534657" | "1927566" | "2135933" | "3472045" | "3727313" | "3740853" | "3757419" | "3822432" | "3869877" | "4014098" | "4060870" | "4075761" | "4182041" | "4490113" | "5020994" | "5028233" | "5040978" | "5145370" | "5169312" | "5209658" |	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 15:37

		"5352119" | "5356340" | "5374189" | "5423679" | "5433605" | "5496218" | "5503555" | "5529495" | "5531599" | "5645426" | "5730595").PN. OR ("6168433").URPN.				
S52	2	"6350276".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/11/03 13:26
S53	418	a61b2018/00559.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/12/11 13:38
S54	2	"6350276".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:05
S55	1982	(vagina introitus vulva) and "606".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:11
S56	127	(vagina introitus vulva) and "606".clas. and epithelium	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:11
S57	1132	a61b2018/00559.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:20
S58	32	a61b2018/00559.cpc. and (vulva vagina introitus) and (epithelium) and (heat$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:21
S59	2	("20070233191").pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:23

S60	3	wo-9622739-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:23
S61	0	2004/0206365-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:23
S62	0	20040206365-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:24
S63	2	"20040206365".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:24
S64	166	a61b2018/00559.cpc. and (vulva vagina introitus) and (ablat$3 tight$5 heat$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/08 12:20
S65	2	"6350276".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/08 12:21
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EAST Search History (Interference)

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PTO/SB/08a (07-09)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	181	US- 5,469,857	11/28/1995	Laurent et al.	
	180	US- 5,673,695	10/7/1997	McGee et al.	
	179	US- 5,836,990	11/17/1998	Li	
	178	US- 6,569,160	5/27/2003	Goldin	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Patent Application Fee Transmittal

Application Number:	11704067
Filing Date:	07-Feb-2007
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Filer:	Richard Douglas Shoop/Salisa K. Skinner
Attorney Docket Number:	10095-701.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt

EFS ID:	20378771
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	Richard Douglas Shoop/Salisa K. Skinner
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	10095-701.201
Receipt Date:	09-OCT-2014
Filing Date:	07-FEB-2007
Time Stamp:	17:20:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$90
RAM confirmation Number	3855
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		10095_701201_IDS_Filing_10092014.pdf	255985 c1592fab551b77a56863377465095c31f41f0821	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	4

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on 10/9/2014.

Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 11/704,067	Confirmation No.: 4378
First Named Inventor	: Jonathan B. Parmer	
Filed	: February 7, 2007	
Art Unit	: 3739	
Examiner	: Hupczey, Jr, Ronald James	
Title	: VAGINAL REMODELING DEVICE AND METHODS	
Customer No.	: 66854	

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

- ☐ **1).** Within 3 months of the application filing date, or
- ☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or
- ☐ **3).** Before the mail date of a first Office Action on the merits, or
  - ☐ **3a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below
- ☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.
  - ☐ **4a).** Certifications as specified in § 1.97(e) and § 1.704(d) are provided below

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☒ **A).** A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under §1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180 ($90 for small entity) as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW. Cite no(s):

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and 609.04(a)III, Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached

--AND—

☐ **2a).** An English language abstract or an English language copy of a foreign search report or other action by a foreign patent office is provided herewith to fulfill the requirement for a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language: Cite no(s):

--AND/OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached: Cite no(s):

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Cite no(s):

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. Cite no(s):

STATEMENT UNDER 37 CFR § 1.704(d)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $90.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 10/9/2014

By: _____

Richard D. Shoop, Reg. No. 45,763

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8
I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on October 9, 2014.
/Mary Buggie/ 10/9/2014
Mary Buggie **Date**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	11/704,067	Confirmation No.	: 4378
First Named Inventor	:	Jonathan B. Parmer		
Filing Date	:	February 7, 2007		
Art Unit	:	3739		
Examiner	:	Hupczey, Jr., Ronald James		
Title	:	VAGINAL REMODELING DEVICE AND METHODS		
Customer No.	:	66854		

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

This reply is in response to the non-final Office Action mailed August 8, 2014 for which a response is due November 8, 2014. Thus, this response is timely filed. The Commissioner is authorized to charge any fees to make this filing timely to Deposit Account number 50-4050 and to credit any over payments to Deposit Account number 50-4050.

Amendments to the Claims are shown in the listing of claims that begins on page 2.

Remarks begin on page 9.

Reconsideration and allowance of the pending claims, in light of the amendments and remarks presented herein is respectfully requested.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) 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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from ~~about~~ 1 cm to ~~about~~ 3.5 cm in from the introitus.

2. (Currently amended) The method of claim 1, wherein heating the target tissue comprises heating it to a temperature between ~~about~~ 45 degrees C. and ~~about~~ 80 degrees C.

3. (Currently amended) The method of claim 1, wherein heating the target tissue comprises heating it to a temperature between ~~about~~ 50 degrees C. and ~~about~~ 75 degrees C.

4. (Currently amended) The method of claim 1, wherein heating the target tissue comprises heating it to a temperature between ~~about~~ 55 degrees C. and ~~about~~ 70 degrees C.

5. (Original) The method of claim 1, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

6. (Original) The method of claim 5, wherein the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy.

7. (Original) The method of claim 1, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

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

9. (Canceled)

10. (Original) The method of claim 1, wherein the method further comprises cooling the epithelium.

11. (Original) The method of claim 10, wherein cooling is by contacting the epithelium with a treatment tip, the tip including a cooling mechanism.

12. (Currently amended) The method of claim 10, wherein cooling the epithelium comprises cooling it to a temperature between ~~about~~ 0 degrees C. and ~~about~~ 10 degrees C.

13. (Original) The method of claim 10, 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.

14. (Original) The method of claim 10, wherein the cooling precedes the heating, and continues during the heating.

15. (Original) The method of claim 10, wherein the cooling is during the heating, and continues after heating.

16. (Original) The method of claim 10, wherein the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue.

17. (Currently amended) The method of claim 16, wherein the reverse thermal gradient ranges from a low temperature of ~~about~~ 0 degrees C. to ~~about~~ 10 degrees C. at the epithelium to a high temperature of ~~about~~ 45 degrees C. to ~~about~~ 80 degrees C. in the underlying target tissue.

18. (Original) The method of claim 1, 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.

19. (Previously presented) The method of claim 18, 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.

20. (Original) The method of claim 18, 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.

21. (Previously presented) The method of claim 20, wherein any one of the contact sites is contacted one or more times during a procedure.

22. (Original) The method of claim 20, the method further comprising repeating the procedure one or more times.

23. (Previously presented) The method of claim 22, 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.

24. – 26. (Canceled)

27. (Currently amended) 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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion of the vagina circumferentially around its wall from ~~about~~ 1 o'clock to ~~about~~ 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock.

28. (Previously presented) 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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion radiating outward from the introitus to Hart's line.

29. (Previously presented) 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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a mucosal surface of the labia minora.

30. (Previously presented) The method of claim 1, wherein the target tissue heating includes heating submucosa and muscularis below a mucosal epithelium.

31. (Currently amended) The method of claim 1, wherein the heating does not ~~substantially~~ modify a mucosal epithelium of the genital tissue.

32. (Original) The method of claim 1, wherein remodeling comprises contracting target tissue.

33. (Original) The method of claim 1, wherein remodeling comprises tightening the introitus.

34. (Original) The method of claim 1, wherein remodeling comprises tightening the vagina.

35. (Original) The method of claim 1, wherein remodeling comprises denaturing collagen.

36. (Original) The method of claim 1, wherein remodeling comprises tightening collagen-rich sites in the target tissue.

37. (Canceled)

38. (Original) The method of claim 1, wherein at least some of the remodeling occurs during the heating.

39. (Original) The method of claim 1, wherein at least some of the remodeling occurs after the heating.

40. (Original) The method of claim 39, wherein the remodeling after the heating is by a depositing of collagen in the target tissue.

41. – 57. (Canceled)

58. (Currently amended) The method of claim 27, wherein heating the target tissue comprises heating it to a temperature between ~~about~~ 45 degrees C. and ~~about~~ 80 degrees C.

59. (Currently amended) The method of claim 28, wherein heating the target tissue comprises heating it to a temperature between ~~about~~ 45 degrees C. and ~~about~~ 80 degrees C.

60. (Currently amended) The method of claim 29, wherein heating the target tissue comprises heating it to a temperature between ~~about~~ 45 degrees C. and ~~about~~ 80 degrees C.

61. (Previously presented) The method of claim 27, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

62. (Previously presented) The method of claim 28, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

63. (Previously presented) The method of claim 29, wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.

64. (Previously presented) The method of claim 27, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

65. (Previously presented) The method of claim 28, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

66. (Previously presented) The method of claim 29, wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.

67. (Previously presented) The method of claim 27, wherein the method further comprises cooling the epithelium.

68. (Previously presented) The method of claim 28, wherein the method further comprises cooling the epithelium.

69. (Previously presented) The method of claim 29, wherein the method further comprises cooling the epithelium.

70. (Previously presented) The method of claim 27, 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.

71. (Previously presented) The method of claim 28, 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.

72. (Previously presented) The method of claim 29, 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.

73. (New) The method of claim 1, wherein heating comprises delivering energy by any of: radiofrequency energy, microwave energy, or ultrasound energy.

74. (New) The method of claim 1, wherein heating comprises delivering energy by ultrasound energy.

75. (New) The method of claim 27, wherein heating comprises delivering energy by any of: radiofrequency energy, microwave energy, or ultrasound energy.

76. (New) The method of claim 27, wherein heating comprises delivering energy by ultrasound energy.

77. (New) The method of claim 28, wherein heating comprises delivering energy by any of: radiofrequency energy, microwave energy, or ultrasound energy.

78. (New) The method of claim 28, wherein heating comprises delivering energy by ultrasound energy.

79. (New) The method of claim 29, wherein heating comprises delivering energy by any of: radiofrequency energy, microwave energy, or ultrasound energy.

80. (New) The method of claim 29, wherein heating comprises delivering energy by ultrasound energy.

REMARKS

Claims 1-8, 10-23, 27-40, and 58-72 were pending. Claims 9, 24-26, and 41-57 were previously canceled. By this response, claims 1-4, 12, 17, 27, 31, and 58-60 have been amended, claim 37 has been canceled, and new claims 73-80 have been added. Support for these amendments, and for any new claims, may be found throughout the specification, but especially in paragraphs [009], [0015], [0039] and [044]. Cancellation or amendment of any claim is not to be considered a dedication to the public of any subject matter.

Thus, claims 1-8, 10-23, 27-36, 38-40, and 58-80 are currently under consideration.

INFORMATION DISCLOSURE STATEMENT

Applicants note with thanks that the Examiner has considered all references submitted in Information Disclosure Statements dated 06/09/2014. A Supplemental Information Disclosure Statement is filed herewith. It is respectfully requested that this Supplemental Information Disclosure Statement be considered and the PTO Form 1449/SB08 be initialed and returned with the next Action.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 1-8, 10-23, 27, 30-40, 58-61, 64, 67, and 70

Claims 1-8, 10-23, 27, 30-40, 58-61, 64, 67, and 70 currently stand rejected under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Regarding claims 1-4, 12, 17, 27 and 58-60, in order to expedite prosecution, claims 1-4, 12, 17, 27, and 58-60 have been herein amended to remove the term "about".

Regarding claim 31, in order to expedite prosecution, the word "substantially" has been removed by amendment herein.

Regarding claim 37, this claim has been herein canceled in order to expeditc prosecution.

Thus, all of the 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, rejections of pending claims 1-8, 10-23, 27, 30-40, 58-61, 64, 67, and 70 have been rendered moot, and Applicants respectfully request withdrawal of this rejection and allowance of all of the currently pending claims.

ALLOWABLE SUBJECT MATTER

Applicants thank the examiner for indicating the allowance of claims 28, 29, 62, 63, 65, 66, 68, 69, 71, and 72.

Claims 1-8, 10-23, 27, 30-40, 58-61, 64, 67, and 70 were indicated as allowable if rewritten or amended to overcome the rejections under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), 2nd paragraph. By this response, these claims have been so amended. Further, new claims 73-80 depend from allowable independent claims 1, 27, 28 or 29, and thus are allowable for the same reasons. Applicants respectfully submit that all of the currently pending claims are in condition for allowance.

CONCLUSION

Applicants respectfully request that the Examiner expedite the prosecution of this patent application to issuance. If the Patent Office determines that an extension of time and/or other relief is required, Applicants petition for any required relief including extension of time, and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-4050**, referencing 10095-701.201. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: October 9, 2014 By: _____

Richard D. Shoop
Registration No. 45,763

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2755 CAMPUS DRIVE, SUITE 210
SAN MATEO, CA 94403
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Electronic Patent Application Fee Transmittal

Application Number:	11704067
Filing Date:	07-Feb-2007
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Filer:	Richard Douglas Shoop/Mary Buggie
Attorney Docket Number:	10095-701.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	2202	1	40	40
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**40**

Electronic Acknowledgement Receipt

EFS ID:	20379229
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	Vaginal remodeling device and methods
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	Richard Douglas Shoop/Mary Buggie
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	10095-701.201
Receipt Date:	09-OCT-2014
Filing Date:	07-FEB-2007
Time Stamp:	17:46:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$40
RAM confirmation Number	4234
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10095-701-201_Response_10-9-2014.pdf	449405 42e320953c021642088a5214a35c6e1b1517743e	yes	12

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	9
	Applicant Arguments/Remarks Made in an Amendment	10	12

Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	29911 f036069ef9addff8d5c919d76181f0cec9a39528	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	479316		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/704,067	Filing Date 02/07/2007	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **10/09/2014**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 58	Minus	** 57	= 1	X $40 =	40
Independent (37 CFR 1.16(h))	* 4	Minus	***4	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	**40**

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/Tina J. Barden/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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NOTICE OF ALLOWANCE AND FEE(S) DUE

66854 7590 10/20/2014

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER
HUPCZEY, JR, RONALD JAMES

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 10/20/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201	4378

TITLE OF INVENTION: VAGINAL REMODELING DEVICE AND METHODS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	01/20/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

66854 7590 10/20/2014
SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201	4378

TITLE OF INVENTION: VAGINAL REMODELING DEVICE AND METHODS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	01/20/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
HUPCZEY, JR, RONALD JAMES	3739	606-041000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201	4378

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EXAMINER	
HUPCZEY, JR, RONALD JAMES	
ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 10/20/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 11/704,067	Applicant(s) PARMER, JONATHAN B.	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the response of 10/09/2014*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-8,10-23,27-36,38-40 and 58-80*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 10/9/14
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/RONALD HUPCZEY, JR/
Primary Examiner, Art Unit 3739

DETAILED ACTION

1. Applicant's amendments and remarks, filed October 9th, 2014, are fully acknowledged by the Examiner. Currently, claims 1-8, 10-23, 27-36, 38-40 and 58-80 are pending with claims 9, 24-26, 37 and 41-57 cancelled, claims 73-80 newly added, and claims 1-4, 12, 17, 27, 31 and 58-60 amended. Applicant's amendments and cancellations in the claims are sufficient to obviate the previously-filed rejection of claims 1-8, 10-23, 27, 30-40, 58-61, 64, 67 and 70 under 35 U.S.C. 112 (pre-AIA), second paragraph. The following is a complete response to the October 9th, 2014 communication.

Allowable Subject Matter

2. Claims 1-8, 10-23, 27-36, 38-40 and 58-80 are allowed.

3. The following is an examiner's statement of reasons for 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.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD HUPCZEY, JR/
Primary Examiner, Art Unit 3739

RJH

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	8	US-5469857-$.DID. OR US-5673695-$.DID. OR US-5836990-$.DID. OR US-6569160-$.DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/10/14 18:06
L2	3	((vulva introitus vagina) and heat$3 and remodel$3).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/10/14 18:07
S1	1	11/704067	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 14:45
S2	0	("2007/0233191").URPN.	USPAT	OR	ON	2010/08/06 14:45
S3	1	((JONATHAN) near2 (PARMER)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/06 14:45
S4	7	("5919219" "5755753" "5143063" "6350276" "6387380" "6425912" "6453202").pn.	USPAT	OR	ON	2010/08/06 15:00
S5	0	us-2002004983-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:00
S6	2	us-20020004983-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:00
S7	0	us-200300212393-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:00

S8	2	us-20030212393-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:00
S9	0	us-200400003163-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:01
S10	2	us-20040000316-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:01
S11	236	("20020032441" | "20020049483" | "20020062142" | "20020120260" | "20020151887" | "20020156471" | "20020183735" | "20020195593" | "20030028180" | "20030097162" | "20030120326" | "20030120575" | "20030130575" | "20030139790" | "20030144576" | "20030178032" | "20030195604" | "20030199866" | "20030212393" | "20030216728" | "20030216729" | "20030220635" | "20030236487" | "20040000316" | "20040002704" | "20040002705" | "20040030332" | "20040034346" | "20040034400" | "20040049251" | "20040102824" | "20040111087" | "20040111136" | "20040111137" | "20040127895" | "20040172291" | "20040186535" | "20040193238" | "20040206365" | "20040210214" | "20040210282" | "20040236177" | "20040236393" | "20040249425" | "20040260368" | "20040267336" | "20050154433" | "20050171582" | "20050171583" | "20050187599" | "20050203399" | "20050288544" | "20050288680" | "20060025837" | "20060047331" | "20060167533" | "20070078502" | "20070083247" | "20070088413" | "20070106349" | "4326529" | "4381007" | "4785807" | "4785828" | "4907589" | "4920978" | "4976709" | "5046511" | "5143063" | "5230349" | "5301692" | "5334193" | "5348554" | "5458596" | "5569242" | "5660836" | "5755753" | "5765567" | "5824076" | "5871524" | "5919219" | "5937863" | "5947891" | "5948011" | "6002968" | "6024743" | "6035238" | "6044847" | "6081749" | "6091995" | "6139569" | "6156060" | "6216704" | "6236891" | "6241753" | "6277116"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:13

		"6283987" | "6292700" | "6311090" | "6322584" | "6350276" | "6377854" | "6377855" | "6381498" | "6387380" | "6405090" | "6413255" | "6416504" | "6425912" | "6427089" | "6430446" | "6453202" | "6461332" | "6461378" | "6470216" | "6478791" | "6480746" | "6482204" | "6533780" | "6546934" | "6558381" | "6572639" | "6579266" | "6579566" | "6587731" | "6629535" | "6685623" | "6743165" | "6749624" | "6751507" | "6772013" | "6776779" | "6830052" | "6836688" | "6840954" | "6852110" | "6879858" | "6882885" | "6889090" | "6976492" | "7004942" | "7022121" | "7141049" | "7238183").PN.				
S12	3046	606/32-40.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:14
S13	4154	606/41.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:15
S14	1565	606/50-52.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:15
S15	260	607/50.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:21
S16	705	607/115.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:21
S17	287	607/138.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:21
S18	1236	S15 S16 S17	US-PGPUB; USPAT; USOCR;	OR	ON	2010/08/06 15:27

