

Patent Owner InMode's Demonstratives

IPR2024-0703

**BTL Industries, Inc., *Petitioner*,
v. InMode Ltd., *Patent Owner***

U.S. Patent No. 8,961,511

July 8, 2025, Oral Hearing

InMode EX2019
IPR2024-00703

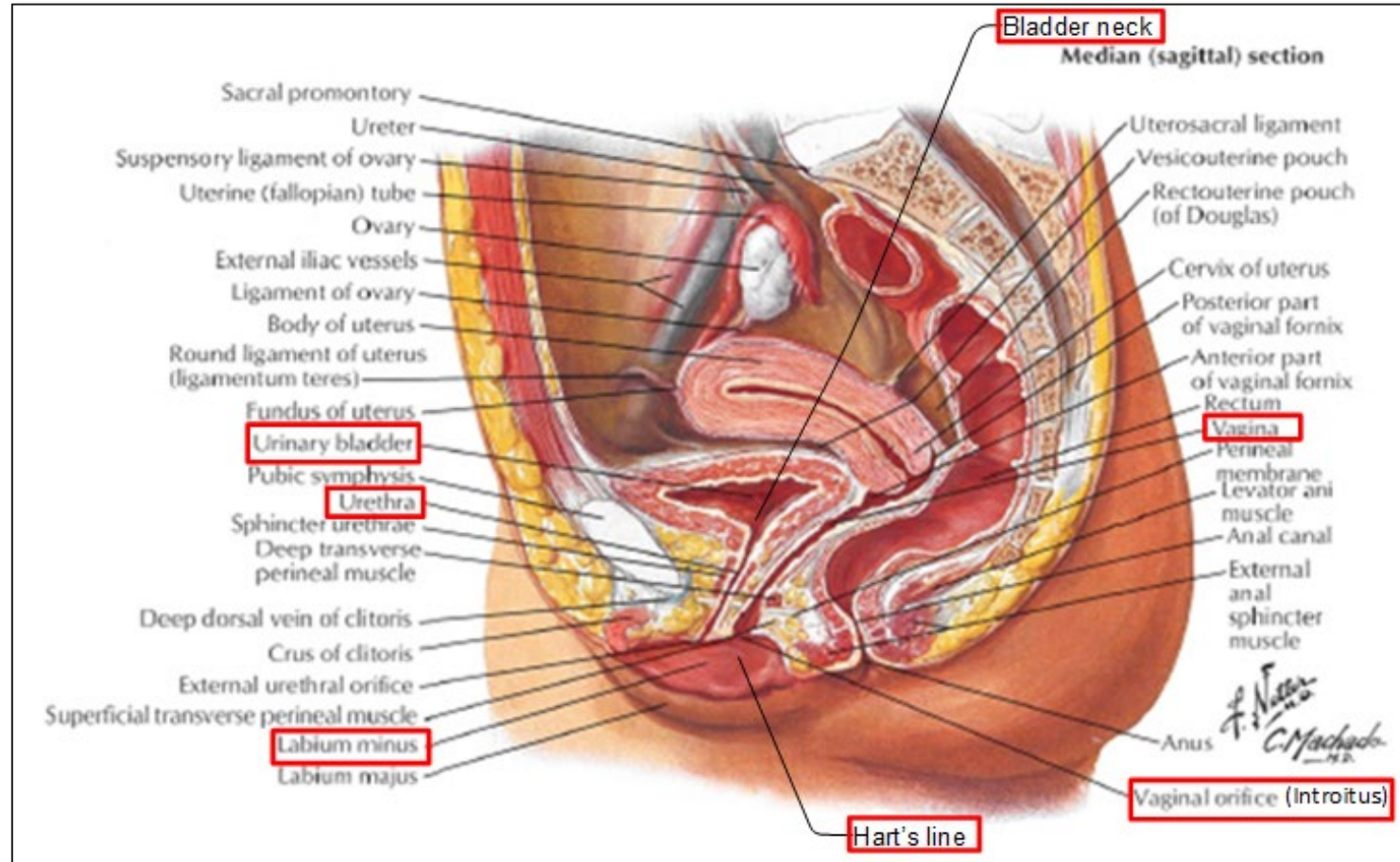
VENABLE_{LLP}

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Summary

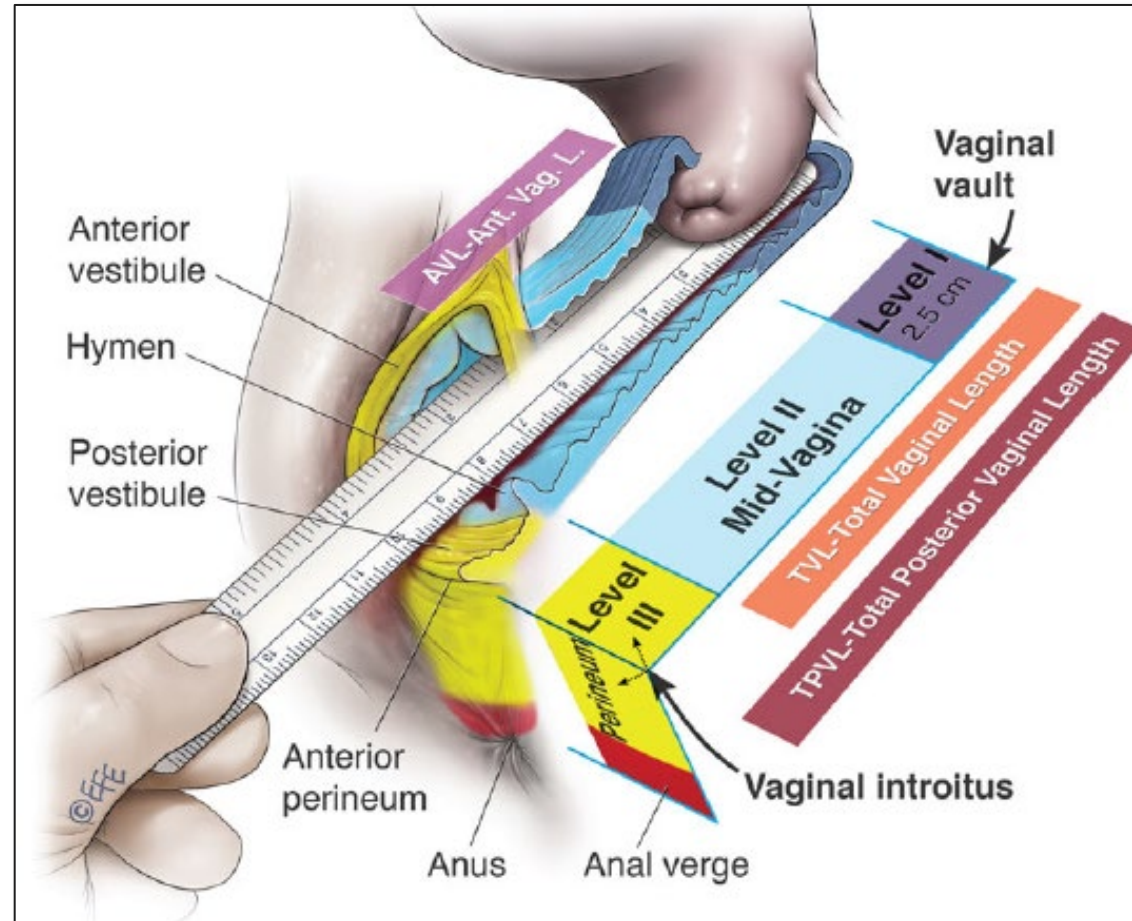
- I. Anatomy and the '511 Patent
- II. Claim Construction
- III. Ground 1 – Edwards, Mosher, and Ingle do not teach the claimed treatment areas – All claims
- IV. Ground 1 – Edwards, Mosher, and Ingle do not teach “remodeling the . . . target tissue” – All claims
- V. Ground 2 – Edwards, Mosher, Ingle, and Ollivier do not render obvious external treatments – Claims 43-58
- VI. Objective Indicia of Non-Obviousness in the form of Praise from Petitioner’s Expert’s Mentor and Employer

