
BTL Industries, Inc. v. InMode Ltd.

IPR2024-00703 (U.S. Patent No. 8,961,511)

Petitioner's Demonstratives

July 8, 2025



Agenda

- Instituted Grounds and Independent Claims
- Level of Ordinary Skill & State of the Art
- Scope of Claims & Prior Art
- Ground 1: Edwards, Mosher, and Ingle
- Ground 2: Edwards, Mosher, Ingle, and Ollivier
- Secondary Considerations



Instituted Grounds and Independent Claims

Instituted Grounds

IPR2024-00703 ('511 Patent)		
Claims Challenged	Basis	Applied References
1-58	35 U.S.C. § 103(a)	Edwards (EX1005), Mosher (EX1006), and Ingle (EX1007)
43-58	35 U.S.C. § 103(a)	Edwards, Mosher, Ingle, and Ollivier (EX1011)

Independent Claim 1

IPR2024-00703 ('511 Patent) – Claim 1

[1.P] 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:

[1.1] heating the target tissue, and

[1.2] remodeling the therapeutic zone of target tissue,

[1.3] 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.

Independent Claim 35

IPR2024-00703 ('511 Patent) – Claim 35

[35.P] 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:

[35.1] heating the target tissue, and

[35.2] remodeling the therapeutic zone of target tissue,

[35.3] 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.

Independent Claim 43

IPR2024-00703 ('511 Patent) – Claim 43

[43.P] 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:

[43.1] heating the target tissue, and

[43.2] remodeling the therapeutic zone of target tissue,

[43.3] wherein the heating includes heating a portion radiating outward from the introitus to Hart's line.

Independent Claim 51

IPR2024-00703 ('511 Patent) – Claim 51

[51.P] 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:

[51.1] heating the target tissue, and

[51.2] remodeling the therapeutic zone of target tissue,

[51.3] wherein the heating includes heating a mucosal surface of the labia minora.



Level of Ordinary Skill & State of the Art

Person of Ordinary Skill in the Art of the '511 Patent

Dr. Berenholz:

58. A person of ordinary skill in the art (POSA) at the time of the '511 patent was filed would have been a medical doctor, and would have had at least three years of experience in the non-surgical treatment of urogynecological conditions and/or the non-surgical cosmetic treatment of female genital tissues. A POSA could be a physician practicing in the specialties of urogynecology, gynecology, or similar, or a general practitioner that provides such tissue treatment as part of their practice.

EX1003, Berenholz Decl., ¶ 58

Dr. Poulos:

37. I understand that in the ThermiGen IPR, the panel adopted a different definition of a POSA that I believe is more appropriate. In the ThermiGen IPR, the panel applied the following definition of a POSA:

one of ordinary skill in the art 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.

EX1009, 8-9.

EX2001, Poulos Decl., ¶ 37

Known that Vaginal Loosening Causes Medical & Sexual Issues

'511 Patent, Background:

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

EX1001, 1:62-2:9

Known that Loose Vagina & Introitus May Decrease Sexual Pleasure

Dr. Poulos:

15 Q And so it was known to a person of skill
16 in the art that a loose vagina introitus may lead
17 to decreased sexual pleasure, correct?

18 MR. HECTOR: Objection. Foundation.

19 A Correct.

EX1032, Poulos Dep. Tr., 103:15-19.

Known to Tighten Tissue Via Collagen Denaturation

'511 Patent, Background:

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. Pat. No. 5,919, 219 to Knowlton for “Method for Controlled Contraction of Collagen Tissue Using RF Energy” and U.S. Pat. No. 5,755, 753 to Knowlton for “Method for Controlled Contraction of Collagen Tissue”; and U.S. Pat. No. 5,143,063 to Fellner for “Method of Removing Adipose Tissue”.

EX1001, 1:35-46.

Experts Agree: Known that Heating Collagen will Tighten Tissue

Dr. Berenholz:

39. The background of the '511 patent describes the nature and role of collagen as follows, which is consistent with the understanding of a POSA in February 2006:

Collagen molecules are produced by cells resident in 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 the direction parallel to an axis of collagen fibers.

EX1001, 1:22–34. Collagen is mostly found in connective tissue throughout the body, including the tissues of the female urogenital system, and specifically in the tissues underlying the epithelia of the vagina, introitus, and labia minora.

Dr. Poulos:

8 Q Okay. Do you agree -- do you agree with
9 Dr. Berenholz in paragraph 39 of his declaration?

10 MR. HECTOR: Objection. Foundation.

11 A Yes.

EX1032, Poulos Dep. Tr., 86:8-11.

Experts Agree: Known that Heating Collagen will Tighten Tissue

Dr. Berenholz:

40. By the time of the invention in February 2006¹, it was well-known that the triple helix structure of collagen chains are held together by hydrogen bonds. *See* EX1018, 180; EX1016, 180. These molecules then aggregate and organize themselves into fibers caused by intermolecular cross-links, which imparts tensile strength and the elastic properties associated with collagen. *See* EX1018, 180. However, when collagen fibers are heated, the intramolecular hydrogen bonds are broken and the long triple-helical strands unwind—a process known as denaturation—to produce a “gel” of randomly oriented molecules, essentially shortening the fibers. *See* EX1018, 180; EX1016, 180. Because the heat-stable, intermolecular cross-links are maintained, the shortening of the fibers causes an increase in the elastic properties of the collagen. *See* EX1018, 180. This causes an immediately noticeable tightening effect in the tissue. *See* EX1016, 180; EX1021, 639.

EX1003, Berenholz Decl., ¶40.

