

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BTL INDUSTRIES, INC.,  
Petitioner,  
v.  
INMODE LTD.,  
Patent Owner.

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

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**CORRECTED PATENT OWNER'S RESPONSE**

*Authorized by Board email dated June 27, 2025 (EX3003)*

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| <b>Exhibit</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                        |
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| 2001           | Declaration of Denise M. Poulos, M.D.                                                                                                                                                                                                                                                                                                                                     |
| 2002           | Curriculum Vitae of Denise M. Poulos, M.D.                                                                                                                                                                                                                                                                                                                                |
| 2003           | Stedman's Medical Dictionary (28 <sup>th</sup> Edition), Lippincott Williams & Wilkins (2006)                                                                                                                                                                                                                                                                             |
| 2004           | Stedman's Medical Dictionary (25 <sup>th</sup> Edition), Williams & Wilkins (1990)                                                                                                                                                                                                                                                                                        |
| 2005           | Transcript of Deposition of Dr. Berenholz, dated January 9, 2025                                                                                                                                                                                                                                                                                                          |
| 2006           | <i>Viveve, Inc. v. ThermiGen, LLC</i> , 2-16-cv-01189, Summary Judgment Order (E.D. Tex. May 26, 2018)                                                                                                                                                                                                                                                                    |
| 2007           | Merriam-Webster's Collegiate Dictionary (Tenth Edition), Merriam-Webster (2000)                                                                                                                                                                                                                                                                                           |
| 2008           | Taber's Cyclopedic Medical Dictionary, F.A. Davis Company (2005)                                                                                                                                                                                                                                                                                                          |
| 2009           | Neurology and Urodynamics (Cover image), Vol. 41, Issue 6 (2022)                                                                                                                                                                                                                                                                                                          |
| 2010           | Speculum, Cleveland Clinic, available at <a href="https://my.clevelandclinic.org/health/drugs/24238-speculum">https://my.clevelandclinic.org/health/drugs/24238-speculum</a>                                                                                                                                                                                              |
| 2011           | About Debra Ollivier, available at <a href="https://www.debraollivier.com/about">https://www.debraollivier.com/about</a>                                                                                                                                                                                                                                                  |
| 2012           | <RESERVED>                                                                                                                                                                                                                                                                                                                                                                |
| 2013           | Red Alinsod, "What are the Differences Between ThermiVa Radiofrequency and FemiLift/MonaLisa/IntimaLase lasers for use in Aesthetic Vulvovaginal Therapies?" (2015)                                                                                                                                                                                                       |
| 2014           | M. Bajka, "Detailed Anatomy of the Abdomen and Pelvis of the Visible Human Female," Clinical Anatomy (2004)                                                                                                                                                                                                                                                               |
| 2015           | Salon.com, Wikipedia, available at <a href="http://en.wikipedia.org/wiki/Salon.com">http://en.wikipedia.org/wiki/Salon.com</a>                                                                                                                                                                                                                                            |
| 2016           | Thermi Announces Settlement of Patent Infringement Litigation with Viveve, available at <a href="https://www.prnewswire.com/news-releases/thermi-announces-settlement-of-patent-infringement-litigation-with-viveve-300659000.html">https://www.prnewswire.com/news-releases/thermi-announces-settlement-of-patent-infringement-litigation-with-viveve-300659000.html</a> |
| 2017           | Y. Sekiguchi, "Laxity of the Vaginal Introitus After Childbirth: Nonsurgical Outpatient Procedure for Vaginal Tissue Restoration and Improved Sexual Satisfaction Using Low-Energy Radiofrequency Thermal Therapy," Journal of Women's Health (2013)                                                                                                                      |

| Exhibit | Description                                                                                                                                           |
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| 2018    | L. Millheiser, “Radiofrequency Treatment of Vaginal Laxity after Vaginal Delivery: Nonsurgical Vaginal Tightening,” Journal of Sexual Medicine (2010) |

## **I. INTRODUCTION**

The '511 patented methods remodel specific regions of female genital tissue using non-ablative techniques that do not damage the surface layer at the treatment area—the mucosal epithelium. The express goal of the '511 patent is “treating a loose vagina and introitus with a non-invasive procedure” to “provide greater sexual satisfaction for” the patient. EX1001, 2:17-21, 13:5-11. Petitioner relies on references directed to treatment of a different condition—stress urinary incontinence (“SUI”)—which are unrelated to the claimed treatments and are directed to different anatomical structures. The SUI references include Edwards, which ablates the mucosal epithelium. Moreover, Edwards’ delivery of energy to deeper regions of the vagina and using spot treatments of the anterior and posterior vaginal wall does not suggest the treatment areas of claim 1 (introitus inwardly to a location from 1 cm to 3.5 cm) or claim 35 (circumferentially around the vaginal wall from 1 o'clock to 11 o'clock). *Id.*, claims 1, 35. The other SUI references, Mosher and Ingle, suffer similar deficiencies.

The SUI references also do not suggest treatment of external female genital tissues as recited in the remaining independent claims, claim 43 (heating a portion radiating outward from the introitus to Hart’s line) and claim 51 (heating a mucosal surface of the labia minora).

For claim 1, no reference teaches 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.” In fact, both experts agree that no reference teaches treatment near the introitus and Petitioner’s expert—Dr. Berenholz—testified that, using Edwards’ instrument, a doctor could not treat closer than 4.5 cm away from the introitus.

For claim 35, the references, even in combination, do not suggest heating “a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock.” Both experts agree that to heat circumferentially you would need to heat multiple locations in a pattern that, in the words of Petitioner’s expert, is “as close to as contiguous as possible.”

For claims 43 and 51, none of Edwards, Mosher, and Ingle teaches heating either “a portion radiating outward from the introitus to Hart’s line” or “heating a mucosal surface of the labia minora.” In fact, both experts agree that no reference in Ground 1 teaches treating external vulval tissue, tissue that according to both experts would require different considerations and have different effects than internal vaginal tissue. In view of this deficiency, Petitioner cites, in Ground 2, to Ollivier. Ollivier is an article from Salon.com—a politically-slanted news and opinion website—that vaguely reports that one surgeon (Dr. Matlock) used a laser surgery technique that involves cutting away vaginal tissue. As Petitioner’s expert

concedes, the actual technique is not described in the article and in fact it was maintained as a trade secret by Dr. Matlock.

Ollivier cannot correct the deficiencies of the other references, and in any case Petitioner provides no credible basis for combining the vague laser surgical techniques alluded to in Ollivier with techniques in the SUI references.

Finally, the so-called declaration of Petitioner's expert Dr. Berneholz should be given little or no weight. Dr. Berenholz conceded at his deposition that it was Petitioner's counsel, and not he, who drafted the declaration, that he made no changes to the document, and that he was not even sure where in the declaration his expertise was utilized. It is plain from those admissions that the declaration is a lawyer's document, not an expert's, and as such it should not be given evidentiary weight.