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S19	17	S18 and (mucosal)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 15:28
S20	555	("1827306" | "3324847" | "3369549" | "3750653" | "3789829" | "3840016" | "3901224" | "3924628" | "3934580" | "4014988" | "4016270" | "4072147" | "4102342" | "4160455" | "4198981" | "4292960" | "4296760" | "4311154" | "4349033" | "4375220" | "4377168" | "4409993" | "4469103" | "4491131" | "4494539" | "4549533" | "4552127" | "4572190" | "4622972" | "4638436" | "4658836" | "4662383" | "4674481" | "4676258" | "4692452" | "4700701" | "4754752" | "4754757" | "4758592" | "4771778" | "4773899" | "4776349" | "4818954" | "4823812" | "4836189" | "4852579" | "4860752" | "4865047" | "4927413" | "4935003" | "4938217" | "4946440" | "4949718" | "4955377" | "4960109" | "4961435" | "4967765" | "4974587" | "4979948" | "4985027" | "4993430" | "4997653" | "4998930" | "5003991" | "5006119" | "5026959" | "5032124" | "5035694" | "5041089" | "5045056" | "5050597" | "5057106" | "5059191" | "5084044" | "5092841" | "5098429" | "5100388" | "5188122").PN. OR ("5277201").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/06 15:28
S21	131	("3831604" | "4074718" | "4140130" | "4164226" | "4290435" | "4343301" | "4346715" | "4375220" | "4381007" | "4441486" | "4545368" | "4556070" | "4633875" | "4676258" | "4709701" | "4756310" | "4881543" | "4887614" | "4889122" | "4944302" | "4957480" | "4962761" | "4976709" | "5003991" | "5133351" | "5143063" | "5186181" | "5190517" | "5230334" | "5231997" | "5249575" | "5282797" | "5304169" | "5315994" | "5334193" | "5342357" | "5348554" | "5366443" | "5370642" | "5374265" | "5423807" | "5423811" | "5437662" | "5458596" | "5462521" | "5464436" | "5496312" | "5507790" | "5569242" | "5660836" | "5681282" | "5683366" | "5692058" | "5693045" | "5697281" | "5697536" | "5697882" | "5697909" | "5755753" | "5769879" | "5775338" | "6139569" | "RE32849").PN. OR ("6350276").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/06 15:36
S22	0	coad and introitus	US-PGPUB;	OR	ON	2010/08/06

			USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			16:38
S23	254	coad.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 16:38
S24	0	coad.in. and cryoablation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 16:38
S25	14	vaginal near3 laxity	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/06 16:41
S26	19	vaginoplasty	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 09:50
S27	4154	606/41.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:00
S28	1565	606/50-52.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:00
S29	23832792	s "12" S27 S28	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:00
S30	3046	606/32-40.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	ON	2010/08/09 10:01

			IBM_TDB			
S31	7361	S30 S27 S28	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:01
S32	160	S31 and (vagina or vaginoplasty or labiaplasty or introitus or genital)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:02
S33	10187	606/1-31.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:24
S34	222	606/1-31.ccls. and (vagina or vaginoplasty or labiaplasty or introitus or genital)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 10:24
S35	32	("3626931" | "3800800" | "4396019" | "4541439" | "4616640" | "4757823" | "4869258" | "4909263" | "4911149" | "4972839" | "5007437" | "5046511" | "5388583" | "5499631" | "5562717" | "5573499" | "5662699" | "5690604" | "5699805" | "5725473" | "5782778" | "5833611" | "5851175" | "5875778" | "5881731" | "5916173" | "6169914").PN. OR ("6741895").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/09 13:13
S36	74	(electrode and ablation and (revers$3 near3 thermal near3 gradient))	US-PGPUB; USPAT; USOCR	OR	ON	2010/08/09 13:18
S37	74	(electrode and ablation and (revers$3 near3 thermal near3 gradient))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/08/09 13:18
S38	1	((JONATHAN) near2 (PARMER)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2011/01/20 17:12
S39	0	12/884108	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/01/20 17:12

S40	2	"6350276".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/12/14 19:11
S41	71	"606".clas. and introitus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/25 14:28
S42	66	"606".clas. and vulva	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/25 14:36
S43	24	("3278738" | "4616631" | "5026368" | "5125925" | "5179937" | "5242437" | "5242438").PN. OR ("5458595").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:37
S44	21	("4090517" | "5009655" | "5376087" | "5500009").PN. OR ("5830211").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:40
S45	14	11/295204	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:48
S46	6	11/295204 and vulva	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:48
S47	0	11/295204 and vagina$3	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:48
S48	0	11/295204 and introitus	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 14:48
S49	1	"7153133".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 15:31
S50	4	("5348473" | "6168433").PN. OR ("7153133").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 15:36
S51	45	("0118237" | "1534657" | "1927566" | "2135933" | "3472045" | "3727313" | "3740853" | "3757419" | "3822432" | "3869877" | "4014098" | "4060870" | "4075761" | "4182041" | "4490113" | "5020994" | "5028233" | "5040978" | "5145370" | "5169312" | "5209658" | "5352119" | "5356340" | "5374189" | "5423679" | "5433605" | "5496218" | "5503555" | "5529495" | "5531599" | "5645426" | "5730595").PN. OR ("6168433").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/25 15:37
S52	2	"6350276".pn.	US-PGPUB; USPAT;	OR	ON	2012/11/03 13:26

			USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
S53	418	a61b2018/00559.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/12/11 13:38
S54	2	"6350276".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:05
S55	1982	(vagina introitus vulva) and "606".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:11
S56	127	(vagina introitus vulva) and "606".clas. and epithelium	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:11
S57	1132	a61b2018/00559.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:20
S58	32	a61b2018/00559.cpc. and (vulva vagina introitus) and (epithelium) and (heat$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:21
S59	2	("20070233191").pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:23
S60	3	wo-9622739-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:23

S61	0	2004/0206365-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:23
S62	0	20040206365-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:24
S63	2	"20040206365".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/05 15:24
S64	166	a61b2018/00559.cpc. and (vulva vagina introitus) and (ablat$3 tight$5 heat$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/08 12:20
S65	2	"6350276".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/08 12:21
S66	189	("20040215296" | "3901241" | "4949147" | "5057107" | "5078717" | "5156151" | "5190541" | "5257451" | "5314438" | "5328467" | "5348554" | "5363861" | "5365926" | "5370675" | "5409453" | "5454809" | "5486161" | "5520684" | "5522815" | "5536240" | "5554110" | "5556377" | "5562720" | "5566221" | "5624439" | "5730128" | "5833688" | "5861036" | "6044846" | "6092528" | "6096054" | "6138046" | "6179836" | "6182666" | "6325798" | "6363937" | "6425877" | "6428536" | "6454790" | "6547776" | "6872206" | "6918906" | "6964661" | "20050273095" | "6929642" | "7125212" | "6551315" | "5807261" | "5830129" | "6245065" | "5383874" | "20030069572" | "6575966" | "7416549" | "6164283" | "20060135956" | "20090036733" | "5840077" | "20020183739" | "20030216727" | "20040147916" | "20050245926" | "20060009758" | "20060282071" | "20070066973" | "4943290" | "4947842" | "5197963" | "5197964").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/08 12:31

S67	516	("5242441" | "5275162" | "5281217" | "5313943" | "5421819" | "5454782" | "5470308" | "5490984" | "5496271" | "5509419" | "5514131" | "5524622" | "5542928" | "5558672" | "5599345" | "5823197" | "5830213" | "5836874" | "5964755" | "5997534" | "6016437" | "6033397" | "6053913" | "6071277" | "6091993" | "6091995" | "6238392" | "6338726" | "6689130" | "6752806" | "7165551" | "7167758" | "6183468" | "5425704" | "5984861" | "6039701" | "6416511" | "6917834" | "4895138" | "7063694" | "20070288001" | "7850685" | "20090012512" | "20090177194" | "20040122452" | "20040204708" | "20040215180" | "20040215235" | "20050107829" | "20060259029" | "20070100333" | "20080097427" | "3924628" | "4907589" | "4930521" | "4955377" | "5046512" | "5084044" | "5163938" | "5277201" | "5309910" | "5314466" | "5368557" | "5383917" | "5403311" | "5484400" | "5507743" | "5514130" | "5531677" | "5571116" | "5609151" | "5651780" | "5658278" | "5672153" | "5702438" | "5716410" | "5738096" | "5748699" | "5860974" | "5902263" | "6012457" | "6059719" | "6086558" | "6102908" | "6123703" | "6197022" | "6321121" | "6355031" | "6355032" | "6432104" | "6440128" | "6572639" | "6712074" | "6800083" | "6837886" | "6953469" | "6971395" | "7122031" | "7083620" | "6500174" | "4662383" | "20010051802" | "20070255296" | "20090299355" | "6149647" | "20050171525" | "20090036886" | "20070239011" | "20030109837" | "20050288664" | "20090012512" | "4640298" | "5006119" | "5010895" | "5088979" | "5122137" | "5125928" | "5256138" | "5292321" | "5383876" | "5531676" | "5533958" | "5536267" | "5578007" | "5588432" | "5588960" | "5713942" | "5769846" | "5800429" | "5846196" | "6162237" | "6258087" | "6273886" | "6325800" | "6589238" | "6712815" | "6740082" | "RE35330" | "20030191512" | "4407298" | "6468272" | "20070027449" | "4311154" | "20040243124" | "20070287994" | "20100204560" | "20090187181" | "20030181905" | "20050033271" | "20050187546" | "20060015162" | "20060086363" | "20090012513" | "4658836" | "4676258" | "4765331" | "4776349" | "4969890" | "4998539" | "5019075" | "5045056" | "5106360" | "5281218" | "5423812" | "5433739" | "5435805" | "5456662" | "5462545" | "5500012" | "5517989" | "5540655" | "5779698" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/08 12:31

		"5871483" | "5876340" | "5976129" | "6006755" | "6095966" | "6112123" | "6123718" | "6146149" | "6383181" | "6394949" | "6409723" | "6464697" | "6544226" | "6562034").PN.				
S68	529	("6682528" | "6974456" | "7150745" | "5035696" | "6010511" | "6451014" | "6641581" | "6860878" | "4860744" | "20070276361" | "5316020" | "5823955" | "6120434" | "20010007940" | "20030028227" | "6443947" | "6514246" | "7004938" | "20060199999" | "20090012518" | "20050159743" | "20060095032" | "20080275445" | "20080319350" | "4532924" | "4674481" | "4966597" | "4976711" | "5047028" | "5275169" | "5345936" | "5366490" | "5368592" | "5370678" | "5398683" | "5415657" | "5423808" | "5428658" | "5443470" | "5458597" | "5471982" | "5496311" | "5505730" | "5542916" | "5558673" | "5621780" | "5769880" | "5827273" | "6027499" | "6041260" | "6415016" | "6551310" | "6749607" | "6994704" | "7179257" | "7326207" | "20100063495" | "5540679" | "5720293" | "6023638" | "20040153120" | "20070088344" | "5925044" | "5375594" | "20020177847" | "20040087936" | "20050096713" | "20050215983" | "20060069303" | "20060259030" | "20090012518" | "4011872" | "4565200" | "4979948" | "5100423" | "5151100" | "5215103" | "5236413" | "5263493" | "5281216" | "5324284" | "5336222" | "5385544" | "5397339" | "5401272" | "5441499" | "5456682" | "5458596" | "5465717" | "5549661" | "5569241" | "5591195" | "5676674" | "5709224" | "5797903" | "5800334" | "5842984" | "5863291" | "5888743" | "5891134" | "5895355" | "6402744" | "6423058" | "6535768" | "6673070" | "6712814" | "7056320" | "7125407" | "7160294" | "7293563" | "5171299" | "5255679" | "5938694" | "20030093117" | "5458571" | "6663626" | "20040236316" | "20050090817" | "20070088247" | "20070135796" | "20080051882" | "0552832" | "6813520" | "20060247614" | "20110270249" | "20080097427" | "20080275445" | "20080319350" | "20090012513" | "20010041887" | "20030153905" | "20030158550" | "20030181900" | "20040172016" | "20050010162" | "20050070978" | "20050154386" | "20060041256" | "20060259028" | "4304239" | "4411266" | "4887614" | "5056532" | "5083565" | "5117828" | "5290286" | "5293869" | "5409483" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/08 12:32

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S69	328	607/138.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/08 12:33
S70	151	("20030130575" | "20040030332" | "20040111136" | "20050154433" | "20050171583" | "4920978" | "5046511" | "5348554" | "5919219" | "6241753" | "6405090" | "6461378" | "6482204" | "6587731" | "6685623" | "6751507" | "7141049" | "20020183735" | "5242440" | "7998137" | "20020049483" | "20020151887" | "20020156471" | "20020183735" | "20030139790" | "20030212393" | "20040172291" | "20040186535" | "20040249425" | "20070106349" | "4381007" | "5755753" | "5947891" | "5948011" | "6091995" | "6236891" | "6277116" | "6836688" | "6976492" | "20040249425" | "5330469" | "20020062142" | "20020120260" | "20030120326" | "20030120575" | "20040111137" | "20040260368" | "20060025837" | "4785807" | "4907589" | "5334193" | "6002968" | "6035238" | "6377855" | "6416504" | "6572639" | "6579266" | "6882885" | "6889090" | "7022121" | "20070093807" | "20040034400" | "20040193238" | "20040206365" | "5765567" | "6024743").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/02/09 23:36
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S76	2995	a61b18/12.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/06/24 15:11
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			DERWENT; IBM_TDB			
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EAST Search History (Interference)

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10/14/2014 6:08:13 PM
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	Art Unit
	RONALD HUPCZEY, JR	3739

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	1-52	08/06/2010	RJH
607	50, 115, 138	08/06/2010	RJH

SEARCH NOTES		
Search Notes	Date	Examiner
East Search	08/06/2010	RJH
Inventor Search	08/06/2010	RJH
Updated Search	1/20/2011	RJH
Updated Search	2/9/14	RJH
Updated Search	8/4/2014	RJH
Updated	10/14/2014	RJH

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	SEE ATTACHED EAST SEARCH	8/4/14	RJH
	Updated	10/14/14	RJH

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	**Art Unit**
	RONALD HUPCZEY, JR	3739

CPC							
Symbol						**Type**	**Version**
A61B		18	/	1485		F	2013-01-01
A61B		18	/	1206		A	2013-01-01
A61B		18	/	18		A	2013-01-01
A61B		2018	/	00023		A	2013-01-01
A61B		2018	/	00559		A	2013-01-01
A61B		2018	/	00702		A	2013-01-01
A61B		2018	/	00791		A	2013-01-01
A61B		2018	/	00875		A	2013-01-01
A61N		7	/	022		A	2013-01-01
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CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
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NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	58	
/RONALD HUPCZEY, JR/ Primary Examiner.Art Unit 3739	10/14/14	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	18D

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	**Art Unit**
	RONALD HUPCZEY, JR	3739

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS
606	49

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
606	41				
607	138				
601	3				

INTERNATIONAL CLASSIFICATION					
CLAIMED					NON-CLAIMED
A	6	1	B	18 / 12 (2006.0)	
A	6	1	B	18 / 18 (2006.0)	
A	6	1	N	7 / 02 (2006.01.01)	

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	58	
/RONALD HUPCZEY, JR/ Primary Examiner.Art Unit 3739	10/14/14	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	18D

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11704067	PARMER, JONATHAN B.
	Examiner	**Art Unit**
	RONALD HUPCZEY, JR	3739

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 58	
/RONALD HUPCZEY, JR/ Primary Examiner.Art Unit 3739 (Primary Examiner)	10/14/14 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 18D

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BIB DATA SHEET

CONFIRMATION NO. 4378

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/704,067	02/07/2007	606	3739	10095-701.201

APPLICANTS

INVENTORS

Jonathan B. Parmer, Woodside, CA;

**** CONTINUING DATA ***************************

This appln claims benefit of 60/743,247 02/07/2006

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **

03/13/2007

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /RONALD JAMES HUPCZEY, JR/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	9	57	2

ADDRESS

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403
UNITED STATES

TITLE

Vaginal remodeling device and methods

FILING FEE RECEIVED		
1740	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	181	US- 5,469,857	11/28/1995	Laurent et al.	
	180	US- 5,673,695	10/7/1997	McGee et al.	
	179	US- 5,836,990	11/17/1998	Li	
	178	US- 6,569,160	5/27/2003	Goldin	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	10/14/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.H./

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Mary Buggie	(Depositor's name)
/Mary Buggie/	(Signature)
FILED VIA EFS ON 1/16/2015	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201	4378

TITLE OF INVENTION: VAGINAL REMODELING DEVICE AND METHODS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	01/20/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
HUPCZEY, JR, RONALD JAMES	3739	606-041000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 **Shay Glenn LLP**
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: **Viveve, Inc.**

(B) RESIDENCE: (CITY and STATE OR COUNTRY): **Sunnyvale, CA**

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ■ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ■ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

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- ☐ Payment by credit card. Form PTO-2038 is attached.
- ■ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number **50-4050** (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status.
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NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date **January 16, 2015**

Typed or printed name **Richard D. Shoop** Registration No. **45,763**

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	11704067
Filing Date:	07-Feb-2007
Title of Invention:	VAGINAL REMODELING DEVICE AND METHODS
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Filer:	Richard Douglas Shoop/Mary Buggie
Attorney Docket Number:	10095-701.201

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	2501	1	480	480

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**480**

Electronic Acknowledgement Receipt

EFS ID:	21238152
Application Number:	11704067
International Application Number:	
Confirmation Number:	4378
Title of Invention:	VAGINAL REMODELING DEVICE AND METHODS
First Named Inventor/Applicant Name:	Jonathan B. Parmer
Customer Number:	66854
Filer:	Richard Douglas Shoop/Mary Buggie
Filer Authorized By:	Richard Douglas Shoop
Attorney Docket Number:	10095-701.201
Receipt Date:	16-JAN-2015
Filing Date:	07-FEB-2007
Time Stamp:	19:40:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$480
RAM confirmation Number	5792
Deposit Account	504050
Authorized User	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	10095-701-201_Issue_Fee.pdf	102408 45a8d7d272521f1c3701cd0fad9b91fe944196a4	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30734 04f58c0f0130eb6512c78e70e2bbd26a79a32162	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	133142		

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PTO/SB/08a (07-09)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/704,067
Filing Date	February 7, 2007
First Named Inventor	Jonathan B. Parmer
Art Unit	3739
Examiner Name	Hupczey, Jr, Ronald James
Attorney Docket Number	10095-701.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	163	US- 5,242,440	9/7/1993	Shippert	
	165	US- 5,450,293	9/12/1995	Hoffman	
	162	US- 7,294,127	11/13/2007	Leung et al.	
Change(s) ~~applied~~ to document, /M.A.H./ 11/24/2014	167	US- 7,998,137 8/2011	~~8/5/2010~~	Elkins et al.	
	164	US- 2007/0093807	4/26/2007	Baxter et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	168	WO2006/105121A2	10/5/2006	Minnow Medical LLC		

Examiner Signature	/Ronald Hupczey, Jr/	Date Considered	02/09/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.H./

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/704,067	02/24/2015	8961511	10095-701.201	4378

66854 7590 02/04/2015

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1179 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Jonathan B. Parmer, Woodside, CA;

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AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Eastern District of Texas, Marshall Division on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	10/21/2016	Eastern District of Texas, Marshall Division

PLAINTIFF	DEFENDANT
VIVEVE, INC.	THERMIGEN, LLC; THERMIAESTHETICS, LLC; AND RED ALINSOD, M.D.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	8,961,511	2/24/2015	Viveve, Inc.
2			
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 **Director of the U.S. Patent and Trademark Office** **P.O. Box 1450** **Alexandria, VA 22313-1450**	

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DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

Trials@uspto.gov
571-272-7822

Paper No. 7
Entered: May 8, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THERMIGEN, LLC AND THERMIAESTHETICS, LLC
Petitioner,

v.