Dr. Poulos:

12	Q Do you agree with Dr. Berenholz in
13	paragraph 40 of his declaration?
14	A Yes.

EX1032, Poulos Dep. Tr., 86:12-14.

Experts Agree: Known To Use Radiant Energy to Heat and Tighten Collagen-Rich Tissue

Dr. Berenholz:

44. The use of radiant energy to treat and tighten collagen-rich tissue generally was well known by February 2006. *See* EX1018, 180; EX1016, 180–181; EX1021, 638–639. As discussed above, radiant energy was known to heat the collagen within the tissue, causing denaturation and remodeling, and resulting in the tightening of the tissue. Two prevalent methods at the time involved the use of light and radiofrequency (“RF”)-based technologies as the source of the radiant energy. *See* EX1018, 180; EX1016, 180; EX1021, 638–639.

EX1003, Berenholz Decl., ¶44.

Dr. Poulos:

8 Q Do you agree with Dr. Berenholz in
9 paragraph 44 of his declaration?
10 MR. HECTOR: Objection. Foundation.
11 A Yes.

EX1032, Poulos Dep. Tr., 88:8-11.

Experts Agree: Devices Employing RF Energy Were Already in Use

Dr. Berenholz:

47. As an alternative to non-ablative light-based systems, devices employing RF energy were also in use at the time of the invention. *See* EX1018, 181; EX1016, 180–181. Using these devices, most of the heating occurs in the tissue beneath the electrode, to depths greater than those achieved with lasers and light sources. *See* EX1018, 182; EX1016, 180.

EX1003, Berenholz Decl., ¶47.

Dr. Poulos:

24 Q Do you agree with Dr. Berenholz in
25 paragraph 47 of his declaration?

1 MR. HECTOR: Objection. Foundation.

2 A Yes.

EX1032, Poulos Dep. Tr., 88:24-89:2.

Known that Tightening the Introitus May Enhance Sexual Pleasure

Dr. Poulos:

20 Q Is it fair to say that the person of skill
21 in the art would have understood that tightening a
22 vagina introitus may lead to enhanced sexual
23 pleasure?

24 MR. HECTOR: Objection. Foundation.

25 A **Yes.**

EX1032, Poulos Dep. Tr., 103:20-25.

Experts Agree: Known to Treat Introitus and Vulva for Cosmetic Purposes and to Improve Sexual Function

Dr. Berenholz:

49. By February 2006, the use of these technologies was also well known in the field of urogynecology. Based on a modification of a decades-old, traditional gynecological surgery for stress urinary incontinence, clinicians also performed Laser Vaginal Rejuvenation (“LVR”) to tighten vaginal support tissue and the outer third of the vagina, including the introitus, vulva, and the perineal body, both for cosmetic purposes and to improve sexual function. See EX1008, 0001. And even as early as November 2000, some clinicians began to feel that lasers have fallen out of favor and were turning to more sophisticated tools to replace lasers in these procedures. See EX1008, 0003. These more sophisticated tools would have included broad-spectrum light and RF-based technologies, as discussed above.

EX1003, Berenholz Decl., ¶49.

Dr. Poulos:

1 Q Do you agree that by February 2006, based
2 on the modification of a decades-old traditional
3 gynecological surgery for stress urinary
4 incontinence, clinicians also performed laser
5 vaginal rejuvenation to tighten vaginal support
6 tissue in the outer third of the vagina, including
7 the introitus, vulva, and the perineal body, both
8 for cosmetic purposes and to improve sexual
9 function?

10 MR. HECTOR: Objection. Foundation. The
11 document speaks for itself.

12 A Yes.

EX1032, Poulos Dep. Tr., 90:1-12.

Known to Treat Labia for Cosmetic and Medical Purposes

Dr. Poulos:

22 Q And what condition does a labioplasty

23 treat?

24 MR. HECTOR: Objection. Vague.

25 A It treats a number of conditions from pain

1 with certain activities, appearance. I've seen a

2 number of women that are involved in professions

3 where they need to wear very tight clothing, such

4 as gymnasts and ballerinas. And it also could

5 simply be a patient is uncomfortable with the

6 appearance of the labia. They may cause pain

7 during sex if they become enlarged.

EX1032, Poulos Dep. Tr., 23:22-24:7.



Scope of Claims & Prior Art

Dr. Poulos Admitted Her Claim Constructions Were Provided by InMode's Counsel

Dr. Poulos:

3 Q Okay. So were you provided the claim
4 constructions that are in your declaration?

5 MR. HECTOR: Objection. Vague.

6 A These claim constructions that you just
7 mentioned?

8 Q Yes. All of the claim constructions that
9 you have in Section 6 of your declaration,
10 starting on page 24.

11 A Yes.

12 Q They were provided to you by counsel?

13 A Yes.

EX1032, Poulos Dep. Tr., 57:3-13.

Claimed Methods Do Not Require Treatment Via a Particular Device

Dr. Poulos improperly read the '511 patent's disclosed device into the claims:

17 Q Claim 1 is just describing the method,
18 correct?
19 A I read it to be the method that would be
20 using the device described by the patent.

EX1032, Poulos Depo. Tr., 128:17-20.

