

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BTL INDUSTRIES, INC.,
Petitioner

v.

INMODE LTD.,
Patent Owner

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

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 8,961,511**

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PETITIONER'S EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 8,961,511 to Parmer (“the ’511 patent”)
1002	File History of U.S. Patent No. 8,961,511 (“’511 File History”)
1003	Declaration of Dr. Joseph Berenholz in Support of Petition for <i>Inter Partes</i> Review (“Berenholz Decl.”)
1004	<i>Curriculum Vitae</i> of Dr. Joseph Berenholz
1005	U.S. Patent No. 6,463,331 to Edwards (“Edwards”)
1006	U.S. Patent Application Publication No. 2004/0193238 to Mosher et al. (“Mosher”)
1007	U.S. Patent No. 6,216,704 to Ingle et al. (“Ingle”)
1008	Ollivier, D., “Designer Vaginas,” Salon.com, accessed at https://web.archive.org/web/20010124063400/http://www.salon.com/sex/feature/2000/11/14/vagina/print.html (Nov. 14, 2000) (“Ollivier”)
1009	<i>Thermigen, LLC v. Viveve, Inc.</i> , IPR2018-00088, Decision to Institute (PTAB May 8, 2018)
1010	<i>Thermigen, LLC v. Viveve, Inc.</i> , IPR2018-00088, Patent Owner’s Preliminary Response (PTAB February 14, 2018)
1011	<i>Thermigen, LLC v. Viveve, Inc.</i> , IPR2018-00089, Decision to Institute (PTAB May 8, 2018)
1012	<i>Thermigen, LLC v. Viveve, Inc.</i> , IPR2018-00089, Patent Owner’s Preliminary Response (PTAB February 14, 2018)
1013	U.S. Patent No. 6,350,276 to Knowlton
1014	U.S. Patent No. 6,283,987 to Laird et al.
1015	F.H. Netter, “Netter's Atlas of Human Anatomy,” 4 th Ed., Saunders Elsevier, 2006 (“Netter”)
1016	D.J. Goldberg, “Nonablative Laser Technology: Radiofrequency,” <i>Aesthetic Surg J</i> 2004; 24:180–181 (“Goldberg”)
1017	C. Squier and K.A. Brogden, “Human Oral Mucosa: Development, Structure, and Function,” 1 st Ed., Wiley-Blackwell 2011 (“Squier”)

Exhibit No.	Description
1018	N. Sadick, “Tissue Tightening Technologies: Fact or Fiction,” <i>Aesthetic Surg J</i> 2008; 28:180–188 (“Sadick”)
1019	N.T. Wright and J.D. Humphrey, “Denaturation of Collagen Via Heating: An Irreversible Rate Process,” <i>Annu. Rev. Biomed. Eng.</i> 2002; 4:109–128 (“Wright”)
1020	M. Paul et al., “Three-Dimensional Radiofrequency Tissue Tightening: A Proposed Mechanism and Applications for Body Contouring,” <i>Aesth Plast Surg</i> 35:87-95 (2011) (“Paul”)
1021	J.A. Burns, “Thermage: Monopolar Radiofrequency,” <i>Aesthetic Surgery Journal</i> , 25:638–642 (“Burns”)
1022	Barry E. DiBernardo, “Clinically Relevant Lasers for the Plastic Surgeon,” <i>Aesthetic Surgery Journal</i> (2005)
1023	Salon.com, “Salon Traffic & Audience Profile” Webpage, accessed at https://web.archive.org/web/20010401003237/http://www.salon.com/adsales/index2.html
1024	<i>Viveve, Inc. v. ThermiGen, LLC</i> , 2-16-cv-01189, Claim Construction Order (E.D. Tex. November 13, 2017)
1025	Alinsod, R.M., “Temperature Controlled Radiofrequency for Vulvovaginal Laxity,” <i>Prime Journal</i> , pp. 16-21 (July/August 2015)
1026	ThermiVa, “Doctors are Weighing in on ThermiVa,” (IPR2018-00088, EX2007, accessed August 20, 2015)
1027	Kern, Louis J. “Venus Envy – Penis Envy: Aesthetic Autoplasty, Genital Reconstruction, and Erotic Embodiment,” pp. 43-57 in “The EmBodyment of American Culture,” <i>Lit Verlag Münster</i> (Tschachler, H., et al., eds., 2003)
1028	Wilson, Robert R., “The Hydra’s Tale: Imagining Disgust,” <i>The University of Alberta Press</i> (2002)
1029	Salon.com Search Webpage, accessed at https://web.archive.org/web/20010331124153/http://search.salon.com/

Exhibit No.	Description
1030	Salon.com Advanced Search Webpage, accessed at https://web.archive.org/web/20001117105100/http://search.salon.com/query.html?op0=+&fl0=&ty0=n&tx0=&op1=&fl1=url:&ty1=w&tx1=&op2=-&fl2=&ty2=w&tx2=&nh=25&rf=0&lk=1&qp=&qt=&qs=&qc=&ws=0&qm=0&st=1&oq=&rq=0&ql=a
1031	Affidavit of Nathaniel E. Frank-White (April 2, 2024)

I. INTRODUCTION

BTL Industries, Inc. (“Petitioner”) requests *inter partes* review and cancellation of claims 1-58 of U.S. Patent No. 8,961,511 (“the ’511 patent”; EX1001), assigned to InMode Ltd. (“Patent Owner”).

At the time of the ’511 patent, it was well known that collagen-rich tissue could be “remodeled” by heating the tissue, which causes the collagen to denature. Collagen denaturing was known to cause a tightening effect. Tightening tissues of the female genital region, for both therapeutic and cosmetic reasons, was also known to be beneficial. The ’511 patent adds nothing new to the art, simply claiming heating and remodeling collagen-rich tissues of the female genital region, specifically the vulva, introitus, and vagina tissue.

As supported by the declaration of Dr. Joseph Berenholz (EX1003), an expert in the field of treating uro-gynecological conditions, the asserted references confirm that the claimed methods were known. Dependent claims recite specific process details—e.g., treatment temperatures or cooling adjacent tissue to avoid damage thereto—or particular results—e.g., tightening tissue or denaturing collagen—all of which also were known.

In fact, the Board has recognized the likelihood that these claims are obvious, previously instituting review on similar grounds. However, the Board did

not reach a final written decision due to the prior parties' settlement. The Board should similarly consider Petitioner's challenges here.

Discretionary considerations also favor institution. Petitioner has not previously challenged the '511 patent, which Patent Owner has asserted against Petitioner in co-pending litigation. This co-pending litigation is in its very early stages; BTL, the defendant in that action, has not yet answered.

Accordingly, the Board should institute review and invalidate all claims of the '511 patent.

II. TECHNOLOGY BACKGROUND AND ANATOMY OVERVIEW

Collagen is prevalent in the human body. At the time of the '511 patent, it was known that collagen-rich tissue could be "remodeled" by heating the tissue, which causes a collagen denaturing effect. EX1003, ¶¶39-43. These treatments resulted in the tightening of tissue, and were known to be used, for example, for the cosmetic treatment of loose skin on the face and other areas of the body. EX1003, ¶¶44-48. Collagen also is found in tissues of the female urogenital system. EX1003, ¶¶34, 39. The use of collagen remodeling techniques for therapeutic and/or cosmetic treatment of these tissues also was known. EX1003, ¶49.

The vagina is an elastic, muscular tube that extends from the cervix, which connects the vagina to the uterus, to the vaginal opening, called the introitus.

EX1003, ¶¶32-33. The vulva is the female genital structure external to the vaginal opening, including the vulvar vestibule and the labia. EX1003, ¶¶37-38. The vagina and portions of the vulva are lined by a layer of stratified squamous epithelium, known as the vaginal mucosa. EX1003, ¶¶34-36. Under the vaginal mucosa is a layer of tissue known as the lamina propria, or submucosa, which is rich in elastic fibers such as collagen. *Id.* Beneath the lamina propria is a layer of smooth muscle known as the muscularis. *Id.*

The '511 patent claims “method[s] 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.” EX1001, 15:47-18:48. There is nothing new about using a known collagen remodeling technique on a collagen-rich area of the body known to benefit from such remodeling treatments. EX1003, ¶¶57, 32-49.

III. THE '511 PATENT

A. Summary

The '511 patent relates to methods for tightening tissue of the female genitalia using radiant energy. EX1001, Abstract; EX1003, ¶¶50-57. The patent purports to solve certain problems related to stretched vaginal tissue—occurring, for example, during childbirth—by providing “effective approaches to treating a

loose vagina and introitus with a non-invasive procedure.” EX1001, 2:17-18, 5:5-

11. The patent describes:

Embodiments of the invention include methods for remodeling a therapeutic zone of tissue within a target tissue of female genitalia. The target tissue lies immediately beneath the mucosal epithelium of genital tissues, and includes the lamina propria, a connective tissue that includes collagen in the extracellular space, and the muscularis, which includes smooth muscle. The target zone of embodiments of the invention does not include deeper tissue, such as endopelvic fascia.

EX1001, 3:41-48. The patent’s method of remodeling tissue includes “applying heat to a target tissue underlying the surface mucosal epithelium, while cooling the surface epithelium itself.” EX1001, 11:5-14.

The patent discloses that the target tissue is heated to a therapeutic temperature, which it describes as a temperature that causes remodeling. EX1001, 11:19-23. The “portion of the target tissue which attains the therapeutic temperature, for a sufficient time, is termed the therapeutic zone within the target tissue.” EX1001, 11:23-29. Tissue remodeling may include “heat-denaturing collagen within collagen-rich areas in the target tissues” or “biological healing responses to the stress of heating, [which] may include the deposition of new collagen.” EX1001, 4:58-5:2. In either case, “the effect of remodeling on the tissue is generally one of tissue contraction or tightening.” EX1001, 5:2-5, 12:39-65.

Cooling the epithelium protects it from damage and prevents remodeling of the epithelium. EX1001, 13:13-26.

The “target tissue” is illustrated in Figure 8:

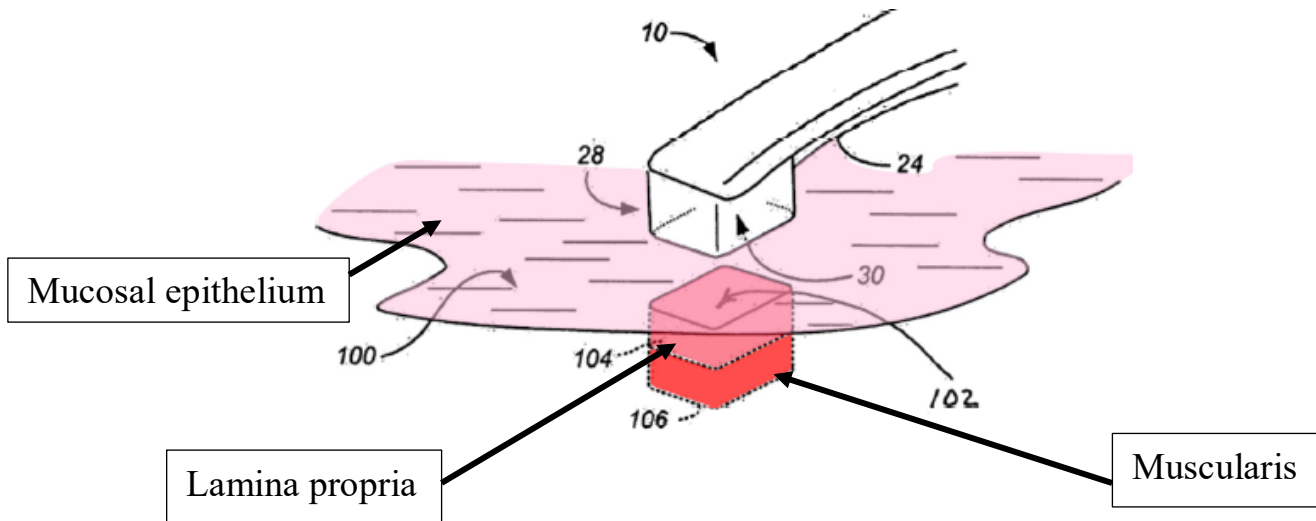


FIG. 8

EX1001, FIG. 8 (annotated).

During treatment, energy delivery element 30 of treatment tip 10 contacts the epithelium 100 at contact site 102. EX1001, 14:18-24, 2:53-62, 8:8-15. Layers of target tissue underlying the epithelium, including lamina propria 104 and muscularis 106, are shown below the contact site. EX1001, 14:24-29.

According to the '511 patent, its methods provide “for corrective or restorative remodeling” of tissues of the vagina, introitus, and vulva. EX1001, 2:17-21. The disclosed embodiments, however, merely describe previously known methods for remodeling female genital tissues using radiant energy. EX1001, 4:4-

13; EX1003, ¶57. Each independent claim is directed to a “method for remodeling a therapeutic zone within a target tissue” including “heating the target tissue, and remodeling the therapeutic zone of target tissue.” *See* EX1001, 15:46-18:48. The independent claims differ in the particular area to which the heating is applied. *Id.*

B. Level of Ordinary Skill in Art

A person of ordinary skill in the art (“POSA”) at the time 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 uro-gynecological conditions and/or the non-surgical cosmetic treatment of female genital tissues. EX1003, ¶¶58-60.