The Female Anatomy



Ex. 1015, Plate 360 (annotated)

The Female Anatomy

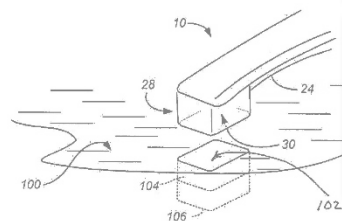


Ex. 2009

The '511 Patent – Independent Claims

(12) United States Patent		(10) Patent No.:
Parmer		(45) Date of Patent:
(54) VAGINAL REMODELING DEVICE AND METHODS	(56) References:	
(75) Inventor: Jonathan B. Parmer, Woodside, CA (US)	4,326,529 A 4/19/80	4,381,007 A 4/19/80
(73) Assignee: Vireve, Inc., Sunnyvale, CA (US)	4,785,807 A 11/19/84	4,785,828 A 11/19/84
(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1179 days.		
(21) Appl. No.: 11/704,067	JP 1105-209144	JP 1109-122141
(22) Filed: Feb. 7, 2007	OTHER	
(65) Prior Publication Data		Parmer et al., U.S. Appl. No. 11/704,067, filed Feb. 7, 2007, "Vaginal remodeling device and methods," filed
US 2007/0233191 A1 Oct. 4, 2007		
Related U.S. Application Data		Primary Examiner — Rosemary J. Adams
(60) Provisional application No. 60/743,247, filed on Feb. 7, 2006.		(74) Attorney, Agent, or Firm: Venable LLP
(51) Int. Cl.		(57) Abstract
A61B 18/12 (2006.01)		This invention relates generally to methods and devices for tightening tissue of the female genital area, and more particularly to methods and devices for tightening the vaginal tissue.
A61B 18/18 (2006.01)		The invention provides a method and device for tightening the vaginal tissue by applying energy to the vaginal tissue.
A61N 7/02 (2006.01)		The invention provides a method and device for tightening the vaginal tissue by applying energy to the vaginal tissue.
A61B 18/14 (2006.01)		The invention provides a method and device for tightening the vaginal tissue by applying energy to the vaginal tissue.
A61B 18/00 (2006.01)		The invention provides a method and device for tightening the vaginal tissue by applying energy to the vaginal tissue.
(52) U.S. Cl.		
CPC A61B 18/1485 (2013.01); A61B 18/1206 (2013.01); A61B 18/18 (2013.01); A61B 2018/00023 (2013.01); A61B 2018/00559 (2013.01); A61B 2018/00602 (2013.01); A61B 2018/00791 (2013.01); A61B 2018/00873 (2013.01); A61N 7/022 (2013.01)		
USPC 606/49; 606/41; 607/138; 601/3		
(58) Field of Classification Search		
USPC 606/1 52; 607/50, 115, 138		
See application file for complete search history.		58 Claims.

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 extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus.

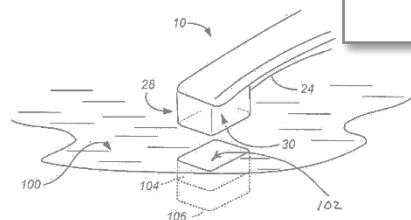


26. The method of claim 1, wherein remodeling comprises tightening the introitus.

The '511 Patent – Independent Claims

 US008961511B2	
(12) United States Patent Parmer	(10) Patent No.: (45) Date of Patent:
(54) VAGINAL REMODELING DEVICE AND METHODS	(56) References: U.S. PATENT 4,326,529 A 4/19 4,381,007 A 4/19 4,785,807 A 11/19 4,785,828 A 11/19 FOREIGN PATENT JP 1105-209144 JP 1109-122141 OTHER Parmer et al., U.S. Appl. No. 2007/0233191 A1, filed Feb. 7, 2006, "Vaginal remodeling device and methods," filed Oct. 4, 2007.
(75) Inventor: Jonathan B. Parmer, Woodside, CA (US) (73) Assignee: Vireve, Inc., Sunnyvale, CA (US) (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1179 days. (21) Appl. No.: 11/704,067 (22) Filed: Feb. 7, 2007 (65) Prior Publication Data: US 2007/0233191 A1 Oct. 4, 2007 Related U.S. Application Data: (60) Provisional application No. 60/743,247, filed on Feb. 7, 2006. (51) Int. Cl. A61B 18/12 (2006.01) A61B 18/18 (2006.01) A61N 7/02 (2006.01) A61B 18/14 (2006.01) A61B 18/00 (2006.01) (52) U.S. Cl. CPC A61B 18/1485 (2013.01); A61B 18/1206 (2013.01); A61B 18/18 (2013.01); A61B 2018/00023 (2013.01); A61B 2018/00559 (2013.01); A61B 2018/00602 (2013.01); A61B 2018/00791 (2013.01); A61B 2018/00873 (2013.01); A61N 7/022 (2013.01) USPC 606/49; 606/41; 607/138; 601/3 (58) Field of Classification Search: USPC 606/1 52; 607/50, 115, 138 See application file for complete search history.	(57) Abstract: This invention relates generally to tightening tissue of the female genital tissue with a mucosal epithelial surface from the heat. Embodiments provide both an energy delivery system. As the treatment tip tip cools the mucosa by cooling the epithelium to the underlying reverse thermal gradient, remodel genital tissue by include a tighter vagina and may be a consequence of well as a longer term he includes an increased depth.

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.