Claimed Methods Do Not Require Treatment of Particular Medical Condition

Dr. Poulos:

22 Q Does claim 1 identify the condition that's
23 being treated?

24 MR. HECTOR: Option. Vague.

25 A Claim 1 does not mention a condition.

1 Q Does claim 35 indicate which condition is
2 being treated?

3 MR. HECTOR: Objection. Vague.

4 A Not specifically in this paragraph.

5 Q Does claim 43 indicate a condition that's
6 being treated?

7 MR. HECTOR: Objection. Vague.

8 A 43 does not mention a specific condition.

9 Q Does claim 51 indicate a condition that's
10 being treated?

11 MR. HECTOR: Objection. Vague.

12 A 51 does not mention a specific condition.

EX1032, Poulos Dep. Tr., 126:22-127:12.

Claimed Methods Do Not Prohibit Heating/Remodeling Tissues in Addition to Claimed “target tissue”

Dr. Poulos:

8 Does the '511 patent say that it's not
9 allowed to treat or heat the endopelvic fascia?
10 MR. HECTOR: Objection. Foundation.
11 Asked and answered.
12 A Again, it's intending to focus energy to
13 treat the depth of lamina propria and muscularis,
14 and I don't -- I did not see them saying it's
15 prohibited or forbidden to treat other regions.

EX1032, Poulos Dep. Tr., 111:8-15.

InMode's Sur-Reply at 5:

2. Petitioner is mistaken that InMode attempts to narrow the claim scope by construing “target tissue” (all claims) to prohibit treating other tissues in addition to the recited “target tissue”

There is no dispute that “target tissue” does not include deeper tissue, such as endopelvic fascia. Reply, 7; POR, 14-17. However, Petitioner misleadingly suggests InMode’s position is that the “target tissue” term “prohibit[s] heating or treating ... the endopelvic fascia.” Reply, 7. InMode’s position is not about prohibiting anything and is rather about what needs to be heated. Specifically, the intrinsic evidence establishes that the “heat[ed] target tissue” of the claims “lies

Claimed Methods Do Not Require “remodeling” or “heating” Without Substantially Affecting the Epithelium

Cooling is the only method disclosed in the specification for protecting the epithelium, BUT cooling is not required in the independent claims:

Dr. Poulos:

25 | Q So do you agree that a person skilled in
1 | the art would have understood that the '511 patent
2 | uses cooling to protect the epithelial surface
3 | from potentially damaging effects of excess heat?
4 | MR. HECTOR: Objection. Foundation.
5 | A Yes.

EX1032, Poulos Dep. Tr., 111:25-112:5.

16 | Q Okay. Just focusing on claim 1,
17 | independent claim 1, does claim 1 require cooling
18 | the epithelium?
19 | A Claim 1 does not mention cooling the
20 | tissue.
21 | Q Okay. Same question for claim 35?
22 | A 35 does not mention cooling the tissue.
23 | Q And when you say "the tissue," you mean
24 | the epithelium?
25 | A The epithelium.

EX1032, Poulos Dep. Tr., 124:16-125:13.

5 | Claim 43 does not require cooling the
6 | epithelium, correct?
7 | A Claim 43 does not mention cooling the
8 | epithelium.
9 | Q And claim 51 does not require cooling the
10 | epithelium, correct?
11 | MR. HECTOR: Objection. Form.
12 | A Claim 51 does not mention cooling the
13 | epithelium.

Prior Art is Not Limited to Treating Incontinence

Edwards

A fourth embodiment of the invention also involves using a radiofrequency generator. The difference between this embodiment and the other embodiments is that the RF energy is delivered to the anterior and posterior regions of the vaginal wall. This has the effect of tightening of vaginal walls so as to increase support of the bladder outlet, proximal and mid-urethra. Moreover, circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function.

EX1005, Edwards, 3:5-13.

FIG. 4 is a block diagram showing a fourth embodiment of the distal end of a system that can be used for vaginal remodeling.

EX1005, Edwards, 3:25-27.

urethra. Remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function. The method 900 is performed using sterile

EX1005, Edwards, 13:19-22.

Mosher

[0046] As the techniques of the present invention will be effective for controllably and repeatably enhancing the structural support of a wide variety of fascia and other collagenous tissues throughout the body, they will find applications in a wide variety of therapies. The most imme-

EX1006, Mosher, ¶46.

Ingle

The present invention generally relates to medical devices, methods, and systems. More specifically, the present invention provides techniques for selectively heating and shrinking tissues, particularly for the noninvasive treatment of urinary incontinence and hernias, for cosmetic surgery, and the like.

EX1007, Ingle, 1:19-24.



Ground 1: Edwards, Mosher, and Ingle

Edwards-Mosher-Ingle Teaches the Preamble

- Edwards teaches delivering RF energy to regions of the vaginal wall to tighten and remodel vaginal tissue to address medical issues and improve sexual function:

A fourth embodiment of the invention also involves using a radiofrequency generator. The difference between this embodiment and the other embodiments is that the RF energy is delivered to the anterior and posterior regions of the vaginal wall. This has the effect of tightening of vaginal walls so as to increase support of the bladder outlet, proximal and mid-urethra. Moreover, circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function.

EX1005, Edwards, 3:5-13.

FIG. 4 is a block diagram showing a fourth embodiment of the distal end of a system that can be used for vaginal remodeling.

EX1005, Edwards, 3:25-27.

urethra. Remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function. The method 900 is performed using sterile

EX1005, Edwards, 13:19-22.

Edwards-Mosher-Ingle Teaches the Preamble

- Mosher teaches treatment via RF energy to remodel “a variety of tissue structures,” expressly including “structures of the vagina” and “lamina propria”:

[0045] The present invention generally provides methods, devices, and systems which enhance the structural support provided by a body's tissues, particularly for treatment of incontinence. The techniques of the invention generally involve directing energy from a probe into collagenous tissues of the pelvic support system. The energy will often cause contraction of the collagenous tissue. In some embodiments, the formation of scar tissue and/or the healing process may cause structural stiffening of the tissue.