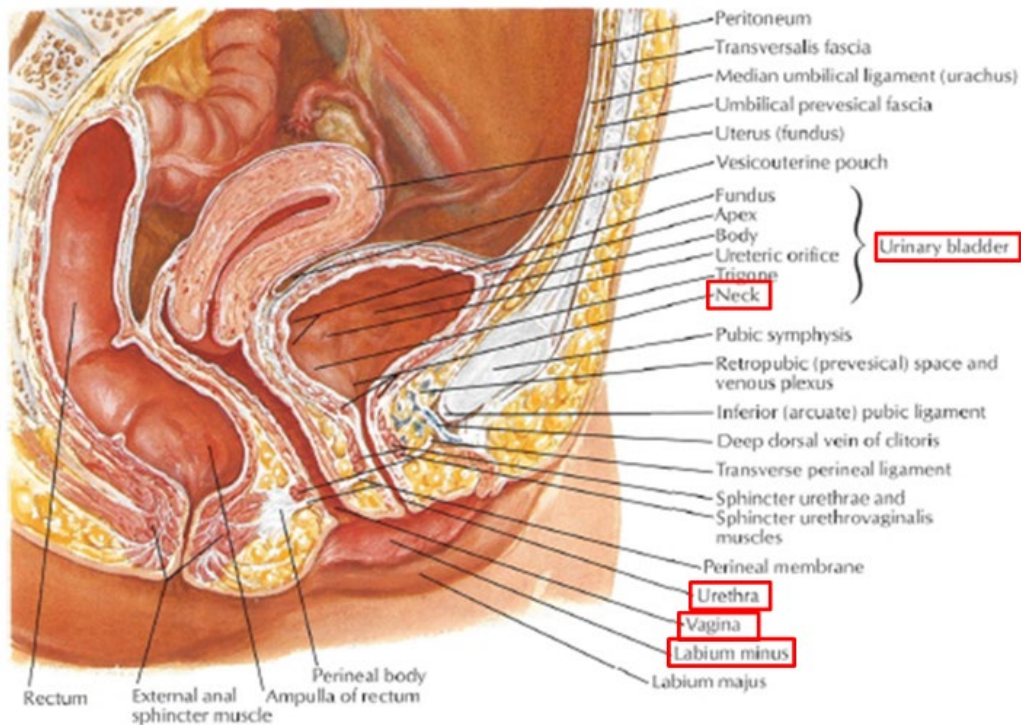
## **II. OVERVIEW OF THE TECHNOLOGY AND THE '511 PATENT**

### **A. Anatomy of the Female Genitourinary System**

The female genitourinary system includes the female genitals, the reproductive system, and the urinary system. EX2001, ¶40. The reproductive system includes, in part, the vulva, the vagina, and the uterus. EX2001, ¶40. The urinary system includes, in part, the urethra and the bladder. EX2001, ¶40. These structures are located within the female pelvis, as can be seen below. EX2001, ¶40.



Female: midsagittal section



EX1015, Plate 365 (annotated).

The vulva is the external genitalia and consists of, in part, the labia majora, labia minora, vaginal orifice (or introitus), and urethral orifice. EX2001, ¶41. The vulva also includes the vulva vestibule, which ends inferiorly at the posterior commissure of the labia minora, so as to border the edge of the labia minora.

EX2001, ¶41. This border, or outer edge of the vestibule, is known as Hart's line.

EX2001, ¶41.

Within the vulva vestibule is the introitus and the urethral orifice. EX2001, ¶41. The introitus is the entrance to the vagina (the distal most portion of the vagina). EX2001, ¶41. When used herein, distal and proximal refer to the patient

unless otherwise noted. Immediately within the introitus is the vaginal canal, which extends inward about 9 cm. EX2001, ¶41. The tissue lining the vaginal canal is generally known as the vaginal wall. EX2001, ¶41. During the treatments described herein, the vaginal canal is tube-like, with the circumferential wall described as having an anterior wall, posterior wall, and two lateral walls. EX2001, ¶41; *see also* EX2005, 71:22-72:4 (stating that the vagina is a “a tube. So think of circumferential. There is – there’s an anterior, posterior, and lateral.”).

Turning next to the urinary system, within the vulva vestibule (and adjacent to the introitus) is the urethral orifice. EX2001, ¶42. Important for the present IPR, the urethra extends inward about 4 cm. EX2001, ¶42; EX2003, 2072 (“about 4 cm long passing from the bladder ... opening in the vestibule of the vagina.”); EX2004, 1672. On the proximal or superior, end of the urethra is the bladder neck. The bladder neck is a group of muscles opening at the base of the bladder where it connects to the urethra. EX2001, ¶42. The muscles acts as a valve that controls the flow of urine from the bladder into the urethra. EX2001, ¶42. The bladder neck extends for roughly 1-1.5 cm. EX2001, ¶42. The urethra runs roughly parallel to the vagina and is in the same sagittal plane as the vagina. EX2001, ¶42; EX2003, 2072; EX2004, 1672.

As discussed in more detail below, the SUI treatments at issue are directed to treating the bladder neck, deeper in the body than the treatments at issue in the present claims. As also discussed in more detail below, the Petition misses these important anatomical distinctions.

## **B. '511 Patent**

The '511 patent claims recite methods of remodeling tissue underlying a surface layer of female genital tissue, by heating specific areas of tissue around, the vulva, the vagina, and the introitus (the opening of the vagina), to a therapeutic temperature. EX1001, claims 1, 35, 43, and 51. In most claims, the claimed treatment locations are close to or outside of the opening of the vagina. EX2001, ¶43. The '511 patent methods aim to restore genital tissue, which can be altered over time (and during childbirth) resulting in decreased sexual pleasure. EX1001, 2:4-9; EX2001, ¶43. Prior to the '511 patent, some doctors used invasive techniques, such as surgery, to treat these issues, but these approaches often caused scarring, resulted in damage, and required lengthy recovery. EX1001, 2:9-12; EX2001, ¶43. The inventive techniques of the '511 patent overcame the problems of prior techniques by providing non-invasive procedures for restorative care of certain female genital tissue that did not (i) require surgical incisions, (ii) cause

thermal damage to the epithelium, or (iii) result in patient down time. EX2001, ¶43.

The '511 patent claims methods for remodeling the target tissue underlying the female genital epithelial surface by heating that tissue. EX1001, claims 1, 35, 43, 51. The target tissue of the embodiments of the '511 patent are the tissues that lie immediately beneath the mucosal epithelium. EX1001, 3:41-48; EX2001, ¶44. RF energy heats and denatures collagen located in the collagen-rich lamina propria, resulting in a contraction of the collagen spaces thereby creating a tightening effect. EX1001, 1:19-39; EX2001, ¶44. As discussed below regarding claim construction, the '511 patent makes clear that its embodiments exclude deeper tissue (e.g., endopelvic fascia), which is a target in SUI treatments discussed below. EX1001, 3:47-48; EX2001, ¶44.

While some invasive surgical techniques (e.g., using lasers, ablative RF, and scalpels) were previously used to treat conditions in the female genitalia, Petitioner's expert, Dr. Berenholz, acknowledged that invasive techniques would ablate and "destroy the surface" of the tissue and "[d]efinitely" cause undesirable scarring, and could lead to malpractice claims. EX2005, 28:10-29:11, 94:3-15, 157:6-13; EX2001, ¶45.