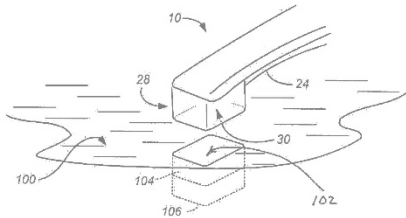


The '511 Patent – Independent Claims

US008961511B2

(12) United States Patent Parmer	(10) Patent No.: (45) Date of Patent
(54) VAGINAL REMODELING DEVICE AND METHODS	(56) References Cited
(75) Inventor: Jonathan B. Parmer, Woodside, CA (US)	4,326,529 A 4/79 4,381,007 A 4/79 4,785,807 A 11/92 4,785,828 A 11/92
(73) Assignee: Vireve, Inc., Sunnyvale, CA (US)	
(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1179 days.	
(21) Appl. No.: 11/704,067	JP 1105-209144 JP 1109-122141
(22) Filed: Feb. 7, 2007	
(65) Prior Publication Data US 2007/0233191 A1 Oct. 4, 2007	OTHER
Related U.S. Application Data (60) Provisional application No. 60/743,247, filed on Feb. 7, 2006.	Parmer et al., U.S. Appl. No. 11/704,067, filed Feb. 7, 2007, entitled "Vaginal remodeling device and methods," filed Feb. 7, 2006.
(51) Int. Cl. A61B 18/12 (2006.01) A61B 18/18 (2006.01) A61N 7/02 (2006.01) A61B 18/14 (2006.01) A61B 18/00 (2006.01)	(57) Abstract This invention relates generally to tightening tissue of the female genital tissue with radiofrequency energy. In one embodiment, a device is used to deliver energy to the mucosal epithelial surface from the heat. Embodiments provide both an energy delivery system. As the treatment tip cools the mucosa by contact with the epithelium to the tissue, a reverse thermal gradient is created, remodeling genital tissue by including a tighter vagina and may be a consequence of the treatment, as well as a longer term healing process.
(52) U.S. Cl. CPC A61B 18/1485 (2013.01); A61B 18/1206 (2013.01); A61B 18/18 (2013.01); A61B 2018/00023 (2013.01); A61B 2018/00559 (2013.01); A61B 2018/00702 (2013.01); A61B 2018/00791 (2013.01); A61B 2018/00873 (2013.01); A61N 7/022 (2013.01) USPC 606/49; 606/41; 607/138; 601/3	
(58) Field of Classification Search USPC 606/1 52; 607/50, 115, 138 See application file for complete search history.	

58 Claims, 9 Drawing Sheets



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.

(12)	United States Patent Parmer	(10)	Patent No.
		(45)	Date of Patent
(54)	VAGINAL REMODELING DEVICE AND METHODS	(56)	References
(75)	Inventor: Jonathan R. Parmer , Woodside, CA (US)		U.S. PATENT
(71)	Assignee: Yvec, Inc. , Sunnyvale, CA (US)		4,326,529 A 4/18
(*)	Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1179 days.		4,381,007 A 4/18
(21)	App. No.: 11/704,867		4,785,807 A 11/19
(22)	Filed: Feb. 7, 2007		4,785,828 A 11/19
(65)	Prior Publication Data		FOREIGN PAT.
	US 2007/023191 A1 Oct. 4, 2007	JP	H05-26944
		JP	H09-12241
			GTHTR
	Related U.S. Application Data		Parmer et al., U.S. Patent App. ing device and methods; filed
(60)	Provisional application No. 60/743,247, filed on Feb. 7, 2006.		<i>Primary Examiner</i> — Ron
(51)	Int. Cl.	(74)	U.S. Patent Attorneys
	A61B 18/12 (2006.01)	(57)	This invention relates gen
	A61B 18/18 (2006.01)		tighening tissue of the fi
	A61B 7/02 (2006.01)		connective tissue with r
	A61B 18/14 (2006.01)		mucosal epifissial surfa
	A61B 18/00 (2006.01)		from the heat. Embodime
(52)	U.S. Cl.		prises both an energy del
	CPC		At the treatment tip
	A61B 18/485 (2013.01), A61B 18/12/06		tip cools the mucosa by us
	A61B 2013/00073 (2013.01), A61B 2013/0019		the epithelium to the us
	A61B 2013/00072 (2013.01), A61B 2013/00073		reverse thermal gradien
	A61B 2013/00072 (2013.01), A61B 2013/00073		remold gened connective
(58)	Classification Search		include a tighter vagin a
	USPC		may be a consequence of
	G06F 12/00 (2006.01), G06F 12/00 , G06F 12/00		well as a longer term b
	G06F 12/00 (2006.01), G06F 12/00 , G06F 12/00		includes an increased de
	G06F 12/00 (2006.01), G06F 12/00 , G06F 12/00		

Claim Construction

Petition Adopted and Approved of Prior Constructions

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:



Does not include deeper tissue, such as endopelvic fascia.

(Reply, 7)

(a) **heating** the target tissue;

Petition adopted *ThermiGen* “heating” construction;

Reply criticized it. (Pet., 9; Reply, 8)

(b) **remodeling** the therapeutic Zone of target tissue

Petition approved *ThermiGen* “remodeling” construction;

Reply criticized it. (Pet., 10; Reply, 8)

Petition Approved of the *ThermiGen* “Heating” and “Remodeling” Constructions

Heating:

Each independent claim recites “heating the target tissue.” In the prior IPRs, the Board preliminarily construed “heating” as “raising the temperature of target tissue to no more than about 80 degrees C.”¹ EX1009, 12-14; EX1011, 11-14. This construction is generally consistent with the patent specification, which discloses

Pet., 9

Remodeling:

Each independent claim recites “remodeling the therapeutic zone of target tissue.” . . . in the prior IPRs, the Board preliminarily construed the “remodeling” step as “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.” EX1009, 14-16; EX1011, 14-15. Both of these constructions . . . are generally consistent with the patent specification, which explains

Pet., 10

The “Heating” and “Remodeling” Limitations Do Not Permit Damage to the Epithelium

InMode’s Evidence:

- ’511 patent specification’s clear statements on ablation
 - Ex. 1001, Abstract, 2:56-62, 8:8-15, 12:17-21, 13:19-23
- Dr. Poulos’s declaration
 - Ex. 2001, ¶¶61-67
- *ThermiGen* IPR panel’s finding of a “clear” teaching
 - Ex. 1009, 14-16; Ex. 1011, 14-15
- *Viveve* court’s finding of a “critical aspect of the invention”
 - Ex. 1024, 10-12

POR, 17-20; Sur-Reply, 3-4

Petitioner’s Evidence:

- None – No reply declaration

Reply, 8

Claim 1: Extending From the Introitus to a Position From 1 CM to 3.5 CM in From the Introitus

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 extending **from** the introitus inwardly **to a location** from 1 cm to 3.5 cm in from the introitus.

Ex. 1001, Cl. 1 (emphasis added)

Claim 1: Extending From the Introitus to a Position From 1 CM to 3.5 CM in From the Introitus

Claim 1 requires heating from introitus to at least one centimeter therefrom

Petitioner's Reading of Claim 1

A POSA would have understood this treatment area includes heating a portion of the vagina starting 1 cm from the opening and extending a further 2.5 cm back towards the cervix (i.e., 3.5 cm from the introitus).

Pet., 35 (citing Ex. 1003, ¶120)

Plain Meaning of the Claim Term “From . . . To”

. . . the plain meaning of the claim language . . . requires that the claimed treatment area must begin at the introitus and extend at least the first centimeter into the vagina and up to 3.5 cm in from the introitus.

Sur-Reply, 6-7 (citation omitted)

Claim 35: “Circumferentially Around Its Wall From 1 O'clock to 11 O'clock”

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.

Ex. 1001, Cl. 35

Construction: “heating multiple, contiguous contact sites in the 300 degree arc extending from 1 o'clock to 11 o'clock along the vaginal wall.” POR, 20.

Claim 35: Modification of the *ThermiGen* Construction to Comport With the Intrinsic Record

Intrinsic Record Demonstrates the Claimed “Portion of the Vagina” Is the 300-Degree Arc From 1 O’clock to 11 O’clock

35 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. 40 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 45 arc.

Ex. 1001, 14:35-45

Prior Panel Found “at Least One Point” Is “Exclude[d]” by the Plain Language

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”).