EX1006, Mosher, ¶45.

the pelvis. Hence, the treatment of the present invention may be directed at a variety of tissue structures defining the pelvic floor and/or diaphragm (including: anterior sacro-coccygeal ligament; arcus tendineus fasciae pelvis ATRP, the

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neck, initiating micturation); structures of the vagina (including: vagino-uterine fascia, lamina propria—the dense connective tissue layer just under the epithelium; pubo-

EX1006, Mosher, ¶48.

Edwards-Mosher-Ingle Teaches the Preamble

- Ingle teaches treatment “from within the vagina” where energy, e.g., RF energy, “heats fascia and other collagenated support tissues, causing them to contract”:

The present invention provides devices, methods, and systems for shrinking of collagenated tissues, particularly for treating urinary incontinence in a noninvasive manner. In contrast to prior art techniques, the present invention does not rely on implantation of balloons or other materials, nor does it rely on suturing, cutting, or other direct surgical modifications to the natural support tissues of the body. 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

EX1007, Ingle, 2:49-63.

The present invention optionally relies on inducing controlled shrinkage or contraction of a support tissue of the body, typically being a collagenated tissue such as fascia, ligament, or the like. For treatment of urinary incontinence, the tissue structure will be one that is responsible in some manner for control of urination, or for supporting a such a tissue. Exemplary tissue structures 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. Treatment of other conditions may be effected by selective shrinking of a wide variety of other tissues, including (but not limited to) the diaphragm, the abdominal wall, the breast supporting ligaments, the fascia and ligaments of the joints, the collagenated tissues of the skin, and the like. Related devices, methods, and system are also described in co-pending U.S. patent application Ser. No. 08/910,370, filed Aug. 13, 1997.

EX1007, Ingle, 11:8-24.

Edwards-Mosher-Ingle Teaches “heating the target tissue”

Edwards:

In a step 908, the energy port 432 is manipulated so as to cause delivery of RF energy to discrete areas of the vaginal wall.

In alternative embodiments, other forms of energy may be delivered, such as microwave, laser, ELF (extremely low frequency) and other therapeutic energies.

EX1005, Edwards, 13:54-59.

Ingle:

In a first aspect, the present invention provides a probe for therapeutically heating a target tissue of a patient body through an intermediate tissue. The probe comprises an

EX1007, Ingle, 3:11-13.

Heat is applied until the target zone is at or above a treatment temperature, typically resulting in a temperature distribution such as that illustrated in FIG. 3C. To minimize

EX1007, Ingle, 16:5-7.

Mosher:

between about 100 and about 800 cubic millimeters. These volumes of tissues can be heated for sufficient time to effect substantial collagenous tissue shrinkage, for example, by heating the volume to a temperature of about 70° C. or more for about 30 seconds or more. Alternative treatments may heat the volume to about 65° C. or more for about 100 seconds or more, or to about 75° C. or more for about 10 seconds or more. Such heating may induce necrosis, but the heating will often be limited to inhibit ablation so that the tissue, after healing, provides continence promoting support.

EX1006, Mosher, ¶9.

Edwards-Mosher-Ingle Teaches “heating the target tissue”

InMode’s Sur-Reply at 15:

B. Mosher’s and Ingle’s catch all phrases do not teach “heating the target tissue” (all claims)

None of Petitioner’s references disclose heating the “tissue immediately beneath the mucosal epithelium” (the lamina propria and muscularis). Instead,

Mosher:

the pelvis. Hence, the treatment of the present invention may be directed at a variety of tissue structures defining the pelvic floor and/or diaphragm (including: anterior sacro-coccygeal ligament; arcus tendineus fasciae pelvis ATRP, the

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neck, initiating micturation); structures of the vagina (including: vagino-uterine fascia, lamina propria—the dense connective tissue layer just under the epithelium; pubo-

EX1006, Mosher, ¶48.

'511 Patent Confirms “remodeling the therapeutic zone of target tissue” is Simply the Result of the Claimed “heating”

'511 Patent:

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.

EX1001, '511 patent, 4:14-22.

Edwards-Mosher-Ingle Teaches “remodeling the therapeutic zone of target tissue”

Edwards:

FIG. 9 is a process flow diagram showing a method for using a fourth embodiment for vaginal remodeling.

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

EX1005, Edwards, 13:12-23.

Mosher:

shrinkage, stiffening, and/or the like. RF heating will typically induce collagen shrinkage so as to provide physical elevation of the urethra by shrinkage of the endopelvic fascia. RF heating may also decrease the compliance of the endopelvic fascia to intra-abdominal pressures, providing increased stiffness through tissue remodeling resulting from the healing process. Within the first 24 hours of the heating

EX1006, Mosher, ¶66.

Ingle:

Tissue contraction results from controlled heating of the tissue by affecting the collagen molecules of the tissue. Contraction occurs as a result of heat-induced uncoiling and repositioning of the collagen β -pleated structure. By maintaining the times and temperatures set forth below, significant tissue contraction can be achieved without substantial collateral tissue damage.

EX1007, Ingle, 11:25-31.

Edwards-Mosher-Ingle Teaches “remodeling” Even Under InMode’s Impermissibly Narrow Construction

Each of Edwards, Mosher, and Ingle teaches cooling to protect the epithelial surface:

Edwards:

The irrigating fluid delivery pores 425 are also coupled to some of the plurality of lumens 440 and are disposed to deliver cooling liquids so as to minimize thermal damage.