C. Prosecution History and Litigation History

During prosecution, the Examiner’s rejections and Applicant’s amendments focused on narrowing the target of the claimed method from “female genital tissue” to “at least one of vulva, introitus and vagina tissue.” *See* EX1002, 0079-0094, 0115-0126, 0135-0151, 0165-0174, 0198-0214, 0234-0244, 0260-0266, 0295-0306. The Notice of Allowance identified the “specific areas of treatment set forth in [the] independent claims” as not being disclosed in the prior art (“Knowlton,” EX1013), which teaches treating cervical tissue. EX1002, 0312-0318.

The '511 patent was involved in a prior proceeding in District Court, *Viveve, Inc. v. Thermigen LLC*, 2:16-cv-01189 (EDTX) (“*Viveve*”), which settled. The patent was also involved in IPR2018-00088 and IPR2018-00089, in which the Board instituted review, but which settled before final written decisions. Petitioner was not involved in any of these prior proceedings.

IV. CLAIM CONSTRUCTION

In an IPR, a claim is “construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b),” i.e., the *Phillips* standard. 37 C.F.R. §42.100(b). Any prior claim construction determinations in a civil action are to be considered. *Id.*

Here, no claim term requires construction—all terms should receive their ordinary and customary meaning in view of the patent specification. EX1003, ¶61. Certain claim terms were construed in prior proceedings involving the '511 patent, namely in *Viveve* and in the May 2018 Institution Decisions in the prior IPRs, where the Board preliminarily construed certain terms under the broadest-reasonable-interpretation standard.

Petitioner demonstrates how the art satisfies the claims under the ordinary and customary meaning and under the prior constructions. EX1003, ¶¶61-62. Thus, it is unnecessary to expressly construe any terms for purposes of this IPR. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed.

Cir. 2017) (Only those terms need be construed “that are in controversy, and only to the extent necessary to resolve the controversy.”). Nevertheless, a discussion of the prior constructions is provided for the Board’s convenience.

A. “target tissue”

Each independent claim recites a “target tissue,” a therapeutic zone that is the subject of the claimed remodeling. In construing the preamble, the *Viveve* Court determined “that the ‘target tissue’ includes, but is not limited to, ‘tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue.’” EX1024, 21-28.

In the prior IPRs, the Board preliminarily construed “target tissue” as “tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissues, such as the endopelvic fascia.” EX1009, 10-12; EX1011, 10-11. The Board’s prior construction was based on statements in the specification that endopelvic fascia was not a target tissue for embodiments of the invention. EX1009, 10-11 (citing EX1001, 3:41-47, 12:2-13); EX1011, 10-11 (same).

Although the claimed “target tissue” does not include the endopelvic fascia under the Board’s prior construction, the claims do not prohibit heating or treating *other areas in addition to* the target tissue, including the endopelvic fascia. Because the claims’ preambles recite the transition “comprising,” the claims are open-ended. *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed.

Cir. 2005); *Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) (“The transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.”). Accordingly, prior art that discloses treating the claimed “target tissue” (in the manner required by the respective claims) as well as treating other areas (e.g., the endopelvic fascia) satisfies the claims under this construction. Indeed, the ’511 patent does not discourage treating other tissue, and in fact does not even discourage treating the endopelvic fascia. Rather, the specification merely states without further elaboration that “deeper tissues, including endopelvic fascia, ... are not a target tissue for embodiments of the present invention.” EX1001, 12:13-16.

B. “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: “Energy delivered from the treatment tip may heat the target tissue to a

¹ The Board rejected Patent Owner’s argument that the “heating” step requires “heating without damaging the mucosal epithelial surface.” EX1010, 9-11; EX1012, 9-12; EX1009, 12-14; EX1011, 11-14.

temperature as high as about 80 degrees C.” EX1001, 4:23-24; EX1001, 11:19-21 (“[H]eating of target tissue, per embodiments of this invention includes raising the temperature of the target tissue to as high as 80 degree C.”). In *Viveve*, the court construed the “heating” step as “heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium.” EX1024, 7-14.

C. “remodeling the therapeutic zone of target tissue”

Each independent claim recites “remodeling the therapeutic zone of target tissue.” The *Viveve* court construed this term as “causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature.” EX1024, 14-21. Similarly, 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, wherein the remodeling step simply refers to the *result* of the heating step, are generally consistent with the patent specification, which explains that “[r]emodeling of genital tissue, as practiced by embodiments of this invention,

may be understood variously as contracting or tightening of tissue.” EX1001,

13:2-5.²

D. “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock”

Independent claim 35 recites that the heating includes “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock.” This term was not construed in *Viveve*. In the prior IPR, Patent Owner argued that this claim element requires heating *substantially the entire 300 degree arc* of vaginal wall from 1 o’clock to 11 o’clock. EX1010, 14-16. The Board preliminarily construed “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock” as “heating *at least one contact site in the 300 degree arc* extending from 1 o’clock to 11 o’clock along the vaginal wall.” EX1009, 18. The Board’s prior construction is consistent with dependent claim 40, which recites “contacting the epithelium with a treatment tip at a [sic] *one or more contact sites* during a procedure.” *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir. 2022) (“By definition, an independent claim is broader than a claim that depends from it, so if a dependent claim reads on a particular embodiment of the claimed invention, the corresponding independent claim must cover that embodiment as well.”).

² Emphasis added unless otherwise noted.

As discussed below, Petitioner demonstrates how the art teaches all of these previously construed elements under their ordinary and customary meaning and under the various prior constructions. Thus, it is unnecessary to construe these terms to resolve this IPR.

V. IDENTIFICATION OF THE CHALLENGE (37 C.F.R. § 42.104(B))

Petitioner requests IPR based on the following grounds:

Ground	35 U.S.C.	Claims	References
1	§103(a)	1-58	Edwards, Mosher, and Ingle
2	§103(a)	43-58	Edwards, Mosher, Ingle, and Ollivier

U.S. Patent No. 6,463,331 (“Edwards,” EX1005) issued October 8, 2002, and qualifies as prior art under 35 U.S.C. §102(b).

U.S. Publication No. 2004/0193238 (“Mosher,” EX1006) published September 30, 2004, and qualifies as prior art under 35 U.S.C. §102(b).

U.S. Patent No. 6,216,704 (“Ingle,” EX1007) issued April 17, 2001, and qualifies as prior art under 35 U.S.C. §102(b).

“Designer Vaginas” article, authored by Debra Ollivier, published on November 14, 2000 on Salon.com (“Ollivier,” EX1011), and qualifies as prior art under 35 U.S.C. §102(b). 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. Research aids confirm that Ollivier was publicly accessible before the '511 patent's critical date. EX1027, 3 (copyright 2003), 20-21 (citing Ollivier); EX1028, 2 (copyright 2002), 77 (citing Ollivier); *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1350 (Fed. Cir. 2016) ("the presence of a 'research aid' can also establish public accessibility").

VI. OVERVIEW OF THE PRIOR ART

Each prior-art reference is analogous art: it is in the same field as and is reasonably pertinent to the problems of the '511 patent. EX1003, ¶63.

A. Edwards

Edwards discloses a method for treatment of female uro-genital disorders by application of therapeutic energy, such as RF energy, to targeted tissues. EX1005, 2:34-36. This energy is "selectively applied so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition." EX1005, 2:37-39. For example, Edwards teaches "circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function." EX1005, 3:5-13.

Edwards's Figure 9A describes a method for "vaginal remodeling." EX1005,

13:12-13, 3:38-39.

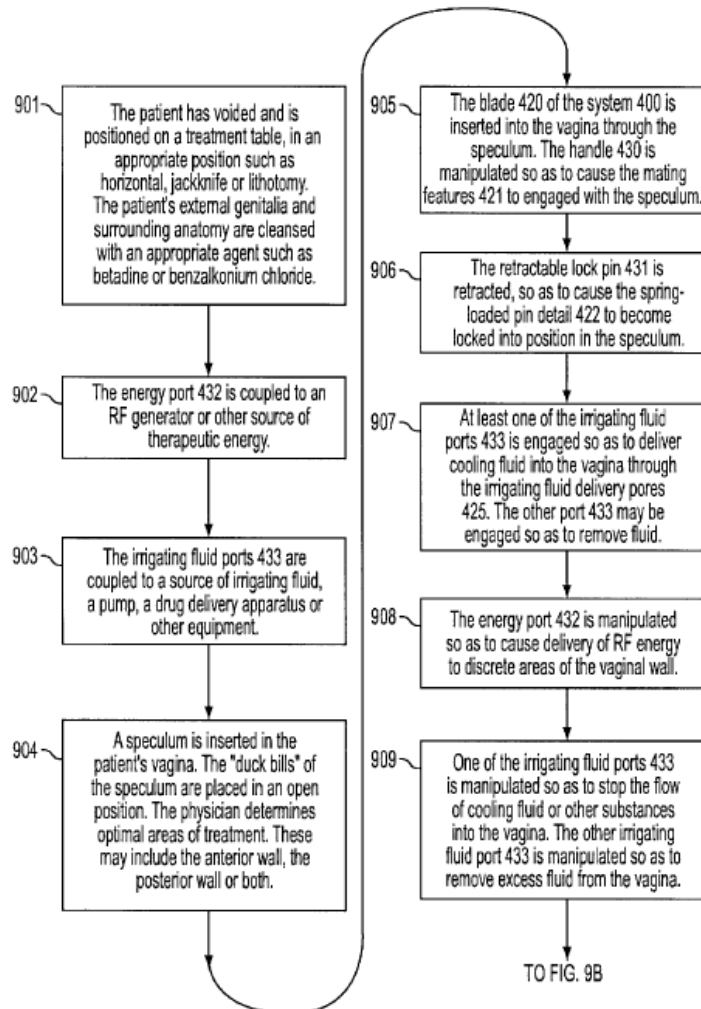


FIG. 9A

EX1005, FIG. 9A.

In Edwards's method, energy is delivered to discrete areas of the vaginal wall.

EX1005, 13:54-62 (FIG. 9A, step 908). The energy may be RF, microwave, laser, or other therapeutic energies. *Id.* Cooling fluid is delivered into the vagina before, during, and after the energy delivery in order to minimize thermal damage.

EX1005, 7:51-53, 13:50-53 (FIG. 9A, step 907, begin fluid delivery), 13:63-67 (FIG. 9A, step 909, stop fluid delivery).

Edwards teaches that “[t]he physician determines optimal areas of treatment,” which can include the anterior vaginal wall, the posterior vaginal wall, or both. EX1005, 13:14-16, 13:38-42. “Remodeling of the anterior wall treats incontinence,” and “[r]emodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting [in] physical and psychological improvement in the area of sexual function.” EX1005, 13:16-23.

Edwards also discloses a device used for “vaginal remodeling.” EX1005, 3:26-28, 7:14-8:5, FIG. 4.

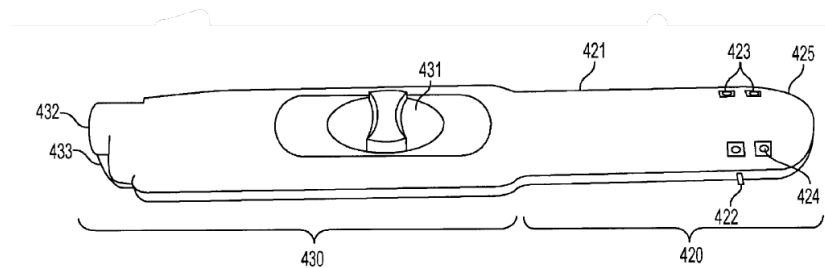


FIG. 4

EX1005, FIG. 4 (excerpt).

Treatment element 410 includes blade 420 and handle 430. EX1005, 7:18-28. The blade includes a plurality of electrodes 423 and a plurality of irrigating fluid delivery pores 425. *Id.* In performing the method of Figure 9, the distal end of the treatment element 410, i.e., blade 420 with electrodes 423, is inserted into the

vagina. EX1005, 7:18-28, 13:43-44. Electrodes 423 deliver therapeutic energy, and each electrode includes at least one thermocouple 434 used to constantly monitor the temperature. EX1005, 7:37-47. *See* EX1003, ¶¶64-69.

B. Mosher

Mosher discloses methods for treating incontinence by heating collagenous support tissue for a sufficient time to effect substantial tissue shrinkage. EX1006, ¶9, Abstract. Mosher expressly recognizes that its techniques “will find applications in *a wide variety of therapies*,” EX1006, ¶46, and “may be *directed at a variety of tissue structures* [including] ... structures of the vagina,” such as the lamina propria. EX1006, ¶48.

Mosher explains, “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.” EX1006, ¶45. This heating may be provided through the vaginal wall. EX1006, ¶9. For example, Figure 4C illustrates probe 10 introduced into the vagina. EX1006, ¶54.