Ex. 1009 (ThermiGen IPR DI), 17

Claim 35: Both Experts Agree the Treatment Sites Should Be as Contiguous as Possible

Petitioner's Expert (Dr. Berenholz):

Q. How far apart would you – would these [contact] points be?

...

A. I have no way of knowing. I'd want it to be as close to contiguous as possible.

Ex. 2005, 117:9-118:1

Dr. Poulos:

71. ... I agree with Dr. Berenholz that a POSA would “want [the contact points] to be as close to contiguous as possible.” EX2005, 117:9-118:1. The exact number of contact sites would depend on the size of the intensity of RF energy used, but a POSA evaluating the specification and claim language would understand that a circumferential treatment includes at least six contact sites, with at least one contact site on each wall of the vagina.

Ex. 2001, ¶71

The Petition Fails to Demonstrate Unpatentability for Any Claim

The Petition Fails for All Claims

- **Ground 1: Edwards, Mosher, and Ingle**
 - No reference teaches treating *from the introitus* to 1-3.5 cm in from the introitus (claim 1).
 - No reference teaches heating *circumferentially* (claim 35).
 - No reference teaches treating *external* tissue (claims 43 and 51).
 - No reference teaches treating remodeling the *target tissue* (all claims).
- **Ground 2: Edwards, Mosher, Ingle, and Ollivier**
 - Ollivier cannot cure any of the deficiencies.
 - Ollivier is not enabling.
 - Petitioner has not established Ollivier is a qualifying printed publication.
 - Ollivier does not teach heating the claimed regions.

Ground 1
**No Reference Teaches Treating From the
Introitus Inwardly to 1-3.5 CM (Claim 1)**

Edwards (Ex. 1005): Edwards Treats the Bladder Neck Area

Edwards Is Focused on Treating at the Bladder Outlet

“bladder outlet and adjacent tissues”

Ex. 1005, 6:20.

The Edwards Device Locks in Place to Provide Treatment Deeper Than the Claimed Treatment Area

- “The blade 420 of the system 400 is inserted into the vagina through the speculum. The handle 430 is manipulated so as to cause the mating features 421 to engaged with the speculum[] ... to become locked into position in the speculum.” Ex. 1005, 13:38-46.
- Dr. Berenholz acknowledged that Edwards’ speculum would extend 1-2 inches into the vagina and that the blade with the electrodes would extend a few centimeters beyond the speculum.
Ex. 2005, 132:25-133:16, 140:14-17.
- Dr. Poulos confirmed that treatment would occur beyond 3.5 cm from the introitus.
Ex. 2001, ¶¶ 95, 100-104.

Edwards (Ex. 1005): Edwards' Speculum Inhibits Treatment From the Introitus Inward to 1-3.5 CM

Petitioner's Expert (Dr. Berenholz):

Q. Okay. So what's the – like what's the minimum depth, like, where the speculum would not pop out?

A. Yeah. I've never researched that question before, so I don't know. I mean common sense is you want to be in far enough to support the tissue so that it opens without losing it.

Q. So maybe like an inch, based on your practice as a medical doctor?

A. I don't think I've ever gone that shallow. But probably a little further than that.

...

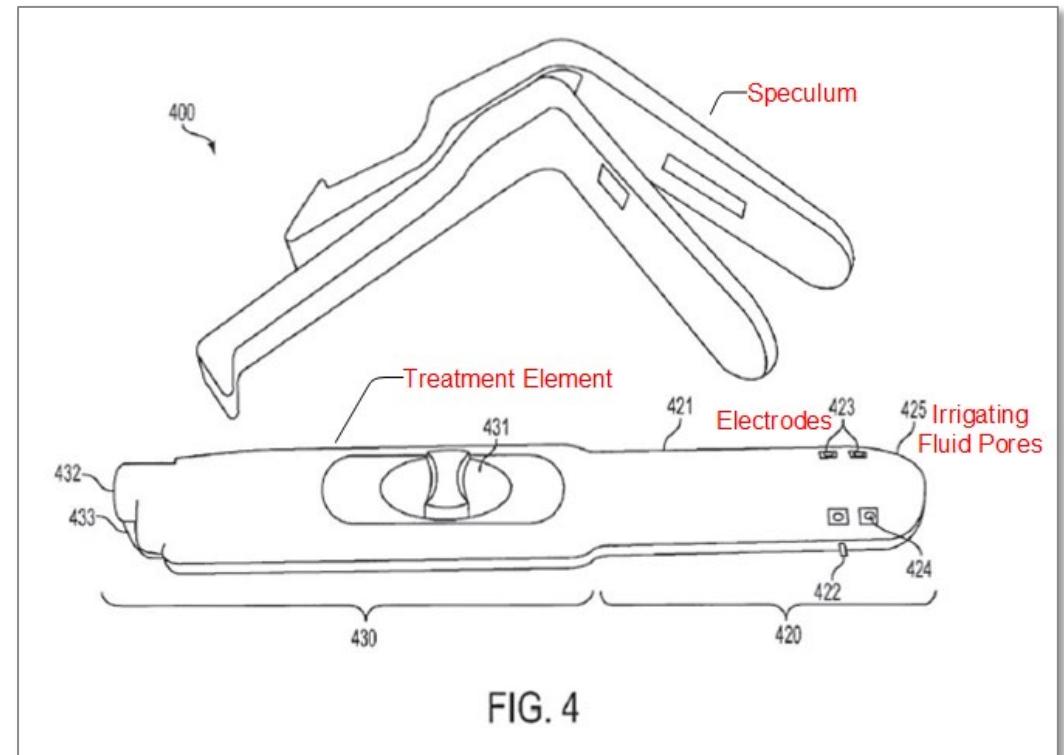
Q. When the handle is – is engaged with the speculum, do you have a feel from this picture how far that blade would stick out into the vagina?

A. I would be willing to guess several centimeters.

Ex. 2005, 137:12-138:1, 140:14-17

VENABLE LLP

Edwards's Fourth Embodiment:



Ex. 1005, Fig. 4 (annotated)

Edwards (Ex. 1005): Edwards Treats the Bladder Neck Area

Petitioner's Belated Reply Theory Relies on the *Result* of Edwards's Treatment Not the *Treatment* (and Is Mere Attorney Argument)

Remodeling both the anterior wall and posterior wall provide circumferential tightening by increasing support for the bladder outlet, as well as the proximal and mid-urethra.

Ex. 1005, 13:14-19

Dr. Poulos - Unrebutted Evidence Establishes that Edwards Does Not Describe the Treatment Area

Q. On what basis do you disagree with the Edwards patent?

A. Well, it's for modeling of the anterior wall, treats incontinence, targeting bladder outlet hypermobility, by providing increasing support for the bladder outlet. And it describes treating at the bladder neck, which may provide support at different parts of the vagina.

Ex. 1032, 141:13-23

Mosher (Ex. 1006): Mosher Treats the Bladder Neck Area

Petitioner's Own Expert's Testimony Rebuts Petitioner's Reliance on Mosher

Mosher:

To avoid injury to nerves in the bladder neck region while providing sufficient treatment volume along the endopelvic fascia, it may be advantageous to distribute the treatment volume along the patient's lateral orientation while limiting the length of treatment along the axis of the patient's urethra.