The '511 patent uses heating without ablation to remodel the female genitalia. As addressed during prosecution (discussed below), applying such treatments to the anatomical areas at issue in the present claims was not known prior to the '511 patent. EX2001, ¶46.

### **C. Prosecution History of the '511 Patent**

During prosecution of the application that issued as the '511 patent, the examiner issued a rejection in view of U.S. Patent No. 6,350,276 (“Knowlton”). EX1002, 82 (“Knowlton discloses a method for remodeling a therapeutic zone within a target tissue ....”). However, Knowlton’s treatments were specifically related to “modifying *skin* surfaces and underlying tissue” including the cervix among other body parts—not the claimed female genital tissue. EX1013, 1:16-29, 6:49-57, 13:35-37; EX2001, ¶47.

The independent claims were amended to specify heating of specific areas of female genital tissue, including introitus (claims 1 and 43), vagina (claim 35), and vulva (claim 51). EX1002, 234-244. In the Notice of Allowance, the Examiner explained “Knowlton fails to contemplate the specific areas of treatment set forth in independent claims [1, 35, 42, and 51]. No other reference has been found which discloses, suggests or makes obvious this area of treatment.” EX1002, 317; EX2001, ¶48. Thus, the Examiner recognized that even though it was known to

heat female genital cervical tissue using RF, this did not fairly suggest or make obvious the specific treatments claimed in the present independent claims.

On October 20, 2017, a prior petitioner, ThermiGen, LLC, filed two petitions for Inter Partes Review against the '511 Patent. IPR2018-00088; IPR2018-00089 (the “ThermiGen IPRs”). These petitions asserted grounds based on Edwards, Mosher, and Ingle, and the Ollivier reference was discussed in the petitions. EX1009, 6; EX1012, 59-60; EX2001, ¶49. That case terminated when the petitioner paid for a license to the '511 patent. EX2016.

#### **D. State of the Field**

Prior to the invention of the '511 patent in 2006, ablative techniques were used to treat vaginal tissue (as distinct from SUI treatments), with laser treatments being the primary mechanism. An article published by Petitioner's expert's mentor—Dr. Alinsod—describes using lasers in 2005 for tightening of vulvar structures. EX2013, 2-3. But these procedures resulted in “quite a cost in terms of pain and recovery” with “downtimes [of] many[,] many weeks to months.” EX2013, 2-3; EX2001, ¶50.

Only after the filing of the '511 patent in 2006, did the industry acknowledge the benefits of the low temperature, non-ablative treatment of vaginal tissue described in the '511 patent. For example, in a 2015 article entitled

“Temperature Controlled Radiofrequency for Vulvovaginal Laxity,” which reports on a clinical study funded Petitioner’s expert’s employer ThermiAesthetics, Dr. Alinsod states that vulvovaginal rejuvenation using RF energy “is a fairly new concept with real potential for success.” EX1025, 18; EX2001, ¶51. That article highlights the importance of features of the present invention, including treatment starting at the introitus and extending inward (EX1025, 16 (left column), 19 (right column)), treatment of the using treatment temperatures below 80° C (*id.*, 18 (right column)), and avoiding damage to the epithelium (*id.*, 20 (left column)). The article explains that the results of the study showed that the treatment resulted in “pronounced improvement,” measured on two different pre-existing measurement scales. *Id.*, 20 (“Results” section). EX2001, ¶51.

Notably, these lauded treatment aspects are missing from the prior art discussed below. EX2001, ¶52.

#### **E. Person of Ordinary Skill in the Art**

In the ThermiGen IPRs, the Board determined that a POSA would have “a medical degree plus at least two years of experience in a field such as gynecology, urogynecology, or plastic surgery involving female genital anatomy, with clinical experience in the application of radiant energy to female genital tissue.” EX1009, 8-9; EX2001, ¶¶36-37.

The Board here should adopt the POSA definition adopted by the ThermiGen IPR's Board. EX2001, ¶¶36-37. Petitioner's definition of a person of ordinary skill in the art ("POSA")—namely, Petitioner's proposal of "a medical doctor ... [with] 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" (Pet., 6)—is an over-credentialed standard, which very few would have satisfied at the relevant time. EX2001, ¶¶35-36. As Petitioner's expert admits, he was only aware of four or five doctors practicing in the field of cosmetic gynecology in 2006 and was not aware of how many doctors were practicing non-surgical treatments of uro-gynecological conditions. EX2005, 55:5-17; EX2001, ¶36. Dr. Berenholz further testified that "any board-certified physician or urogeynecologist or gynecologist, obstetrician, et cetera" would "have a general understanding or ordinary skill related to the technology related to the technology of the '511 patent." *Id.*, 57:17-58:19; EX2001, ¶36. Given this testimony and the general lack of experience in the medical field with "non-surgical" treatments of uro-gynecological conditions and "non-surgical" cosmetic treatment of female genital tissue, the ThermiGen IPR definition more accurately describes an "ordinary" person of skill in February 2006. EX2001, ¶¶36-39.

### III. CLAIM CONSTRUCTION

Petitioner states that no claim term requires construction, but then vacillates between constructions from the *Viveve v. ThermiGen* district court litigation (“*Viveve* litigation”) and from the ThermiGen IPRs in a manner that conflicts with the findings of both tribunals. Pet., 7-11. Petitioner’s proposal should be rejected, and the Board here should adopt the ThermiGen IPR constructions for “target tissue,” “heating,” and “remodeling.” The Board should also adopt the ThermiGen IPR construction for “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock” with the modification described below.

EX2001, ¶54.

In an IPR, a claim is “construed using the same claim construction standard that would be used to construe the claim in” a district court litigation. 37 C.F.R. § 42.100(b). District courts give claims their ordinary and customary meaning, which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). The patentee may act as his/her own lexicographer through clear statements in the specification. *Ericsson, Inc. v. Intellectual Ventures I LLC*, IPR2014-00921, Paper 8, at 8 (P.T.A.B. Dec. 16, 2014); *SciMed Life Sys. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1341

(Fed. Cir. 2001) (“Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent[.]”).

**A. “target tissue”**

All claims of the ’511 patent recite “method[s] for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue.” EX1001, claims 1, 35, 43, 51. The ThermiGen panel construed “target tissue” as “tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissue, such as endopelvic fascia.” EX1009, 12. In support of this construction, the ThermiGen IPR panel explained:

[o]n the present record, we agree with Patent Owner that the passages identified in the Specification comprise a “clear and unmistakable” disclaimer of the scope of target tissue. *See Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1366–67 (Fed. Cir. 2012). We also note that there is no evidence in the record that the term “target tissue” has an ordinary and customary meaning in the art to which the ’511 patent pertains that encompasses the endopelvic fascia.

*Id.*, 11. The Board should adopt ThermiGen Board construction of “target tissue.” EX2001, ¶¶55-56.