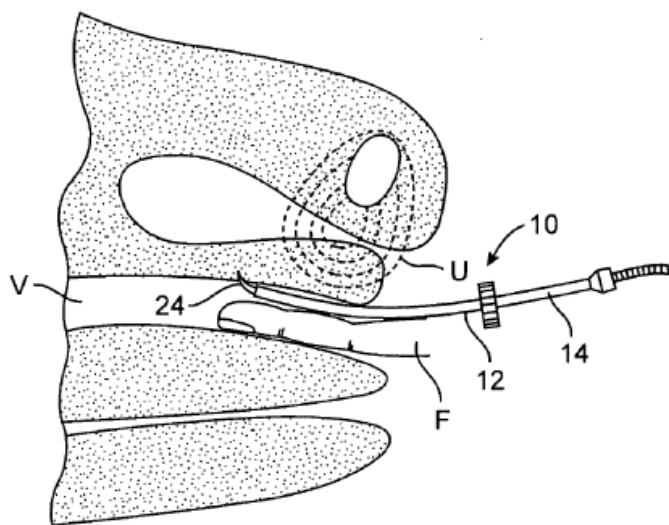


FIG. 4C

EX1006, FIG. 4C.

Similarly, vaginal treatment probe 54 of Figure 6A is used for “indirect treatment of tissue” from within the vagina. EX1006, ¶¶58, 67, FIGs. 6, 6A.

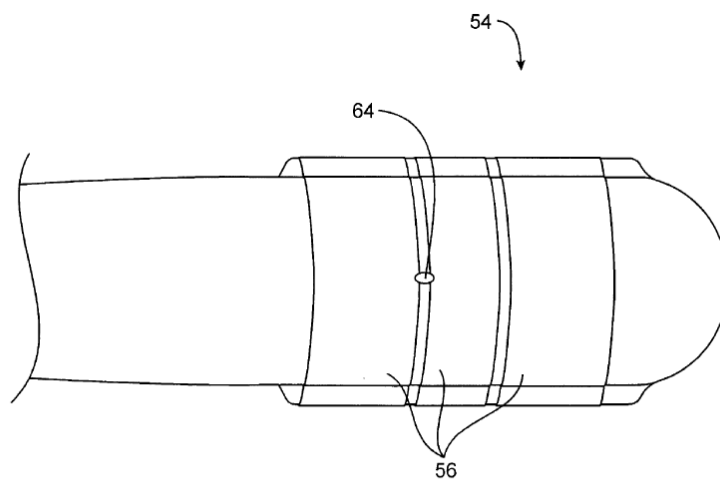


FIG. 6A

EX1006, FIG. 6A.

Electrodes 56 of probe 54 transmit RF current to heat the target tissue indirectly, through the vaginal wall. EX1006, ¶58. Probe 54 also includes fluid conduits 58, which cool the intervening tissue—here, the vaginal wall—between probe body and the target tissue, both prior to and during heating. EX1006, ¶¶58, 69, FIG. 6.

Mosher describes detailed time and temperature parameters required to effect the desired tissue shrinkage, concluding that “to effect significant, repeatable tissue shrinkage, it is generally desirable to subject the treatment volume to temperatures of at least 70° C. for a time of about 30 seconds or more.” EX1006, ¶¶64, 65. Tissue shrinkage occurs, at least in part, due to tissue remodeling resulting from the healing process. EX1006, ¶66. *See* EX1003, ¶¶70-74.

C. Ingle

Ingle discloses “methods ... for shrinking of collagenous tissues, particularly for treating urinary incontinence in a noninvasive manner by directing energy to a patient’s own support tissues.” EX1007, Abstract. Ingle recognizes that a “wide variety of alternative conditions may also be treated using [its] methods,” and that they may also be used “in cosmetic procedures.” EX1007, 17:65-18:7.

Ingle’s method uses “energy [to] heat[] fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues.” EX1007, 2:59-63. This is accomplished by applying energy using a large, cooled electrode. *Id.* The electrode directs the energy through an intermediate tissue, such

as the vaginal wall, while the cooling prevents injury thereto. EX1007, 2:63-67, 20:10-18, FIG. 11.

Figure 11 illustrates a single probe heating system 80 that can be used to practice Ingle's methods.

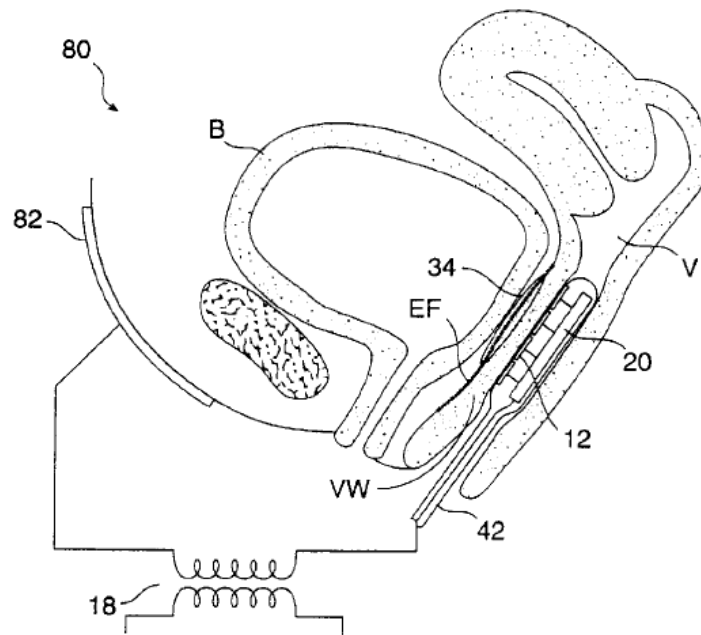
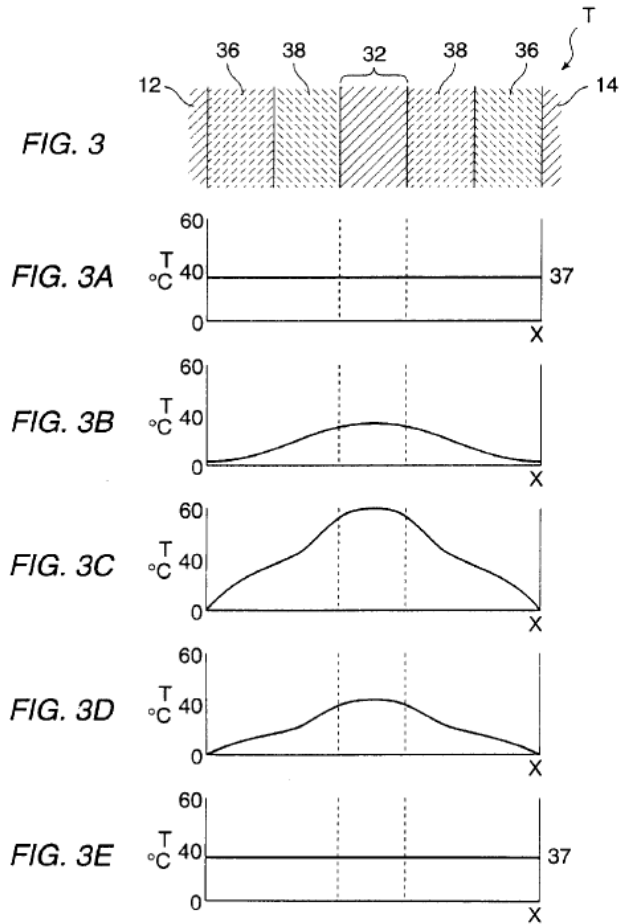


FIG. 11

EX1007, FIG. 11.

Target zone 34 is heated by RF energy directed through electrode 12. EX1007, 20:14-18. Vaginal wall VW is protected by cooling the surface of electrode 12. *Id.*

Referring to Figures 3-3E, Ingle describes a “method for heating a target tissue between cooled electrodes, wherein the electrode surfaces cool the tissue before, during, and after radiofrequency energy is applied.” EX1007, 9:61-64.



EX1007, FIGs. 3-3E.

Figure 3 illustrates three regions of tissue T: target zone 32, stunned tissue 38, and safely cooled intermediate tissue 36. EX1007, 15:5-26. Ingle describes that “[t]o effect shrinkage of fascia, target zone 32 will typically be heated to a temperature above about 60 nC,^[3] and often to a temperature at or above 70 nC.”

³ Ingle’s temperatures are noted as “nC.” A POSA would understand this to mean “°C.” EX1003, ¶80.

Id. Further, the “maximum safe tissue temperature to prevent injury” is “typically ... about 45 nC.” *Id.*

Figures 3A-3E illustrate the temperature profile of the tissue at certain points of the treatment method: Figure 3A—standard body temperature, prior to application of cooling or heating energy; Figure 3B—after pre-cooling of the tissue; Figure 3C—after heat is applied to achieve a temperature at or above a treatment temperature in target zone 32; Figure 3D—after heating is stopped and continued cooling has reduced the entire tissue to below the maximum safe tissue temperature; and Figure 3E—return to standard body temperature. EX1007, 15:27-16:15. Ingle recognizes that this temperature profile can also be achieved with a probe structure engaging a single tissue surface. EX1007, 21:65-22:1. *See* EX1003, ¶¶75-81,

D. Ollivier

Ollivier describes techniques for the cosmetic treatment of the vagina and vulva, and more specifically the labia. *See generally* EX1008. Ollivier describes using “Laser Vaginal Rejuvenation (LVR) to tighten [a patient’s] vagina and ‘enhance sexual gratification’ and Designer Laser Vaginoplasty (DLV) to ‘aesthetically modify’ her labia.” EX1008, 0001. Ollivier explains, “[b]y 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— ... women not only are relieved of incontinence, but they also enjoy increased levels of sexual gratification.” *Id.* See EX1003, ¶82.

VII. GROUND 1: THE COMBINATION OF EDWARDS, MOSHER, AND INGLE RENDERS OBVIOUS CLAIMS 1-58.

Claims 1-58 would have been obvious over Edwards, Mosher, and Ingle. EX1003, ¶¶91-271.

A. A POSA would have been motivated to combine Edwards, Mosher, and Ingle with a reasonable expectation of success.

Edwards, Mosher, and Ingle are all directed to methods for the non-invasive treatment of female uro-genital conditions, for therapeutic and/or cosmetic reasons. In each method, a treatment device provides radiant energy, such as RF energy, to and through the vaginal wall, thereby heating underlying target tissue. This heating results in remodeling or tightening of the target tissue. Each of these references also describes using cooling during treatment to minimize or prevent damage to the mucosal epithelium. A POSA would have understood that regardless of the specific device used, methods of treatment using radiant energy all have the same end result—remodeling collagen-rich tissue. EX1003, ¶84. Thus, a POSA would have relied upon Edward, Mosher, and Ingle for their teachings of treatment methods and rationales, and would have further understood that the relevance of

these teachings would not have been limited to the specific device(s) disclosed in each reference. *Id.*

A POSA would have been motivated to combine these references, and would have had a reasonable expectation of success in doing so, because they all relate to methods of using radiant energy, such as RF energy, to treat uro-genital conditions by tightening and/or shrinking tissue. EX1003, ¶85. Edwards provides general teachings of a non-invasive treatment method, but does not provide details of the treatment parameters (e.g., treatment time and temperature) or the specific physiological mechanism of action (e.g., how the tightening occurs). *Id.* In considering methods of treatment using radiant energy, a POSA would have looked to Mosher and Ingle, which also describe methods of treatment using radiant energy, for specific details regarding treatment parameters and techniques. *Id.* Mosher and Ingle also discuss details of the natural physiological mechanism of action that occurs in collagen when heated using radiant energy. *Id.*

Applying the treatment details provided in Mosher and Ingle to the treatment method taught in Edwards is simply combining prior-art elements according to known methods to yield predictable results. EX1003, ¶¶86-87. Similarly, the combination is merely applying known techniques (Mosher/Ingle's treatment methods) to a known method ready for improvement (Edward's treatment method) to yield the predictable result of tightening via collagen denaturation. *Id.* Further

still, the '511 patent acknowledges that loose vaginal or vulval tissue was a known problem facing women at the time. EX1001, 1:62-2:21. Each of Edwards, Mosher, and Ingle teaches using their method for tightening such tissues, thus a POSA would have looked to them for solving this known problem. EX1003, ¶88.

A POSA further would have had reasonable expectation of success in combining these references because they all apply known thermal dynamics principles to the treatment of tissue using radiant energy. EX1003, ¶89. A POSA would have understood that the treatment parameters and techniques disclosed in Mosher/Ingle could be applied to Edwards's method to result in collagen denaturation and tissue tightening. EX1003, ¶90.

B. Independent Claims

The independent claims all recite a similar method for remodeling tissue of the vulva, introitus, or vagina. Each independent claim includes the same preamble, heating step, and remodeling step, varying only in the final "wherein" clause that defines a particular area subject to heating (i.e., area of treatment) for that claim. 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. EX1003, ¶¶91, 44-49. Further, as Dr. Berenholz confirms, 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. EX1003, ¶¶91, 39-43. In this context, the vaginal region is not a large area, and a POSA would have recognized that there are limited areas of treatment to choose from within that region. EX1003, ¶91. As Edwards confirms, it would have been within the skill of a POSA to determine the optimal area of treatment for a particular patient based on the desired outcome (e.g., treating incontinence, improving sexual function, etc.). EX1005, 13:40-42; EX1003, ¶91. The asserted combination renders obvious the method of treatment and the treatment areas recited in each independent claim.