Ex. 1006, ¶[0074]

Petitioner's Expert (Dr. Berenholz):

Q. Does it surround the bladder neck, the endopelvic fascia?

A. Yes. It's in that area, approximately.

Q. Why "approximately"? Why do you use that term?

A. That's about where it's located.

Okay. On the -- I guess like just below the bladder?

A. Yes. I don't see it listed here.

...

Q. It's kind of like a hammock for the bladder?

A. That's a fair description.

Ex. 2005, 79:24-81:7

Mosher (Ex. 1006): Mosher's Treatment Dimensions Do Not Suggest a Treatment Location

Mosher's Described Treatment Dimensions Define a Size, Not Any Location Relative to the Introitus

Mosher:

it may be advantageous to distribute the treatment volume along the patient's lateral orientation while limiting the length of treatment along the axis of the patient's urethra.... Such 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.

Ex. 1006, ¶[0074]

Dr. Poulos:

- “[A] POSA would not understand this disclosure to reference the [claimed] region....” Ex. 2001, ¶106.
- “A POSA would understand that the primary structures targeted to treat SUI, as in ... Mosher, are the bladder neck and supportive tissues, which are located at the proximal end of the urethra.” *Id.* ¶91.

No Reference Teaches “Tightening the Introitus” (Claim 26)

Petitioner’s Arguments Fail for the Same Reasons as Claim 1

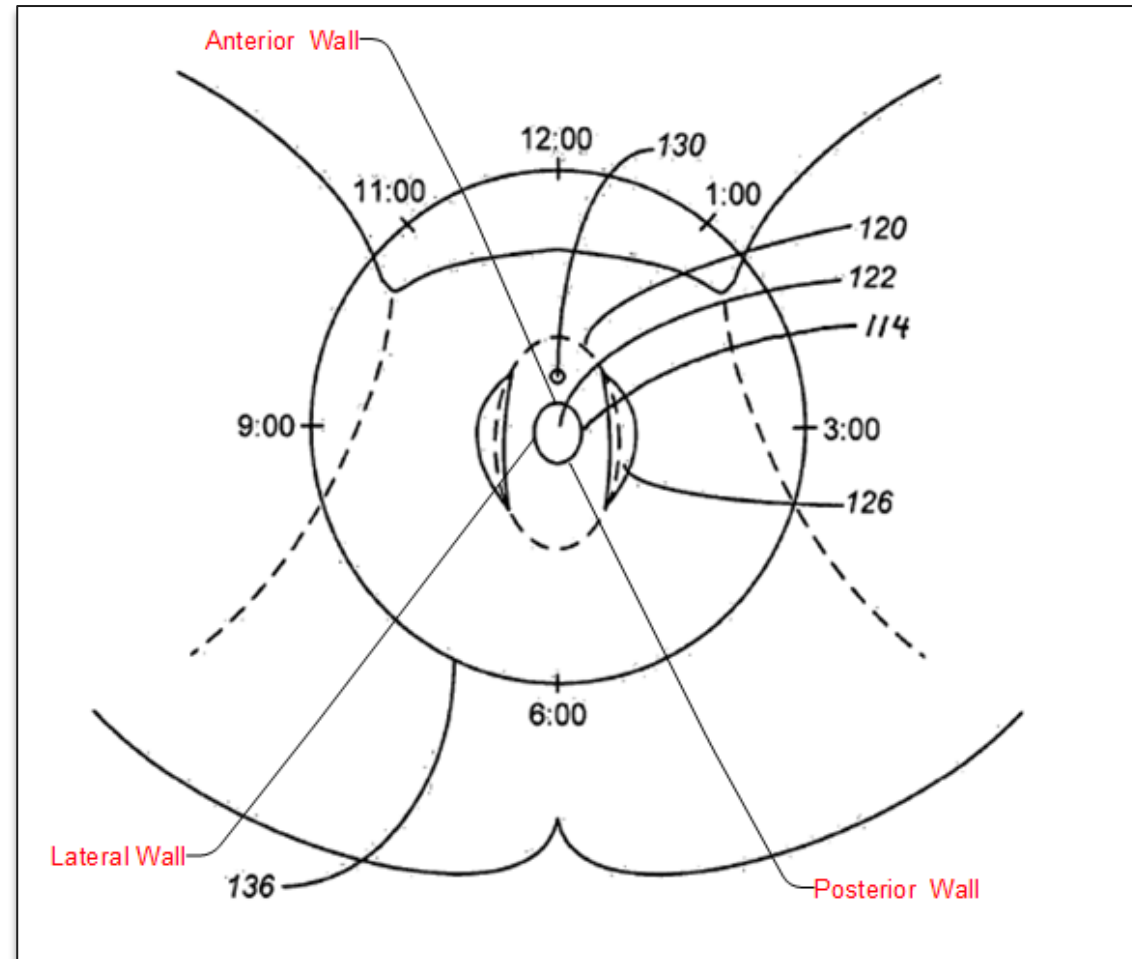
- Edwards’ speculum inhibits treating the introitus.

Ex. 2005, 132:25-133:16, 137:12-138:1, 140:14-17; Ex. 2001, ¶¶ 101-103

- Petitioner fails to explain how a POSA would modify Edwards.

Ground 1
No Reference Teaches Heating
Circumferentially Around the Vaginal Wall
From 1 O'clock to 11 O'clock (Claim 35)

Claim 35: No Reference Suggests Treatment of Lateral Walls



Ex. 1001, Fig. 7 (annotated)

Edwards (Ex. 1005): Edwards Does Not Disclose Heating Circumferentially

The Petition Relied on Edwards's Disclosure of Treating the Anterior and/or the Posterior Walls

- Petitioner relies on Edwards's fourth embodiment. Pet., 26.
- Edwards's fourth embodiment delivers RF energy “to the anterior and/or posterior regions of the vaginal wall.” *Id.* (citing Ex. 1005, 13:12-23).
 - Anterior wall is outside of the claimed treatment area. *See* Ex. 2001, ¶¶72, 113.
 - Posterior wall treatment provides a discrete point treatment, not circumferential treatment. *Id.*

Edwards (Ex. 1005): Edwards Does Not Disclose Heating Circumferentially

Edwards's Anterior or Posterior Treatment Is Not Circumferential

- Reply focuses on Edwards's *result* not Edwards's *treatment*.
 - “Remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening.” Reply, 17-18.
- “Nothing in Edwards suggests the speculum being rotated or moved once engaged in place.” Ex. 2005, ¶114.
- Edwards’ “series of lesions” extend longitudinally, not circumferentially, such that there is only one treatment point along the 300-degree arc. *Id.*, ¶116.
- Mosher fails to remedy Edwards deficiencies. *Id.*, ¶¶118-21.

Claim 35: Petitioner Fails to Dispute Key Issues

Petitioner's Reply Does Not Dispute/Address:

- Edwards' speculum treatment blade is not moved while inside patient.
- Edwards' "series of lesions" extend longitudinally, not circumferentially.
- Patent Owner's arguments that Mosher fails to remedy the deficiencies of Edwards.