Petitioner contends that the “comprising” term indicates that target tissue is permissive of heating or treating non-target tissue such as endopelvic fascia. Pet., 8-9. But that argument fails to address the Board’s prior findings and the intrinsic record. The specification explicitly defines the term target tissue: “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, 3:43-48<sup>1</sup>; EX2001, ¶57

The specification expands on the definition of target tissue, explaining:

The target tissue of embodiments of this invention include the connective tissue underlying these mucosal epithelial surfaces of the genitalia which, progressing down from the epithelial surface, are known as the lamina propria 102 and the muscularis 104 (FIG. 8), respectively (see, for example, Netter, Atlas of Human Anatomy, 4<sup>th</sup> edition, Saunders, 2006). The lamina propria includes a mixture of cell types that populate connective tissue, such as fibroblasts, and the muscularis is a layer of smooth muscle. ... *These described target tissue layers below the*

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<sup>1</sup> Emphasis added throughout.

***epithelium overlay deeper tissues, including endopelvic fascia, which are not a target tissue for embodiments of the present invention.***

EX1001, 12:2-16; EX2001, ¶58. When the specification describes the features of the “present invention” as a whole, this description limits the scope of the invention. Thus, the specification makes clear that the “described target tissue layers” include the tissues adjacent the mucosal epithelium, such as the lamina propria and that the deeper tissues including the endopelvic fascia are excluded. EX2001, ¶59. Where, as here, “the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent[.]” *SciMed*, 242 F.3d at 1341; *see Honeywell Int’l, Inc. v. ITT Indus.*, 452 F.3d 1312, 1318-19 (Fed. Cir. 2006).

Petitioner’s proposed claim construction for this term improperly encompasses the deeper tissues underlying the epithelial mucosal, such as the endopelvic fascia, which the Board previously rejected. EX2001, ¶60; EX1009, 10-12. Because the Board’s construction “cannot be divorced from the specification and the record evidence,” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015), and in view of the explicit definition of this term in the specification, “target tissue” should be construed to mean “tissue

immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissue, such as endopelvic fascia.”

**B. “remodeling”**

This panel should adopt the ThermiGen IPR construction of “remodeling the therapeutic zone of target tissue” defined 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. This construction aligns with the Board’s preliminary construction of the “heating” term (i.e., adopting the temperature limit of 80 degrees C), as discussed below.

Importantly, the ThermiGen IPR construction also captures the ’511 patent’s requirement for avoiding surface damage. EX2001, ¶61; EX1001, 12:17-21.

In the ThermiGen IPR, the Board found that the “[s]pecification makes clear [] that ‘remodeling of the connective tissue underlying the mucosal epithelial surfaces does not substantially affect the epithelium itself. The method and apparatus, as provided by embodiments of the invention are non-invasive and substantially non[-]ablative of genital tissue.’” EX1009, 15 (citing EX1001, 12:17–21). This construction finds ample support throughout the intrinsic record. EX2001, ¶62.

The '511 patent is clear the claimed method is performed without “damaging” or “substantially affecting the epithelium overlying the target tissue.” The Abstract states that “[t]his invention relates ... [to] tightening tissue of the female genitalia by heating targeted connective tissue with radiant energy, while cooling the mucosal epithelial surface over the target tissue to protect it from the heat.” EX1001, Abstract. The specification clearly states that “[t]he method and apparatus, as provided by embodiments of the invention are *non-invasive and substantially non ablative of genital [t]issue*.” EX1001, 12:19-21; 13:19-23 (“[t]he epithelial surface is [] a conduit for energy passing through to underlying layers, but the energy does not manifest in the form of increased temperature at the epithelial surface. As such, *the epithelium itself is not damaged or substantially modified by the method*.”); EX2001, ¶62.

This panel’s Institution Decision provisionally adopts the *Viveve* court construction (Paper 6, 14). But the *Viveve* court’s “remodeling” construction does not capture the non-ablative aspect (“without substantially affecting the epithelium overlying the target tissue”) of the claimed invention, which **both** the *Viveve* court and the panel in the ThermiGen IPR acknowledged. Specifically, the *Viveve* court agreed that the invention requires this understanding, but incorporated the understanding into its “heating” construction. EX1024, 11-12. For its “heating”

construction, the *Viveve* court found that “the intrinsic evidence indicates that a critical aspect of the invention is the manner in which the target tissue is heated. Specifically, the intrinsic evidence indicates that maintaining the epithelium at a temperature lower than the underlying tissue is important *to ensure that the epithelium is not damaged or substantially modified by the method.*” EX1024, 10-11. To ensure that the claims properly recite this “critical aspect of the invention” the “remodeling” term should be construed to recite “without substantially affecting the epithelium overlying the target tissue,” as adopted by the panel in the ThermiGen IPR. EX1009, 14-16; EX1011, 14-15; EX2001, ¶¶63-64.

Alternatively, should the Board’s construction of remodeling not include the requirement “without substantially affecting the epithelium overlying the target tissue,” that requirement should be included in the Board’s construction of heating as explained below. EX2001, ¶65.

### **C. “heating”**

This Board’s Institution Decision adopts the definition of “heating” in the *ThermiGen* IPRs, which construed “heating” as “raising the temperature of target tissue to no more than about 80 degrees C.” EX1009, 14. Patent Owner does not contest this construction to the extent that the Board also adopts the ThermiGen IPR construction for the “remodeling” term.

As noted above, should the Board adopt the *Viveve* court construction of “remodeling,” the heating term should be construed as “raising the temperature of target tissue to no more than about 80 degrees C without substantially affecting the epithelium overlying the target tissue,” so as to include the patent’s requirement for avoiding surface damage. EX1001, Abstract; 2:56-62; 8:8-15; 12:17-21; EX2001, ¶¶66-67. This construction aligns with the *Viveve* district-identified “critical aspect of the invention ... ensur[ing] that the epithelium is not damaged or substantially modified by the method.” EX1024, 10-11.

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

Independent claim 35 recites “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock,” which should be construed as “heating multiple, contiguous contact sites in the 300 degree arc extending from 1 o’clock to 11 o’clock along the vaginal wall.” In the *ThermiGen* IPRs, the panel acknowledged that this is a “close question” and then, as a preliminarily construction, accepted Petitioner’s definition of “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. That preliminary decision was based on expert testimony from only one side. On the present record, the meaning of “circumferentially” requires more. EX2001, ¶68.

The ThermiGen IPR Board acknowledged the importance of the “circumferentially” language noting that the plain language of the claim “requires heating ... over a defined arc, and thus excludes the ‘at least one point’” language that was proposed by ThermiGen. EX1009, 17. The ThermiGen IPR used “contact site” to indicate that the treatment extends around the curvature of the vaginal wall accounting for “accounting for about 10% of the 300 degree arc.” *Id.*, 17 (citing EX1001, 14:35-45). However, the intrinsic record and anatomy of the vagina demonstrate that a “contact site” as used in the ThermiGen IPR construction equates to a point of the vaginal wall. EX2001, ¶69.