EX1005, Edwards, 7:51-53.

Ingle:

The electrode surface will generally be sufficiently flat to direct the current flux through the cooled intermediate tissue and into the target tissue while the cooling system maintains the intermediate tissue at or below a maximum safe tissue temperature. To direct the current flux, heating may be

EX1007, Ingle, 3:21-25.

Mosher:

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. Advantageously, the pre-cooling can inhibit heating of the intervening tissue to a temperature causing surface lesions within the vagina. Feedback on the

EX1006, Mosher, ¶58.

Edwards-Mosher-Ingle Teaches “remodeling” Even Under InMode’s Impermissibly Narrow Construction

Mosher:

between about 100 and about 800 cubic millimeters. These volumes of tissues can be heated for sufficient time to effect substantial collagenous tissue shrinkage, for example, by heating the volume to a temperature of about 70° C. or more for about 30 seconds or more. Alternative treatments may heat the volume to about 65° C. or more for about 100 seconds or more, or to about 75° C. or more for about 10 seconds or more. Such heating may induce necrosis, but the heating will often be limited to inhibit ablation so that the tissue, after healing, provides continence promoting support.

EX1006, Mosher, ¶19.

Ingle:

Tissue contraction results from controlled heating of the tissue by affecting the collagen molecules of the tissue. Contraction occurs as a result of heat-induced uncoiling and repositioning of the collagen β -pleated structure. By maintaining the times and temperatures set forth below, significant tissue contraction can be achieved without substantial collateral tissue damage.

EX1007, Ingle, 11:25-31.

Edwards-Mosher-Ingle Teaches “remodeling” Even Under InMode’s Impermissibly Narrow Construction

Edwards’s 4th embodiment teaches “lesions” not “ablative lesions”:

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

EX1005, Edwards, 13:14-23.

Dr. Berenholz confirmed a “lesion” would not substantially affect the epithelium:

10		THE WITNESS: Well, a lesion would be a
11		disruption of tissue caused by thermal energy.
12		Q. BY MR. HECTOR: What's a disruption of tissue?
13		A. It would be an area of -- a treatment area
14		that's been treated and becomes, let's say, erythematous
15		due to heat.

EX2005, Berenholz Dep. Tr., 102:10-15.



Claimed Treatment Locations

A POSA Would Have Exercised Professional Judgment to Determine the Optimal Treatment Area Based on Desired Outcome

Dr. Berenholz:

91. The independent claims all recite a similar method for remodeling tissue of the vulva, introitus, or vagina. Using radiant energy such as RF to remodel tissues generally, and more particularly to remodel tissue in the vaginal region, was well-known in the art before the '511 patent. *See* Section VI.C. Further, a POSA would have understood that the tissues in the vaginal region, *i.e.*, vulva, introitus, and vagina tissue, would have similar responses to treatment with radiant energy such as RF, namely remodeling of the tissue by, for example,

shrinkage of collagen. *See* Section VI.B. With respect to non-invasive heat-induced remodeling, the vaginal region is not a large area, and a POSA would recognize that there are limited areas of treatment to choose from within that region. It would have been within the skill of a POSA to determine the optimal area of treatment, *e.g.*, portions of the vulva, the introitus, and/or vaginal tissue, for a particular patient based on the desired outcome (*e.g.*, treating incontinence, improving sexual function, etc.). *See* EX1005, 13:40–42. As I discuss in more detail below, the combination of Edwards, Mosher, and Ingle teaches the method of treatment and each of the treatment areas recited in the independent claims.

EX1003, Berenholz Decl., ¶91.

Edwards-Mosher-Ingle Teaches Claim Element [1.3]

“a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus”

Edwards:

both. Remodeling of the anterior wall treats incontinence based on bladder outlet hypermobility by increasing support for the bladder outlet, as well as the proximal and mid-urethra. Remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function. The method 900 is performed using sterile

EX1005, Edwards, 13:19-22.

Mosher:

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. Treatment depths will preferably be at least about 2 mm, optionally being as much as 6 mm.

EX1006, Mosher, ¶74.

Dr. Berenholz:

122. A POSA, based on Edwards’s teachings of improvement of sexual function, would have understood Edwards’s teachings to include treatment near the opening of the vagina. Specifically, Edwards teaches “circumferential tightening of the vaginal wall” to “provide physical and physiological improvement in the area of sexual function.” EX1005, 3:11–13. A POSA would have understood that in order to achieve these improvements of sexual function, the treatment area must include the region near the opening of the vagina. *See, e.g.*, EX1008, 0001.

EX1003, ¶122.

vaginal axis largely runs parallel to the urethral axis. *See* EX1007, FIG. 6. A POSA would have thus understood Mosher’s teaching of a 1.5 cm treatment length as a teaching to focus treatment on the area around the opening of the vagina. Therefore, a POSA would have been motivated to focus heating on the portion of the vagina extending from the introitus inwardly to a location of about 1.5 cm in order to avoid treatment too close to the bladder neck and other nerves. EX1003, ¶124.

Edwards-Mosher-Ingle Teaches Claim Element [1.3]

Edwards:

both. Remodeling of the anterior wall treats incontinence based on bladder outlet hypermobility by increasing support for the bladder outlet, as well as the proximal and mid-urethra. Remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function. The method 900 is performed using sterile technique.