1. Claim 1

- a. [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**

To the extent limiting,⁴ the combination of Edwards, Mosher, and Ingle teaches the preamble. EX1003, ¶¶92-98.

⁴ The *Viveve* court found the preamble limiting “to the extent that it requires ‘the target tissue’ to include ‘tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus, and vagina tissue.’” EX1024, 23-26.

Edwards discloses “a method ... 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, 2:34-39. Edwards’s fourth embodiment discloses a method for “vaginal remodeling.” EX1005, 13:12-23. RF energy is delivered to the anterior and/or posterior regions of the vaginal wall. EX1005, 13:12-23, 3:6-9. This treatment “has the effect of tightening of vaginal walls so as to increase support of the bladder outlet, proximal and mid-urethra,” thereby treating incontinence, and “circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function.” EX1005, 3:9-13, 13:14-23.

Like Edwards, Mosher discloses methods of treatment, e.g., of incontinence, via tissue remodeling achieved by applying RF energy to and through the vaginal wall. EX1006, ¶45. Mosher provides additional details of the physiological mechanism of tissue remodeling, describing “heat[ing] target tissue to temperatures and for time periods which effect[s] a contraction of the collagen within the target tissue and/or enhance[s] stiffening of the support provided by these structures. The supporting collagenous tissues, immediately and/or upon healing, thereby contribute to continence.” EX1006, ¶¶55, 66.

Mosher also identifies “target tissue” for such RF treatment. Specific embodiments target the endopelvic fascia, but Mosher’s treatment method expressly “may be directed at a variety of tissue structures” including “structures of the vagina (including: vagino-uterine fascia, lamina propria—the dense connective tissue layer just under the epithelium ...).” EX1006, ¶48. In fact, Mosher describes that in certain instances the endopelvic fascia may be damaged or missing, and thus “support of the genitourinary tract is instead provided by a variety of fascial layers, muscular tissues, ligaments and/or tendons within the pelvis.” *Id.* A POSA would have understood Mosher’s methods would equally apply to these other disclosed tissue structures, such as the lamina propria. EX1003, ¶95. The ’511 patent expressly identifies the lamina propria as an example of target tissue. EX1001, 2:25-28. A POSA would have understood that, like Mosher, treatment in Edwards also could target lamina propria underlying the epithelium, and would have been motivated to apply Mosher’s known techniques to Edwards’s method. EX1003, ¶95.

Like Edwards and Mosher, Ingle discloses methods of treatment, e.g., of incontinence, via tissue remodeling achieved by applying RF energy. EX1007, 3:11-25, 11:8-17. In particular, Ingle discloses “a probe for applying energy to fascia from within the vagina of a patient body. The fascia is separated from the vagina by a vaginal wall.” EX1007, 3:36-39. Energy from the probe “heats fascia

and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues.” *Id.*, 2:59-61. A POSA would have understood that, like Ingle, treatment in Edwards targets collagenated support underlying the epithelium. EX1003, ¶96.

As discussed in more detail for element [1.2], a POSA would have understood that the “therapeutic zone” is simply the area of the target tissue that is remodeled. Section VII.B.1.c; EX1003, ¶97.

b. [1.1] heating the target tissue

As discussed for the preamble, Edwards, Mosher, and Ingle teach methods for vaginal remodeling, including remodeling a therapeutic zone within a target tissue, as claimed. Section VII.B.1.a. The asserted combination renders obvious the heating step, both using its ordinary and customary meaning and under the Board’s prior preliminary construction. Section IV.B; EX1003, ¶¶99-111.

Edwards teaches “delivery of RF energy to discrete areas of the vaginal wall.” EX1005, 13:54-56, FIG. 9 (step 908), 2:34-39. The ’511 patent confirms the claimed “heating” encompasses “delivering energy by ... radiofrequency energy,” as in Edwards. EX1001, claim 33. Edwards also uses cooling fluid “to minimize thermal damage to tissues,” EX1005, 4:59-61, confirming that the RF energy in Edwards acts to heat tissue. EX1003, ¶100.

Edwards does not disclose specific temperatures to which the target tissue is heated, but explicitly recognizes that the “energy is selectively applied so as to ablate, tighten, shrink or reshape the tissue.” EX1005, 2:37-39. A POSA would have understood the appropriate temperatures to which the target tissue would be heated in order to achieve the desired remodeling result. EX1003, ¶101. Further, a POSA would have looked to references describing similar treatment methods, such as Mosher and Ingle, for express teachings of treatment temperatures. EX1003, ¶¶102-104.

Mosher discloses heating the target tissue to temperatures of “about 65° C. or more,” “about 70° C. or more,” or “about 75° C. or more,” in order “to effect substantial collagenous tissue shrinkage.” EX1006, ¶9; *see* EX1006, ¶64 (“[T]o obtain a significant percentage of shrinkage in a relatively short treatment time, it is generally advantageous to heat tissues to temperatures of about 70° C. or more.”), ¶65 (“[T]o effect significant, repeatable tissue shrinkage, it is generally desirable to subject the treatment volume to temperatures of at least 70° C. for a time of about 30 seconds or more.”), ¶67, FIG. 10. Figure 11 “illustrates maximum tissue temperatures of tissue heated using a non-invasive probe,” such as the vaginal treatment probe of Figures 6 and 6A. EX1006, ¶¶32, 67-70, FIGs. 10A-10C. Figure 15 “illustrates the different volumes of the tissues which can be heated to 70° with different probes and/or different treatment settings.” EX1006, ¶¶36, 73.

Ingle likewise discloses “a probe for therapeutically heating a target tissue of a patient body through an intermediate tissue.” EX1007, 3:11-13. For example, Ingle discloses “a probe for applying energy to fascia from within the vagina of a patient body.” EX1007, 3:36-42. “An energy transmitting element is mounted to the probe body,” which “is capable of transmitting sufficient heating energy through the vaginal wall to heat and contract the fascia.” EX1007, 3:42-45; *see* EX1007, 7:16-23. Ingle discloses using RF energy to perform its methods. EX1007, 5:11-14. “Heat is applied until the target zone is at or above a treatment temperature” EX1007, 16:5-6. “To effect shrinkage of fascia, target zone 32 will typically be heated to a temperature above about 60 nC,” and “preferably between about 60 nC and 80nC.” EX1007, 12:64-13:2, 15:16-18, 5:51-58.

A POSA would also have understood that using the lowest effective temperature would be desired in order to avoid unnecessary damage to the target tissue and/or surrounding tissue. EX1003, ¶105. This is confirmed by Mosher, which teaches that because “the necrosis sensitivity of the tissue is significantly more dependent on the temperature than on the time for which it is heated, it may be advantageous to (as practicable) limit treatment temperatures toward the lower possible temperatures from which sufficient tissue shrinkage can be provided.” EX1006, ¶65. Ingle further confirms this: “[b]y maintaining the times and

temperatures set forth below, significant tissue contraction can be achieved without substantial collateral tissue damage.” EX1007, 11:28-31.

Thus, the asserted combination renders obvious heating, or “raising the temperature of the target tissue to no more than about 80 degrees C.” EX1003, ¶106.

Should Patent Owner argue the claims require “heating without damaging the mucosal epithelial surface,” the asserted combination teaches the heating step under this construction. As explained below, each of Edwards, Mosher, and Ingle teaches cooling the epithelial surface during heating of the target tissue. A POSA would have understood that by cooling the epithelial surface during heating, damage thereto is avoided. EX1003, ¶¶107-110. Each of the references confirms this.

Edwards discloses: “at least one of the irrigating fluid ports 433 is engaged so as to deliver cooling fluid into the vagina through the irrigating fluid delivery pores 425.” EX1005, 13:50-53, FIG. 9 (step 907). These “cooling liquids ... minimize thermal damage.” EX1005, 7:51-53; *see* EX1005, 4:59-61 (“[C]ooling fluid serves to minimize thermal damage to tissues when the electrodes 225 are deployed.”).

Mosher also discloses “cooled electrode vaginal probes” where “fluid conduits cool the intervening or intermediate tissue between probe body 54 and the

endopelvic fascia EF, such as the vaginal wall.” EX1006, ¶58, FIG. 6. Mosher recognizes that “[a]dvantageously, the pre-cooling can inhibit heating of the intervening tissue to a temperature causing surface lesions within the vagina.” *Id.*

Ingle discloses that, in order to heat “fascia and other collagenated support tissues” without “substantial necrosis of adjacent tissues,” 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.” EX1007, 2:59-61, 3:21-25.

Finally, if the Board applies the construction from *Viveve* (see Section IV.B), a POSA would have understood that each of Edwards, Mosher, and Ingle maintains the epithelium at a temperature that does not damage or substantially modify the tissue. EX1003, ¶111. Thus the target tissue (i.e., the tissue underlying the epithelium, and which *is* modified) is necessarily heated to a temperature higher than the epithelium. *Id.* This is achieved, for example, by cooling the epithelium during treatment. *Id.*

c. [1.2] remodeling the therapeutic zone of target tissue

The asserted combination teaches element [1.2]. EX1003, ¶¶112-119.

This claim element recites the result of the prior “heating” step. *See* Section IV.C. The ’511 patent describes the “therapeutic zone” as a “zone of tissue that is

heated within the target tissues to a threshold level, i.e., to a therapeutic temperature.” EX1001, 4:14-16. Importantly, the specification confirms that “[n]ot all tissue within the target tissue necessarily reaches this threshold level of heat.” EX1001, 4:16-18. A POSA would have understood that the “therapeutic zone” is simply the area of the target tissue that is remodeled. EX1003, ¶¶114-115. Each of Edwards, Mosher, and Ingle teaches remodeling at least a portion of the target tissue, i.e., a therapeutic zone.

Edwards discloses that “radiofrequency (RF) energy is applied to uro-genital tissues so as to cause shrinkage and remodeling, reshaping, bulking and other treatment effects.” EX1005, 2:27-31. “Application of this energy is selectively applied so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition.” EX1005, 2:37-39. Edwards teaches “the RF energy is delivered to the anterior and posterior regions of the vaginal wall,” which “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, 3:5-13, 13:19-22.

Mosher, too, discloses “directing energy from a probe into collagenous tissues of the pelvic support system,” which “will often cause contraction of the collagenous tissue.” EX1006, ¶45. Mosher explains that “heat-induced changes”

include “contraction or shrinkage, stiffening, and/or the like.” EX1006, ¶66. These changes are “through tissue remodeling resulting from the healing process.” *Id.*

Mosher describes the remodeling in more detail:

Within the first 24 hours of the heating treatment, fibroblasts will move in to begin repair. Over about two weeks, type III collagen will replace the denatured collagen, initially providing only a decreased tissue stiffness or low tensile strength. Within 8-12 weeks, the percentage of type I collagen will increase relative to the amount of type III collagen resulting in a return to about 85% of the original stiffness.

Id.

Ingle’s method shrinks tissue by “directing energy from a probe, through the intermediate tissue, and into the target tissue. The energy heats the target tissue so that the target tissue contracts.” EX1007, 3:51-56. Ingle explains that the “[t]issue 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 B-pleated structure. By maintaining the times and temperatures set forth below, significant tissue contraction can be achieved without substantial collateral tissue damage.” EX1007, 11:25-31.

- d. [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.**

The combination of Edwards and Mosher teaches heating this claimed treatment area. EX1003, ¶¶120-125. 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). EX1003, ¶120.

Edwards teaches performing its method “to create a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both. ... Remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function.” EX1005, 13:14-22. 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. EX1003, ¶122.

Mosher further provides motivation to focus treatment nearer the opening of the vagina, in order to avoid damage to nerves in the bladder neck region and in the antero-lateral vaginal wall. EX1006, ¶74; EX1003, ¶123. Mosher describes the safety advantages of using an “enhanced treatment width” or “laterally elongate treatment region,” including when performing treatment with non-invasive vaginal probe 54. EX1006, ¶¶58, 74, 75, FIGs. 6, 6A. Mosher describes the preferred

treatment region as “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.” EX1006, ¶74. Despite the reference to “urethral length” in this description, a POSA would have understood this treatment region to apply to non-invasive treatment within the vagina. *Id.*; EX1003, ¶¶123-124. Indeed, Mosher describes several electrode configurations for its vaginal probe 54 to provide this “enhanced treatment width.” EX1006, ¶75; EX1003, ¶¶123-124.

A POSA would have understood Mosher’s treatment length of about 15 mm (1.5 cm) refers to the length of the treatment region extending into the vagina. EX1003, ¶124. Thus, a POSA would have understood that Mosher teaches treating a portion of the vagina extending from the introitus to 1.5 cm inward, which falls within the claimed treatment area. *Id.*

Thus, the asserted combination renders obvious claim 1.

2. Claim 35

Independent claim 35 recites a “method for remodeling a therapeutic zone within a target tissue” and includes the same “heating” and “remodeling” steps recited in claim 1. As in claim 1, the combination of Edwards, Mosher, and Ingle renders obvious elements [35.P], [35.1], and [35.2]. Sections VII.B.1.a-VII.B.1.c; EX1003, ¶¶126-135, 92-119.

Element [35.3] recites that “*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.*” See, e.g., EX1001, 14:29-15:3 (describing this embodiment).