VIVEVE, INC.,
Patent Owner.

Case IPR2018-00088
Patent 8,961,511 B2

Before HYUN J. JUNG, ROBERT A. POLLOCK, and SCOTT C. MOORE, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION TO INSTITUTE
35 U.S.C. § 314(a)

I. INTRODUCTION

Thermigen, LLC and Thermiaesthetics, LLC ("Petitioner")[1] filed a Petition for an *inter partes* review of claims 1–42 of U.S. Patent No. 8,961,511 B2 ("the '511 patent," Ex. 1001). Paper 2 ("Pet."). Viveve, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). We review the Petition, Preliminary Response, and accompanying evidence under 35 U.S.C. § 314.

On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst. Inc. v. Iancu*, No. 16-969, 2018 WL 1914661, at *10 (U.S. Apr. 24, 2018). After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least claim 1 of the '511 patent is unpatentable. Accordingly, we institute an *inter partes* review of claims 1–42.

A. Related Proceedings

According to the parties, the '511 patent is at issue in *Viveve, Inc. v. ThermiGen, LLC et al.*, Civil Action No. 2:16-cv-1189-JRG (E.D. Tex.). Pet. 3, Paper 3, 2.

In addition to the present proceeding, Petitioner concurrently challenges claims 43–58 of the '511 patent in IPR2018-00089.

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[1] Petitioner further identifies Almirall, S.A. of Barcelona, Spain, as a real party-in-interest. Pet. 3.

B. The '511 Patent

The '511 patent pertains to "treating a loose vagina and introitus" via "corrective or restorative remodeling of the mucosal surfaces of the vagina, introitus, and vulva." Ex. 1001, 2:17–21. In particular, the patent discloses "apparatus and methods for tightening tissue of the female genitalia by heating targeted connective tissue with radiant energy [typically radiofrequency (RF) energy], while cooling the mucosal epithelial surface over the target tissue to protect it from the heat." *Id.* Abstract, 4:4–13; *see also id.* at 2:25–28, 4:7–16, 13:16–19, claims 6, 33, 41, and 49 ("heating comprises delivering energy by any of: radiofrequency energy, microwave energy, or ultrasound energy"). According to the Specification, the tightening may be an immediate or near-immediate consequence of thermally denaturing tissue collagen, and/or the result of a longer term healing response involving the deposition of new collagen by cells in the connective tissue. *Id.* Abstract, 4:14–16, 4:63–5:11, 12:39–49.

C. Prosecution History of the '511 patent.

The '511 patent issued to Jonathan B. Parmer from U.S. Application No. 11/704,067, filed February 7, 2007 and claiming the benefit of Provisional Application No. 60/743,247, filed on February 7, 2006.[2]

As noted by both parties, the Examiner rejected then-pending claims over Knowlton.[3,4] *See* Pet. 7–10; Prelim. Resp. 4–5. Knowlton discloses

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[2] Petitioner argues, and Patent Owner does not presently contest, that at least independent claims 1 and 35 are not entitled to the filing date of the provisional application. *See* Pet. 5–6.
[3] US 6,350,276 B1, issued Feb. 26, 2002. Ex. 1007.
[4] Knowlton is cited as background in the '511 patent and incorporated therein by reference. *See* Ex. 1001, 1:47–49, 5:65–26:6.

fluid-cooled apparatus comprising RF electrodes to "appl[y] a mechanical force in combination with the delivery of energy to the skin surface and underlying soft tissue structure, to remodel collagen both esthetically and functionally with minimal thermal damage including cell necrosis." Ex. 1007, 13:9–13; 15:25–28, Abstract. In one embodiment, Knowlton discloses treating pre-term cervical dilation by applying RF energy to tighten the dilated cervix. *See* Ex. 1007, 13:35–47 ("The incorporated energy delivery device 18 contracts the native matrix and induces scar collagen. The dilated cervical OS is tightened and the entire cervix is strengthened."); *see also* Ex. 1003 ¶¶ 66–69, Ex. 1004 ¶¶ 20–21.

During prosecution, the Examiner repeatedly rejected claims as anticipated and/or obvious in view of Knowlton. Ex. 1002, 701–704, 748–755, 934–945. According to the Examiner,

> Knowlton discloses a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue (as in the embodiment of figures 13–14 describing the treatment of cervix, see col. 13; 35–37), the method comprising heating the target tissue and remodeling the therapeutic zone of target tissue.

Ex. 1002, 693; *see also id.* at 759–760 (Final Rejection stating that the cervix is "female genital tissue" and Knowlton discloses treating tissue underlying the cervical epithelium).

To address rejections over Knowlton, applicant amended claim 1 (the only independent method claim then pending) to recite "remodeling a therapeutic zone including at least one of vulva, introitus or vagina" and arguing that Knowlton does not disclose treating these tissues. *Id.* at 777–781, 785. Applicant subsequently also amended claim 1 to require 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," thereby excluding the cervix.[5] *Id.* at 974; Ex. 1003 ¶ 20.

In allowing the claims to issue, the Examiner explained that "Knowlton fails to contemplate the specific areas of treatment set forth in [the] independent claims . . . . 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, 1352 (Notice of Allowance). According to Patent Owner, the Examiner, thus, "recognized that even though it was known to heat one female genital tissue using RF, this did not fairly suggest or make obvious the heating of other female genital tissues using RF." Prelim. Resp. 5.

D. Illustrative Claims

Petitioner challenges claims 1–42 in this proceeding,[6] of which claims 1 and 35 are independent (italicized to highlight differences).

> 1. 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:
>
> heating the target tissue, and
>
> remodeling the therapeutic zone of target tissue, wherein the heating includes *heating a portion of the vagina*

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[5] Applicant also re-drafted certain dependent claims in independent format, which subsequently issued as claims 35, 43, and 51. *See id.* at 977.

[6] Petitioner challenges the remaining claims of the '511 patent, claims 43–58, of which claims 43 and 51 are independent, in co-pending IPR2018-00089.

extending from the introitus[7] *inwardly to a location from 1 cm to 3.5 cm in from the introitus.*

35. 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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, 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.*

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 13):

Ground	Claims	Basis	Reference(s)
1	1–10, 13–14, 17, 23 and 25–33[8]	§ 102	Edwards[9]
2	1–42	§ 103	Edwards, Ingle,[10] and Mosher[11]

[7] The Specification defines "introitus" as "the opening of the vagina" (Ex. 1001, 2:3–4, 3:51).

[8] Petitioner lists claim 24 in its statement of ground 1, but discusses the merits of claim 26, rather than claim 24 in the Petition. *See* Pet. 13, 35–36; *see also* PO Resp. 31–32 (noting that Petitioner fails to address claim 24 under ground 1 but responding to arguments relating to claim 26). Accordingly, we consider Petitioner's substitution of claim 24 for claim 26 in its statement of ground 1 a typographical error.

[9] US 6,463,331 B1, issued Oct. 8, 2002. Ex. 1008.

[10] US 6,216,704 B1, issued Apr. 17, 2001. Ex. 1010.

[11] US 2004/0193238 A1, published Sept. 30, 2004. Ex. 1009.

In support of its patentability challenges, Petitioner relies on the Declarations of Dr. Roger Dmochowski, M.D. (Ex. 1003) and Dr. Robert Tucker, Ph.D., M.D. (Ex. 1004). Patent Owner relies on the Declaration of Dr. Lawrence S. Bass, M.D. (Ex. 2001).

II. ANALYSIS

To anticipate a claim under 35 U.S.C. § 102, "a single prior art reference must expressly or inherently disclose each claim limitation." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). That "single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art." *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* at 418. Rather "the test is whether the references, taken as a whole, would have suggested appellant's invention to one of ordinary skill . . . at the time the invention was made." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the

patent at issue." *KSR*, 550 U.S. at 418. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations and citations omitted).

A. Person of Ordinary Skill in the Art

Petitioner proposes that one of ordinary skill in the art "is a medical doctor practicing in the field of plastic surgery and in particular, in urogynecology or a similar field" or "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." Pet. 20. Petitioner's experts, however, propose definitions indicating experience in both plastic surgery involving female genitalia and the clinical application of radiant energy to human tissue and/or experience performing electrosurgical procedures. *See* Ex. 1003 ¶ 8; Ex. 1004 ¶ 14. Petitioner's experts do not opine on number of years' experience required. *See id.* Although Patent Owner does not propose an alternative definition in the Preliminary Response, Patent Owner's expert similarly states that such a person would have "a medical degree plus at least two years of experience in a field such as gynecology, urogynocology [sic], or plastic surgery, with clinical experience in

application of radiant energy to human tissue and experience involving female genital anatomy." Ex. 2001 ¶ 14.

In considering the testimony of the parties' experts, the field of the '511 patent, and the relevant art, we determine that one of ordinary skill in the art would have a medical degree plus at least two years of experience in a field such as gynecology, urogynecology, or plastic surgery involving female genital anatomy, with clinical experience in the application of radiant energy to female genital tissue.

B. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, we presume that a claim term carries its "ordinary and customary meaning," which "is the meaning that the term would have to a person of ordinary skill in the art in question" at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) ("Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history."). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Limitations, however, may not be read from the specification into the claims (*In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993)), nor may the Board "construe

claims during [an *inter partes* review] so broadly that its constructions are unreasonable under general claim construction principles" (*Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (overruled on other grounds by *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017)).

We address below terms identified by the parties as in need of construction. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (instructing that claim terms need only be construed to the extent necessary to resolve the controversy).

1. "target tissue"

The independent claims before us recite "method[s] for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue." Within the body of the claims, "target tissue" is also the subject of "heating" and "remodeling." Petitioner proposes that we construe the term "target tissue" as "tissue underlying the epithelium." Pet. 21–22 (citing Ex. 1001, 2:25–28, 3:41–47, 11:11–14, 12:2–13).

Patent Owner contends that Petitioner's proposed definition is overly broad as it includes deeper tissue layers expressly excluded in the Specification. Prelim. Resp. 7–9. In accord with Patent Owner's position, column 3, lines 41–48 of the Specification states:

> Embodiments of the invention include methods for remodeling a therapeutic zone of tissue within a target tissue of female genitalia. 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. The target zone of embodiments of the invention does not include deeper tissue, such as endopelvic fascia.

Similarly, column 12, lines 2 through 16 of the Specification 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 . . . . These described target tissue layers below the epithelium overlay deeper tissues, including endopelvic fascia, which are not a target tissue for embodiments of the present invention.

"Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). In particular, patentee must "demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id.* at 1366. On the present record, we agree with Patent Owner that the passages identified in the Specification comprise a "clear and unmistakable" disclaimer of the scope of target tissue. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366–67 (Fed. Cir. 2012). We also note that there is no evidence in the record that the term "target tissue" has an ordinary and customary meaning in the art to which the '511 patent pertains that encompasses the endopelvic fascia. Thus, even though we find a clear and unmistakable disclaimer here, this is not a situation where a disclaimer is necessary in order to depart from the plain and ordinary meaning of a claim term. Rather, the construction we adopt here is a definition set forth in the specification of a term that has not been shown to have an ordinary and customary meaning outside the scope of the '511 patent.

On this record, we construe "target tissue" as used in the claims of the '511 patent to mean tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissues, such as the endopelvic fascia.

2. "heating"

All independent claims of the '511 patent recite the step "heating the target tissue." Patent Owner proposes that we do not apply the plain and ordinary meaning to "heating" as used therein. Prelim. Resp. 9–13. Patent Owner points out that in applying the *Phillips* standard, the District Court construed "heating" to mean "heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium." *Id.* at 11. Patent Owner also rejects this construction, arguing instead that the Specification "makes clear that this heating step requires 'heating without damaging the mucosal epithelial surface.'" Prelim. Resp. 9.

As Patent Owner points out, the '511 patent teaches optimal contact of an energy delivery device and active cooling of the epithelial surface over the target tissue such that "the epithelium itself is not damaged or substantially modified by the method." *Id.* at 9–11 (citing Ex. 1001, Abstract, 12:19–21, 13:16–26, 2:56–62, 8:8–15). But the plain language of the independent claims makes no express mention of protecting the epithelial layer from damage or modification, whether through a configuration of the energy delivery device, by cooling the epithelial layer, or by creating a temperature gradient as indicated under the District Court's construction under *Phillips*. Each of these elements is, however, recited in one or more independent claims, suggesting that the independent claims encompass, but are not necessarily limited to those elements. Depending from claim 1, for example, claim 24 includes the limitation "wherein the

heating does not modify a mucosal epithelium of the genital tissue"; claims 5–8, 10, and17–22 relate to the configuration of an energy delivery device; claim 9 and its dependent claims include the step of "cooling the epithelium"; and claim 15 and its dependent claims state that the step of cooling the epithelium results in "a reverse thermal gradient from the epithelium to the target tissue." *See Nazomi Commc'ns, Inc. v. Arm Holdings, PLC.*, 403 F.3d 1364, 1370 (Fed. Cir. 2005) ("The concept of claim differentiation 'normally means that limitations stated in dependent claims are not to be read into the independent claim from which they depend.'") (quoting *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971–72 (Fed. Cir.1999)).

Applying the broadest reasonable construction consistent with the specification, we do not limit the term "heating" as did the District Court, nor as Patent Owner proposes.[12] *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim. For example, a particular embodiment appearing in the

[12] When a claim term has previously been construed by a district court, the Board must "assess whether [the court's] interpretation [is] consistent with the broadest reasonable construction of the term." *Power Integrations, Inc. v. Lee*, 797 F.3d 1318, 1324–27 (Fed. Cir. 2015). The broadest reasonable interpretation of disputed claim terms is "a different claim construction standard than that applied by a district court" (*id.*), and may sometimes produce a different result.

written description may not be read into a claim when the claim language is broader than the embodiment.").

Although we generally apply the ordinary meaning to the term "heating," we also note that the '511 patent places an upper limit on the temperature to which target tissue is heated. According to the Specification, in heating the target tissue, the "[t]emperature is raised to a level that is therapeutic, i.e., to a temperature that causes remodeling." Ex. 1001 11:21–23. In particular, "[t]he therapeutic temperature . . . may be . . . as high as 80 degrees C. The inventive method, therefore includes heating target tissue to as high as 80 degrees C." *Id.* at 11:25–29; *see also id.* at 4:34–40 (indicating a temperature of "about 80 degrees C. in the target tissue"). Accordingly, we construe "heating" as used in the claims of the '511 patent as raising the temperature of target tissue to no more than about 80 degrees C.

3. "remodeling"

Patent Owner proposes that we construe "remodeling" as used in the claims of the '511 patent as "causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature," with or without the additional requirement, "without damaging the epithelium." Prelim. Resp. 12–13. Patent Owner also notes that the District Court defined "remodeling" under the *Phillips* standard as "a process comprising a doctor's application of specific concrete steps to specific tissue under particularized conditions, which is simply predicated on the ability of collagen to be physically transformed by heat." Prelim. Resp. 13 (citing Ex. 2009, 7). Although we do not disagree with the thrust of these constructions, in the context of the claims as a whole, they appear to render

the "heating" step redundant. In this respect, we agree with Petitioner that the term refers to "a natural phenomenon that results from the heating of the tissue," i.e., "the *result* caused when heated tissue reaches a sufficient temperature." Pet. 27 (citing Ex. 1001, 4:15–16, 5:2–5, 11:22).

The independent claims of the '511 patent recite "method[s] for remodeling a therapeutic zone of a target tissue . . . comprising: heating the target tissue, and remodeling the therapeutic zone of target tissue." Considering the overall structure of these claims and the use of the term in the context of the Specification, "remodeling" in the body of the independent claims refers to the result obtained by heating the target tissue to a therapeutic temperature—i.e., the result obtained by raising the temperature of target tissue to no more than about 80 degrees C. *See* section II(B)(2) above.

Further, the Specification teaches that the result obtained by heating the target tissue "may include a melting or denaturing of preexisting collagen in the tissue," and/or "a healing process in which there is an increase in the rate of cellular production and deposition [of collagen] into the extracellular space. Both types of responses . . . contribute to an overall tightening of the target tissue." Ex. 1001, 12:50–65; *see id.* at 12:39–49.

The Specification makes clear, however, that "remodeling of the connective tissue underlying the mucosal epithelial surfaces does not substantially affect the epithelium itself. The method and apparatus, as provided by embodiments of the invention are non-invasive and substantially non[-]ablative of genital tissue." *Id.* at 12:17–21.

In view of the above, we construe "remodeling" as used in the body of the independent claims of the '511 patent to refer to the result of raising the

temperature of target tissue to no more than about 80 degrees C without substantially affecting the epithelium overlying the target tissue, wherein that result includes a tightening or contraction of the target tissue.