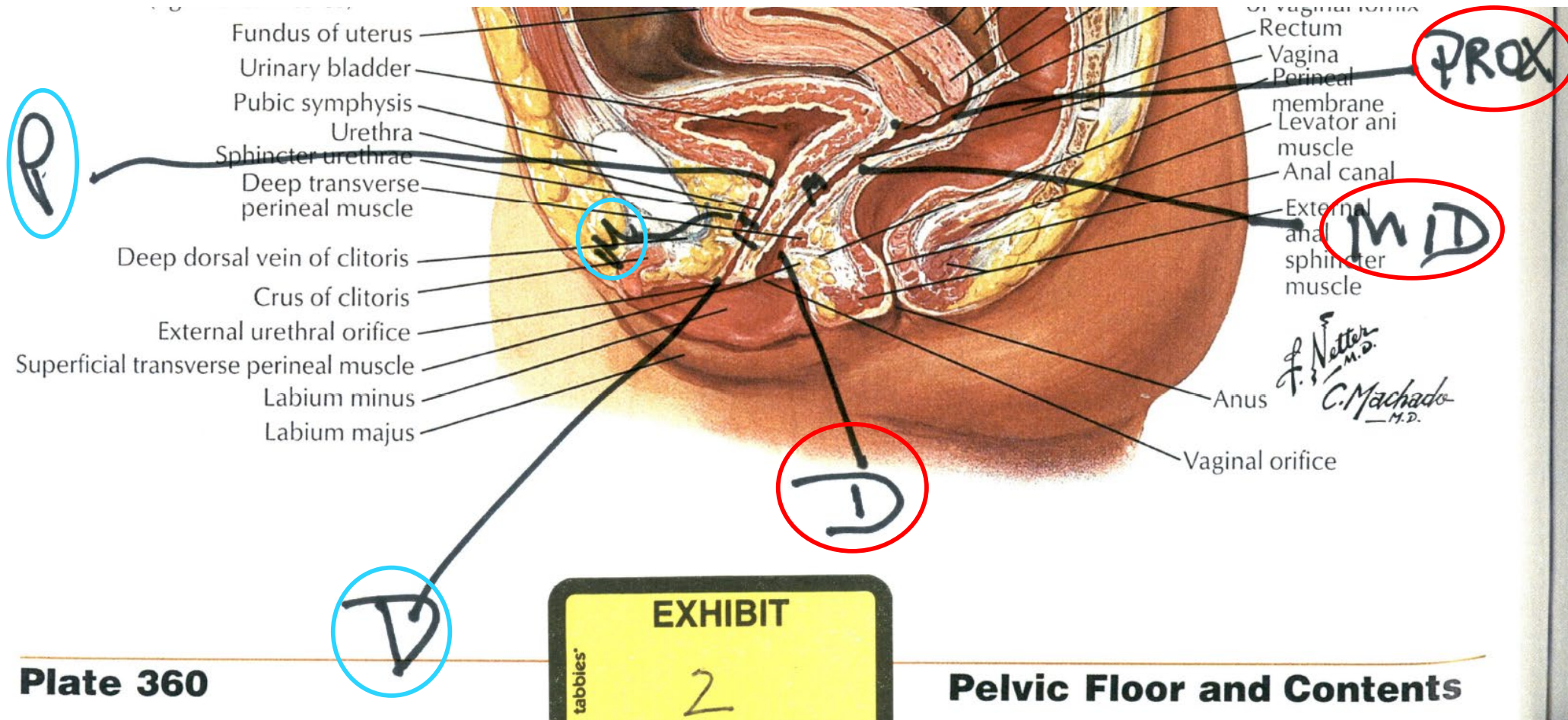
EX1005, Edwards, 13:14-23.

Mosher:

axial location indicator of the urethral guide. Preferably, the location of the treatment volume of endopelvic fascia will be disposed along a length of the urethra between the bladder neck and the external meatus so as to avoid injuring nerves (which might otherwise have deleterious impacts on urge incontinence and the like) while still enhancing the structural support sufficiently to inhibit leakage.

EX1006, Mosher, ¶54.

Edwards-Mosher-Ingle Teaches Claim Element [1.3]



EX1032, Polous Dep. Tr., Exhibit 2.

Edwards-Mosher-Ingle Teaches Claim Element [35.3]

“a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock, wherein the aspect closest to the urethra is at 12 o’clock”

Edwards:

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

EX1005, Edwards, 13:14-23.

Dr. Berenholz:

130. I have also been informed by Petitioner’s counsel that Patent Owner previously argued that the claims require heating along the entire 300 degree arc. Edwards teaches that a physician may treat both the anterior and posterior walls (encompassing the full 360 degrees on the reference clock). Based on Edwards teaching that “[r]emodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function,” EX1005, 13:16–22, a POSA would have been motivated to treat the vagina circumferentially, including the entire 300 degree arc between 1 o’clock to 11 o’clock.

EX1003, Berenholz Decl., ¶130.

The Treatment Area of Claim Element [43.3]

“a portion radiating outward from the introitus to Hart’s line”

’511 Patent:

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

EX1001, ’511 patent, 3:49-54.

Dr. Berenholz:

38. The area of the vulva between the labia minora is known as the vestibule. The outer edge of the vestibule is demarcated by an imaginary boundary, known as Hart’s line, and marks the transition between the smooth, non-keratinized epithelium of the vestibule and the keratinized skin of the labia minora.

Within the vestibule itself are the introitus and the external opening of the urethra—the urethral meatus. See EX1015, Plate 377.

EX1003, Berenholz Decl., ¶38.