The specification states the circumference of the vagina “is approximately 12 cm.” EX1001, 14:35-37; EX2001, ¶70. A contact site, which covers 10% of the 300 degree arc in the vagina, is then roughly 1 cm. EX2001, ¶70. The specification also states that an exemplary treatment tip is “about 1 cm in width.” EX1001, 14:37-40; EX2001, ¶70. Given that the treatment tip is 1 cm and the contact site is the same width, heating “at least one contact site” is equivalent to heating “at least one point.” EX2001, ¶70. Both experts agree that to achieve the desired result of the ’511 patent’s circumferential treatment you would need to treat multiple sites “as contiguously as possible” around the vaginal wall. EX2001, ¶¶71-72; EX2005, 117:9-118:1. Contiguous sites includes multiple sites adjacent

to each other. EX2007, 250. As a result, to properly capture the “circumferentially” language, the claim term should be construed as “heating multiple, contiguous contact sites in the 300 degree arc.” EX2001, ¶73

This definition improves on the ThermiGen IPR construction based on expert testimony from both sides and in reliance on the intrinsic record.

#### **IV. GROUND 1: PETITIONER’S COMBINATION OF EDWARDS, MOSTHER AND INGLE FAILS**

Obviousness requires that each and every limitation of the claim is described or suggested by the combination of prior art references or would have been obvious based on the knowledge of a POSA. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). In order to demonstrate that the challenged claims are obvious, petitioner must articulate “[1] how specific references could be combined, [2] which combination(s) of elements in specific references could yield a predictable result, or [3] how any specific combination would operate or read on the asserted claims.” *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1327-28 (Fed. Cir. 2012). Conclusory statements that a POSA would have known how to combine references “is not sufficient and fraught with hindsight bias.” *Id.*

Further, “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does ... because inventions in most, if not all, instances rely

upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Petitioner fails to demonstrate that Edwards, Ingle, and Mosher render obvious the “remodeling” element and the treatment areas recited in independent claims 1, 35, 43, and 51. Moreover, Petitioner fails to demonstrate that the references are properly combinable. EX2001, ¶76.

#### **A. Overview of Edwards**

Edwards describes methods for treating menorrhagia and female urinary incontinence (a SUI treatment). EX1005, Abstract, 1:24-51. The purported “advantage[]” of the Edwards treatments is they “require only local or regional anesthesia.” EX1005, 2:22-27. While citing some catch all language in Edwards’ summary, Petitioner relies upon the fourth embodiment of Edwards. Pet., 26. In contrast to the non-ablative treatment described in the ’511 patent, the relied upon embodiment in Edwards uses RF energy to cause ablative lesions, which lesions cause the affected area to shrink and be relatively strengthened. EX1005, 13:14-16 (“to create a series of lesions”), 9:66-10:7 (“repeat ... so as to selectively ablate other areas”), 11:28-33 (“so as to create more areas of ablation lesions”), 12:47-55 (“more areas of ablation lesions”), 12:66-67; EX2001, ¶77.

Ablation is the “removal of a part, pathway, or function by surgery, chemical destruction, electrocautery, or radiofrequency.” EX2008, 6. Radiofrequency ablation is defined as “ablation in which an electrode delivers a low-voltage, high-frequency current to cauterize and destroy abnormal tissues.” EX2008, 6; *see also* EX1006, ¶[0046] (“the term ‘ablation’ of a tissue means that the tissue is substantially removed and/or the function of the tissue is substantially destroyed.”); EX2001, ¶78.

While Edwards discloses four embodiments (all of which describe ablative treatment), the first through third embodiments involve inserting needle electrodes into (i) the uterus for intrauterine ablation (“to coagulate the entire endometrium”) (EX1005, 2:40-47, 4:15-31, 9:4-7, 9:30-32, 9:66-67, 10:1-2), (2) the urethra to create ablative lesions within the urethral sphincter muscle for the treatment of urinary incontinence (*id.*, 2:48-58, 5:8-9, 10:15-19, 11:30-31), and (3) the bladder to create ablative lesions to treat urinary incontinence (*id.*, 2:59-4, 11:45-53, 12:11-18, 12:38-40, 12:47-55). The fourth embodiment inserts a speculum that mounts an electrode device thereon to create ablative lesions on the vaginal wall to treat urinary incontinence. EX1005, 2:5-13, 13:43-46; EX2001 ¶¶79.

Edwards explains that “[t]he difference between [the fourth] embodiment and the other embodiments is that the RF energy is delivered to the anterior and

posterior regions of the vaginal wall.” EX1005, 3:6-9. Although Edwards mentions in passing that treating both the anterior wall and posterior wall may provide physical and psychological improvement in the area of sexual function (EX1005, 3:11-13), Edwards does not suggest adjusting the location of the ablation, which as discussed below occurs well into the mid-vaginal canal. EX2001 ¶¶28-30; EX2001, ¶¶80-81.

## **B. Overview of Mosher**

Mosher was cited by the Examiner during prosecution of the ’511 patent but was not applied as a basis for rejection.

Mosher describes treating SUI by “heating between about 100 and about 800 cubic millimeters of endopelvic fascia for sufficient time to effect substantial collagenous tissue shrinkage.” EX1006, Abstract. Mosher’s technique uses “a probe body [that] may directly engage the endopelvic fascia, such as by introducing an endoscopic probe into the body adjacent the endopelvic fascia, or by surgically displacing a flap from the vaginal wall.” *Id.*, ¶[0009]; EX2001, ¶82. The probe “may optionally be used in a laparoscope procedure ... (for example, adjacent the belly button) .... Alternative surgical methods for use of related probes may access the endopelvic fascia using an inferior approach, ... as illustrated in FIG. 2.” *Id.*, ¶[0057]; EX2001, ¶82.

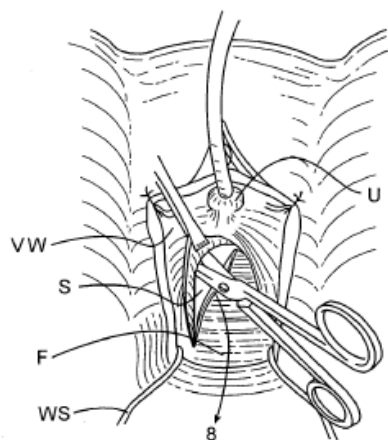


FIG. 2

Mosher describes electrode tips for treating the bladder and bladder neck.

*Id.*, ¶[0055] (“penetration of electrode tips 24”); Fig. 4C; EX2001, ¶83.

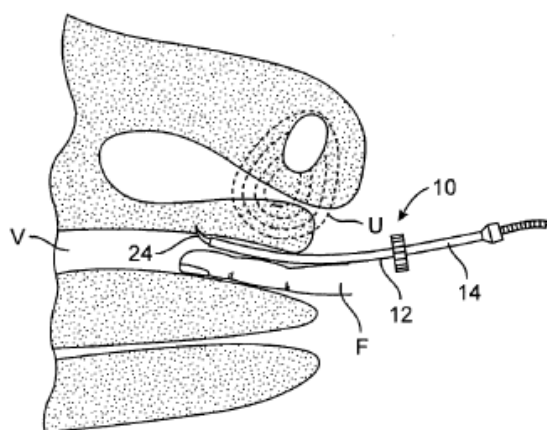


FIG. 4C

Unlike the inventions of the '511 patent, these techniques are (i) invasive—i.e., they require a surgical technique, such as a surgically cut flap in the vaginal wall—to access the surface of the endopelvic fascia and (ii) treat deeper tissues, such as endopelvic fascia. *Id.*, ¶¶[0056]-[0057], FIG. 2; EX2001, ¶84.