Ground 1
**No Reference Teaches Heating the
External Treatment Areas (Claims 43 and 51)**

The Petition Fails to Articulate How the References Render the Claimed Treatment Area Obvious

- Petition's only recitations of "Hart's line" are quoting the '511 Patent claims and specification. Pet., 40.
- Petition does not dispute that the references teach treating at the bladder neck and associated structures rather than external structures. *Id.*
- Petition improperly focuses on what a POSA "would have been *able* to do" rather than what a POSA "would have been *motivated* to do." *Polaris Indus. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1068 (Fed. Cir. 2018) (emphasis added).

Claims 43 and 51: Petitioner's Reliance on Surgical Techniques Falls Short

Dr. Poulos's Purported Concessions that Treatment of the Labia for Cosmetic Reasons Was Known Are Not Persuasive

Dr. Poulos's Purported Concession

Q. And can you tell me what a labioplasty is?

A. It is surgical procedure to change the shape and/or size of the labia.

...

Q. And how long have you been performing labioplasties?

A. Since my residency, which ended in 1992.

Ex. 1032, 23:16-24:10

'511 Patent Specification

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.

Ex. 1001, 2:9-16

Claims 43 and 51: Petitioner's Reliance on Surgical Techniques Falls Short

- Dr. Poulos's purported concession merely agreed that clinicians were performing laser vaginal rejuvenation.
- But Dr. Poulos stated:

I cannot agree that these [LVR] technologies were well known in the field of urogynecology without knowing which technologies.

Ex. 1032, 89:23-25

- The laser vaginal rejuvenation treatment was kept secret.

Ground 1
**No Reference Teaches Remodeling
the Target Tissue (All Claims)**

No Reference Teaches Remodeling the Target Tissue

- Under the proper constructions,
 - Target tissue is the “tissue immediately beneath the mucosal epithelium of genital tissues, exclusive of deeper tissue, such as endopelvic fascia.” Pet., 14.
 - Remodeling means “the result of raising the temperature of target tissue ... without substantially affecting the epithelium” Pet., 17.
- Edwards ablates and creates lesions in the target tissue. Ex. 1005, 2:22-27, 13:50-53; Ex. 1032, 149:1-3, 149:25-150:3.
- Mosher and Ingle cool the target tissue and remodel the endopelvic fascia. Ex. 1006, ¶[0058]; Ex. 1007, 2:59-61, 2:63-67, 3:11-35.

Edwards (Ex. 1005): Edwards Substantially Affects the Epithelium (Features 1.2, 35.2, 43.2, 51.2)

Edwards's Treatment Is Specifically “Performed to Create . . . Lesions”

A method 900 is performed to create a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both.

Ex. 1005, 13:14-16

Edwards's Disclosure is Consistent with Tissue Damage to the Epithelium

Accordingly, it would be advantageous to provide a method and system for treatment of female urogenital disorders that is curative, easy to learn, requires only local or regional anesthesia, does not induce side effects and is not subject to drawbacks of the known art.

Ex. 1005, 2:22-27

Edwards (Ex. 1005): Edwards Creates *Ablative* Lesions (Features 1.2, 35.2, 43.2, 51.2)

The Unrebutted Evidence Establishes That a POSA Would Understand Edwards's Treatment Is Ablative

Dr. Poulos:

Q. Okay. But Edwards does not say that the lesions are ablative; is that correct?

...

A. No, the description indicates that they're ablative. I don't know if it describes it as being ablative.

...

Q. And so it's your position that just based on looking at Figure 4, that the lesions that are created would be ablative; is that correct?

A. Well, by looking at Figure 4, and I believe, as we talked about earlier, the smaller electrodes are going to create more concentrated heat at that position.

Ex. 1032, 148:21-149:3, 149:25-150:3

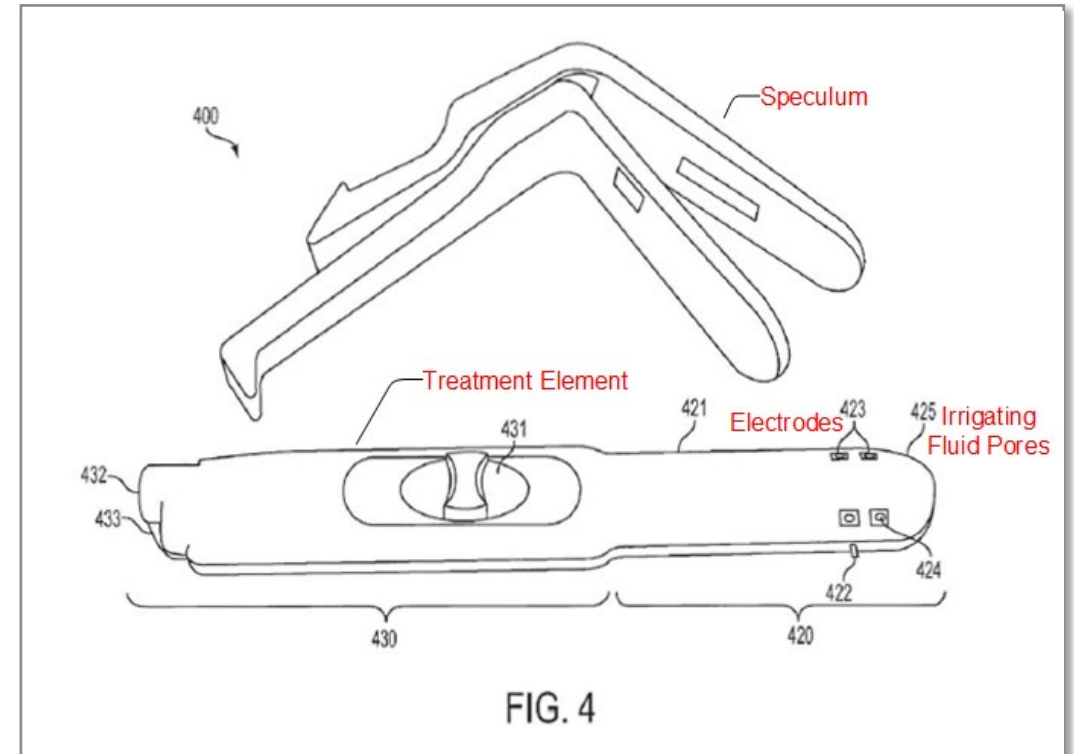
Edwards (Ex. 1005): Edwards Creates *Ablative* Lesions (Features 1.2, 35.2, 43.2, 51.2)

Edwards's “Cooling” Fluid Protects Non-Target Areas and Edwards Does Not Otherwise Provide for Protecting the Epithelium

Dr. Poulos:

In fact, Edwards confirms that its cooling fluid “prevents collateral thermal damage to the urethral wall and associated structures,” (EX1005, 9:42-48)—thus confirming that Edwards causes damage to the contacted tissue and that the cooling fluid is for protecting non-target tissue.