> 4. "heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock"

Petitioner contends that the term "heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock," as recited in claim 35, should be interpreted as "[h]eating 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." Pet. 22–23. In contrast, Patent Owner argues that a dictionary definition of the preposition "over" means "from one point to another across an intervening space or barrier," such that the claim language requires heating substantially the entire 300 degree arc of vaginal wall from 1 o'clock to 11 o'clock, as shown in the embodiment illustrated in figures 9A and 9B of the Specification, illustrated below. *See* Prelim. Resp. 14–16.

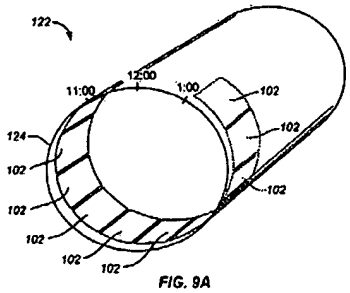


FIG. 9A

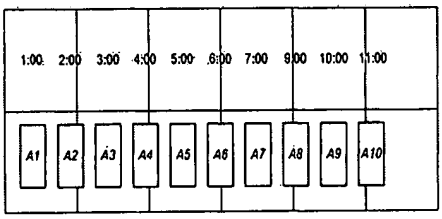


FIG. 9B

Figure 9A depicts a treatment area of a mucosal epithelium comprising multiple contact sites; figure 9B is a representation of the treatment area as a mapping grid. Ex. 1001, 5:55–57. More particularly:

> FIG.9A is a schematic representation of a vagina 122, with the introitus 124 forming the entrance to the vagina. In a typical procedure, the treatment tip would contact various contact sites

> in the lower vagina, just inside the introitus. As shown in FIG.9A, an accumulated set of contact sites 102 that have been treated by the treatment tip, and they collectively comprise a treatment area on the vaginal epithelium.

Id. at 14:46–53. As illustrated in Figure 9B,

> the contact sites may be recorded on a grid 115, the completed grid thus being a mapped representation of the treatment area, which can be referred to during evaluation of the remodeling at some time point following the treatment. As shown, the treatment grid may contain reference points with respect to the circumferential location on the vagina, as provided, for example, by the clock dial scheme.

Id. at 14:62–15:3. The Specification further explains:

> The circumference of the lower portion of an unfolded vagina, gently stretched as it is during the practice of this method, is approximately 12 cm. Accordingly, with a treatment tip of about 1cm in width, a series of about 10 contact sites allows completion of an [sic] 300 degree arc of the circumference, between the 1 o'clock and 11 o'clock positions. These dimensional considerations underlie the rationale for an embodiment of the treatment wherein the surface of the energy delivery element has a curvature of about 30 degrees, each contact site accounting for about 10% of the 300 degree arc.

Id. at 14:35–45.

As an initial matter, the plain language of claim 35, "heating a portion of the vagina *circumferentially* around its wall," requires the heating of a vaginal wall over a defined arc, and thus excludes the "at least one point" language of Petitioner's proposed instruction. As illustrated above in Figure 9A, for example, a "contact site" along the vaginal wall extends some distance around the curvature of the vaginal wall. *See, e.g., id.* ("each contact site accounting for about 10% of the 300 degree arc").

Whether "heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock" requires heating substantially *all* of the wall 1 o'clock to 11 o'clock, however, is a close question. According to Petitioner, claim 35 should not be interpreted to require a series of contact sites as described in the above embodiment as this would improperly import limitations from the Specification. Pet. 23. Petitioner further argues that construing claim 35 to require a series of contact sites as shown in Figures 9A and 9B would ignore the principle of claim differentiation because claim 40, depending from claim 35, recites "contacting the epithelium with a treatment tip at one or more contact sites during a procedure." *Id.*

On the record presently before us, we find Petitioner's arguments more persuasive. Accordingly, we construe "heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock," as heating at least one contact site in the 300 degree arc extending from 1 o'clock to 11 o'clock along the vaginal wall.

C. Ground 1: Anticipation by Edwards

Petitioner challenges claims 1–10, 13–14, 17, 23, and 25–33 as anticipated by Edwards. Pet. 24–38. Patent Owner opposes. Prelim. Resp. 20–33. We begin with an overview of Edwards.

1. Overview of Edwards (Ex. 1008)

Edwards "provides a method and system for the curative treatment of female uro-genital disorders by application of radiofrequency (RF) energy to targeted tissues. Application of this energy is selectively applied so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition." Ex. 1008, 2:33–38. "In alternative embodiments, other forms of

energy may be delivered, such as microwave, laser, ELF (extremely low frequency) and other therapeutic energies." *Id.* at 13:57–59.

Edwards discloses four embodiments of the invention. *Id.* at 2:40–3:13. In the fourth embodiment, "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." *Id.* at 3:5–11.

Figure 4 of Edwards is reproduced below.

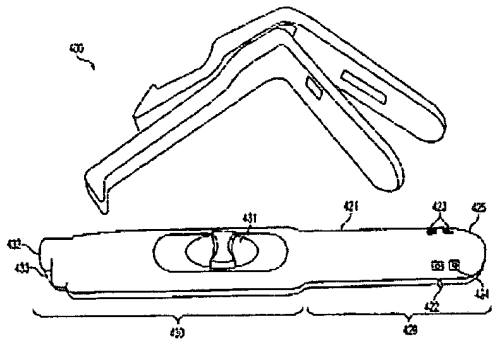


FIG. 4

Figure 4 illustrates the distal end of a system 400 that can be used for vaginal remodeling in accord with the fourth embodiment. *Id.* at 3:25–27, 7:14–8:5. Briefly, the system comprises a treatment element coupled to an RF generator. *Id.* at 7:14–15. "The distal end of the treatment element . . . is inserted into a vagina using a speculum." *Id.* at 7:18–19. A plurality of relatively flat electrodes 423 are disposed on the distal end of the treatment unit. *Id.* at 7:34–39. "Each electrode 423 includes at least one thermocouple 424 that is used to monitor the temperature of each electrode 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." *Id.* at 7:43–50. Also on the distal end of the treatment element, "irrigating

fluid delivery pores 425 . . . are disposed to deliver cooling liquids so as to minimize thermal damage." *Id.* at 7:51–55, 7:66–8:5.

Figure 9A of Edwards is reproduced below.

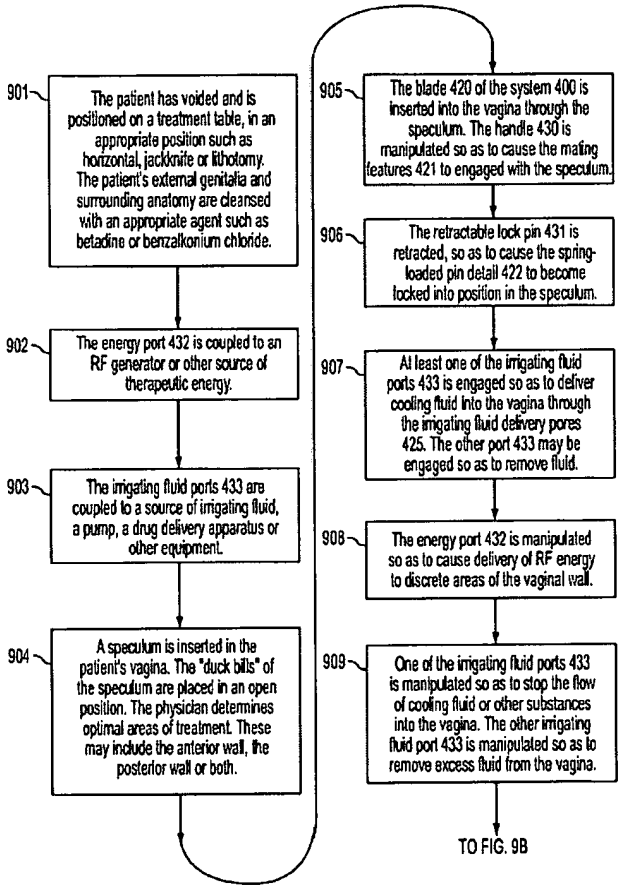


Figure 9A illustrates the method of Edward's fourth embodiment for vaginal remodeling. *Id.* at 3:38–39. As explained in detail at column 13, line 12 through column 14, line 4: "[A] speculum is inserted in the patient's vagina. The blades of the speculum are placed in an open position. The physician determines optimal areas of treatment. These may include the anterior wall, the posterior wall, or both." *Id.* at 13:38–42. The treatment element of system 400 is inserted into the vagina through the speculum. *Id.* at 13:43–46. Cooling fluid is delivered into the vagina through irrigating fluid

delivery pores 425, and RF energy is delivered "to discrete areas of the vaginal wall." *Id.* at 13:54–56.

According to Edwards, the method "create[s] a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both. . . . 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." *Id.* at 13:14–22.

2. Analysis of Ground 1

a) Claim 1

Petitioner relies on the testimony of Drs. Dmochowski and Tucker in asserting that Edwards discloses all elements of independent claim 1. Pet. 24–29 (citing Ex. 1003 ¶¶ 79, 81–88; Ex. 1004 ¶¶ 18–19. We find Petitioner's arguments and evidence to be reasonable in light of Edward's teaching to deliver RF energy "to the anterior and posterior regions of the vaginal wall" in conjunction with the delivery of "cooling liquids, so as to minimize thermal damage," in order to effect "circumferential tightening of the vaginal wall." *See* section II(C)(1), above.

Contrary to Petitioner's arguments and the testimony of Petitioner's experts, Patent Owner contends that "Edwards does not disclose heating without damaging the mucosal epithelial surface," or "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," as required by claim 1. Prelim. Resp. 20–31 (citing Ex. 2001 ¶¶ 19–23, 25–30); *see also*, Ex. 2001 ¶ 24 (Dr. Bass's testimony that "A POSITA would understand that all embodiments in Edwards create a healing response based on this top down injury, such that the mucosal epithelium is thermally damaged.").

Because the conflicting testimony of the parties' experts creates a genuine issue of material fact, "such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute inter partes review." 37 C.F.R. § 42.108(c). Accordingly, on the present record, we determine that Petitioner has demonstrated a reasonable likelihood that at least claim 1 is anticipated by Edwards.

b) Claims 2–4

Depending from claim 1, claims 2–4 recite specific temperature ranges for the heating of target tissue. As Patent Owner points out at pages 30–31 of the Preliminary Response, Petitioner fails to show where Edwards expressly or inherently discloses those claimed ranges. *See* Pet. 29–30 (citing Ex. 1003 ¶¶ 90, 125; Ex. 1004 ¶¶ 57–62). Rather than apply the legal standards of anticipation, Petitioner, not unreasonably, argues that the claimed ranges are *obvious* in view of the understanding of one or ordinary skill in the art. *See, e.g.,* Pet. 30 (quoting Examiner's statement that "[i]t would have been obvious to one of ordinary skill in the art . . . to heat the target tissue to the claimed temperature ranges").[13] Although we will consider these arguments in the context of Ground 2, Petitioner has not demonstrated a reasonable likelihood that claims 2–4 are anticipated by Edwards.

[13] Petitioner also appears to have inadvertently addressed claim 35 in the section discussing Ground 1. *See* Pet. 38.

c) Summary

Patent Owner presents additional arguments regarding why Petitioner has not shown that Edwards discloses elements of certain dependent claims. Prelim. Resp. 31–33. As with claim 1, we find that the parties' arguments are best evaluated on a more developed record. Because Petitioner has demonstrated a reasonable likelihood that at least one claim is anticipated by Edwards we institute *inter partes* review on Ground 1.

D. Ground 2: Obviousness in view of Edwards, Ingle, and Mosher

Petitioner challenges claims 1–42 as obvious in view of Edwards, Ingle, and Mosher. Pet. 39–67. Patent Owner opposes. Prelim. Resp. 33–59. As the teachings of Edwards are discussed above, we begin with an overview of Ingle and Mosher.

1. Overview of Ingle (Ex. 1010)

Ingle discloses devices and methods "for selectively heating and shrinking tissues, particularly for the noninvasive treatment of urinary incontinence and hernias, for cosmetic surgery, and the like." Ex. 1010, 1:18–23. Ingle's methods can "induc[e] controlled shrinkage or contraction of a support tissue of the body, typically being a collagenated tissue such as fascia, ligament, or the like" (*id.* at 11:8–11). "Tissue contraction results from controlled heating of the tissue by affecting the collagen molecules of the tissue." *Id.* at 11:25–26.

According to Ingle, tissue is heated by applying RF or ultrasound energy. *See, e.g., id.* at 5:10–13, 30–32, 8:53–65. This energy "heats fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues." *Id.* at 2:58–61. The energy is "preferably . . . 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." *Id.* at 2:61–67; *see id.* at 5:40–58. "Preferably the target tissue will be raised to a temperature of about 60 nC[14] or more, while the intermediate tissue remains at or below a maximum safe temperature of about 45 nC." *Id.* at 8:41–44; *see also, id.* at 11:33–37 ("The temperature of the target tissue structure will . . . often be[] in the range from about 60 nC to 80 nC. . . .").

According to Ingle, the selective shrinkage of fascia may be used to treat a wide variety of conditions, "and may even be used in cosmetic procedures . . . to remove wrinkles by shrinking the collagenated skin tissues, or to lift sagging breasts by shrinking their support ligaments." *Id.* at 17:65–18:7. Exemplary target tissues, however, "include the urethral wall, the bladder neck, the bladder, the urethra, bladder suspension ligaments, the sphincter, pelvic ligaments, pelvic floor muscles, fascia, and the like." *Id.* at 11:14–17. In one embodiment, energy is applied "to fascia . . . within the vagina" via an energy transmitting element on the distal end of a probe introduced into the vagina. *Id.* at 3:36–43. In this embodiment,

> [t]he 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

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[14] "nC" appears to be a pervasive formatting error in the published patent. Absent evidence to the contrary, we understand "nC" in Ingle to mean "°C". *See id.* at 15:31 (referring to body temperature as "approximately 37 nC"), 15:5–39 and Figures 3A–E (illustrating exemplary temperature ranges, in °C).

> temperature when the fascia is heated by the transmitting element.

Id. at 3:43–50. "[I]ntermediate tissue is cooled with the probe to avoid injuring the intermediate tissue when the target tissue is heated by the probe." *Id.* at 3:51–58; *see id.* at 4:4–10, 15:65–16:4.

2. Overview of Mosher (Ex. 1009)

Mosher is generally directed to the treatment of urinary incontinence by selectively heating and remodeling a portion of the pelvic support tissue. *See, e.g.,* Ex. 1009, Abstract, ¶¶ 9, 45. Mosher discloses techniques for "directing energy from a probe into collagenous tissues of the pelvic support system" to cause contraction of the collagenous tissue and/or structural stiffening related to scarring or healing. *Id.* ¶ 45. According to Mosher, the treatment may be directed to a variety of tissue structures, including "structures of the vagina" such as the lamina propria, a "dense connective tissue layer just under the epithelium." *Id.* ¶ 48; *see also id.* ¶ 9 (disclosing "heating provided through . . . the vaginal wall").

Mosher discloses figures 6 and 6a as "illustrative non-invasive vaginal probes and a method for non-invasively treating endopelvic fascia using cooled [RF] electrodes." *Id.* ¶¶ 27, 58. In one embodiment, "[a] non-invasive cooled electrode probe similar to that shown in Figs.6 and 6A heats tissue until the temperature sensing needle at 4.5 mm depth reaches a set point of 75 °C at 185 seconds." *Id.* ¶ 85. In one embodiment

> a laterally elongate treatment region of the endopelvic fascia will preferably be significantly wider (along the medial-lateral orientation) than its urethral length, ideally having a width of about 25 mm and a length of about 15 mm. Treatment depths will preferably be at least about 2 mm, optionally being as much as 6 mm.

Id. ¶ 74.

3. Analysis of Ground 2

a) Claim 1

Petitioner reasonably contends that each of Edwards, Mosher, and Ingle "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." Pet. 42. Relying on the testimony of Drs. Dmochowski and Tucker, Petitioner argues that, as with Edwards (*see* section II(C), above), Mosher and Ingle disclose "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," as required by claim 1. *Id.* at 42–44 (citing Ex. 1003 ¶¶ 29–30, 59–62; Ex. 1004, ¶ 30).

We are unaware of any rule requiring Petitioner to rely on all cited references to show obviousness. *See In re Kronig*, 539 F.2d 1300, 1304 (CCPA 1976) (affirming obviousness rejection on subset of asserted references). Insofar as Petitioner has demonstrated a reasonable likelihood that at least claim 1 is anticipated by Edwards, it has also demonstrated a reasonable likelihood that it is obvious.[15] *See Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) ("a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for 'anticipation is the epitome of obviousness'") (citing *In re Fracalossi,* 681 F.2d 792 (CCPA

[15] Although Patent Owner purports to rely on secondary consideration evidence (*see* Prelim. Resp. 19, 43–45), Petitioner has not had an opportunity to test this evidence at trial. We will consider the parties' arguments and evidence on the fully developed record.

1982)). Accordingly, for reasons similar to those set forth in section II(C)(2), above, we institute *inter partes* review on Ground 2.

With respect to a reason to combine Edwards with Ingle and Mosher, we note that all three references relate to the use of RF and other energy sources to heat, and thereby remodel, female genito-urinary target tissue, while cooling non-target tissue. *See generally*, Pet. 44–46. Because the three references disclose similar treatments for female urinary incontinence and other uro-genital disorders, we find it reasonable on the current record that one of ordinary skill would have looked to their combined teachings to improve upon such treatments. *See id.*

Petitioner also points to the overlapping functionality of the energy delivery devices disclosed in Edwards, Ingle, and Mosher. *See id.* at 45–46. According to Petitioner, "[g]iven Edwards' stated goal of minimizing thermal damage to the mucosal epithelium," one of ordinary skill in the art would have been motivated "to combine the more robust cooling mechanisms described in Ingle . . . and Mosher with the treatment probe in Edwards" to better minimize thermal damage to the mucosal epithelium. *Id.* at 45–46; *see* Ex. 1003 ¶ 132 (indicating that one of ordinary skill in the art would have understood Edwards to contemplate ultrasound energy as disclosed in Ingle).

Patent Owner argues that Petitioner presents insufficient motivation to combine the cited references, stating, for example, that Petitioner does not sufficiently articulate how the Edward's apparatus could have been combined with that of Mosher or "address why a POSITA would have a reasonable expectation of success in modifying Edwards, which aims to create ablative lesions, with Mosher and Ingle, which purport to inhibit

ablation." Prelim. Resp. 40. We note, however, that Edwards teaches the application of RF energy "so as to ablate, *tighten, shrink or reshape*" female uro-genital tissue. Ex. 1008, 2:33–38 (italics added). Moreover, although Edwards refers to "ablative lesions" in connection with embodiments 1–3 (*see, e.g., id.* at Figs. 6A, 7B, 8B), we do not discern where Edwards defines "lesions" as "ablative" in the context of the fourth embodiment (*see id.* at 13:14–16). On the present record, we find Patent Owner's argument unpersuasive, but invite the parties to discuss the meaning and implication of Edward's use of the terms "tighten, shrink or reshape" and "lesions" in the Patent Owner Response and Petitioner's Reply.