Mosher does describe treatments using “cooled electrode vaginal probes” in FIGS. 6 and 6A. EX1006, FIG. 6, 6A, ¶[0058]. As discussed below in Section IV.H.2, however, this treatment cools the entire “tissue between probe body 54 and the endopelvic fascia EF, such as the vaginal wall VW,” which includes target tissues of the ’511 patent. EX1006, FIG. 6, ¶[0058]; EX2001, ¶85.

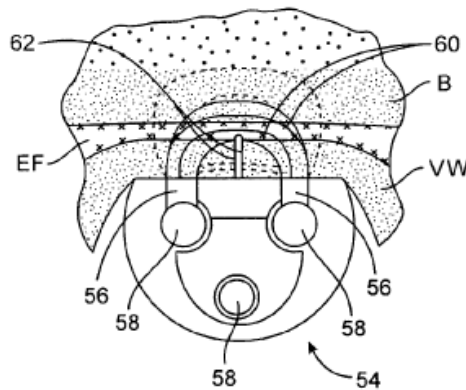


FIG. 6

EX1006, FIG. 6.

Mosher provides a laundry list of tissues that Mosher purports may also be the target of treatment for SUI. EX1006, ¶[0048]. However, Mosher does not describe how its techniques would be adapted—if at all—to treat such other tissues. EX2001, ¶86. Nor does it provide any coherent teaching as to which specific tissues or structures would replace the support lost due to damage to the endopelvic fascia to treat SUI. EX2001, ¶86. Further establishing the problems with Mosher’s laundry list, some structures listed in Mosher’s laundry list are *not*

*even found in female anatomy*, such as puboprostatic ligaments and posterior puboprostatic ligaments, which are *male* anatomic structures. EX2001 ¶89.

Mosher’s laundry list of anatomical structures simply fails to provide any guidance to a POSA on alternative treatments. *See, e.g., Regents of the Univ. of Minn. v. Gilead Scis., Inc.*, 61 F.4th 1350, 1357 (Fed. Cir. 2023) (finding that “a laundry list disclosure” cannot “constitute a written description of every” possible option where it is “quite unclear how many [options] actually fall within the described” laundry list.”); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996) (“In the absence of such blazemarks, simply describing a large genus ... is not sufficient to satisfy the written description requirement as to particular species or subgenuses.”); EX2001 ¶86.

### **C. Overview of Ingle**

Ingle describes treating a patient’s fascia in connection with incontinence relief. EX1007, 2:51-53, 2:59-60. Specifically, Ingle aims to heat the endopelvic fascia so that “the endopelvic fascia EF and arcus tendineus fascia pelvis ATFP are controllably contracted to shrink them and re-elevate the bladder toward its original position.” *Id.*, 17:30-59; EX2001 ¶87.

Ingle discloses embodiments in which “a first electrode having a first electrode surface which is engageable against the tissue. A second electrode has a

second electrode surface which can be aligned substantially parallel to the first electrode surface, with the tissue positioned therebetween.” EX1007, 4:33-37; EX2001 ¶88. Ingle explains that “the electrodes will generally be mechanically coupled to each other, ideally using a clamp structure which allows the target tissue to be compressed between the electrode surfaces.” EX1007, 7:54-61, 8:24-27 (“clamping a target”); EX2001 ¶88.

While Ingle generically discusses several tissue structures that may be responsible in some manner for control of urination, Ingle’s embodiments are drawn to treatment of the endopelvic fascia adjacent the bladder wall. *See* EX1007, Figs. 6, 11, 12, 12K, 13, 14:63-67; EX2001 ¶89. As shown in Figure 6, “the endopelvic fascia will preferably be disposed between the electrodes of the urethral probe 44 and the vaginal probe 42.” EX1007, 18:46-50, 29:66-67, 30:1-2.

Ingle’s embodiments differ from the ’511 patent and the other references in that they require a parallel electrode on the opposite side of the vaginal wall, inserted into another orifice, which limits the regions of the vaginal wall available for treatment. EX2001 ¶90.

**D. Claim 1: The Combination does not render obvious “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”**

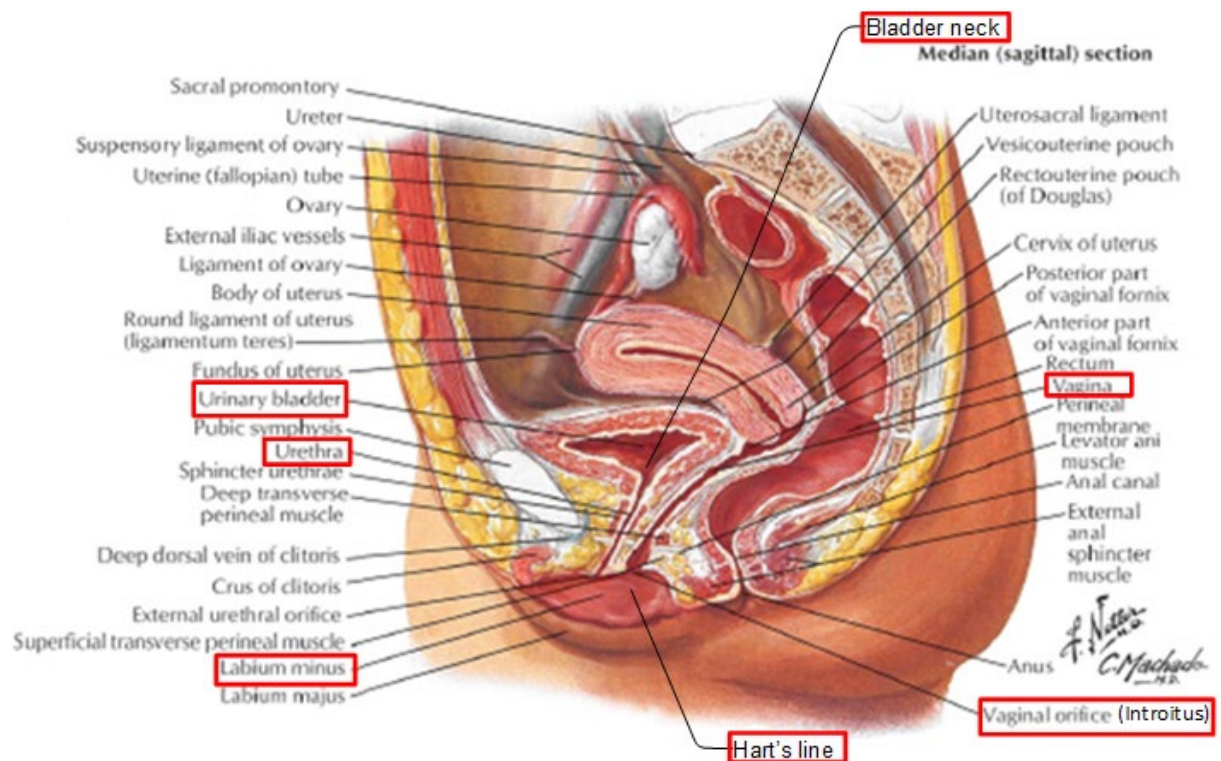
The Petition relies only on Edwards and Mosher for this claim element. Pet., 35-36. Petitioner essentially argues that because Edwards and Mosher teach treating *a* portion of the vagina, they must teach treating *the* portion of the vagina most proximal to the introitus. Pet., 35-36. Not so. Not only do they not teach treating the portion of the vagina most proximal to the introitus, but both references specifically target a different part of the vagina in order to affect the bladder neck—a structure located deeper than the claimed treatment location. EX2005, 126:2-23. Further, Edwards’s device is simply not suitable for treating the introitus. EX2001, ¶91. Therefore, the combination fails to suggest treating the portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus. EX2001, ¶91.