Dr. Poulos:

41. Starting with the female reproductive system, the vulva is the external female genitalia. The external female genitalia consists of the labia majora, labia minora, vaginal orifice (or introitus), urethral orifice, and clitoris. The vulva also includes the vulva vestibule, which is a surface of the vulva that begins superiorly just below the clitoris and ends inferiorly at the posterior commissure of the labia minora, with its borders formed from the edge of the labia minora. This border, or outer edge of the vestibule, is also known as Hart’s line. Within the vulva vestibule is the introitus and the urethral orifice. The introitus is the entrance to the vagina

EX2001, Poulos Decl., ¶41.

The Treatment Area of Claim Element [51.3]

“a mucosal surface of the labia minora”

Dr. Berenholz:

EX1001, 11:59–12:2. Based on an understanding of the female reproductive system, a POSA would have understood “*a mucosal surface of the labia minora*” as claimed to refer only possibly to inner surfaces or lining of the labia minora adjacent the vulval vestibule, in that it requires the treated surface to be mucosal epithelium. The transition from non-keratinized epithelium (*i.e.*, mucosal epithelium of the vulvar vestibule) to keratinized epithelium (*i.e.*, skin of the outer

surfaces of labia minora and the labia majora) is not an instant transition. As I explained previously, Hart’s line is the demarcation between the labia minora and vulval vestibule, but this line is defined based on the transition between the smooth, non-keratinized epithelium of the vestibule and the keratinized skin of the labia minora. *See* Section VI.A. Thus, a POSA reading the ’511 patent would have understood “*a mucosal surface of the labia minora*” to mean the outer-most edge of the vulval vestibule and/or inner surfaces of the labia minora, prior to this transition because the claim requires heating a *mucosal surface*.

EX1003, Berenholz Decl., ¶145.

Experts Agree: Known to Treat Vulva for Cosmetic Purposes and to Improve Sexual Function

Dr. Berenholz:

49. By February 2006, the use of these technologies was also well known in the field of urogynecology. Based on a modification of a decades-old, traditional gynecological surgery for stress urinary incontinence, clinicians also performed Laser Vaginal Rejuvenation (“LVR”) to tighten vaginal support tissue and the outer third of the vagina, including the introitus, vulva, and the perineal body, both for cosmetic purposes and to improve sexual function. See EX1008, 0001. And even as early as November 2000, some clinicians began to feel that lasers have fallen out of favor and were turning to more sophisticated tools to replace lasers in these procedures. See EX1008, 0003. These more sophisticated tools would have included broad-spectrum light and RF-based technologies, as discussed above.

EX1003, Berenholz Decl., ¶49.

Dr. Poulos:

1 Q Do you agree that by February 2006, based
2 on the modification of a decades-old traditional
3 gynecological surgery for stress urinary
4 incontinence, clinicians also performed laser
5 vaginal rejuvenation to tighten vaginal support
6 tissue in the outer third of the vagina, including
7 the introitus, vulva, and the perineal body, both
8 for cosmetic purposes and to improve sexual
9 function?

10 MR. HECTOR: Objection. Foundation. The
11 document speaks for itself.

12 A Yes.

EX1032, Poulos Dep. Tr., 90:1-12.

Edwards-Mosher-Ingle Renders Obvious Elements [43.3], [51.3]

Ingle:

The present invention generally relates to medical devices, methods, and systems. More specifically, the present invention provides techniques for selectively heating and shrinking tissues, particularly for the noninvasive treatment of urinary incontinence and hernias, for cosmetic surgery, and the like.

EX1007, Ingle, 1:18-23.

Edwards:

This invention 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.

EX1005, Edwards, 2:33-39.

Dr. Berenholz:

tightening the treated tissue. *See* Section VI.C. Combined with the knowledge that the application of radiant energy, and specifically RF energy, would be beneficial for tightening, shrinking, and/or smoothing collagen-containing tissue throughout the body, a POSA would have been motivated to apply the RF treatments described in Edwards, Mosher, and Ingle to the vulval vestibule region described in element [43.3]. *See* Sections VI.B–VI.C. A POSA also would have had a reasonable expectation of success in doing so because the mucosal epithelium of the vulval vestibule is the same as that of vaginal mucosal epithelium, with the same underlying collagen-rich layers, as described in Edwards, Mosher, and Ingle.

EX1003, Berenholz Decl., ¶142; *also* ¶146.

Edwards's Speculum is Irrelevant

Dr. Poulos:

14 Q If a person skilled in the art wanted to
15 treat the opening of the vagina, which I believe
16 is called the introitus, would they use a
17 speculum?

18 MR. HECTOR: Objection. Vague.

19 A Again, it depends on the patient's
20 anatomy, but usually no.

EX1032, Poulos Dep. Tr., 37:14-20.

Edwards’s Speculum is Irrelevant

Dr. Berenholz:

the temperature. EX1005, 7:37–47. Edwards describes its treatment device as being used with a speculum. EX1005, 13:38–62. A POSA would have understood that, not only could the “blade 420 ... be disengaged and relocked into another position on the speculum,” EX1005, 13:61–62, but also the speculum itself could be rotated to a different position. A POSA also would have understood that in treating areas of the vaginal wall closer to the introitus, a physician would be able to complete the treatment without a speculum. EX1003, Berenholz Decl., ¶¶69.

treatment tip would end up *contacting the epithelium*. This is confirmed by the teaching that in order “to deliver energy to another area of the vagina,” the *treatment tip* should “be disengaged and relocked into another position in the speculum.” EX1005, 13:60–63. As discussed above, the device of Edwards also could be used without a speculum. EX1003, Berenholz Decl., ¶¶159.