Ex. 2001, ¶142



Ex. 1005, Fig. 4 (annotated)

Edwards (Ex. 1005): Edwards Creates “Thermal Injury” (Features 1.2, 35.2, 43.2, 51.2)

No Dispute That Edwards’s Treatment Creates “Thermal Injury”

Petitioner’s Expert (Dr. Berenholz):

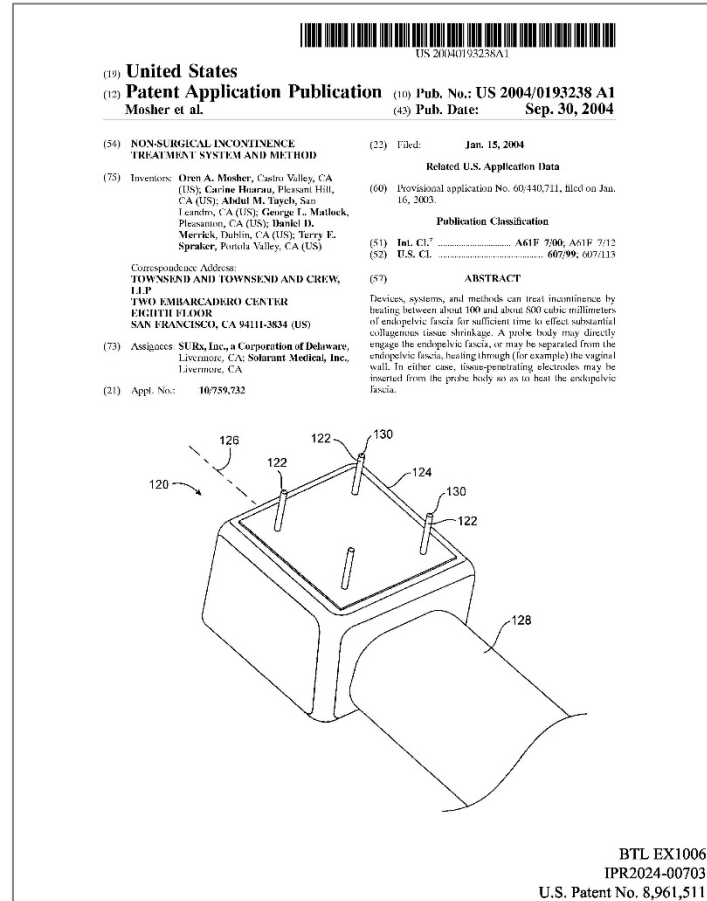
Q. A lesion in the vagina, what is happening [on] a cellular level?

...

A. You're going to get thermal injury of some kind. Cell walls may be disrupted. You can have cellular breakdown.

Ex. 2005, 103:7-12

Mosher (Ex. 1006): Mosher Heats Deeper Tissue Than the Target Tissue (Features 1.2, 35.2, 43.2, 51.2)



Ex. 1006

Mosher's Disclosure Is Directed to Heating and Remodeling the Endopelvic Fascia

Devices, Systems, and methods can treat incontinence by heating between about 100 and about 800 cubic millimeters of endopelvic fascia for sufficient time to effect substantial collagenous tissue shrinkage. A probe body may directly engage the endopelvic fascia, or may be separated from the endopelvic fascia, heating through (for example) the vaginal wall. In either case, tissue-penetrating electrodes may be inserted from the probe body so as to heat the endopelvic fascia.

Ex. 1006, Abstract

In Some embodiments, a probe body may directly engage the endopelvic fascia, such as by introducing an endoscopic probe into the body adjacent the endopelvic fascia, or by Surgically displacing a flap from the vaginal wall. Alternatively, the probe body may be separated from the endopelvic fascia, with heating provided through (for example) the vaginal wall. In either case, tissue-penetrating electrodes may be used to heat the endopelvic fascia.

Ex. 1006, ¶[0009]

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Mosher (Ex. 1006): Mosher Does Not Teach Remodeling the Target Tissue (Features 1.2, 35.2, 43.2, 51.2)

Mosher's Laundry List of Tissues Does Not Teach “remodeling . . . tissue immediately beneath the mucosal epithelium”

- Mosher provides no description of how treatment would be applied to other structures. Ex. 2001, ¶¶86, 148.
- The laundry list includes male anatomical structures. Ex. 2001, ¶¶86, 148; Ex. 1006, ¶[0048].

Mosher (Ex. 1006): Mosher Cools the Target Tissue (Features 1.2, 35.2, 43.2, 51.2)

Mosher's Specification Describes Treating Deeper Fascia While Cooling the '511 Patent's Target Tissue

FIGS. 6 and 6A illustrate alternative cooled electrode Vaginal probes for indirect treatment of tissue to inhibit incontinence through an intervening or intermediate tissue, which may comprise a Spared Zone or Safety Zone where tissue necrosis is inhibited. In these embodiments, a vaginal probe body 54 includes a plurality of electrodes 56 which are cooled by fluid conduits 58. The fluid conduits cool the intervening or intermediate tissue between probe body 54 and the endopelvic fascia EF, such as the vaginal wall VW as seen in FIG. 6. The probe body between electrodes 56 also cools the intervening tissue. Once the intervening tissue of the vaginal wall VW (and optionally, the urethra, bladder neck, and bladder) are cooled sufficiently, RF current is transmitted between the electrodes of the probe body to heat the endopelvic fascia.

Ex. 1006, ¶[0058]

Ingle (Ex. 1007): Ingle Does Not Teach Remodeling the Target Tissue (Features 1.2, 35.2, 43.2, 51.2)

Ingle's Disclosure Is Directed to Heating and Remodeling the Endopelvic Fascia

Instead, the present invention directs energy to a patient's own support tissues. This energy heats fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues. The energy will preferably be applied through a large, cooled electrode having a substantially flat electrode surface. Such a cooled plate electrode is capable of directing electrical energy through an intermediate tissue and into fascia, while the cooled electrode surface prevents injury to the intermediate tissue.

Ex. 1007, 2:51-3:10

The probe comprises an electrode with an electrode surface which is engagable against the intermediate tissue. The electrode surface is substantially flat, and a cooling system is coupled to the electrode. The cooling system allows the electrode surface to cool the engaged intermediate tissue while an electrical current flux from the electrode surface therapeutically heats the target tissue.

Ex. 1007, 3:11-35

Ingle (Ex. 1007): Ingle Does Not Teach Remodeling the Target Tissue (Features 1.2, 35.2, 43.2, 51.2)

Ingle's Disclosure of "Other Collagenated" Tissues Does Not Cure This Deficiency

- Ingle defines "collagenated tissue [] as fascia, ligament, or the like." Ex. 1007, 11:8-11.
- Ingle explicitly differentiates the target tissue from the intermediate tissue. Ex. 1007, 7:16-21, 15:19-25.

The Petition Fails for All Claims

- **Ground 1: Edwards, Mosher, and Ingle**
 - No reference teaches treating *from the introitus* to 1-3.5 cm in from the introitus (claim 1).
 - No reference teaches heating *circumferentially* (claim 35).
 - No reference teaches treating *external* tissue (claims 43 and 51).
 - No reference teaches treating remodeling the *target tissue* (all claims).
- **Ground 2: Edwards, Mosher, Ingle, and Ollivier**
 - Ollivier cannot cure any of the deficiencies.
 - Ollivier is not enabling.
 - Petitioner has not established Ollivier is a qualifying printed publication.
 - Ollivier does not teach heating the claimed regions.