As an initial matter, Petitioner’s arguments are based on a fundamental misunderstanding of the claim language. Petitioner states that “[a] POSA would have understood this treatment area includes heating a portion of the vagina starting 1 cm from the opening and extending a further 2.5 cm back towards the cervix (i.e., 3.5 cm from the introitus).” Pet., 35. This reading of the claim language is illogical, as the plain reading of the subject claim limitation requires

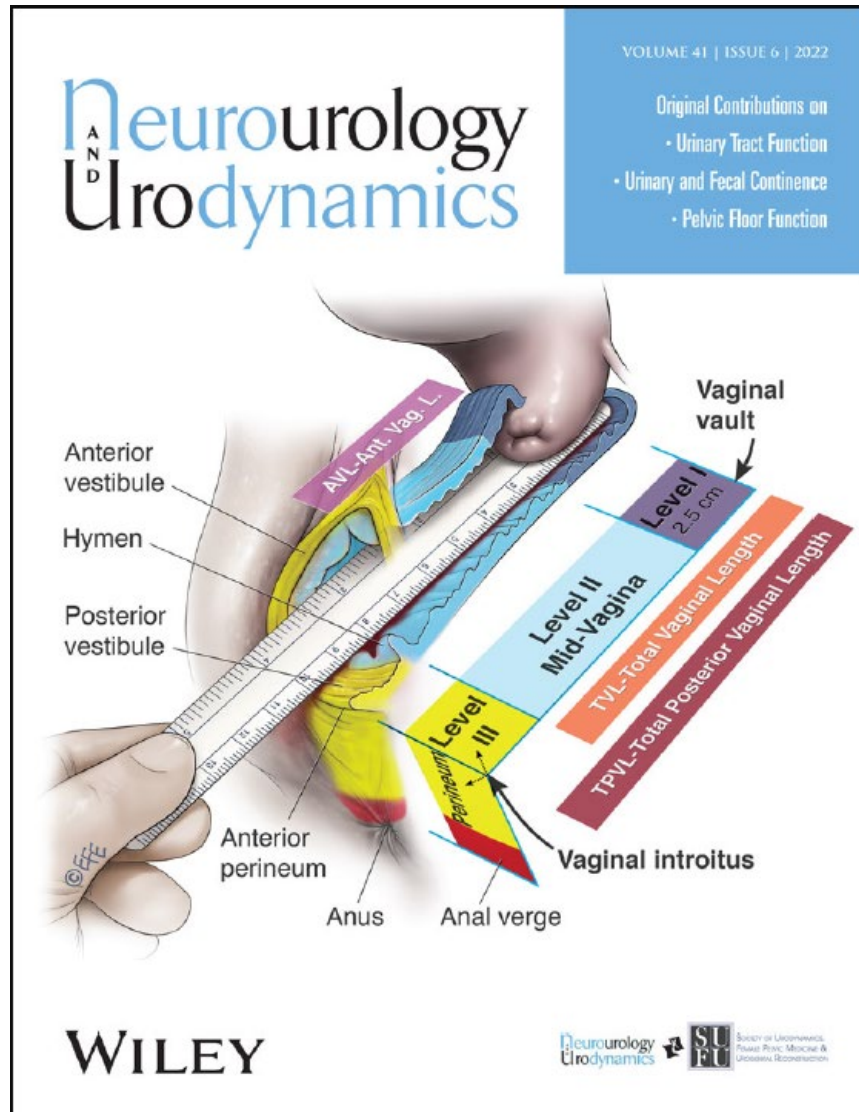
the treating of at least the introitus and the first 1 cm of the vagina (up to 3.5 cm in from the introitus). EX2001, 92.

As explained above, the introitus is the external opening of the vagina at the distal end of the vagina. *Supra* Section II.A. The primary structures targeted to treat SUI, as in Edwards and Mosher, are the bladder neck and supportive tissues, which are located at the proximal end of the urethra. *Supra* Section II.A; EX1005, 2:1-5 (“bladder[]neck”); EX1006, ¶¶[0006], [0046]; EX2001, ¶93. Petitioner’s expert agreed. EX2005, 126:2-23 (Edwards and Mosher address SUI by “strengthening the tissues surrounding ... [the bladder] neck.”) Therefore, when treating a patient for SUI, a POSA would understand that one would treat the proximal portion of the vaginal canal, which is not near the introitus. *Supra* Section II.A; EX2001, ¶93.

As established above, the bladder neck—the focal treatment location for the type of RF-based SUI treatments described in Edwards and Mosher—**starts** at the proximal end of the urethra, which extends about 4 cm into the body. EX2001, ¶94; EX2003, 2072 (“about 4 cm long passing from the bladder ... opening in the vestibule of the vagina.”); EX2004, 1672. The bladder neck treatment is provided through the vaginal wall, which does not run perfectly parallel to the urethra, given that it curves away from the urethra, as can be seen below. EX2001, ¶94.



EX1015, Plate 360 (annotated).



EX2009.

Thus, to treat the bladder neck through the vaginal wall, a POSA would have understood that the treatment position would be approximately 4 cm, or more, into the vagina, given the curvature away from the urethra, to affect the bladder neck (particularly given Edward's electrode arrangement). EX2001, ¶95.

Accordingly, Edwards, which is directed to SUI treatments, would not suggest to a POSA treating 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 opening of the vagina). EX2001, ¶96. Indeed, Edwards treats the posterior and anterior vaginal walls opposite the ***bladder outlet***. EX1005, Fig. 8A (“proximate to the bladder outlet”), 3:9-11, 6:20, 11:48-53; EX2001 ¶96. A POSA would not understand these treatment areas to be within 3.5 cm of the introitus. EX2001, ¶¶96-97.