Patent Owner also attempts to distinguish Mosher and Ingle as "directed to heating the 'endopelvic fascia,' which is not a target tissue in connection with the '511 patent." Prelim. Resp. 45–49. Although we agree with Patent Owner that target tissue as used in the claims of the '511 patent refers to tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissues, such as the endopelvic fascia (*see* section II(B)(1), above), we are not persuaded on the present record that either Mosher or Ingle is limited to the treatment of such deeper tissues. Mosher, for example, teaches the treatment of a variety of tissues including vaginal lamina propria, a "dense connective tissue layer just under the epithelium" (*see* section II(D)(2), above) which, Patent Owner admits, comprises target tissue within the meaning of the '511 patent (*see* Prelim. Resp. 8-9). Moreover, whether Mosher and/or Ingle are limited to the remodeling of endopelvic fascia, is a disputed factual issue best resolved on the full record. *See, e.g., id.* at 47–48 (indicating that the parties' experts dispute whether Ingle discloses heating tissue immediately beneath the mucosal epithelium).

b) Claim 35

Claim 35, along with its dependent claims 36–42, recites "heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock." According to Petitioner,

> 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.)

Pet. 38. Petitioner makes similar arguments with respect to Mosher and Ingle. *Id.* at 67.

As set forth in section II(B)(4), above, we construe "heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock" as heating at least one contact site in the 300 degree arc extending from 1 o'clock to 11 o'clock along the vaginal wall. Applying a similar construction, Petitioner presents uncontroverted argument and evidence that the cited references further disclose this limitation. Accordingly, we institute *inter partes* review for claim 35 and its dependent claims.[16]

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[16] We invite Patent Owner to consider the guidance regarding motions to amend set forth in the accompanying scheduling order. *See also*, *Sprint Spectrum L.P. v. General Access Solutions, Ltd.*, Case IPR2017-01885, Paper 7 (PTAB Mar. 9, 2018) for general guidance regarding motions to amend.

c) Summary

Because Petitioner has demonstrated a reasonable likelihood that at least one claim is rendered obvious by Edwards, and/or Edwards in light of Ingle and Mosher, we institute *inter partes* review on Ground 2 as to claims 1–42.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one challenged claim of the '511 Patent is unpatentable.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and completion of the record.

In keeping with our mission of resolving patentability disputes in a just, speedy, and inexpensive manner, we exercise our discretion to institute *inter partes* review as set forth in the following Order.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–42 of the '511 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '511 patent shall commence on

the entry date of this Order, and notice is hereby given of the institution of a trial.

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Paper No. 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THERMIGEN, LLC AND THERMIAESTHETICS, LLC
Petitioner,

v.

VIVEVE, INC.,
Patent Owner.

Case IPR2018-00089
Patent 8,961,511 B2

Before HYUN J. JUNG, ROBERT A. POLLOCK, and SCOTT C. MOORE, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION TO INSTITUTE
35 U.S.C. § 314(a)

I. INTRODUCTION

Thermigen, LLC and Thermiaesthetics, LLC ("Petitioner")[1] filed a Petition for an *inter partes* review of claims 43–58 of U.S. Patent No. 8,961,511 B2 ("the '511 patent," Ex. 1001). Paper 2 ("Pet."). Viveve, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 7 ("Prelim. Resp."). We review the Petition, Preliminary Response, and accompanying evidence under 35 U.S.C. § 314.

On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst. Inc. v. Iancu*, No. 16-969, 2018 WL 1914661, at *10 (U.S. Apr. 24, 2018). After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least claim 1 of the '511 patent is unpatentable. Accordingly, we institute an *inter partes* review of claims 43–58.

A. Related Proceedings

According to the parties, the '511 patent is at issue in *Viveve, Inc. v. ThermiGen, LLC et al.*, Civil Action No. 2:16-cv-1189-JRG (E.D. Tex.). Pet. 2; Paper 3, 2.

In addition to the present proceeding, Petitioner concurrently challenges claims 1–42 of the '511 patent in IPR2018-00088.

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[1] Petitioner further identifies Almirall, S.A. of Barcelona, Spain, as a real party-in-interest. Pet. 2.

B. The '511 Patent

The '511 patent pertains to "treating a loose vagina and introitus" via "corrective or restorative remodeling of the mucosal surfaces of the vagina, introitus, and vulva." Ex. 1001, 2:17–21. In particular, the patent discloses "apparatus and methods for tightening tissue of the female genitalia by heating targeted connective tissue with radiant energy [typically radiofrequency (RF) energy], while cooling the mucosal epithelial surface over the target tissue to protect it from the heat." *Id.* Abstract, 4:4–13; *see also id.* at 2:25–28, 4:7–16, 13:16–19, claims 6, 33, 41, and 49 ("heating comprises delivering energy by any of: radiofrequency energy, microwave energy, or ultrasound energy"). According to the Specification, the tightening may be an immediate or near-immediate consequence of thermally denaturing tissue collagen, and/or the result of a longer term healing response involving the deposition of new collagen by cells in the connective tissue. *Id.* Abstract, 4:14–16, 4:63–5:11, 12:39–49.

C. Prosecution History of the '511 patent.

The '511 patent issued to Jonathan B. Parmer from U.S. Application No. 11/704,067, filed February 7, 2007 and claiming the benefit of Provisional Application No. 60/743,247, filed on February 7, 2006.[2]

As highlighted by both parties, the Examiner rejected then-pending claims over Knowlton.[3,4] *See* Pet. 6–9; Prelim. Resp. 5. Knowlton discloses

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[2] Petitioner argues, and Patent Owner does not presently contest, that at least independent claims 43 and 51 are not entitled to the filing date of the provisional application. *See* Pet. 4.
[3] US 6,350,276 B1, issued Feb. 26, 2002. Ex. 1007.
[4] Knowlton is cited as background in the '511 patent and incorporated therein by reference. *See* Ex. 1001, 1:47–49, 5:65–26:6.

fluid-cooled apparatus comprising RF electrodes to "appl[y] a mechanical force in combination with the delivery of energy to the skin surface and underlying soft tissue structure, to remodel collagen both esthetically and functionally with minimal thermal damage including cell necrosis." Ex. 1007, 13:9–13; 15:25–28, Abstract. In one embodiment, Knowlton discloses treating pre-term cervical dilation by applying RF energy to tighten the dilated cervix. *See* Ex. 1007, 13:35–47 ("The incorporated energy delivery device 18 contracts the native matrix and induces scar collagen. The dilated cervical OS is tightened and the entire cervix is strengthened."); *see also* Ex. 1003 ¶¶ 66–69, Ex. 1004 ¶¶ 20–21.

During prosecution, the Examiner repeatedly rejected claims as anticipated and/or obvious in view of Knowlton. Ex. 1002, 701–704, 748–755, 934–945. According to the Examiner,

> Knowlton discloses a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue (as in the embodiment of figures 13–14 describing the treatment of cervix, see col. 13; 35–37), the method comprising heating the target tissue and remodeling the therapeutic zone of target tissue.

Ex. 1002, 693; *see also id.* at 759–760 (Final Rejection stating that the cervix is "female genital tissue" and Knowlton discloses treating tissue underlying the cervical epithelium).

To address rejections over Knowlton, applicant amended claim 1 (the only independent method claim then pending) to recite "remodeling a therapeutic zone including at least one of vulva, introitus or vagina" and argued that Knowlton does not disclose treating these tissues. *Id.* at 777–781, 785. Applicant subsequently also amended claim 1 to require 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," thereby excluding the cervix.[5] *Id.* at 974; Ex. 1003 ¶ 20.

In allowing the claims to issue, the Examiner explained that "Knowlton fails to contemplate the specific areas of treatment set forth in [the] independent claims . . . . 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, 1352 (Notice of Allowance). According to Patent Owner, the Examiner, thus, "recognized that even though it was known to heat one female genital tissue using RF, this did not fairly suggest or make obvious the heating of other female genital tissues using RF." Prelim. Resp. 5.

D. Illustrative Claims

Petitioner challenges claims 43–58 in this proceeding,[6] of which claims 43 and 51 are independent (italicized to highlight differences).

> 43. 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:
>
> heating the target tissue, and
>
> remodeling the therapeutic zone of target tissue, wherein the heating includes *heating a portion radiating outward from the introitus to Hart's line.*[7]

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[5] Applicant also re-drafted certain dependent claims in independent format, which subsequently issued as claims 35, 43, and 51. *See id.* at 977.

[6] Petitioner challenges the remaining claims of the '511 patent, claims 1–42, of which claims 1 and 35 are independent, in co-pending IPR2018-00088.

[7] The Specification defines "introitus" as "the opening of the vagina" (Ex. 1001, 2:3–4, 3:51) and "Hart's line" as the portion of the vulva "where mucosal epithelium gives way to skin on the outer surface of the labia

51. 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:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes *heating a mucosal surface of the labia minora.*

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 13):

Ground	Claims	Basis	References
1	43–58	§ 103	Edwards,[8] Ingle,[9] Mosher,[10] and the knowledge of one of ordinary skill in the art
2	43–58	§ 103	Edwards, Kreuter,[11] Beattie,[12] Smith,[13] and the knowledge of one of ordinary skill in the art

In support of its patentability challenges, Petitioner relies on the Declarations of Dr. Roger Dmochowski, M.D. (Ex. 1003) and Dr. Robert

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minora," i.e., "the boundary where mucosal epithelium and labial skin meet" (*id.* at 3:49–54, 11:59–62).

[8] US 6,463,331 B1, issued Oct. 8, 2002. Ex. 1008.

[9] US 6,216,704 B1, issued Apr. 17, 2001. Ex. 1010.

[10] US 2004/0193238 A1, published Sept. 30, 2004. Ex. 1009.

[11] Kreuter et al., *Low-dose ultraviolet A1 phototherapy for extragenital lichen sclerosus: Results of a preliminary study*, 46(2) J. Am. Acad. Dermatol. 251–55. Ex. 1012.

[12] Beattie et al., *UVA1 phototherapy for genital lichen sclerosis, 31 Clin. Exp. Dermatol.* 343–47. Ex. 1013.

[13] Smith and Haefner, Vulvar Lichen Sclerosus, 5(2) Am. J. Clin. Dermatol. 105–25. Ex. 1014.

Tucker, Ph.D., M.D. (Ex. 1004). Patent Owner relies on the Declaration of Dr. Lawrence S. Bass, M.D. (Ex. 2001).

II. ANALYSIS

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* at 418. Rather "the test is whether the references, taken as a whole, would have suggested appellant's invention to one of ordinary skill . . . at the time the invention was made." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re*

Magnum Oil Tools Int'l, Ltd., 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations and citations omitted).

A. Person of Ordinary Skill in the Art

Petitioner proposes that one of ordinary skill in the art "is a medical doctor practicing in the field of plastic surgery and in particular, in urogynecology or a similar field" or "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." Pet. 25. Petitioner's experts, however, propose definitions indicating experience in both plastic surgery involving female genitalia and the clinical application of radiant energy to human tissue and/or experience performing electrosurgical procedures. *See* Ex. 1003 ¶ 8; Ex. 1004 ¶ 14. Petitioner's experts do not opine on number of years' experience required. *See id.* Although Patent Owner does not propose an alternative definition in the Preliminary Response, Patent Owner's expert similarly states that such a person would have "a medical degree plus at least two years of experience in a field such [] as gynecology, urogynecology, [sic] or plastic surgery, with clinical experience in application of radiant energy to human tissue and experience involving female genital anatomy." Ex. 2001 ¶ 14.

In considering the testimony of the parties' experts, the field of the '511 patent, and the relevant art, we determine that one of ordinary skill in the art would have a medical degree plus at least two years of experience in a field such as gynecology, urogynecology, or plastic surgery involving female genital anatomy, with clinical experience in the application of radiant energy to female genital tissue.

B. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, we presume that a claim term carries its "ordinary and customary meaning," which "is the meaning that the term would have to a person of ordinary skill in the art in question" at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) ("Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history."). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Limitations, however, may not be read from the specification into the claims (*In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993)), nor may the Board "construe claims during [an *inter partes* review] so broadly that its constructions are *unreasonable* under general claim construction principles" (*Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (overruled on other grounds by *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017)).

We address below terms identified by the parties as in need of construction. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (instructing that claim terms need only be construed to the extent necessary to resolve the controversy).

1. "target tissue"

The independent claims before us recite "method[s] for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue." Within the body of the claims, "target tissue" is also the subject of "heating" and "remodeling." Petitioner proposes that we construe the term "target tissue" as "tissue underlying the epithelium." Pet. 26–27 (citing Ex. 1001, 2:25–28, 3:41–47, 11:11–14, 12:2–13).

Patent Owner contends that Petitioner's proposed definition is overly broad as it includes deeper tissue layers expressly excluded in the Specification. Prelim. Resp. 7–9. In accord with Patent Owner's position, column 3, lines 41–48 of the Specification states:

> Embodiments of the invention include methods for remodeling a therapeutic zone of tissue within a target tissue of female genitalia. 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. The target zone of embodiments of the invention does not include deeper tissue, such as endopelvic fascia.

Similarly, column 12, lines 2 through 16 of the Specification 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 . . . . These described target tissue layers below the epithelium overlay deeper tissues, including endopelvic fascia, which are not a target tissue for embodiments of the present invention.

"Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly

disclaim[s] the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). In particular, patentee must "demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id.* at 1366. On the present record, we agree with Patent Owner that the passages identified in the Specification comprise a "clear and unmistakable" disclaimer of the scope of target tissue. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366–67 (Fed. Cir. 2012). We also note that there is no evidence in the record that the term "target tissue" has an ordinary and customary meaning in the art to which the '511 patent pertains that encompasses the endopelvic fascia. Thus, even though we find a clear and unmistakable disclaimer here, this is not a situation where a disclaimer is necessary in order to depart from the plain and ordinary meaning of a claim term. Rather, the construction we adopt here is a definition set forth in the specification of a term that has not been shown to have an ordinary and customary meaning outside the scope of the '511 patent.

On this record, we construe "target tissue" as used in the claims of the '511 patent to mean tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissues, such as the endopelvic fascia.

2. "heating"

All independent claims of the '511 patent recite the step "heating the target tissue." Patent Owner proposes that we do not apply the plain and ordinary meaning to "heating" as used therein. Prelim. Resp. 9–13. Patent Owner points out that in applying the *Phillips* standard, the District Court construed "heating" to mean "heating the tissue underlying the epithelium to

a temperature that is higher than the temperature of the epithelium." *Id.* at 11. Patent Owner also rejects this construction, arguing instead that the Specification "makes clear that this heating step requires 'heating without damaging the mucosal epithelial surface.'" Prelim. Resp. 9.

As Patent Owner points out, the '511 patent teaches optimal contact of an energy delivery device and active cooling of the epithelial surface over the target tissue such that "the epithelium itself is not damaged or substantially modified by the method." *Id.* at 9–11 (citing Ex. 1001, Abstract, 12:19–21, 13:16–26, 2:56–62, 8:8–15). But the plain language of the independent claims makes no express mention of protecting the epithelial layer from damage or modification, whether through a configuration of the energy delivery device, by cooling the epithelial layer, or by creating a temperature gradient as indicated under the District Court's construction under *Phillips*. Each of these elements is, however, recited in one or more independent claims, suggesting that the independent claims encompass, but are not necessarily limited to those elements. Depending from claim 1, for example, claim 24 includes the limitation "wherein the heating does not modify a mucosal epithelium of the genital tissue"; claims 5–8, 10, and 17–22 relate to the configuration of an energy delivery device; claim 9 and its dependent claims include the step of "cooling the epithelium"; and claim 15 and its dependent claims state that the step of cooling the epithelium results in "a reverse thermal gradient from the epithelium to the target tissue." *See Nazomi Commc'ns, Inc. v. Arm Holdings, PLC.*, 403 F.3d 1364, 1370 (Fed. Cir. 2005) ("The concept of claim differentiation 'normally means that limitations stated in dependent claims are not to be read into the independent claim from which they

depend.'") (quoting *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971–72 (Fed. Cir.1999)).

Applying the broadest reasonable construction consistent with the specification, we do not limit the term "heating" as did the District Court, nor as Patent Owner proposes.[14] *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.").

Although we generally apply the ordinary meaning to the term "heating," we also note that the '511 patent places an upper limit on the temperature to which target tissue is heated. According to the Specification, in heating the target tissue, the "[t]emperature is raised to a level that is therapeutic, i.e., to a temperature that causes remodeling." Ex. 1001 11:21–23. In particular, "[t]he therapeutic temperature . . . may be . . . as high as 45 degrees C., or as high as 80 degrees C. The inventive method, therefore includes heating target tissue to as high as 80 degrees C." *Id.* at 11:25–29;

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[14] When a claim term has previously been construed by a district court, the Board must "assess whether [the court's] interpretation [is] consistent with the broadest reasonable construction of the term." *Power Integrations, Inc. v. Lee*, 797 F.3d 1318, 1324–27 (Fed. Cir. 2015). The broadest reasonable interpretation of disputed claim terms is "a different claim construction standard than that applied by a district court" (*id.*), and may sometimes produce a different result.

see also id. at 4:34–40 (indicating a temperature of "about 80 degrees C. in the target tissue"). Accordingly, we construe "heating" as used in the claims of the '511 patent as raising the temperature of target tissue to no more than about 80 degrees C.

3. "remodeling"

Patent Owner proposes that we construe "remodeling" as used in the claims of the '511 patent as "causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature," with or without the additional requirement, "without damaging the epithelium." Prelim. Resp. 13–14. Patent Owner also notes that the District Court defined "remodeling" under the *Phillips* standard as "a process comprising a doctor's application of specific concrete steps to specific tissue under particularized conditions, which is simply predicated on the ability of collagen to be physically transformed by heat." Prelim. Resp. 13–14 (citing Ex. 2009, 7). Although we do not disagree with the thrust of these constructions, in the context of the claims as a whole, they appear to render the "heating" step redundant. In this respect, we agree with Petitioner that the term refers to "a natural phenomenon that results from the heating of the tissue," i.e., "the *result* caused when heated tissue reaches a sufficient temperature." Pet. 32 (citing Ex. 1001, 4:15–16, 5:2–5, 11:22).