Edwards discloses this treatment area. EX1003, ¶129. Edwards discloses that its “method 900 is performed to create a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both.” EX1005, 13:14-16. A POSA would have understood that the “anterior vaginal wall” comprises the area from 9:00 through 12:00 to 3:00 on the ’511 patent’s reference clock dial 136, and the “posterior vaginal wall” comprises the area from 3:00 through 6:00 to 9:00 on the reference clock dial. EX1003, ¶129. Treatment of any portion of the 300 degree arc of the vaginal wall from 1 o’clock to 11 o’clock is sufficient to teach element [35.3] under the Board’s prior construction. A POSA would have understood that treating any portion of the posterior wall would necessarily fall within the recited 300 degree arc, and thus Edwards teaches this element. *Id.*

Edwards also teaches treating the entire vaginal circumference, which would include heating along the entire 300 degree arc under the Patent Owner’s previously proposed construction (*see* Section IV.D). Edwards recognizes that a “physician determines optimal areas of treatment. These may include the anterior wall, the posterior wall *or both.*” EX1005, 13:38-42. 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, ¶130.

Additionally, Mosher teaches that “it may be advantageous to distribute the treatment volume *along the patient’s lateral orientation* while limiting the length of treatment along the axis of the patient’s urethra. ... Such a laterally elongate treatment region ... will preferably be significantly wider (along the medial-lateral orientation) than its urethral length.” EX1006, ¶74. Based on Mosher’s teachings of distributing the treatment volume along a lateral orientation, a POSA would have been motivated to treat more locations around the circumference of the vagina to expand the treatment area. EX1003, ¶130.

Claim 35 does not require that the heating be limited to only the 1-to-11-o’clock area; rather, it recites that the heating “includes” this area. EX1001, 17:17-21. *Gillette*, 405 F.3d at 1371; *Invitrogen*, 327 F.3d at 1368. Further, the ’511 patent provides no discussion of the criticality of avoiding treatment in the 60 degree arc between 11 o’clock and 1 o’clock treatment area, instead simply stating that “[e]mbodiments of the invention do not include treating the approximately 60 degree arc between 11 o’clock and 1 o’clock because the practice of this invention

is not directed toward tissue in the vicinity of the urethra.” EX1001, 3:66-4:3;
EX1003, ¶133.

But even if claim 35 was so limited, Mosher provides an express suggestion to avoid treatment in the 60 degree arc between 11 o’clock and 1 o’clock. Mosher teaches that the “treatment volume will preferably be separated from a urethra of a patient by at least about 1 cm to inhibit injury to nerves along the urethra,” where the treatment volume is “offset laterally from the urethra to a right side of the patient” and “another treatment volume [is] similarly offset laterally from the urethra to a left side of the patient.” EX1006, ¶11. As confirmed by the ’511 patent, the distance between 12 o’clock and 1 o’clock, for example, is approximately 1 cm. EX1001, 14:37-40 (“[W]ith 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.”); EX1003, ¶133. In combination with Edwards’s teaching to provide “circumferential vaginal wall tightening,” a POSA would have been motivated to provide treatment to only the *300 degree arc of the circumference, between the 1 o’clock and 11 o’clock positions*, thereby providing a maximum treatment area for circumferential tightening, while also limiting potential injury to nerves along the urethra. EX1003, ¶134.

Thus, the asserted combination renders obvious claim 35.

3. Claim 43

Independent claim 43 recites a “method for remodeling a therapeutic zone within a target tissue” and includes the same “heating” and “remodeling” steps recited in claim 1. As in claim 1, the combination of Edwards, Mosher, and Ingle renders obvious elements [43.P], [43.1], and [43.2]. Sections VII.B.1.a-VII.B.1.c; EX1003, ¶¶136-143, 92-119.

Element [43.3] recites that “*the heating includes heating a portion radiating outward from the introitus to Hart’s line.*” The asserted combination renders obvious element [43.3]. A POSA would have understood this treatment area includes the part of the vulva known as the vulval vestibule, which includes a mucosal epithelium. EX1003, ¶¶138, 37-38. This is consistent with the ’511 patent, which describes that 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.” EX1001, 3:51-54.

Edwards, Mosher, and Ingle each disclose heating a variety of tissues, revealing that it was known that RF treatment is widely beneficial. EX1003, ¶¶139-140. For example, Edwards describes four embodiments applying RF energy to different targeted tissues: interior of the uterus, urethral sphincter muscle, submucosal bladder outlet musculature, and vaginal wall. EX1005, 2:34-3:13.

Likewise, Mosher provides a long list of tissue structures appropriate for treatment with its methods. EX1006, ¶48.

Ingle also teaches that a “wide variety of alternative conditions may also be treated” using Ingle’s methods for “selectively heating and shrinking tissues.”

EX1007, 1:18-23, 17:65-18:1. “[S]elective shrinkage of fascia ... may even be used in cosmetic procedures ... to remove wrinkles by shrinking the collagenated skin tissues, or to lift sagging breasts by shrinking their support ligaments.”

EX1007, 18:1-7, 1:18-23 (Ingle’s methods may be used “for cosmetic surgery.”).

As confirmed by Ingle, a POSA would have known that radiant energy treatments were previously used to treat other tissues, e.g., face, breasts, for cosmetic purposes. EX1003, ¶141.

A POSA would have known that treating the vulva is often done for cosmetic purposes. EX1003, ¶¶142, 49. In view of all of this, a POSA would have been motivated to apply the treatments described in Edwards, Mosher, and Ingle to cosmetically enhance the area recited in claim 43. EX1003, ¶¶142, 39-49, 91. A POSA would have had a reasonable expectation of success in doing so because that area comprises similar mucosal epithelium, with the same underlying collagen-rich layers, as described in Edwards, Mosher, and Ingle. EX1003, ¶142.

Thus, the asserted combination renders obvious claim 43.

4. Claim 51

Independent claim 51 recites a “method for remodeling a therapeutic zone within a target tissue” and includes the same “heating” and “remodeling” steps recited in claim 1. As in claim 1, the combination of Edwards, Mosher, and Ingle renders obvious elements [51.P], [51.1], and [51.2]. Sections VII.B.1.a-VII.B.1.c; EX1003, ¶¶144-147, 92-119.

Element [51.3] recites that “*the heating includes heating a mucosal surface of the labia minora.*” The asserted combination renders obvious element [51.3]. A POSA would have understood element [51.3] to refer to inner surfaces or lining of the labia minora, in that it requires the treated surface to be mucosal epithelium. EX1003, ¶¶145, 37-38. The labia minora are part of the vulva adjacent the vulval vestibule. *Id.*

As discussed for claim 43, a POSA would have known that radiant energy treatments were previously used for cosmetic treatment of other tissue, e.g., face, breasts. EX1003, ¶¶146, 136-143. A POSA also would have known that treating the vulva (including the labia) was often done for cosmetic purposes. *Id.* Thus, a POSA would have been motivated to apply the treatments described in Edwards, Mosher, and Ingle to cosmetically enhance the area recited in claim 51. EX1003, ¶¶146, 136-143, 91. A POSA would have had a reasonable expectation of success in doing so because that area comprises similar mucosal epithelium, with the same

underlying collagen-rich layers, as described in Edwards, Mosher, and Ingle.

EX1003, ¶146.

Thus, the asserted combination renders obvious claim 51.

C. Dependent Claims

As discussed below, the asserted combination renders obvious each of the dependent claims.

1. Claims 2, 36, 44, and 52

These claims recite: “*heating [the target tissue] to a temperature between 45 degrees C. and 80 degrees C.*” Mosher and Ingle teach heating the tissue to the claimed temperature range. EX1003, ¶¶148-152, 99-106.

A POSA would have understood the appropriate temperatures to which the target tissue would be heated to achieve remodeling. EX1003, ¶¶149, 39-43; Section VII.B.1.b. Further, Mosher teaches a treatment temperature of “at least 70°.” EX1006, ¶65. Ingle discloses heating “fascia and other collagenated tissues ... to a temperature range of ... *preferably between about 60 nC and 80 nC,*” which results in the tissue contracting. EX1007, 12:64-13:2, 11:32-38.

As here, an overlap in the claimed ranges and those disclosed by the prior art demonstrates obviousness. *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1341 (Fed. Cir. 2020) (affirming Board’s obviousness conclusion). “[S]uch an overlap creates a presumption of obviousness, and ... the burden of production falls upon

the patentee to come forward with pertinent evidence that the overlapping range would not have been obvious in light of the prior art.” *Id.* (citing *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006, 1008 (Fed. Cir. 2018)).

2. Claims 3-4

Claim 3 recites: “*heating [the target tissue] to a temperature between 50 degrees C. and 75 degrees C.*,” and claim 4 recites: “*heating it to a temperature between 55 degrees C. and 70 degrees C.*” Mosher and Ingle teach heating the tissue to these temperatures. EX1003, ¶¶153-156.

Mosher teaches a treatment temperature of “at least 70°.” EX1006, ¶65. Ingle teaches heating to a temperature of “preferably between about 60 nC and 80 nC.” EX1007, 12:64-13:2. As here, an overlap between the claimed ranges and those disclosed by the prior art demonstrates obviousness. *Genentech*, 946 F.3d at 1341.

The ’511 patent includes no discussion of the criticality of the narrower range recited in claim 3 or 4.

3. Claims 5, 37, 45, and 53

These claims recite: “*heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.*”

Each of Edwards, Mosher, and Ingle teaches a device having a *treatment tip including an energy delivery element*. EX1003, ¶¶157-162. Edwards discloses a

“system 400 [that] includes a treatment element 410. The proximal end of the treatment element 410 is coupled to an RF generator.” EX1005, 7:16-18, FIG. 4. Edward’s treatment element includes a “plurality relatively flat electrodes 423” that “are disposed to deliver RF energy,” i.e., *energy delivery element*. EX1005, 7:34-39. These electrodes are disposed on a blade end 420, i.e., a *treatment tip*, of the treatment element. EX1005, 7:18-19, 7:26-28.

Mosher’s Figures 6 and 6A illustrate “cooled electrode vaginal probes for indirect treatment of tissue.” EX1006, ¶58. The end of vaginal probe body 54, i.e., *treatment tip*, includes a plurality of electrodes 56, i.e., *energy delivery element*. *Id.* The “relatively flat tissue-engaging electrode surface” directs electrical current flux 60 toward the target tissue. *Id.* Similarly, Ingle discloses a vaginal probe 42 having electrodes 12 disposed at a distal end thereof, and that directs RF energy to a target tissue. EX1007, 20:14-24, FIG. 11.

Further, these devices *deliver energy by contacting the epithelium with the treatment tip*. EX1003, ¶¶157-162. In Edwards, the “distal end of the treatment element 410 is inserted into a vagina.” EX1005, 7:16-19. During treatment, RF energy is delivered “to discrete areas of the vaginal wall.” EX1005, 13:38-56, FIG. 9 (step 908). Edwards further teaches that blade 420 may be moved “into another position ... , so as to deliv[er] energy to another area of the vagina.” EX1005, 13:60-62. A POSA would have understood the treatment tip in Edwards to contact

the surface of the vaginal wall, i.e., the epithelium. EX1003, ¶159. This is further confirmed by Mosher, which expressly teaches that its electrode is “tissue engaging” and that “tissues between a vaginal treatment probe and [the target tissue] includes typically about 0.04 mm of *epithelium along the surface of the vaginal wall*.” EX1006, ¶¶58, 66. Ingle similarly teaches that its electrode surface “is engagable against the intermediate tissue.” EX1007, 3:13-15, 4:33-34, 4:58-61.

4. Claims 6, 33, 41, 49, and 57

These claims recite the energy is “*any of radiofrequency energy, microwave energy, or ultrasound energy*.” Each of Edwards, Mosher, and Ingle teaches these claims. EX1003, ¶¶163-167.

Edwards discloses that electrodes 423 of treatment element 410 deliver *RF energy*, however, “in other embodiments[,] the electrodes 423 may also deliver *microwave energy*, ELF (extremely low frequency energy), laser and other forms of therapeutic energy.” EX1005, 7:37-42, 5:30-34 (RF, microwave, and ultrasound energy), 6:55-59 (same). Mosher discloses using RF current to heat the target tissue. EX1006, ¶¶55, 58, 66. Ingle discloses that multiple types of energy may be used as the “tissue contraction energy,” such as “radiofrequency (RF) electrical current,” EX1007, 7:1-8:4, “focused ultrasound energy,” EX1007, 8:32-65, 24:41-25:3, or “microwave heating energy,” EX1007, 24:14-40.

To render these claims obvious, only one of the recited energy types must be taught in the prior art. Here, all three alternatives are disclosed.

5. Claims 7, 38, 46, and 54

These claims recite: “*the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined temperature.*” Each of Edwards, Mosher, and Ingle teaches this claim element. EX1003, ¶¶168-173.

The ’511 patent describes that “[t]he electrodes may further comprise thermal sensors that provide feedback control based on local temperature.” EX1001, 2:48-52. This “[f]eedback may be provided by one or more thermistors (thermal sensors) or impedance monitors.” EX1001, 4:33-34. Such “thermistors (thermal sensors) 38 (shown in FIG. 4) may be provided at each corner of an RF electrode, or otherwise in close proximity to the electrode, to provide feedback to the system on the temperature at their location.” EX1001, 9:27-31.