Ground 2

Ollivier Is Not an Enabling Reference

Ollivier (Ex. 1008) Does Not Enable the Treatments of Claims 43 and 51

Ollivier Contains No Technical Detail

“I think this is a way of preying on vulnerable women,” says Dr. Linda Brubaker, fellowship director of Female Pelvic Medicine & Reconstructive Surgery at Loyola University Medical Center. “I reconstruct vaginas all the time. I agree that the field of women's sexual functioning is a poorly studied area. But I don't buy any of what Matlock is saying. There are standard pre- and post-operative intervention tests and tools that could be applied here to substantiate his claims. Curious that Matlock has not applied any of them to his own work, nor published any scientific material relating to his work, nor subjected anything to peer review. The longer this is untested, the better for him.”

Ex. 1008, 2

Ollivier (Ex. 1008) Does Not Enable the Treatments of Claims 43 and 51

The Vague Report of LVR Treatments Cannot Enable the Claimed Treatments

- Dr. Matlock kept the alluded to technique confidential. Ex. 2005, 162:3-6; Ex. 2001, ¶164.
- Both experts testified it was protected by an NDA and substantial fee. Ex. 2001, ¶164; Ex. 2005, 162:23-163:4.

Ground 2
Ollivier Is Not a Qualifying Printed Publication

Ollivier (Ex. 1008) Was Not Made Sufficiently Accessible to the Public Interested in the Art

Petitioner's Theory on Accessibility Cannot Be Reconciled With Its Own Expert's Testimony

Petitioner's Argument In Petition:

Ollivier was publicly accessible on Salon.com at least by January 24, 2001, EX1008; EX1031, 1-2, 7-9, because interested persons would have known of or been able to locate Salon.com, EX1023 (2.6 million unique visitors in December 2000); EX1031, 1-2, 4-6, and would have been able to locate Ollivier on Salon.com using, e.g., Salon.com's search functionality, EX1029, EX1030.

Pet., 12-13

Petitioner's Expert (Dr. Berenholz):

Q. Are you -- are you aware of the Salon.com website?

A. Not at all.

Q. Not at all?

A. No.

Q. You've never visited the Salon.com website?

A. No. I'm happily married. That was an attempt at humor. Nothing else.

...

Q. Okay. Are you aware of any other doctors that read Salon.com?

A. I don't know of any, no.

Ex. 2005, 158:5-12, 158:25-159:2

Ollivier (Ex. 1008) Was Not Made Sufficiently Accessible to the Public Interested in the Art

Technical Accessibility via the *Wayback Machine* Is Insufficient

- Petitioner provides no evidence Ollivier was indexed.
- Petitioner provides no evidence that a POSA would have been familiar with Salon.com.
- Petitioner has not shown Ollivier was sufficiently accessible the public interested in the art.

Ground 2

**Ollivier Does Not Teach or Suggest Treating the
Claimed Regions**

Ollivier (Ex. 1008) Does Not Teach the Treatment Area of Claims 43 and 51

Petition's Cursory Analysis Fails to Support Petitioner's Theory (Pet., 66-67)

- Ollivier does not suggest the specific treatment claimed.
 - Ollivier makes vague reference to *invasive* surgical techniques where the labia are “trim[med] back,” but provides no details on the actual treatment. Ex. 1008, 1.
 - Ollivier does not suggest treating the area from the introitus to Hart's line (claim 43) or mucosal surface of the labia minora (claim 51).

Ollivier (Ex. 1008) Does Not Teach Heating or Remodeling the Treatment Area of Claims 43 and 51

- Petitioner's expert admits that Ollivier references treatments that use lasers to cut, while RF treatments do not.

Petitioner's Expert (Dr. Berenholz):

A. The laser is a fiber that transmits very high thermal energy resulting in tissue both being cut, shrunk, and ablating at the same time. It's a cutting tool that does all three things.

...

Q. And when you do that laser vaginal rejuvenation with an RF device, are you cutting coagulating, and ablating like you would with a ... laser?

A. No.

Ex. 2005, 31:16-21

The Objective Indicia of Nonobviousness

InMode Established Nexus

InMode's Patent Owner Response Established a Nexus

- InMode established that the Sekeguchi and Millheiser studies are “reasonably commensurate with the scope of the claims.” *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011); *see* Pet., 69-70.
 - The treatments were described as “nonablative.” Pet., 69-70; Ex. 2018, 3; Ex. 2017, 779, 780; Ex. 2001, ¶180.
 - The treatments extended from introitus (“hymenal ring”) to about 1.6 cm from the introitus. Ex. 2018, 3; Ex. 2017, 777; Ex. 2001, ¶¶179-80.
 - The treatments involved treating “the entire area from the 1:00 o’clock to 11:00 o’clock position ... with RF energy pulses.” Ex. 2018, 3; Ex. 2017, 777; Ex. 2001, ¶180.

InMode Is Entitled to a Presumption of Nexus

InMode's Patent Owner Response Established a Nexus

- Petitioner's sole argument against nexus relies on the studies' description of cryogenic cooling. Reply, 24-25.
- Cooling allows for heating and remodeling without substantially affecting the epithelium as required by the claims. Ex. 2001, ¶141.
- In fact, cooling is recited in dependent claims 9-16 and 39.



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Extra Slides

Petitioner Has Not Sufficiently Shown a Motivation to Combine

InMode explained in detail why a POSA would not have been motivated to combine Ollivier with the SUI references

To those considering LVR or DLV -- two procedures that are not without their risks, among them hemorrhage, infection, loss of sensitivity, lingering pain from nerve damage - - Brubaker says simply: "Run away, run away, run away."

Ex. 1008, 2

Vaginal tightening has been done for decades to help women with extremely compromised vaginal integrity. For the even fewer women out there with true genital "deformities" -- extraordinarily long or protruding labia, for example, or excessive vaginal flesh - - surgery has also been an option for years.

Ex. 1008, 3

"I think this is a way of preying on vulnerable women," says Dr. Linda Brubaker, fellowship director of Female Pelvic Medicine & Reconstructive Surgery at Loyola University Medical Center. "I reconstruct vaginas all the time. I agree that the field of women's sexual functioning is a poorly studied area. But I don't buy any of what Matlock is saying. There are standard pre- and post-operative intervention tests and tools that could be applied here to substantiate his claims. Curious that Matlock has not applied any of them to his own work, nor published any scientific material relating to his work, nor subjected anything to peer review. The longer this is untested, the better for him."

Ex. 1008, 2

Petitioner Has Not Sufficiently Shown a Motivation to Combine

InMode explained in detail why a POSA would not have been motivated to combine Ollivier with the SUI references

In a step 904, 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.

Ex. 1005, 13:38-42

25 In another aspect, the present invention provides a method for selectively shrinking a target tissue. The method comprises clamping a target tissue between a plurality of electrode surfaces. The clamped target tissue is heated by transmitting a current flux between the electrode surfaces. At least one of the electrode surfaces is cooled to limit heating of intermediate tissue disposed between the at least one electrode and the target tissue.

Ex. 1007, 8:24-27

[0058] FIGS. 6 and 6A illustrate alternative cooled electrode vaginal probes for indirect treatment of tissue to inhibit incontinence through an intervening or intermediate tissue, which may comprise a spared zone or safety zone where tissue necrosis is inhibited. In these embodiments, a vaginal probe body 54 includes a plurality of electrodes 56 which are cooled by fluid conduits 58. The fluid conduits cool the ...

causing surface lesions within the vagina. Feedback on the pre-cooling and heating temperatures may be provided by needle-mounted temperature sensors 62 which may option-

Ex. 1006, ¶[0058]