The independent claims of the '511 patent recite "method[s] for remodeling a therapeutic zone of a target tissue . . . comprising: heating the target tissue, and remodeling the therapeutic zone of target tissue." Considering the overall structure of these claims and the use of the term in the context of the Specification, "remodeling" in the body of the independent claims refers to the result obtained by heating the target tissue

to a therapeutic temperature—i.e., the result obtained by raising the temperature of target tissue to no more than about 80 degrees C. *See* section II(B)(2) above.

Further, the Specification teaches that the result obtained by heating the target tissue "may include a melting or denaturing of preexisting collagen in the tissue," and/or "a healing process in which there is an increase in the rate of cellular production and deposition [of collagen] into the extracellular space. Both types of responses . . . contribute to an overall tightening of the target tissue." Ex. 1001, 12:50–65; *see id.* at 12:39–49; 13:2–5 ("Remodeling of genital tissue, as practiced by embodiments of this invention, may be understood variously as contracting or tightening of tissue, this may apply to the vulva, the vagina, and the introitus.").

The Specification makes clear, however, that "remodeling of the connective tissue underlying the mucosal epithelial surfaces does not substantially affect the epithelium itself. The method and apparatus, as provided by embodiments of the invention are non-invasive and substantially non[-]ablative of genital tissue." *Id.* at 12:17–21.

In view of the above, we construe "remodeling" as used in the body of the independent claims of the '511 patent to refer to the result of raising the temperature of target tissue to no more than about 80 degrees C without substantially affecting the epithelium overlying the target tissue, wherein that result includes a tightening or contraction of the target tissue.

C. Ground 1: Obviousness in view of Edwards, Ingle, and Mosher

Petitioner challenges claims 43–58 as obvious in view of Edwards, Ingle, and Mosher. Pet. 28–55. Patent Owner opposes. Prelim. Resp. 17–42. We begin with an overview of Edwards, Ingle, and Mosher.

1. Overview of Edwards (Ex. 1008)

Edwards "provides a method and system for the curative treatment of female uro-genital disorders by application of radiofrequency (RF) energy to targeted tissues. Application of this energy is selectively applied so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition." Ex. 1008, 2:33–38. "In alternative embodiments, other forms of energy may be delivered, such as microwave, laser, ELF (extremely low frequency) and other therapeutic energies." *Id.* at 13:57-59.

Edwards discloses four embodiments of the invention. *Id.* at 2:40–3:13. In the fourth embodiment, "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." *Id.* at 3:5–11.

Figure 4 of Edwards is reproduced below.

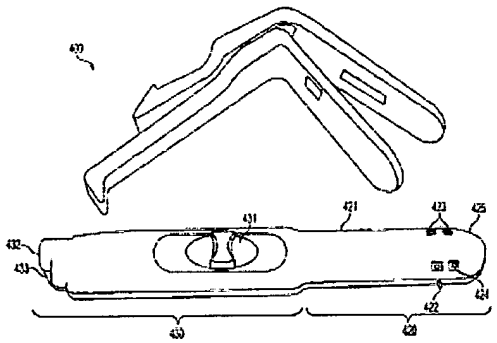


FIG. 4

Figure 4 illustrates the distal end of a system 400 that can be used for vaginal remodeling in accord with the fourth embodiment. *Id.* at 3:25–27, 7:14–8:5. Briefly, the system comprises a treatment element coupled to an RF generator. *Id.* at 7:14–15. "The distal end of the treatment element . . . is inserted into a vagina using a speculum." *Id.* at 7:18–19. A plurality of relatively flat electrodes 423 are disposed on the distal end of the treatment

unit. *Id.* at 7:34–39. "Each electrode 423 includes at least one thermocouple 424 that is used to monitor the temperature of each electrode 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." *Id.* at 7:43–50. Also on the distal end of the treatment element, "irrigating fluid delivery pores 425 . . . are disposed to deliver cooling liquids so as to minimize thermal damage." *Id.* at 7:51–55, 7:66–8:5.

Figure 9A of Edwards is reproduced below.

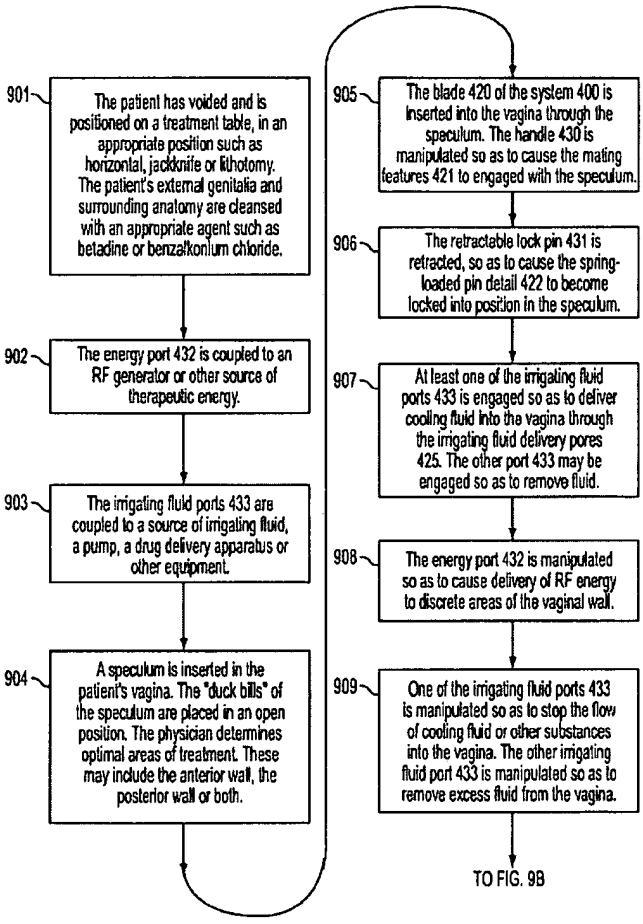


Figure 9A illustrates the method of Edward's fourth embodiment for vaginal remodeling. *Id.* at 3:38–39. As explained in detail at column 13, line 12 through column 14, line 4: "[A] speculum is inserted in the patient's vagina.

The blades of the speculum are placed in an open position. The physician determines optimal areas of treatment. These may include the anterior wall, the posterior wall, or both." *Id.* at 13:38–42. The treatment element of system 400 is inserted into the vagina through the speculum. *Id.* at 13:43–46. Cooling fluid is delivered into the vagina through irrigating fluid delivery pores 425, and RF energy is delivered "to discrete areas of the vaginal wall." *Id.* at 13:54–56.

According to Edwards, the method "create[s] a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both. . . . . 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." *Id.* at 13:14–22.

2. Overview of Ingle (Ex. 1010)

Ingle discloses devices and methods "for selectively heating and shrinking tissues, particularly for the noninvasive treatment of urinary incontinence and hernias, for cosmetic surgery, and the like." Ex. 1010, 1:18–23. Ingle's methods can "induc[e] controlled shrinkage or contraction of a support tissue of the body, typically being a collagenated tissue such as fascia, ligament, or the like" (*id.* at 11:8–11). "Tissue contraction results from controlled heating of the tissue by affecting the collagen molecules of the tissue." *Id.* at 11:25–26.

According to Ingle, tissue is heated by applying RF or ultrasound energy. *See, e.g., id.* at 5:10–13, 30–32, 8:53–65. This energy "heats fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues." *Id.* at 2:58–61. The energy is "preferably . . . 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." *Id.* at 2:61–67; *see id.* at 5:40–58. "Preferably the target tissue will be raised to a temperature of about 60 nC[15] or more, while the intermediate tissue remains at or below a maximum safe temperature of about 45 nC." *Id.* at 8:41–44; *see also, id.* at 11:33–37 ("The temperature of the target tissue structure will . . . often be[] in the range from about 60 nC to 80 nC. . . .").

According to Ingle, the selective shrinkage of fascia may be used to treat a wide variety of conditions, "and may even be used in cosmetic procedures . . . to remove wrinkles by shrinking the collagenated skin tissues, or to lift sagging breasts by shrinking their support ligaments." *Id.* at 17:65–18:7. Exemplary target tissues, however, "include the urethral wall, the bladder neck, the bladder, the urethra, bladder suspension ligaments, the sphincter, pelvic ligaments, pelvic floor muscles, fascia, and the like." *Id.* at 11:14–17. In one embodiment, energy is applied "to fascia . . . within the vagina" via an energy transmitting element on the distal end of a probe introduced into the vagina. *Id.* at 3:36–43. In this embodiment,

> [t]he 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

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[15] "nC" appears to be pervasive formatting error in the published patent. Absent evidence to the contrary, we understand "nC" in Ingle to mean "°C". *See id.* at 15:31 (referring to body temperature as "approximately 37 nC"), 15:5–39 and Figures 3A–E (illustrating exemplary temperature ranges, in °C).

> temperature when the fascia is heated by the transmitting element.

Id. at 3:43–50. "[I]ntermediate tissue is cooled with the probe to avoid injuring the intermediate tissue when the target tissue is heated by the probe." *Id.* at 3:51–58; *see id.* at 4:4–10, 15:65–16:4.

3. Overview of Mosher (Ex. 1009)

Mosher is generally directed to the treatment of urinary incontinence by selectively heating and remodeling a portion of the pelvic support tissue. *See, e.g.,* Ex. 1009, Abstract, ¶¶ 9, 45. Mosher discloses techniques for "directing energy from a probe into collagenous tissues of the pelvic support system" to cause contraction of the collagenous tissue and/or structural stiffening related to scarring or healing. *Id.* ¶ 45. According to Mosher, the treatment may be directed to a variety of tissue structures, including "structures of the vagina" such as the lamina propria, a "dense connective tissue layer just under the epithelium." *Id.* ¶ 48; *see also id.* ¶ 9 (disclosing "heating provided through . . . the vaginal wall").

Mosher discloses figures 6 and 6a as "illustrative non-invasive vaginal probes and a method for non-invasively treating endopelvic fascia using cooled [RF] electrodes." *Id.* ¶¶ 27, 58. In one embodiment, "[a] non-invasive cooled electrode probe similar to that shown in FIGS.6 and 6A heats tissue until the temperature sensing needle at 4.5 mm depth reaches a set point of 75 °C. at 185 seconds." *Id.* ¶ 85. In one embodiment

> a laterally elongate treatment region of the endopelvic fascia will preferably be significantly wider (along the medial-lateral orientation) than its urethral length, ideally having a width of about 25 mm and a length of about 15 mm. Treatment depths will preferably be at least about 2 mm, optionally being as much as 6 mm.

Id. ¶ 74.

4. Analysis of Ground 1

a) Claim 43

(1) Elements a-c

Relying on the testimony of Drs. Dmochowski and Tucker, Petitioner argues that Edwards, Ingle, and Mosher, independently, teach all elements preceding the wherein clause of claim 43—designated by Petitioner as elements a through c.[16] *See* Pet. 28–34 (citing Ex. 1003 ¶¶ 36, 48–54, 56–59, 79, 81–86; Ex. 1004 ¶¶ 18–19). We find Petitioner's arguments and evidence to be reasonable in light of, e.g., Edward's teaching to treat female uro-genital disorders by delivering RF energy "to the anterior and posterior regions of the vaginal wall" in conjunction with the delivery of "cooling liquids, so as to minimize thermal damage," in order to effect "circumferential tightening of the vaginal wall"; Ingle's teaching to treat female urinary incontinence through selective shrinkage of fascia by directing energy "through an intermediate tissue and into fascia, while the cooled electrode surface prevents injury to the intermediate tissue"; and Mosher's teaching to treat female urinary incontinence by selectively heating and remodeling a portion of the pelvic support tissue using non-invasive vaginal probes comprising cooled RF electrodes. *See* sections II(C)(1)–(3), above.

Contrary to Petitioner's arguments and the testimony of Petitioner's experts, Patent Owner contends that "Edwards does not disclose heating without damaging the mucosal epithelial surface," as required by claim 43.

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[16] This language is the same as the corresponding portion of independent claim 51 and, accordingly, the same arguments and analysis apply.

Prelim. Resp. 30–33 (citing Ex. 2001 ¶¶ 21–23); *see also*, Ex. 2001 ¶ 24 (Dr. Bass's testimony that "A POSITA would understand that all embodiments in Edwards create a healing response based on this top down injury, such that the mucosal epithelium is thermally damaged.").

Because the conflicting testimony of the parties' experts creates a genuine issue of material fact, "such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review." 37 C.F.R. § 42.108(c). Accordingly, on the present record, we determine that Petitioner has demonstrated a reasonable likelihood that Edwards discloses elements a–c of claim 43.

Patent Owner also attempts to distinguish Mosher and Ingle as "directed to heating the 'endopelvic fascia,' which is not a target tissue in connection with the '511 patent." Prelim. Resp. 32–35. Although we agree with Patent Owner that target tissue as used in the claims of the '511 patent refers to tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissues, such as the endopelvic fascia (*see* section II(B)(1), above), we are not persuaded on the present record that either Mosher or Ingle is limited to the treatment of such deeper tissues. Mosher, for example, teaches the treatment of a variety of tissues including vaginal lamina propria, a "dense connective tissue layer just under the epithelium" (*see* section II(C)(3), above) which, Patent Owner admits, comprises target tissue within the meaning of the '511 patent (*see* Prelim. Resp. 9). Moreover, whether Mosher and/or Ingle are limited to the remodeling of endopelvic fascia, is a disputed factual issue best resolved on the full record.

See id. Prelim. Resp. 34 (noting that Dr. Bass disputes Dr. Dmochowski's testimony that Mosher describes remodeling the muscularis).

(2) Element d

With respect to the wherein clause of claim 43 (element d), "wherein the heating includes heating a portion [of the target tissue] radiating outward from the introitus to Hart's line," Petitioner argues that "[i]n light of the variety of procedures and target tissues structures disclosed in Edwards, Mosher, and Ingle, and the knowledge of the POSITA, it would have been obvious to apply energy to heat target tissue located radiating outward from the introitus to Hart's line." Pet. 36 (citing Ex. 1003 ¶¶ 70, 89; Ex. 1004 ¶ 76). According to Petitioner,

> Because it was well-known in the art that the nature of the mucosal epithelium of the vaginal wall is the same type of simple squamous epithelial tissue which makes up not only the epithelia of other, non-vaginal female genital tissue, but also the epithelial surface of *extra*genital tissue– i.e., "normal" skin surface tissue all over the body – the vaginal tissue remodeling teachings of Edwards were obviously applicable to remodel any other bodily tissue where the dermal surface is likewise simple squamous epithelial tissue. (EX. 1003, ¶69-70.) As, e.g., Ingle teaches, this is the case in the facial, abdominal, and breast tissue. (EX. 1003, ¶54, 69, 91.) This was also well-known to be the case with the "external" female genital tissue which extends beyond the introitus – i.e. the vulva – including the labia, and specifically the labia minora. (EX. 1003, ¶54, 69, 91.)

Id. at 55.

Further in support of its position that it would have been obvious to apply the techniques of Edwards, Mosher, and Ingle to "vulva-specific claims 43 (requiring heating genital tissue radiation outward from the

introitus to the Hart's line), and 51 (heating the labia)," Petitioner points to Olivier's[17] discussion of Laser Vaginal Rejuvenation (LVR) and Designer Laser vaginoplasty (DLV) for vaginal tightening, and aesthetic modification of vulva and labia. Pet. 56, 36–38. Relying on the testimony of Dr. Dmochowski, Petitioner argues that the techniques highlighted in Olivier demonstrate that one of ordinary skill would have recognized that well-known treatments similar to those claimed were used to treat not only vaginal wall tissue, but labial tissue and tissue radiating outward from the introitus to Hart's line. *See* Pet. 36–38 (citing Ex. 1003 ¶¶ 92–102).

Dr. Dmochowski explains that well-known LVR techniques discussed in Olivier, (electrosurgical vaginoplasty and labiaplasty) involve "heating the to-be-excised genital tissue to at least 100°C so as to ablate the tissue." Ex. 1003 ¶¶ 94–98. According to Dr. Dmochowski, in electrosurgical labiaplasty, sub-epithelial "dermal tissue . . . adjacent to the line of vaporization is heated to some temperature between 60° C and 100° C," which one of ordinary skill in the art would have understood to result in collagen denaturation and subsequent "remodeling of at least a portion of the therapeutic zone of the target tissue by way of denaturation of collagen and induction of new collagen." *Id.* ¶¶ 99-100; *see* Pet. 37. Dr. Dmochowski further testifies that similar heating and remodeling occurs in the context of electrosurgical vaginoplasty. *Id.* ¶¶ 101–102; *see id.* ¶ 102 (noting that "[t]he mucosal epithelium surface of the vaginal wall to which the laser is directly applied is completely vaporized.").

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[17] D. Olivier, "Designer Vaginas," SALON (Nov. 14, 2000), http://www.salon.com/2000/11/14/vagina_3/. Ex. 1011.

(3) Reason to Combine

Petitioner argues that it would have been obvious to combine Edwards, Mosher, and Ingle because they "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"; "all describe methods of cooling the intermediate tissue while heating the underlying tissue"; and "[a]ll . . . 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. Pet. 38–39. In sum, all three references relate to the use of RF and other energy sources to heat, and thereby remodel, female genito-urinary target tissue, while cooling non-target tissue. *See generally*, Pet. 44–46. Because the three references disclose similar, non-invasive treatments to treat female urinary incontinence and other uro-genital disorders, we find it reasonable on the current record that one of ordinary skill would have looked to their combined teachings to improve upon such treatments. *See id.*

Petitioner also points to the overlapping functionality of the energy delivery devices disclosed in Edwards, Ingle, and Mosher. *See id.* at 40–42, 45–46. According to Petitioner, one of ordinary skill in the art would have been motivated "to combine the more robust cooling mechanisms described in . . . Ingle and Mosher with the non-invasive urogenital treatment probe in Edwards" to better minimize thermal damage to the mucosal epithelium. *Id.* at 40, 45–46; *see* Ex. 1003 ¶ 132 (indicating that one of ordinary skill in the art would have understood Edwards to contemplate ultrasound energy as disclosed in Ingle). According to Petitioner, the combined teachings "would

lead to a safer treatment for the patients and easier treatments to administer by physicians." *Id.* at 42.