Edwards teaches “[e]ach electrode 423 includes at least one thermocouple 424 that is used to monitor the temperature of each electrode 423,” and that this “monitoring, combined with a computerized algorithm, is utilized to independently control the electrodes 423” such that if an electrode exceeds temperature safety limits, it can be disengaged. EX1005, 7:43-50. Similarly, Mosher discloses “needle-mounted temperature sensors 62” that provide “[f]eedback on the pre-cooling and heating temperatures.” EX1006, ¶¶58, 68 (discussing the temperature

sensor being “used in a feedback loop to control the RF energy applied by the probe”). Ingle, too, discloses a “control system ... coupled to the electrode surface segments” of Ingle’s probe, to “selectively energize the electrode surface segments so as to heat the target tissue while the cooling system maintains the intermediate tissue ... at or below a maximum safe tissue temperature.” EX1007, 4:61-67. Ingle teaches “controller 22 will typically include a computer program which directs the application of cooling flow and RF power through electrodes 12, 14, ideally based at least in part on a temperature signal sensed by a temperature sensor 24” and that “[t]emperature sensor 24 may sense the temperature of the electrode, the tissue at the tissue/electrode interface, the intermediate tissue, or may alternatively sense the temperature of the fascia itself.” EX1007, 12:37-45, 7:10-15 (temperature sensors “provide direct feedback of the tissue temperature” to heat the “selected treatment zone” to a treatment temperature while limiting heating of adjacent tissue), 23:50-65 (discussing “computer control based on [] feedback [from the temperature sensors]” to control tissue temperature during treatment).

A POSA would have understood that feedback control would be used to regulate the treatment temperature in order to prevent tissue damage. EX1003, ¶172.

6. Claim 8

Claim 8 recites: “*the feedback control is provided by one or more thermal sensors.*” As discussed above, Edwards, Mosher, and Ingle teach feedback control *provided by one or more thermal sensors*. EX1005, 7:43-44; EX1006, ¶58; EX1007, 7:10-15, 12:37-45, 23:50-65; *see* Section VII.C.5. EX1003, ¶¶174-176.

7. Claims 9, 39, 47, and 55

These claims further recite: “*cooling the epithelium.*” Each of Edwards, Mosher, and Ingle teaches a method including cooling. EX1003, ¶¶177-182.

Edwards teaches “deliver[ing] cooling fluid into the vagina through the irrigating fluid delivery pores 425.” EX1005, 13:50-52. This “cooling fluid serves to minimize thermal damage to tissues when the electrodes 225 are deployed.” EX1005, 4:59-61.

Mosher discloses “at least one cooling element” that “provide[s] cooling of the intermediate tissue while heating the treatment volume.” EX1006, ¶15. Mosher teaches the fluid cools the intermediate tissue, “such as the vaginal wall VW.” EX1006, ¶58. Ingle also discloses cooling the vaginal wall during treatment. EX1007, 3:43-58 (“The cooling system is capable of *maintaining the vaginal wall adjacent the probe below a maximum safe temperature* when the fascia is heated by the transmitting element.”).

A POSA would have understood that delivering cooling fluid to the vagina or vaginal wall would act to cool the epithelium, because cooling occurs by surface contact and the epithelium is the surface tissue layer of the vagina. EX1003, ¶181.

8. Claim 10

Claim 10 recites: “*cooling is by contacting the epithelium with a treatment tip, the tip including a cooling mechanism.*”

Each of Edwards, Mosher, and Ingle teaches a device having a *treatment tip*. See Section VII.C.3. These references also teach that the treatment tips *include a cooling mechanism*. EX1003, ¶¶183-188, 158-161.

Edwards’s blade end 420, i.e., *treatment tip*, includes “irrigating fluid delivery pores 425” through which cooling liquid is delivered, i.e., *a cooling mechanism*. EX1005, 7:51-53, FIG. 4.

Mosher’s probe body 54 includes fluid conduits 58, i.e., *cooling mechanism*, that cool the electrodes 56 located at the *treatment tip*. EX1006, ¶58, FIG. 6; see EX1014,⁵ 5:54-67 (surfaces of electrodes are cooled by a cooling system, “typically includ[ing] a conduit through the electrode for the circulation of a

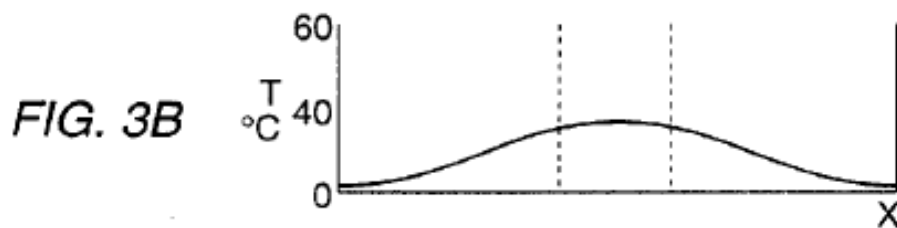
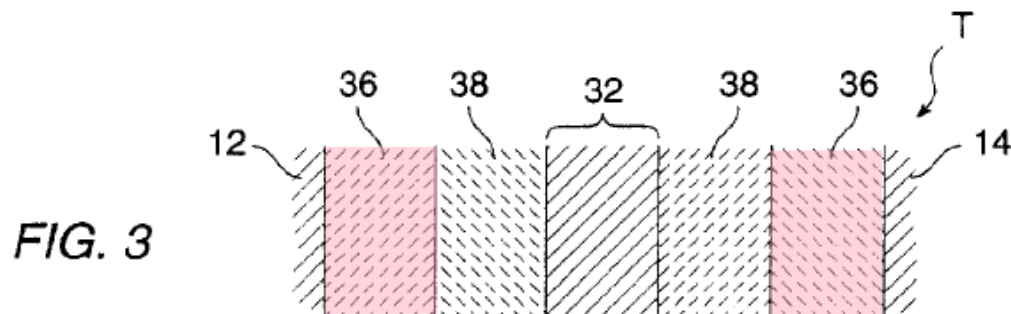
⁵ US 6,283,987 is incorporated by reference into Mosher for its teachings of “[e]xemplary cooled electrode structures.” EX1006, ¶58.

cooling fluid”). Ingle also discloses that the vaginal wall “is protected by cooling the surface of electrode 12” of vaginal probe 42. EX1007, 20:14-18, FIG. 11.

9. Claim 11

Claim 11 recites: “cooling [the epithelium] to a temperature between 0 degrees C. and 10 degrees C.” Ingle teaches this claim. EX1003, ¶¶189-192.

Ingle discloses pre-cooling the vaginal tissue “by the surfaces of electrodes 12, 14, generally using an electrode surface temperature of at or above 0 nC.” EX1007, 15:31-34. “Pre-cooling will substantially decrease the temperature of intermediate tissues 36,” to near 0 °C. EX1007, 15:5-11, 15:34-37, FIGs. 3, 3B.



EX1007, FIGs. 3 (annotated), 3B.

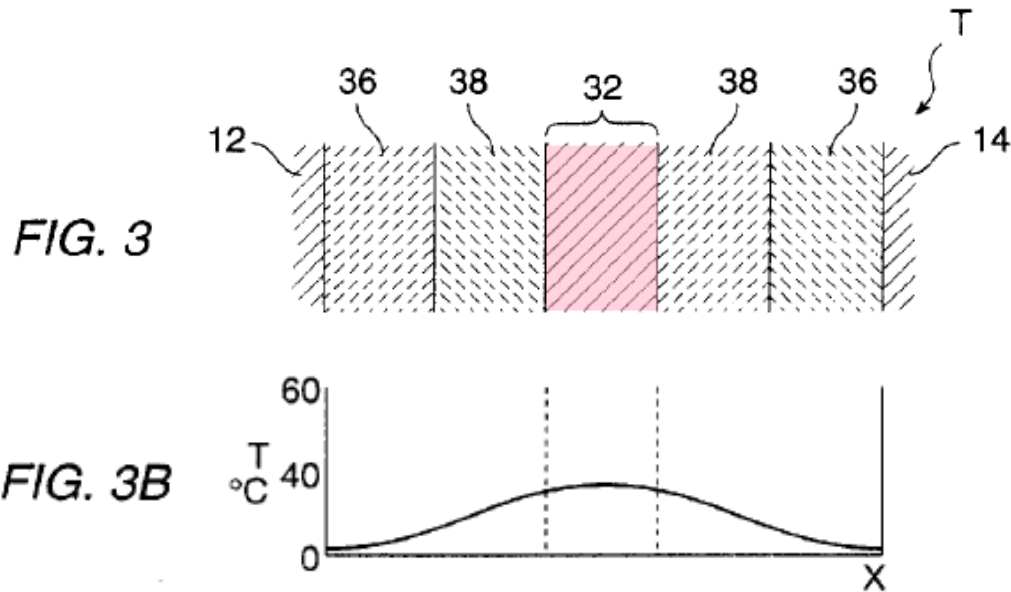
A POSA would have understood Ingle's Figure 3B to illustrate a cooling of the epithelium in contact with the electrode to a temperature between 0 and 10 °C. EX1003, ¶191.

10. Claim 12

Claim 12 further recites: “*cooling of at least some of the target tissue, the cooling of the target tissue having an effect on the therapeutic zone.*” The combination of Edwards, Mosher, and Ingle teaches this claim. EX1003, ¶¶193-200, 158-161, 184-187.

The '511 patent describes the “therapeutic zone” as a “zone of tissue that is heated within the target tissues to a threshold level, i.e., to a therapeutic temperature that causes remodeling.” EX1001, 4:14-18.

The combination of Edwards, Mosher, and Ingle teaches cooling the epithelium. *See* Section VII.C.7. As confirmed by Ingle, when pre-cooling intermediate tissue 36, i.e., the epithelium, some cooling to the target zone 32 also occurs. EX1007, 15:5-11, 15:34-37, FIGs. 3, 3B.



EX1007, FIGs. 3 (annotated), 3B.

Because Ingle describes only “a portion” of the target zone remains at or near the initial body temperature, another portion of target zone is necessarily cooled. *See* EX1007, 15:37-40, FIG. 3B; EX1003, ¶197.

Ingle further teaches that “[h]eat 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.” EX1007, 16:5-7.

FIG. 3

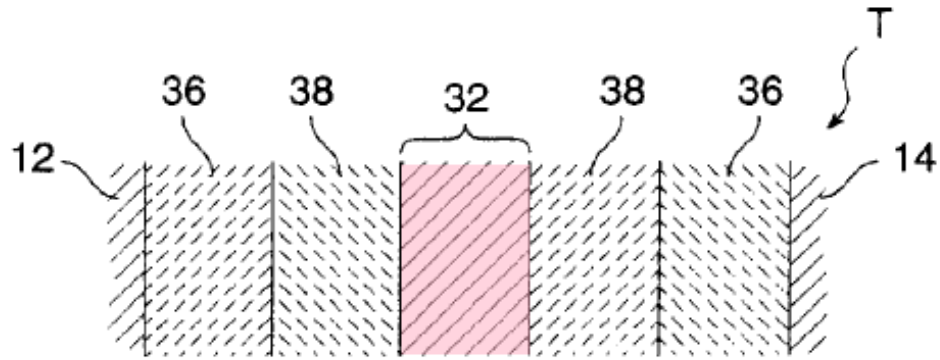
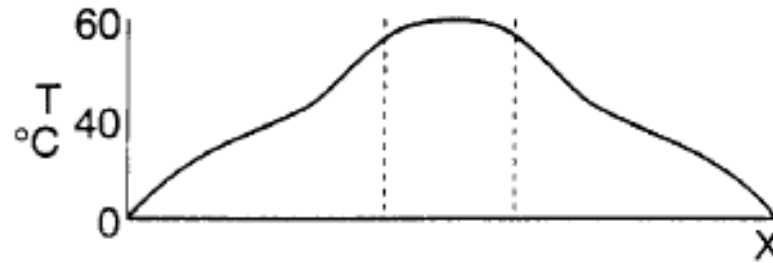


FIG. 3C



EX1007, FIGs. 3 (annotated), 3C.

Figure 3C shows the tissue at the edges of target zone 32 is at a lower temperature than the tissue in the middle of the target zone. A POSA would have understood that this lower temperature at the edges of the target zone would have an effect on the therapeutic zone because it is defined by the remodeling effect, which depends on the treatment temperature. EX1003, ¶¶194-199.

11. Claims 13-14

Claim 13 recites: “the cooling precedes the heating, and continues during the heating.” Claim 14 recites: “wherein the cooling is during the heating, and continues after heating.” The combination of Edwards, Mosher, and Ingle teaches these claims. EX1003, ¶¶201-205.

As discussed above, the asserted combination teaches cooling. *See* Section VII.C.7. Mosher teaches cooling before and during heating, and Edwards and Ingle both teach cooling before, during, and after heating. EX1003, ¶¶202-204.

Mosher discloses “cooling prior to and during RF energy application.” EX1006, ¶69.

In Edwards’s method of Figure 9, “delivery [of] cooling fluid into the vagina” begins at step 907, “delivery [of] RF energy to discrete areas of the vaginal wall” occurs at step 908, and the flow of cooling fluid is stopped in step 909. EX1005, 13:50-67, FIG. 9A, 7:51-53 (“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.”). A POSA would have understood from these disclosures that the flow of cooling fluid in Edwards continues during the heating of step 908. EX1003, ¶202.