Dr. Poulos:

17 Q That's not answering my question, though.
18 I'm asking does Edwards explain that the treatment
19 element cannot be used without a speculum?
20 MR. HECTOR: Objection. Asked and
21 answered.
22 A It does not. It only explains using it
23 with a speculum.

EX1032, Poulos Dep. Tr., 144:17-23.

Edwards-Mosher-Ingle Teaches “tightening the introitus”

Dr. Berenholz:

122. A POSA, based on Edwards’s teachings of improvement of sexual function, would have understood Edwards’s teachings to include treatment near the opening of the vagina. Specifically, Edwards teaches “circumferential tightening of the vaginal wall” to “provide physical and physiological improvement in the area of sexual function.” EX1005, 3:11–13. A POSA would have understood that in order to achieve these improvements of sexual function, the treatment area must include the region near the opening of the vagina. See, e.g., EX1008, 0001.

EX1003, Berenholz Decl., ¶122.

IX.B.1.d. Therefore, a POSA would have understood Edward’s disclosure of circumferential tightening of the vaginal wall starting at *a portion of the vagina extending from the introitus* to include *tightening the introitus* itself.

250. A POSA further would have been motivated to tighten the introitus to provide treatment for decreased sensitivity during intimacy, for example to increase sensation.

EX1003, Berenholz Decl., ¶¶249-250.

Dr. Poulos:

20	Q	Is it fair to say that the person of skill
21		in the art would have understood that tightening a
22		vagina introitus may lead to enhanced sexual
23		pleasure?
24	MR. HECTOR:	Objection. Foundation.
25	A	Yes.

EX1032, Poulos Dep. Tr., 103:20-25.

Ground 2: Edwards, Mosher, Ingle, and Ollivier

Ollivier discloses that techniques existed to treat both the vagina and portions external of the introitus, i.e., the vulvar vestibule and labia minora.

Ollivier

Laser Vaginal Rejuvenation began as a modification of a traditional gynecological vaginal surgery for stress urinary incontinence. The procedure, which has been a standard gynecological surgery for decades, involves the tightening of the vaginal muscles and support tissues, as well as the reduction of redundant vaginal mucosa (relaxed vaginal lining). By reconstructing the "optimum structural architecture" of the vagina -- namely, by reconstructing the outer third of the vagina: the orgasmic platform, internal and external vaginal diameter (introitus) and the perineal body -- Matlock claims that women not only are relieved of incontinence, but they also enjoy increased levels of sexual gratification.

EX1008, Ollivier, 0001.

Hymenalplasty and its bizarre implications aside, there is nothing new about LVR and DLV. 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. "Labial surgery?" says ob/gyn Dr. Cornelia Daly. "There's nothing to it. It's been around for 30 years. Lasers have even fallen out of favor. We have more sophisticated tools that do the same thing these days." According to the ob/gyn community, Matlock has simply put a new spin (sex sells) on an old procedure.

EX1008, Ollivier, 0003.

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²² See "The Facts of Life, and Vaginal Tightening," <<http://www.my.webmd.com/content/article/html>> 3, "Testimonials" from the LVR Institute, L.A., <<http://www.drmatlock.com/testimonials.htm>> 2, and Debra Ollivier, "Designer Vaginas," <<http://www.salon.com/sex/feature/2000/11/14/vagina.html>>, 1.

²³ "Facts of Life, and Vaginal Tightening" 1

EX1027, 1, 3, 20.

"The Hydra's Tale"

Imagining Disgust

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A volume in (*currents*), an interdisciplinary series. Jonathan Hart, series editor.

Ollivier, Debra. "Designer Vaginas." *Salon.com*, 14 November 2000.

Chris Burdell. *The Idea of the Hydra: An Inquiry into the Monstrous*. Edited by

EX1028, 1, 2, 77.



Secondary Considerations

InMode Has Not Established Nexus With Claims 1, 26, or 35

- “A presumption of nexus requires *both* that the product embodies the invention and is coextensive with it.” *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1211-12 (Fed. Cir. 2023) (emphasis added).
- “A patent claim is not coextensive with a product that includes a ‘critical’ unclaimed feature ... that materially impacts the product’s functionality.” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1375 (Fed. Cir. 2019).

The Viveve Device is Not Coextensive with Claims 1, 26, and 35 Because it Includes a Critical Unclaimed Feature: Cooling

A single RF treatment was performed on each subject as an in-office procedure; no prior sedation or analgesics was required. The RF device (Viveve® Vaginal Laxity RF Therapy System, Viveve, Inc. Sunnyvale, California USA) provides a nonablative approach to creating heat within the submucosal layer of vaginal tissue while keeping the surface cooled. The system consists of a RF console, a cooling module, a horizontal handpiece, and a treatment tip (Fig. 1). It uses reverse thermal gradient RF technology. The monopolar RF pulse is generated to selectively heat a given volume of tissue beneath the surface, while the integrated cryogen is delivered to the inside of the treatment tip to cool and protect the surface tissue—the vaginal mucosa. RF energy pulses delivered at

EX2017, 776-777.

This study represents the first application of monopolar RF thermal therapy for vaginal laxity after childbirth. The procedure is minimally invasive and limited to treatment of the vaginal introitus. It relies on the concept that carefully controlled RF energy can be used to heat deeper submucosal tissue in conjunction with concomitant cryogen cooling to prevent superficial heat injury. The therapeutic goal is to stimulate connective tissue restoration with subsequent tissue tightening. RF energy has been extensively used for tissue tightening of human skin [10,11]. Increased collagen formation appears to contribute to the mechanism of skin tightening over time

EX2018, 6.