Arguing that Petitioner presents insufficient motivation to combine the cited references, Patent Owner states, for example, that Petitioner does not sufficiently articulate how the Edward's apparatus could have been combined with that of Mosher or "address why a POSITA would have a reasonable expectation of success in modifying Edwards, which aims to create ablative lesions, with Mosher and Ingle, which purport to inhibit ablation." Prelim. Resp. 26. We note, however, that Edwards teaches the application of RF energy "so as to ablate, *tighten, shrink or reshape*" female uro-genital tissue. Ex. 1008, 2:33–38 (italics added). Moreover, although Edwards refers to "ablative lesions" in connection with embodiments 1–3 (*see, e.g.*, *id.* at Figs. 6A, 7B, 8B), we do not discern where Edwards defines "lesions" as "ablative" in the context of the fourth embodiment (*see id.* at 13:14–16). Accordingly, we do not find Patent Owner's argument persuasive. We, nevertheless, invite the parties to discuss the meaning and implication of Edward's use of this term in Patent Owner's Response and Petitioner's Reply.

Patent Owner further argues that one of ordinary skill in the art would not have been motivated to treat the tissue radiating outward from the introitus to Hart's line, as required by claim 43. *See* 35–38. As discussed above, Petitioner reasonably describes the combined disclosures of Edwards, Mosher, and Ingle as teaching the application of electromagnetic energy to heat, remodel, and tighten, target tissue underlying a mucosal epithelium of female genital tissue for the treatment of female uro-genital disorders and, as set forth in Edwards, to "provide physical and psychological improvement in

the area of sexual function." *See* Ex. 1008, 3:11–13. Petitioner also reasonably argues that, as exemplified in Olivier, another form of electromagnetic energy, lasers, were used to tighten a patient's vagina and aesthetically modify a patients labia. On the current record, we are persuaded that one of ordinary skill in the art would have applied the techniques of Edwards, Mosher, and Ingle to the target tissues identified in Olivier.

Further, relying on the testimony of Dr. Bass, Patent Owner asserts that one of ordinary skill in the art would not have had "a reasonable expectation of success in modifying the laser labia treatment [discussed in Olivier] by substituting UV energy with RF energy, given the significant differences between UV energy and RF energy." *Id.* at 38–39 (citing Ex. 2001 ¶¶ 63–65). The cited testimony of Dr. Bass, however, does not discuss the laser energy used in the Olivier procedures but, instead, compares "the mechanisms of action between RF and the UVA1 light sources used to treat [lichen sclerosus]"—i.e., the light source used in Kreuter and Beattie. *See* Ex. 2001 ¶¶ 46, 56, 65; section II(D), below. Accordingly, while Patent Owner's argument may ultimately prove persuasive, we will consider this issue on the fuller record developed at trial.

(4) Secondary Considerations

Finally, we acknowledge the evidence of secondary considerations and Patent Owner's argument that such evidence establishes the non-obviousness of the challenged claims. Prelim. Resp. 28–30 (citing Ex. 2006, 2007). Evidence of secondary considerations, when present, must always be considered in determining obviousness. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983). Here, however, the secondary-

considerations evidence Patent Owner relies on is first presented together with the Preliminary Response, and Petitioner has not yet had an opportunity to respond to that evidence and arguments. Thus, in this case, a better course of action is to permit the parties to fully develop the record during trial before further weighing the alleged evidence of secondary considerations.

(5) Conclusion

Patent Owner presents similar arguments regarding why Petitioner has not shown that independent claim 51 is obvious in view of Edwards, Ingle, and Mosher. Prelim. Resp. 40–42 (arguing, inter alia, that "[t]he labia minora is also external to the vaginal canal, and the Petition does not articulate how (or why) a POSITA would modify Edwards to treat outside the canal."). As with claim 43, we find that the parties' arguments are best evaluated on a more developed record. Because Petitioner has demonstrated a reasonable likelihood that at least one claim would have been rendered obvious by Edwards, Ingle, and Mosher, we institute *inter partes* review of all claims challenged under Ground 1.

D. Ground 2: Obviousness in view of Edwards, Kreuter, Smith, and Beattie

Petitioner challenges claims 43–58 as obvious in view of Edwards, in light of Kreuter, Smith, and Beattie. Pet. 55–66. Patent Owner opposes. Prelim. Resp. 42–61. As the teachings of Edwards are discussed above, we begin with an overview of Kreuter, Smith, and Beattie (collectively, "the LS references").

1. Overview of Kreuter (Ex. 1012)

According to Kreuter, "[l]ichen sclerosus (LS) is a relatively rare, chronic inflammatory skin disease characterized by white porcelain-like polygonal plaques and atrophic and/or hypertrophic skin lesions," which can affect genital and extra-genital tissues, particularly the anogenital area. Ex. 1012, 251.[18] Both male and female patients were treated 4 times weekly for 10 weeks with about 15 minutes of UVA1 radiation at 20J/cm^2. *Id.* at 252. Of the eight female patients treated, three had extragenital LS and five had combined genital and extragenital involvement. *Id.* All patients responded with "obvious softening of sclerotic plaques . . . [and] repigmentation of former porcelain-like polygonal patches." *Id.*

Kreuter discloses that "3 pathways are thought to be responsible for the development of scleroderma and LSA: increased collagen synthesis and deposition, vascular damage, and altered immunoregulation." *Id.* at 254. Noting that previous studies have shown that UVA1 radiation results in "an increase of interstitial collagenase mRNA and protein expression," and the induction of cytokines and soluble factors implicated in stimulation of collagenase, Kreuter "speculate[s] that UVA1 irradiation may suppress collagen synthesis and induce collagenase activity, resulting in clinically observed softening of former sclerotic plaques." *Id.* at 255.

Figure 1 of Kreuter presents representative photomicrographs of skin before and after UVA1 phototherapy indicating "[n]ormalization of dermal architecture, [and] regularly sized collagen bundles" post-treatment. *Id.* at 253. Petitioner's expert, Dr. Tucker, interprets Figure 1 of the reference as

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[18] Where possible, we refer to the native page numbers rather than those added by the parties.

showing an increase in the synthesis of new collagen following UVA1 phototherapy. *See* Ex. 1004 ¶ 80.

2. Overview of Smith (Ex. 1014)

Smith is a review article of the pathophysiology and treatment of vulval LS. Ex. 1014. According to Smith,

> Lichen sclerosus is a chronic disorder of the skin and mucosal surfaces, and is most commonly seen on the female genital skin. It also occurs on other areas of the body. Any age group may be affected, although it is seen more often in elderly women. The exact cause of lichen sclerosus is unknown. There have been reports of family members with lichen sclerosus; thus it may have a genetic link. There is also the possibility of an autoimmune connection.

Id. at Abstract.

> The location of the lichen sclerosus varies. The entire vulvar area (from the clitoris to the anus) may be involved. Often, swelling of the clitoral foreskin hides the clitoris. The labia minora may completely disappear. The most common areas where lichen sclerosus is found are on the labia majora and labia minora. Extragenital lesions (neck, shoulder, breast, etc.) occur less frequently. The frequency of lichen sclerosus varies depending on the location. A study by Lorenz et al. found lichen sclerosus to be located on the labia (100%), clitoris (70.4%), perineum (67.9%), buttocks (32.3%), perianal area (32.1%), crural area (8.6%), and urethra (3.7%).

Id. at 106 (internal endnotes omitted).

> The area involved may vary from a small, single area to the entire vulva, extending out to the thighs. The most common description of lichen sclerosus is that of a thinned, whitened, crinkling, skin condition that often forms a figure-of-eight appearance. Initially the lesions are white, polygonal, and flat-topped papules or plaques which later form large atrophic patches. Fissuring and erosion may occur in the genital area. Fissuring is especially common between the clitoris and urethra, and on the perineum. Tears may also develop in the interlabial sulci. The skin may

> appear bruised with small broken blood vessels. The vaginal opening may become smaller, interfering with intercourse (figure 2).

Id.

"Currently, ultra-potent topical corticosteroids are the medical treatment of choice. Other treatments that have been utilized for this condition include testosterone, progesterone, tacrolimus, surgery, and phototherapy." *Id.* at Abstract. With respect to the latter, "[l]ow-dose UVA1 phototherapy has been used for extragenital lichen sclerosis." *Id.* at 119 (noting that Kreuter "demonstrated a marked reduction or clearing of lichen sclerosus with low-dose UVA1 irradiation").

3. Overview of Beattie (Ex. 1013)

Also citing Kreuter's results in the treatment of extragenital LS, Beattie reports on the results of a study to determine the effectiveness of UVA1 on seven women with severe genital LS. Ex. 1013, Abstract, 344. "Patients received a variable number of total exposures (from 15 to 65) to whole body and perineum, given 3–5 times/week." *Id.* For perineal irradiation, [i]rradiance at the skin surface, a distance of 300 mm from the lamp, was 65–74 mW/cm^2" *Id.* Five patients showed minimal or moderate improvement. *Id.* at 345.

With respect to mechanism of action, Beattie states that, "a principal mechanism of action of UVA1 is immunomodulation via T-cell apoptosis and hence regulation of pro-inflammatory cytokines, including IL-1α, -1β and -6, which stimulate collagenase and cytokine receptors such as soluble IL-4R. UVA1 irradiation has also been shown to induce collagenase mRNA in a dose dependent manner." *Id.* at 346 (internal footnotes omitted).

4. Analysis of Ground 2

According to Petitioner, one of ordinary skill in the art "would have understood that the dose of UVA1 phototherapy described in Beattie would necessarily heat tissue underlying the treated epithelial surface." Pet. 58; *see* Ex. 1003 ¶ 108 ("A POSITA would have understood that if the UV radiation treatment of Kreuter was applied to female genital tissue, the 'target tissue' would have been heated to a collagen denaturing temperature by the application of energy at 20 J/cm2."). Moreover, Petitioner argues, Kreuter's Figure 1 shows fibroblasts synthesizing new collagen in response to the UVA1 treatment and, thus, "taught remodeling of target tissue underlying the extragenital epithelium where ultraviolet energy is delivered to and through that epithelial surface to heat the target tissue." Pet. 58; *see also id.* at 59 (arguing that, like Kreuter, "Beattie teach[es] remodeling of [sic] by heating a therapeutic zone of female genital tissue underlying the vulva").[19]

Petitioner reasons that the UVA1 treatments described in Kreuter, Smith, and Beattie, therefore, "reshape female genital tissue through the manipulation of collagen using a penetrating form of energy." *Id.* at 61. And, accordingly, one of ordinary skill in the art "would have been

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[19] Whereas Petitioner's expert, Dr. Tucker, states that the effects of UVA1 are "attributable to both the light and heat generated," he does not definitively link these effects to the treatment of LS. *See* Ex. 1004 ¶ 77. Dr. Bass, in contrast, testifies that in treating LS, "UVA1 is not being used to heat the tissue but works in a non-thermal fashion. Instead, it is absorbed by chromophores in nucleotides in DNA, suppressing DNA synthesis which in turn has a number of immunomodulatory effects in the epidermis and superficial dermis such as reducing the number of T lymphocytes and mast cells and stimulating synthesis of prostaglandins and cytokines that are immune suppressive." Ex. 2001 ¶ 65.

motivated to combine the teachings of Edwards with Kreuter, Beattie, and Smith because Edwards sought to remodel the vaginal wall by applying therapeutic heating energy to targeted tissue. . . . [and]. . . would have been motivated to look to the treatments for conditions which were improved by the induction of new collagen in the target tissue and/or treatments relating to the appearance of genital tissue as abnormal or deformed." *Id.* at. 62.

We do not find Petitioner's arguments persuasive. The LS references are directed to treating a dermatological disease of genital and non-genital tissue by applying UVA1 phototherapy "to down regulate inflammatory cells so the skin layers return to a normal state." Ex. 2001 ¶ 60; *see* Ex. 1012, 255; Ex. 1013, 346. This is not the type of remodeling contemplated in Edwards, which discloses heating (via RF, microwave, laser, or other energies) to create lesions in the vaginal wall, which ultimately tighten the underlying tissue. *See* section II(C)(1), above; Ex. 2001 ¶ 52 ("Figure 1 [of Kreuter] does not indicate any tightening or contracting of the tissues."). As stated by Patent Owner, "[a] nebulous directive to look to treatments 'relating to the appearance of genital tissue as abnormal' is hardly a rational basis to combine" these disparate teachings. Prelim. Resp. 54.

Rather, we agree with the thrust of Patent Owner's arguments that the LS references are (1) non-analogous art (Prelim. Resp. 48–51 (arguing, inter alia, that Edwards is directed to urogynecologists, gynecologists, and plastic surgeons, whereas LS is a dermatological disease typically treated by dermatologists)); and (2) that the LS references are not properly combinable with Edwards (*id.* at 51–55; *see also id.* at 55 (arguing that heating is merely incidental to the UVA1 treatments of the LS references)).

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of success in proving that at least one challenged claim of the '511 patent is obvious over Edwards, in light of Kreuter, Smith, and Beattie.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one challenged claim of the '511 Patent is unpatentable. In particular, because Petitioner has demonstrated a reasonable likelihood that at least one claim is rendered obvious by the combination of Edwards, Ingle and Mosher, we institute *inter partes* review on Ground 1.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and completion of the record.

In keeping with our mission of resolving patentability disputes in a just, speedy, and inexpensive manner, we exercise our discretion to institute *inter partes* review as set forth in the following Order.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 43–58 of the '511 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '511 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Eastern District of Texas, Marshall Division on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	10/21/2016	Eastern District of Texas, Marshall Division

PLAINTIFF	DEFENDANT
VIVEVE, INC.	THERMIGEN, LLC; THERMIAESTHETICS, LLC; AND RED ALINSOD, M.D.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	8,961,511	2/24/2015	Viveve, Inc.
2			
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: INMODE LTD

Application No./Patent No.: 8,961,511 Filed/Issue Date: February 24, 2015

Titled: VAGINAL REMODELING DEVICE AND METHODS

INMODE LTD, a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

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This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Robert J. Sovesky/	July 26, 2023
Signature	Date
Robert J. Sovesky	73,798
Printed or Typed Name	Title or Registration Number

SECURED PARTY BILL OF SALE

This BILL OF SALE is entered into on July 13, 2023 and made effective as of March 27, 2023 by CRG Servicing LLC ("**Secured Party**"), amending and restating the Bill of Sale entered into on March 27, 2023 to reflect certain corrections to the description of the Collateral (as defined below).

1. **Purchase**. In consideration of a credit bid by Secured Party at a public sale pursuant to Article 9 of the New York Uniform Commercial Code in the sum of $2,500,000 (the "Purchase Price"), Secured Party hereby sells, transfers and assigns to itself as purchaser and hereby accepts delivery of, all the right, title and interest of Viveve Medical, Inc., a Delaware corporation, and Viveve, Inc., a Delaware corporation (collectively, "Debtors"), in and to the "Collateral", as defined in and described on attached **Exhibit A**.

   Payment of the foregoing consideration shall be effected in the form of a credit bid in the amount equal to the Purchase Price, which amount shall be applied to the outstanding principal amount of the Loans (excluding PIK Loans) under and defined in that certain Term Loan Agreement, dated as of May 22, 2017, as amended by the Waiver and Amendment to Loan Agreement dated as of November 29, 2017, as modified by Waiver No. 2 to Loan Agreement, dated as of December 12, 2017, as further amended by Amendment No. 2 to Loan Agreement, dated as of November 29, 2018, as further amended, restated, amended and restated, modified or supplemented from time to time, between Debtors, the lenders from time to time party thereto, and Secured Party.

2. **No Warranties**. THE COLLATERAL IS TRANSFERRED WITHOUT ANY WARRANTIES OR REPRESENTATIONS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTIES AS TO TITLE, POSSESSION, QUIET ENJOYMENT, MERCHANTABILITY, VALUE, USEFUL LIFE, FITNESS FOR INTENDED USE, OR SIMILAR REPRESENTATIONS AND WARRANTIES. PURCHASER AGREES THAT THE COLLATERAL IS PLACED AT PURCHASER'S DISPOSAL IN "**AS IS**" AND "**WHERE IS**" CONDITION.

3. **No Assumption of Liabilities**. For avoidance of doubt, Secured Party shall not assume any liabilities in connection with the purchase of the Collateral under this Bill of Sale, including without limitation, any of Debtor's existing debts of whatever nature.

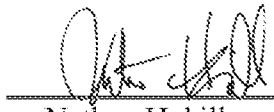
4. **Governing Law**. This instrument is governed by the laws of the State of New York.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed and delivered this Secured Party Bill of Sale as of the date first above written.

Secured Party:

CRG SERVICING LLC

By: 
Name: Nathan Hukill
Title: Authorized Signatory

CRG SERVICING LLC

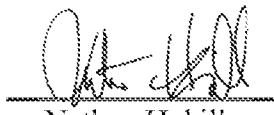
By: 
Name: Nathan Hukill
Title: Authorized Signatory

Exhibit A

The Collateral consists of all of Debtor's right, title and interest in and to the following (with all capitalized terms not otherwise defined herein having the respective meanings given to such terms in the Uniform Commercial Code as in effect in the State of New York as of the date of this Bill of Sale):

- All cash, cash equivalents, marketable securities, money market funds and other moneys of the Debtors;
- All patents, trademarks and other intellectual property of the Debtors, including, but not limited to, the patents and trademarks listed on Exhibit B, including the following:

  (a) any and all applications, patents, or registrations thereof, including any legal equivalent thereof in a foreign country, including the right to claim priority both in the United States and in all foreign countries, in and to, all Letters Patent and registrations to be obtained for the Asset or any continuation, division, renewal, non-provisional, or substitute thereof, and as to Letters Patent any reissue or re-examination thereof;

  (b) in the case of such trademarks, all of the goodwill of the business connected with the use of and symbolized by any and all of the marks; and

  (c) all causes of action for any and all previously occurring infringements of the rights being assigned and the right to receive and retain proceeds relating to those infringements and all other rights to collect damages for past infringement or misappropriation of any of the foregoing;
- All rights, including, but not limited to, Accounts, Payment Intangibles and other rights to payment, in and under the Intellectual Property Assignment and License Agreement with Edward W. Knowlton, dated as of February 10, 2006, as amended from time to time including, without limitation, Amendment 1 dated May 22, 2006 and Amendment 2 dated July 20, 2007;
- All rights, including, but not limited to, Accounts, Payment Intangibles and other rights to payment, in and under the Settlement and License Agreement, dated June 3, 2018 by and between the Debtor, ThermiGen LLC and ThermiAesthetics LLC and Dr. Red Alinsod;
- All rights, including, but not limited to rights to intellectual property rights, in and under the Development and Manufacturing Agreement, dated June 12, 2006 with Stellartech;
- All rights, including, but not limited to rights to intellectual property rights, in and under the Amended and Restated Development and Manufacturing Agreement, dated October 4, 2007 with Stellartech;
- All inventory, including both inventory constituting "finished goods" and inventory consisting of raw materials and all rights to inventory under any manufacturing and supply agreements of the Debtors;
- Customer lists of the Debtors, including direct customers, "customers via partner", and subscription customers; and
- All rights to insurance, insurance proceeds and the proceeds resulting from the refund of insurance policies, including, but not limited to, the directors and officers insurance policy.