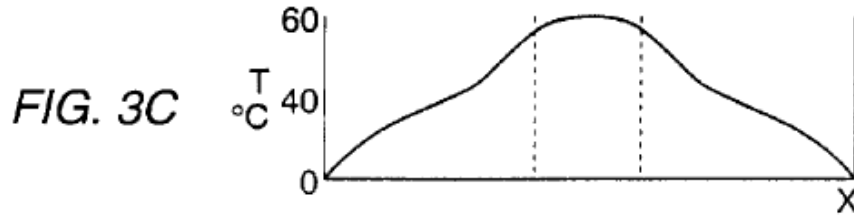
Ingle similarly discloses that the tissue “be *pre-cooled*.” EX1007, 15:31. “Once the tissue has been pre-cooled,” in Ingle, treatment begins. EX1007, 15:58-60, 4:4-10. Ingle recognizes that, “the electrode surfaces are often *cooled throughout the heating process*.” EX1007, 15:62-65. Further, “[t]o minimize collateral damage to the adjacent tissues ... , the cooling system *continues to circulate cold fluid* through the electrode, and to remove heat from the tissue, *after the heating radiofrequency energy is halted*.” EX1007, 16:7-11.

12. Claims 15-16

Claim 15 recites: “*the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue.*” Claim 16 further recites: “*the reverse thermal gradient ranges from a low temperature of 0 degrees C. to 10 degrees C. at the epithelium to a high temperature of 45 degrees C. to 80 degrees C. in the underlying target tissue.*”

The '511 patent describes that “a reverse thermal gradient is created, with a lower temperature at the mucosal epithelium, and a higher temperature in the underlying tissue.” EX1001, 13:43-45. This is consistent with how a POSA would have understood *reverse thermal gradient*. EX1003, ¶207.

Mosher and Ingle teach heating the target tissue to a temperature of 45 °C to 80 °C. *See* Section VII.C.1. Ingle teaches cooling the epithelium to a temperature of 0 °C to 10 °C. *See* Section VII.C.9. The combination of these teachings, i.e., heating the target tissue and cooling the epithelium to these temperatures, creates a reverse thermal gradient, as recited in claims 15 and 16. EX1003, ¶¶206-209, 148-151, 190-191; *see, e.g.*, EX1007, 15:45-57 (recognizing the benefits of the temperature differential between the target tissue and the epithelium). Ingle’s Figure 3C also illustrates a reverse thermal gradient, as claimed.



EX1007, FIG. 3C.

13. Claims 17, 40, 48, and 56

These claims further recite: “*contacting the epithelium with a treatment tip at a one or more contact sites during a procedure, the tip comprising an energy delivery element adapted to heat the target tissue.*”

Edwards, Mosher, and Ingle teach *contacting the epithelium with a treatment tip, the tip including an energy delivery element*. See Section VII.C.3; EX1003, ¶¶210, 214, 158-161. The devices in the prior art are *adapted to heat the target tissue*, using RF or other radiant energy. See Section VII.B.1.b; EX1003, ¶¶210, 214, 100-111. The claims recite “contacting ... *one or more* contact sites,” meaning a single contact site suffices to satisfy this element.

Further, a POSA would have understood that to treat the target tissue using the device of Edwards or Mosher, multiple sites must be contacted. EX1003, ¶¶210-214, 44-49. This is confirmed by Edwards and Mosher, which discuss moving the device to treat multiple areas. Edwards teaches that “blade 420 may be disengaged and relocked into another position in the speculum, so as *to deliv[er] energy to another area of the vagina.*” EX1005, 13:60-62. Mosher teaches

“heat[ing] a treatment surface with a ‘paint’ tip movement pattern.” EX1006, ¶71, claim 19, FIG. 12A.

14. Claim 18

Claim 18 recites: “*the method is performed during a procedure,*” and “*the contacting of any one or more contact sites is repeated one or more times during a procedure.*”

Edwards, Mosher, and Ingle teach *contacting one or more contract sites*. See Section VII.C.13. A POSA also would have understood that during a procedure, a physician would often contact multiple contact sites in order to treat a larger area of tissue. EX1003, ¶¶215-220, 44-49.

Ingle discloses that “the electrode may be energized for 15 secs. and turned off for 15 secs. repeatedly during a heating session,” thus teaching that *contacting of any one or more contact sites is repeated one or more times during a procedure*. EX1007, 7:25-29. Mosher teaches “heat[ing] a treatment surface with a ‘paint’ tip movement pattern as shown in FIG. 12A Arrow 37 indicates a tip movement pattern of five passes in the treatment zone.” EX1006, ¶71, claim 19, FIG. 12A. At the disclosed “tip movement speeds of about 0.4 cm/sec. for a treatment of 140 seconds and tip movement speeds of about 1.1 cm/sec. for a treatment period of 90 seconds,” the tip travels a total distance of 56 cm and 99 cm, respectively, along a

14 cm path. EX1006, ¶71, FIG. 12A. A POSA would have understood this to teach repeating contact at the sites several times during the procedure. EX1003, ¶218.

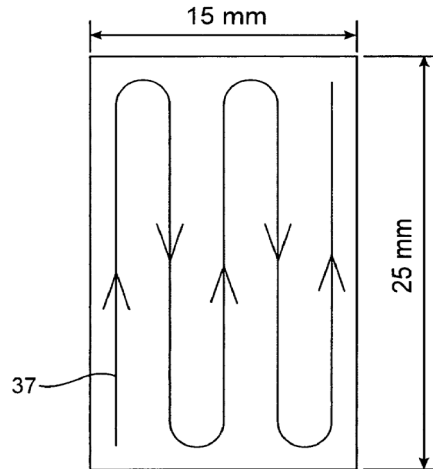


FIG. 12A

EX1006, FIG. 12A.

A POSA would also have understood that it was typical to contact each particular contact site more than once during a procedure because moving the device allows for more even distribution of the thermal energy resulting in a more uniform effect on the tissue. EX1003, ¶219.

15. Claim 19

Claim 19 further recites: “*contacting the tip to the epithelium at a plurality of contact sites during a procedure, moving the tip from site to site, the combined contact sites comprising a treatment area.*”

The combination of Edwards, Mosher, and Ingle teaches *contacting the tip to the epithelium at a plurality of contact sites during a procedure*, as well as

moving the tip from site to site. See Sections VII.C.3, VII.C.13; EX1003, ¶¶221-225, 158-161, 210-213.

A POSA would have understood that contacting a plurality of contact sites would create a *combined treatment area* comprised of the target tissue treated at each contact site. EX1003, ¶222. Edwards teaches contacting both the anterior wall and posterior wall to provide a combined treatment area resulting in circumferential vaginal tightening. EX1005, 13:14-22; EX1003, ¶223. Edwards also teaches that “the blade 420 may be disengaged and relocked into another position in the speculum, so as to deliv[er] energy to another area of the vagina.” EX1005, 13:60-62. Mosher teaches contacting the tip to a plurality of contact sites and recognizes that total treatment volume is dependent on the speed of tip movement. *See* EX1006, ¶¶13, 71, FIG. 12A; EX1003, ¶224.

16. Claim 20

Claim 20 recites: “*any one of the contact sites is contacted one or more times during a procedure.*”

As discussed for claim 18, *see* Section VII.C.14, the asserted combination renders obvious repeating contact at one or more contact sites. EX1003, ¶¶226-227, 216-219.

17. Claim 21

Claim 21 further recites: “*repeating the procedure one or more times.*”

Claim 21 does not specify whether “the procedure” is claim 17’s procedure in which “one or more contact sites” are contacted or claim 19’s procedure in which “a plurality of contact sites” are contacted. Either way, claim 21 is rendered obvious by the asserted combination for the same reasons as claims 18 and 19.

Sections VII.C.14, VII.C.15; EX1003, ¶¶228-230, 216-219, 222-224.

Additionally, Mosher teaches that its techniques are “effective for controllably and *repeatably enhancing* the structural support of a wide variety of fascia and other collagenous tissues.” EX1006, ¶46. A POSA would have understood that the treatment procedure could be repeated to treat additional areas or provide further treatment results. EX1003, ¶¶229, 44-49; *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1330 (Fed. Cir. 2009) (“[R]epetition of a known procedure until success is achieved ... would have been obvious as a matter of common sense.”); *In re Harza*, 274 F.2d 669, 671 (C.C.P.A. 1960) (“[T]he mere duplication of parts has no patentable significance unless a new and unexpected result is produced”).

18. Claim 22

Claim 22 recites: “*the treatment areas of the one or more procedures may be any of the same treatment area, different treatment areas, or overlapping treatment areas.*”

A POSA would have understood that the treatment procedure could be repeated. *See* Section VII.C.17; EX1003, ¶¶231-233, 229. When the procedure is repeated, the treatment area is necessarily the same as, different from, or overlapping with the previous treatment area. EX1003, ¶232.

19. Claim 23

Claim 23 recites: “*the target tissue heating includes heating submucosa and muscularis below a mucosal epithelium.*”

Edwards teaches an “RF energy” treatment area of “the anterior and posterior regions of the vaginal wall.” EX1005, 3:6-9. A POSA would have recognized that in treating regions of the vaginal wall, energy would penetrate the layers underlying the epithelium, including the *submucosa and muscularis*. EX1003, ¶¶234-239; EX1001, 3:43-47, FIG. 8 (showing lamina propria 104 and muscularis 106). A POSA would have understood how to target particular layers based on the desired treatment outcome (e.g., treating incontinence, improving sexual function, etc.). EX1003, ¶¶91, 238. It further would have been within the

skill of a POSA to determine optimal temperature and time of treatment parameters in order to achieve the desired treatment target. *Id.*; EX1006, ¶85, FIG. 23.

Mosher expressly teaches treating the lamina propria and the pubovesical muscle. EX1006, ¶48. A POSA would have understood that the lamina propria is included within the submucosa and that the pubovesical muscle is a portion of the muscularis. EX1003, ¶237.

20. Claim 24

Claim 24 recites: “*the heating does not modify a mucosal epithelium of the genital tissue.*”

Each of Edwards, Mosher, and Ingle teaches cooling the epithelial surface during heating of the target tissue, and a POSA would have understood that such cooling avoids epithelial damage. *See* Sections VII.B.1.b, VII.C.7-VII.C.12; EX1003, ¶¶240-245.

21. Claim 25

Claim 25 recites: “*remodeling comprises contracting target tissue.*”

A POSA would have understood that remodeling comprises contracting target tissue. EX1006, ¶¶45, 66; *see* Section VII.B.1.c; EX1003, ¶¶246-247.

22. Claim 26

Claim 26 recites: “*remodeling comprises tightening the introitus.*”

Edwards discloses “circumferential tightening of the vaginal wall” to provide “physical and psychological improvement in the area of sexual function.”

EX1005, 3:11-13, 13:19-22. A POSA would have recognized that using Edwards's teaching of "circumferential tightening" at "a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus," as recited in claim 1, would result in *tightening the introitus*, as claimed. EX1003, ¶¶248-251.

23. Claim 27

Claim 27 recites: "*remodeling comprises tightening the vagina.*"

The asserted references teach that remodeling results in tightening of the vagina. *See* Section VII.B.1.c. Edwards discloses "circumferential tightening of the vaginal wall." EX1005, 3:11-13, 13:19-22. Mosher teaches causing a "contraction of the collagenous tissue" in "structures of the vagina." EX1006, ¶¶45, 48. Based on these teachings, a POSA would have found it obvious to treat the vagina to cause tightening. EX1003, ¶¶252-254.

24. Claim 28

Claim 28 recites: "*remodeling comprises denaturing collagen.*"

The asserted references teach remodeling collagenous tissue. *See* Section VII.B.1.c. A POSA would have understood that at least some of this remodeling involves *denaturing*. EX1003, ¶¶255-257.

This is confirmed by Mosher, which teaches:

Within the first 24 hours of the heating treatment, fibroblasts will move in to begin repair. Over about two weeks, type III collagen will replace

the *denatured collagen*, initially providing only a decreased tissue stiffness or low tensile strength. Within 8-12 weeks, the percentage of type I collagen will increase relative to the amount of type III collagen resulting in a return to about 85% of the original stiffness.

EX1006, ¶66. Ingle confirms that “controlled heating of the tissue” causes tissue contraction resulting from “heat-induced uncoiling and repositioning of the collagen β -pleated structure.” EX1007, 11:25-28.

25. Claim 29

Claim 29 recites: “*remodeling comprises tightening collagen-rich sites in the target tissue.*”

The asserted references teach that remodeling can result in *tightening* of the tissues. *See* Section VII.B.1.c. Further, a POSA would have understood that remodeling may occur due to denaturing collagen during treatment, to cause this tightening. *See* Section VII.C.24. Based on these teachings, it would have been obvious to a POSA to treat collagen-rich sites to achieve a tightening effect through denaturing collagen. EX1003, ¶¶258-260.