To the extent not otherwise included, all Proceeds and products of any and all of the foregoing, all accessions to, substitutions and replacements for, and rents and profits of, the foregoing and all books, correspondence, credit files, records, invoices and other papers relating to the foregoing.

EXHIBIT B

PATENTS AND PATENT APPLICATIONS

Title	Territory	Filing Date	Application No. / Patent No.	Status	Owner
METHODS AND SYSTEMS FOR TREATING URINARY STRESS INCONTINENCE	US	9/16/2015	62/219,354	Expired	Viveve, Inc.
METHODS AND SYSTEMS FOR TREATING URINARY STRESS INCONTINENCE	US	9/16/2016	15/268,398	Pending	Viveve, Inc.
METHODS AND SYSTEMS FOR TREATING URINARY STRESS INCONTINENCE	PCT	9/16/2016	PCT/US2016/052320	Pending	Viveve, Inc.
SYSTEM FOR ENDOVAGINAL DELIVERY OF THERAPEUTIC ENERGIES	US	5/19/2017	62/508,856	Expired	Viveve, Inc.
VAGINAL REJUVENATION TREATMENT DEVICE AND METHODS	US	2/7/2006	60/743,247	Expired	Tivamed, Inc.
VAGINAL REMODELING DEVICE AND METHODS	US	2/7/2007	8961511	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	US	2/23/2015	14/629,186	Pending	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	PCT	2/7/2007	PCT/US07/03542	Expired	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	US	9/18/2009	61/243,686	Expired	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	US	9/16/2010	9271785	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	US	1/19/2016	15/001,021	Pending	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	PCT	9/16/2010	PCT/US10/49045	Expired	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	AT	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	AU	9/16/2010	2010295586	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	BE	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	BR	9/16/2010	11 2012 006059 7	Pending	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	CA	9/16/2010	2774265	Pending	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	CH	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	CZ	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	DE	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	DK	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	EP	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	ES	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	FR	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	GB	9/16/2010	2477695	Issued	Viveve, Inc.

Title	Territory	Filing Date	Application No. / Patent No.	Status	Owner
VAGINAL REMODELING DEVICE AND METHODS	GR	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	HK	9/16/2010	1167590	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	HR	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	HU	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	IE	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	IN	9/16/2010	2321/DELNP/2012	Pending	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	IT	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	JP	9/16/2010	5763646	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	KR	9/16/2010	10-1643799	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	KR	9/16/2010	10-1681880	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	KR	9/16/2010	10-2016-7032868	Pending	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	LU	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	MC	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	NL	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	NO	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	PL	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	PT	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	SE	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	SI	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	TR	9/16/2010	2477695	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	TW	9/29/2010	99133093	Pending	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	CN	5/18/2012	ZL201080049557.4	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	CN	4/12/2016	201610223768.4	Pending	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	MC	5/30/2016	J/002193	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	HK	9/7/2016	16110627.2	Pending	Viveve, Inc.
TREATMENT DEVICE FOR REPAIRING FEMALE VAGINAL TISSUE	CN	3/16/2012	201220099603.8	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE	HK	3/11/2013	1175355	Issued	Viveve, Inc.
THERAPY DEVICE WITH ELECTRODE FINGER COT FOR REPAIRING FEMALE VAGINAL TISSUE	CN	3/16/2012	201220099605.7	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE WITH ELECTRODE FINGER HOLDER	HK	3/11/2013	1175354	Issued	Viveve, Inc.

Title	Territory	Filing Date	Application No. / Patent No.	Status	Owner
VAGINAL REMODELING DEVICE WITH TEMPERATURE SENSOR	CN	3/16/2012	ZL201220099618.4	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE WITH TEMPERATURE SENSOR	HK	3/11/2013	1175353	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE WITH DIRECTIONAL SENSORS	CN	3/16/2012	ZL201220099620.1	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE WITH DIRECTIONAL SENSORS	HK	3/11/2013	1175352	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND SYSTEM WITH DEPTH MARKERS	CN	3/16/2012	ZL201220099634.3	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE	HK	3/11/2013	1175351	Issued	Viveve, Inc.
CURER FOR REPAIRING FEMALE VAGINAL TISSUE	CN	3/16/2012	201210069908.9	Pending	Viveve, Inc.
VAGINAL TISSUE REPAIR TREATMENT DEVICE WITH TEMPERATURE SENSOR OR DEPTH MARKER	CN	3/16/2012	201210069910.6	Pending	Viveve, Inc.
THERAPEUTIC EQUIPENT USED FOR REPAIRING VAGINA TISSUE AND PROVIDED WITH DIRECTION SENSOR OR DEPTH LABEL	CN	3/16/2012	ZL 201210069909.3	Issued	Viveve, Inc.
CURER FOR REPAIRING FEMALE VAGINAL TISSUE	CN	3/16/2012	ZL201210069906.X	Issued	Viveve, Inc.
CURER FOR REPAIRING FEMALE VAGINAL TISSUE	HK	3/15/2014	1189531	Issued	Viveve, Inc.
THERAPEUTIC DEVICE FOR REPAIRING FEMALE VAGINAL TISSUES	CN	3/16/2012	ZL201200996485	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE	MC	5/30/2016	J/002194	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE	HK	3/11/2013	1175350	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	US	3/15/2013	9415235	Issued	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	PCT	3/15/2013	PCT/US13/32066	Expired	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	BR	9/16/2014	1120140228663.0	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	CA	10/6/2014	2869728	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	DE	3/10/2015	202013012099.1	Issued	Obtaining confirmatory Assignment to Viveve, Inc.

Title	Territory	Filing Date	Application No. / Patent No.	Status	Owner
VAGINAL REMODELING DEVICE AND METHOD	EP	10/10/2014	13760612.5	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	IN	10/15/2014	2014MUMNP2062	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	JP	9/16/2014	2015-500653	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	KR	10/16/2014	1020147029000	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	MX	9/15/2014	341571	Issued	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE	RU	10/14/2014	2014141309	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	SG	9/11/2014	11201405630T	Abandoned	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	TW	3/14/2013	102109033	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	CN	4/19/2016	201610244844.X	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	SG	9/16/2016	10201607753W	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	HK	10/6/2016	16111609	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHOD	US	6/21/2016	15/188,948	Pending	Obtaining confirmatory Assignment to Viveve, Inc.
METHOD AND APPARATUS FOR SURGICAL DISSECTION	US	7/14/2003	7442192	Issued	Licensed
METHODS FOR TREATING URINARY STRESS INCONTINENCE	US	11/29/2022	11511110	Issued	Viveve, Inc.
DEVICES FOR DUAL MECHANISM AESTHETIC TREATMENT AND METHODS OF USE THEREOF	US	7/31/2019	16/482581	Pending	Viveve, Inc.
METHODS AND SYSTEMS FOR TREATING URINARY STRESS INCONTINENCE	US	9/18/2020	17/025912	Pending	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	US	10/26/2021	11154349	Issued	Viveve, Inc.
VAGINAL REMODELING DEVICE AND METHODS	US	4/13/2021	17/228,999	Pending (OA Issued)	No Assignment Recorded

Title	Territory	Filing Date	Application No. / Patent No.	Status	Owner
VAGINAL REMODELING DEVICE AND METHODS	US	10/7/2021	17/496,448	Pending (OA issued)	No Assignment Recorded
METHOD AND APPARATUS FOR ELECTROSURGICAL TISSUE TREATMENT	US	7/14/2002	60/396,038	Expired	No Assignment Recorded
METHOD AND APPARATUS FOR SURGICAL DISSECTION	US	10/3/2002	60/416,206	Expired	No Assignment Recorded
METHOD AND APPARATUS FOR SURGICAL DISSECTION	US	10/13/2002	60/418,089	Expired	No Assignment Recorded
THERAPEUTIC COOLING METHODS FOR TREATING TISSUE	US	1/29/2021	63/143,698	Expired	Viveve, Inc.
DEVICES FOR DUAL MECHANISM AESTHETIC TREATMENT AND METHODS OF USE THEREOF	US	1/31/2017	62/452,889	Expired	Viveve, Inc.
METHODS FOR TREATING URINARY STRESS INCONTINENCE	US	6/27/2018	62/690,534	Expired	Viveve, Inc. and Bruce Baldwin Allan
DEVICES FOR DUAL MECHANISM AESTHETIC TREATMENT AND METHOD OF USE THEREOF	US	1/28/2022	17/587,993	Pending	No Assignment Recorded
METHOD FOR TREATING URINARY STRESS INCONTINENCE	US	11/4/2022	17/981,174	Pending	Not publically available
METHOD AND APPARATUS FOR SURGICAL DISSECTION	US	4/2/2008	12/061,090	Abandoned	No Assignment Recorded

TRADEMARKS AND TRADEMARK APPLICATIONS

Mark	Jurisdiction	Status	Application No.	Application Date	Registration No.	Registration Date
VIVEVE	Argentina	Registered	2996075	4/19/2010	2424113	2/21/2011
VIVEVE	Argentina	Registered	2996074	4/19/2010	2423938	2/21/2011
VIVEVE	Argentina	Registered	2996073	4/19/2010	2423937	2/21/2011
VIVEVE (From Int'l Reg No. 1024357)	Australia	Registered	1024357	11/25/2009	1024357	11/25/2009
GENEVEVE	Brazil	Pending	911579150	9/2/2016		
GENEVEVE	Brazil	Pending	911579192	9/2/2016		
GENEVEVE	Brazil	Published	912266821	2/7/2017		
GENEVEVE (Expanded)	Brazil	Published	912266872	2/7/2017		
Miscellaneous Design (Geneveve Logo)	Brazil	Pending	911579036	9/2/2016		
Miscellaneous Design (Geneveve Logo)	Brazil	Pending	911579109	9/2/2016		
VIVEVE	Brazil	Registered	830522239	1/27/2010	830522239	12/18/2012
VIVEVE	Canada	Registered	1460488	11/25/2009	TMA859758	9/10/2013
GENEVEVE	China	Published	17766348	8/27/2015		
GENEVEVE	China	Published	17744749	8/25/2015		
GENEVEVE (Expanded)	China	Pending	tbd	4/11/2017		
Miscellaneous Design (Geneveve Logo)	China	Pending	20990207	8/16/2016		
VIVEVE (Chinese Characters)	China	Registered	10892457	8/14/2013	10892457	8/14/2013
VIVEVE (Chinese Characters)	China	Registered	10892458	8/14/2013	10892458	8/14/2013
VIVEVE (Chinese Characters)	China	Registered	10892459	8/14/2013	10892459	8/14/2013
VIVEVE (From Int'l Reg No. 1024357)	China	Registered	1024357	11/25/2009	1024357	11/25/2009
VIVEVE	Colombia	Registered	9146592	12/22/2009	403764	6/24/2010
VIVEVE	Colombia	Registered	9146590	12/22/2009	403763	6/24/2010
GENEVEVE	European Community	Registered	15802838	9/5/2016	015802838	1/6/2017
GENEVEVE (Expanded)	European Community	Published	16326837	2/7/2017		
Miscellaneous Design (Geneveve Logo)	European Community	Registered	15802887	9/5/2016	15802887	1/6/2017
VIVEVE (From Int'l Reg No. 1024357)	European Community	Registered	1024357	11/25/2009	1024357	11/25/2009
VIVEVE	Hong Kong	Registered	301484956	11/26/2009	301484956	6/14/2010
VIVEVE	India	Registered	1892699	12/7/2009	1892699	6/6/2016
VIVEVE	Israel	Registered	226640	1/24/2010	226640	3/7/2011
VIVEVE	Israel	Registered	226638	1/24/2010	226638	3/7/2011
VIVEVE	Israel	Registered	226639	1/24/2010	226639	3/7/2011
VIVEVE (From Int'l Reg No. 1024357)	Japan	Registered	1024357	11/25/2009	1024357	11/25/2009
VIVEVE	Madrid Protocol (TM)	Registered	1024357	11/25/2009	1024357	11/25/2009
VIVEVE	Mexico	Registered	1063744	1/29/2010	1144600	2/22/2010
VIVEVE	Mexico	Registered	1063725	1/29/2010	1144596	2/22/2010
VIVEVE	Mexico	Registered	1063741	1/29/2010	1144599	2/22/2010
VIVEVE (From Int'l Reg No. 1024357)	Norway	Registered	1024357	11/25/2009	1024357	11/25/2009
GENEVEVE	Republic of Korea	Registered	4520150007909	8/26/2015	45-0067590	8/31/2016
GENEVEVE (Expanded)	Republic of Korea	Pending	4020170046090	4/11/2017		
Miscellaneous Design (Geneveve Logo)	Republic of Korea	Published	4520160006664	8/17/2016		

Mark	Jurisdiction	Status	Application No.	Application Date	Registration No.	Registration Date
VIVEVE (From Int'l Reg No. 1024357)	Republic of Korea	Registered	1024357	11/25/2009	1024357	11/25/2009
VIVEVE (Korean Characters)	Republic of Korea	Registered	4020150038512	5/26/2015	401156448	1/22/2016
VIVEVE (From Int'l Reg No. 1024357)	Russian Federation	Registered	1024357	11/25/2009	1024357	11/25/2009
VIVEVE	Saudi Arabia	Registered	153508	4/7/2010	128305	10/9/2011
VIVEVE	Saudi Arabia	Registered	153507	4/7/2010	128304	10/9/2011
VIVEVE	Saudi Arabia	Registered	153506	4/7/2010	128303	10/9/2011
VIVEVE	Singapore	Registered	T1002460H	3/1/2010	T1002460H	9/9/2010
VIVEVE (From Int'l Reg No. 1024357)	Singapore	Registered	1024357	11/25/2009	1024357	11/25/2009
VIVEVE (From Int'l Reg No. 1024357)	Switzerland	Registered	1024357	11/25/2009	1024357	11/25/2009
GENEVEVE	Taiwan	Pending	105053033	9/5/2016		
GENEVEVE (Expanded)	Taiwan	Pending	106020656	4/11/2017		
Miscellaneous Design (Geneveve Logo)	Taiwan	Pending	105053035	9/5/2016		
GENEVEVE	Thailand	Pending	160105704	9/7/2016		
GENEVEVE (Expanded)	Thailand	Pending	170106204	2/24/2017		
Miscellaneous Design (Geneveve Logo)	Thailand	Pending	160105703	9/7/2016		
VIVEVE (From Int'l Reg No. 1024357)	Turkey	Registered	1024357	11/25/2009	1024357	11/25/2009
GENEVEVE	United States of America	Abandoned	86/546576	2/26/2015		
GENEVEVE	United States of America	Abandoned	86/732394	8/21/2015		
GENEVEVE (Expanded)	United States of America	Abandoned	87/321846	2/2/2017		
Miscellaneous Design (Geneveve Logo)	United States of America	Abandoned	86/931037	3/7/2016		
THE SCIENCE OF SATISFACTION	United States of America	Abandoned	87/105962	7/15/2016		
VIVEVE	United States of America	Registered	77/833814	9/24/2009	4222217	10/9/2012
VIVEVE	Argentina	Registered	2996075	4/19/2010	2424113	2/21/2011

PTO/AIA/81A (02-15)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT - POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Patent Number	8,961,511
Issue Date	February 24, 2015
First Named Inventor	Jonathan B. Parmer
Title	VAGINAL REMODELING DEVICE AND METHODS
Attorney Docket No.	10095-701.201

I hereby revoke all previous powers of attorney given in the above-identified patent.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the Customer Number identified in the box at right as my/our attorney(s) or agent(s) with respect to the patent identified above, and to transact all business in the United States Patent and Trademark Office connected therewith: 26285

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) with respect to the patent identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified patent to:

☒ The address associated with the above-identified Customer Number.

OR

☐ The address associated with the Customer Number identified in the box at right:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the:

☐ Applicant.

OR

☒ Patent owner.

Statement under 37 CFR 3.73(c) (Form PTO/AIA/96) submitted herewith or filed on _____.

SIGNATURE of Applicant or Patent Owner

Signature		Date	July 21, 2023
Name	Yair Malca	Telephone	949-636-5095
Title and Company	Chief Financial Officer - INMODE LTD		

NOTE: Signatures of all the applicants or patent owners of the entire interest or their representative(s) are required. If more than one signature is required, submit multiple forms, check the box below, and identify the total number of forms submitted in the blank below.

☑ A total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
11/704,067	**07/26/2023 01:18:37 PM ET**	**10095-701.201**

Title of Invention

VAGINAL REMODELING DEVICE AND METHODS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	8961511
CONFIRMATION #	4378	FILED BY	Amanda Kernan
PATENT CENTER #	62506911	FILING DATE	02/07/2007
CUSTOMER #	66854	FIRST NAMED INVENTOR	Jonathan B. Parmer
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Robert Sovesky

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
7-26-2023 - US8961511 - POA.pdf	1	Power of Attorney	163 KB
7-26-2023 - US8961511 - 3-73c.pdf	13	Assignee showing of ownership per 37 CFR 3.73	332 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
7-26-2023 - US8961511 - POA.pdf	44760E13875481A6BF6EC52DD769C91A77F71BE84C987693E8D3B22E92B5B6708DD88FCA1699AF73603119AFA288230A253

D3C778672BB19A1FE8B7568E6A999

7-26-2023 - US8961511 - 3-73c.pdf	F188494D72E13D7B90A8CE9ADB41B50E51B8A49082082F6EEBCCFDD9137D200AF98C4AC1A5CACBA556F302A39A4C546B89F93F5081A81A36B6E3124C1DDFC5B9

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201

CONFIRMATION NO. 4378

26285
K&L GATES LLP-Pittsburgh
210 SIXTH AVENUE
PITTSBURGH, PA 15222-2613

POA ACCEPTANCE LETTER

OC000000060074161

Date Mailed: 08/02/2023

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 07/26/2023.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/sltorres/

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UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/704,067	02/07/2007	Jonathan B. Parmer	10095-701.201

CONFIRMATION NO. 4378

66854
SHAY GLENN LLP
155 BOVET ROAD, SUITE 710
SAN MATEO, CA 94402

POWER OF ATTORNEY NOTICE

OC000000060074157

Date Mailed: 08/02/2023

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 07/26/2023.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/sltorres/