26. Claims 30-31

Claim 30 recites: “*at least some of the remodeling occurs during the heating.*” Claim 31 recites: “*at least some of the remodeling occurs after the heating.*”

A POSA would have understood that some of the heat-induced collagen remodeling occurs immediately, i.e., *during the heating*, and some occurs *after the heating*. EX1003, ¶¶261-264, 39-43. Mosher teaches that RF heating (1) “will typically induce collagen shrinkage,” i.e., immediate response, and (2) “may also ... provid[e] increased stiffness through tissue remodeling resulting from the healing process,” i.e., delayed response. EX1006, ¶66; *see* EX1006, ¶55 (discussing that the collagenous tissues subject to RF energy provide support “immediately and/or upon healing”), ¶64, FIG. 8A.

27. Claim 32

Claim 32 recites: “*the remodeling after the heating is by a depositing of collagen in the target tissue.*”

The combination of Edwards, Mosher, and Ingle discloses that collagen is denatured during treatment. *See* Section VII.C.24.

Mosher teaches that “[w]ithin the first 24 hours of the heating treatment, fibroblasts will move in to begin repair,” then “[o]ver about two weeks, type III collagen will replace the denatured collagen,” and “[w]ithin 8-12 weeks, the percentage of type I collagen will increase relative to the amount of type III collagen.” EX1006, ¶66. A POSA would have recognized this collagen deposition as part of the normal tissue healing process. EX1003, ¶¶265-268.

28. Claims 34, 42, 50, and 58

These claims recite: “*heating comprises delivering energy by ultrasound energy.*” Edwards and Ingle each teaches delivering energy by *ultrasound energy*. See Section VII.C.4; EX1003, ¶¶269-270.

VIII. GROUND 2: THE COMBINATION OF EDWARDS, MOSHER, INGLE, AND OLLIVIER RENDERS OBVIOUS CLAIMS 43-58.

Claims 43-58 would have been obvious in view of Edwards, Mosher, Ingle, and Ollivier. EX1003, ¶¶271-277.

As discussed above for Ground 1, a POSA would have known that treating the vulva, including areas specifically recited in claims 43 and 51, is often done for cosmetic purposes. To the extent Patent Owner argues or the Board finds that this was not within the general knowledge of a POSA, it would have been obvious in view of Ollivier’s teachings. EX1003, ¶272.

Ollivier teaches that “by reconstructing the outer third of the vagina: the orgasmic platform, internal and external vaginal diameter (introitus) and the perineal body ... women not only are relieved of incontinence, but they also enjoy increased levels of sexual gratification.” EX1008, 0001. Ollivier describes techniques to not only tighten the vagina and introitus, but also to “aesthetically modify” the labia. *Id.*

A POSA would have been motivated to use the treatment method of the Edwards-Mosher-Ingle combination, which teaches treating at least the vagina and

introitus, to also treat the vulvar vestibule and labia minora in order to achieve the desired aesthetic modification expressly described in Ollivier. EX1003, ¶274.

Ollivier teaches using earlier laser techniques to provide cosmetic treatment to these vulvar tissues, as recited in claims 43 and 51, and adds that lasers have “fallen out of favor” and there are “more sophisticated tools that do the same thing.” EX1008, 0003. And as discussed above for Ground 1, it was known to use RF treatments to tighten other tissue areas for both therapeutic and cosmetic purposes. EX1007, 1:18-23, 18:1-7; EX1003, ¶¶44-51, 84-90. A POSA would have had a reasonable expectation of success in doing so because the vulval region comprises similar mucosal epithelium, with the same underlying collagen-rich layers as the vagina. EX1003, ¶275.

Accordingly, claims 43 and 51 would have been obvious over the combination of Edwards, Mosher, Ingle, and Ollivier. Dependent claims 44-50 and 52-58 further would have been obvious for the same reasons as discussed above in Ground 1.

IX. SECONDARY CONSIDERATIONS DO NOT DEMONSTRATE NON-OBVIOUSNESS.

In the prior IPRs, Patent Owner argued that “industry praise of RF treatment of the vulva, introitus, and vagina tissue” weighed against obviousness. EX1010, 43-45; EX1012, 28-30. Institution should not be denied on the basis of these alleged secondary considerations. The Federal Circuit has held that “[i]n evaluating

whether the requisite nexus exists, the identified objective indicia must be directed to what was not known in the prior art.” *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1331 (Fed. Cir. 2017). But as shown herein, RF treatment of the vulva, introitus, and vagina tissue was known in the prior art. Thus, the alleged praise lacks the requisite nexus. Moreover, the alleged secondary-considerations evidence is tenuous at best and cannot overcome the strong obviousness showing above. EX1003, ¶¶278-280.

X. DISCRETIONARY CONSIDERATIONS STRONGLY FAVOR INSTITUTION.

A. *Fintiv* strongly favors institution.

The *Fintiv* factors strongly favor institution. On October 11, 2023, Patent Owner filed a complaint alleging infringement of the ’511 patent against Petitioner in the CDCA. The stage and location of the parallel litigation (factors 2 and 3), lack of overlapping issues (factor 4), and the compelling merits of the Petition (factor 6) strongly favor institution. *See* June 2022 *Fintiv* Memo, 3-5, 7-9.

Factor 1 is neutral or favors institution. No motion for stay has been filed and the CDCA court has not indicated whether it would grant any such motion.

Factor 2 strongly favors institution because the CDCA case is in its early stages, BTL has not yet answered, no trial date is set, and the median time to trial for civil actions in CDCA is about two and a half years (29.7 months). *Fintiv* Memo, 3.

Factor 3 favors institution because, by the time of institution, neither the parties nor the court will have invested significant resources in the parallel litigation. Currently, the court has not made any substantive rulings (e.g., a claim construction order). Petitioner's diligence filing the Petition over six months before the statutory deadline confirms that factor 3 favors institution.

Factor 4 favors institution. The Petition challenges all 58 claims of the '511 patent whereas only claims 1, 33, 35, and 41 are mentioned in Patent Owner's CDCA complaint. Petitioner's challenge to all claims significantly mitigates the concerns for duplication of efforts under factor 4.

Factor 6 is *dispositive* in favor of institution because the Grounds of Unpatentability present compelling, meritorious challenges that present evidence which, if unrebutted, would plainly lead to a conclusion that the challenged claims are unpatentable by a preponderance of the evidence. *Fintiv* Memo, 4. The Petition is also supported by the testimony of Dr. Berenholz, who supports and adds further weight to the Petition's compelling invalidity challenges. As Dr. Berenholz confirms, the claimed methods simply recite the well-known method of using radiant energy to remodel vaginal tissue.

B. *General Plastic* and *Valve Corp.* strongly favor institution.

Serial petitioning concerns are not at play here and the *General Plastic* factors strongly favor institution. The '511 patent was previously challenged in

2018 by ThermiGen, LLC (IPR2018-00088, IPR2018-00089) in response to an infringement suit against ThermiGen. The Board instituted review, but the IPRs were terminated by the parties' agreement. EX1009; EX1011.

General Plastic factor 1 heavily favors institution. Petitioner has not previously petitioned for IPR of the '511 patent. Petitioner has no relationship with ThermiGen, so considerations under *Valve Corp. v. Electronic Scripting Products, Inc.*, IPR2019-00062, Paper 11 (PTAB April 12, 2019) (precedential), are not relevant here.

As to *General Plastic* factors 2-5, the Board has recognized that they "bear little relevance" when *General Plastic* factor 1 indicates a Petitioner has not previously filed a petition against the same patent. *Samsung Bioepis Co. v. Regeneron Pharms., Inc.*, IPR2023-00442, Paper 10, 46-47 (PTAB July 19, 2023); *Mercedes-Benz USA, LLC v. Yechezkal Evan Spero*, IPR2023-01034, Paper 17, 7-8 (PTAB Jan. 19, 2024) (finding factors 2-5 are "substantially diminished" in view of finding factor 1 weighed against denial). This is the case here. Further, any potential roadmapping concerns are outweighed by the fact that Patent Owner chose to file its complaint against BTL in October 2023, nearly six years after the filing of the prior IPRs. BTL should have the opportunity to proceed with its own challenge against a patent for which it has been accused of infringing. *See Mercedes-Benz*, IPR2023-01034, Paper 17, 8-9.

Considerations of efficiency and timing (*General Plastic* factors 6 and 7)

also favor institution. The prior IPRs were terminated before the Board issued a final written decision, and at the parties' joint request. The Board's mission "to improve patent quality" and the fact that this is Petitioner's first petition, filed within one year of being sued, outweigh the impact on Board resources needed to reach a final evaluation of the merits of the asserted grounds. *See Code2000, UAB v. Bright Data Ltd.*, IPR2022-00861, Paper 18, 6 (PTAB Aug. 23, 2022) (precedential).

C. Denial under §325(d) is not appropriate.

Denial under §325(d) and *Advanced Bionics* is not appropriate. Under *Advanced Bionics* part one, Edwards and Ollivier were not before the Examiner during prosecution. Mosher and Ingle were considered by the Examiner during prosecution, but were not the subject of any rejection. EX1002, 0069, 0074, 0095, 0108, 0113. Thus, the Examiner did not consider the combinations or arguments presented in the Petition and *Advanced Bionics* part one is not met.

Petitioner recognizes that Edwards, Mosher, Ingle, and Ollivier were asserted against the challenged claims in the prior IPRs. However, *no final written decision issued* because the parties settled their dispute and terminated the proceeding. Thus, there was no decision on the merits based on these references.

Even if part one were met (which it is not), *Advanced Bionics* part two requires a consideration of whether the Office erred. The Board correctly instituted review in the prior IPRs, on anticipation and obviousness grounds, but did not issue a final written decision due to settlement. The Board's mission to improve patent quality dictates institution here, despite the asserted references being previously presented to the Office. Patent Owner should not be able to evade a meritorious challenge by settling a prior proceeding after institution.

Further, the policy underlying § 325(d) and *Advanced Bionics* is to give deference to prior office determinations. To the extent the Board defers to its prior evaluation, that evaluation strongly *favors* institution here because the Board previously found a reasonable likelihood that the claims were unpatentable but did not complete its evaluation due to settlement.

XI. CERTIFICATION AND STANDING (37 C.F.R. § 42.104(A))

Petitioner certifies the '511 patent is available for IPR and Petitioner is not barred or estopped from requesting IPR of any '511 patent claim.

XII. MANDATORY NOTICES (37 C.F.R. § 42.8(A)(1))

Real Party-in-Interest (37 C.F.R. § 42.8(b)(1)): The real party-in-interest is Petitioner BTL Industries, Inc.

Related Matters (37 C.F.R. § 42.8(b)(2)): The '511 patent is at issue in the pending litigation *InMode Ltd. v. BTL Industries, Inc.*, Case No. 2:23-cv-08583 (C.D. Cal.), filed October 11, 2023.

U.S. Patent No. 10,980,596 and pending U.S. Patent Application Nos. 17/228,999 and 18/431,250 claim the benefit of the '511 patent.

Lead and Back-up Counsel (37 C.F.R. § 42.8(b)(3)):

Lead counsel for Petitioner is:

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Service Information (37 C.F.R. § 42.8(b)(4)): Please direct all correspondence regarding this Petition to counsel at rbemben-PTAB@sternekessler.com, jchagnon-PTAB@sternekessler.com, rcoller-PTAB@sternekessler.com, cvira-PTAB@sternekessler.com, and PTAB@sternekessler.com. Petitioner consents to service by email at the addresses above.

Procedural Statements: This Petition is filed in accordance with 37 C.F.R. § 42.106(a). Concurrently filed herewith are a Power of Attorney and Exhibit List under 37 C.F.R. §§ 42.10(b) and 42.63(e), respectively. The required fee is paid through Deposit Acct. No. 19-0036 (Customer ID No. 45324). The Office is authorized to charge any fee deficiency, or credit any overpayment, to Deposit Acct. No. 19-0036 (Customer ID No. 45324).

XIII. CONCLUSION

The challenged claims are unpatentable and IPR is warranted.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

A handwritten signature in black ink, reading "Richard M. Bemben". The signature is written in a cursive, flowing style with a large initial 'R'.

Richard M. Bemben
Registration No. 68,658
Lead Counsel for Petitioner

Date: April 10, 2024

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CERTIFICATE OF WORD COUNT (37 C.F.R. § 42.24(d))

1. This Petition for *Inter Partes* Review complies with the type-volume limitation of 14,000 words, comprising 13,987 words, excluding the parts exempted by 37 C.F.R. § 42.24(a)(1).

2. This Petition for *Inter Partes* Review complies with the general format requirements of 37 C.F.R. § 42.6(a) and has been prepared using Microsoft® Word 2016 in 14-point Times New Roman font.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

A handwritten signature in black ink, reading "Richard M. Bemben". The signature is fluid and cursive, with the first name "Richard" being the most prominent.

Richard M. Bemben
Registration No. 68,658
Lead Counsel for Petitioner

Date: April 10, 2024

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

I certify that the above-captioned **PETITION FOR *INTER PARTES***
REVIEW FOR U.S. PATENT NO. 8,961,511 and associated **Exhibits 1001-**
1031 were served in their entireties upon the Patent Owner on April 10, 2024, via
FedEx® Express at the following address:

K&L GATES LLP
210 Sixth Avenue
Pittsburgh, PA 15222-2613
Patent Owner's Correspondence Address of Record for U.S. Patent No. 8,961,511

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

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Date: April 10, 2024

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