Moreover, Edwards device would not be suitable for treating the claimed anatomical structure, as its treatment position would be too deep to meet the claim limitation. EX2001, ¶97. As shown below, the Edwards device includes “a speculum [] inserted in the patient’s vagina.” EX1005, 13:38-44. Blade 420, which has the treating electrode at a distal end thereof, “is inserted into the vagina through the speculum.” *Id.* Because blade 420 is passed through the speculum, the electrodes on the blade treat the anterior or posterior vaginal walls *deeper* into the vagina (i.e., away from the vaginal opening) relative to the tip of the speculum. EX2001 ¶98.

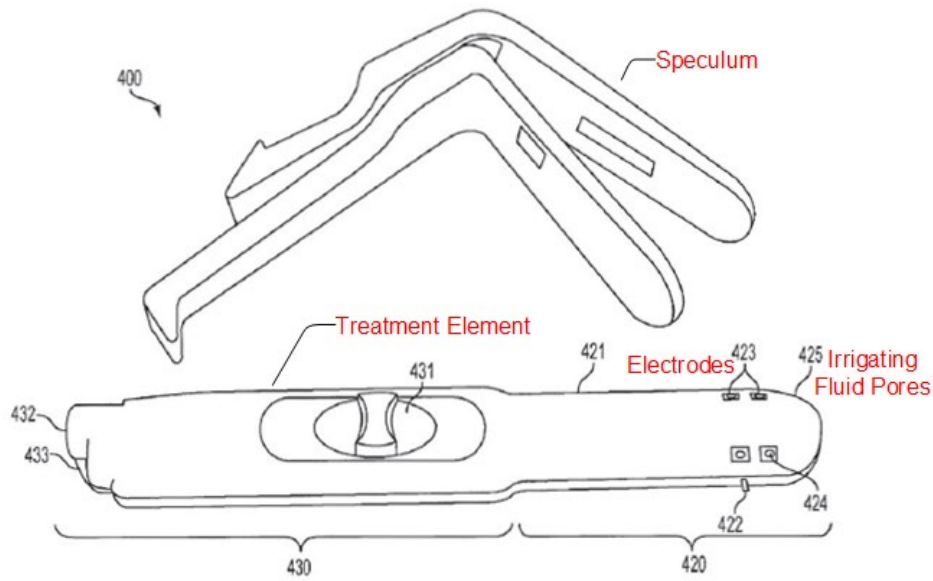


FIG. 4

EX1005, FIG. 4 (annotated).

For context, a speculum is a device that dilates a vagina. EX2001 ¶100. In Edwards, blade 420 is not used until it mounted on the speculum, which has already been inserted into a vagina. See EX1005, Figs. 9A-9B; EX2001, ¶100; EX2005, 128:7-18, 132:1-12, 132:25-133:6. As shown in Figure 4, “[t]he blade 420 includes mating features 421, a spring-loaded pin detail 422, a plurality of relatively flat electrodes 423 and a plurality of irrigating fluid delivery pores 425. The mating features 421 are constructed to engage with features in the speculum following simple positioning of the speculum within the vagina. The spring-loaded pin detail 422 locks the blade 420 into the correct position in the inserted speculum.” EX1005, 7:26-33, 13:43-46; EX2001, ¶100. Edwards only ever

discloses that the blade 420 is locked into position with the speculum during delivery of RF energy to the vaginal wall. *See* EX1005, 13:43-62; EX2001, ¶100.

Both experts also agree that, when blade 420 mates with the speculum, the electrodes would extend beyond the end of the speculum, such that the electrodes would be positioned about 2 cm deeper into the vagina than the tip of the speculum. EX2005, 132:25-133:16, 140:14-17; EX2001, ¶101. Furthermore, a POSA would have understood that when inserting a speculum into the vaginal canal, it would need to be inserted at least a few centimeters beyond the introitus in order to properly engage with the tissue and prevent the speculum from falling out. EX2005, 137:12-138:1; EX2001, ¶101. While the experts disagreed on expected depth (2.5 cm for Petitioner and 5 cm for Patent Owner's expert), both estimates result in Edwards' failing to meet the claim limitation, with Petitioner's expert estimate placing treatment at 4.5 cm away from the introitus and Patent Owner's expert placing it 7 cm away from the introitus. EX2005, 137:12-138:1, 140:14-17; EX2001, ¶¶101-103

Thus, the Edwards device would not provide for treatment of the area from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus. EX2001, ¶104. In fact, the speculum dilates the introitus and moves it out of the way so that deeper structures of the vagina can be treated. EX2001, ¶104.

Mosher does not remedy the deficiencies of Edwards. Mosher is directed to treating the endopelvic fascia for treating incontinence, which supports and is located adjacent to the bladder. EX2001, ¶105. Mosher explains that “[t]o avoid injury to nerves in the *bladder neck* region while providing sufficient treatment volume along the endopelvic fascia, it may be advantageous to distribute the treatment volume along the patient’s *lateral* orientation while *limiting the length of treatment along the axis of the patient’s urethra*.” EX1006, ¶[0074]. To achieve this, Mosher explains that the *size* of the treatment patch is wider than it is long, “ideally having a width of about 25 mm and a length of about 15 mm.” *Id.* Petitioner mistakenly reads that stated *size* of the treatment area to be a position of the treatment relative to the introitus. Pet., 35-36. That understanding is simply wrong. EX2001, ¶¶105-106.

A POSA would not understand this disclosure to reference the region from vagina from the introitus to 3.5 cm inward. EX2001, ¶106. While Mosher describes a treatment area with a specific size (25 mm x 15 mm), it does not explicitly state the location of treatment area. EX2001, ¶106; EX1006, ¶[0074]. However, as discussed above, both experts agree that the treatment area for SUI is at the bladder neck, which is not near the introitus. EX2001, 106. Moreover, Mosher explicitly states that that the rationale for its treatment area is to *avoid*

extending along the urethra. EX1006, ¶[0074]. Under Petitioner’s interpretation of Mosher, the treatment area would be along the urethra to the exclusion of the bladder neck, given the anatomical relationship of the structure discussed above. Indeed, with the limited treatment length, a POSA would readily understand that the introitus is not treated, as the introitus is spaced more than about 4 cm, from the bladder neck. EX2001, ¶107. Thus, Mosher fails to suggest the claim limitation.

Petitioner does not rely upon Ingle for this claim element. Pet., 35-36. In any event, Ingle suffers from the same deficiencies because it is directed to treating incontinence at the bladder, as opposed to treating the introitus. EX1007, 17:30-34, Figs. 6, 11, 12, 12K, and 13; EX2001, ¶108.

Finally, Petitioner fails to articulate a credible reason for why a POSA would have made the proposed combination. EX2001, ¶109. Petitioner provides only a conclusory statement, without any argument as to why a POSA “would have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention.” *InTouch Techs., Inc. v. VGO Communications, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014). The Petition states that “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.” Pet., 35. In addition to being incorrect, this falls far short because Petitioner in no

way “articulates how [Edwards and Mosher] could be combined, which combination(s) of elements in [Edwards and Mosher] could yield a predictable result, or how any specific combination would operate or read on [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].” *ActiveVideo*, 694 F.3d at 1327-28. In particular, it gives no basis or context for “nearer the opening” other than as a misunderstanding of Mosher’s treatment dimensions.

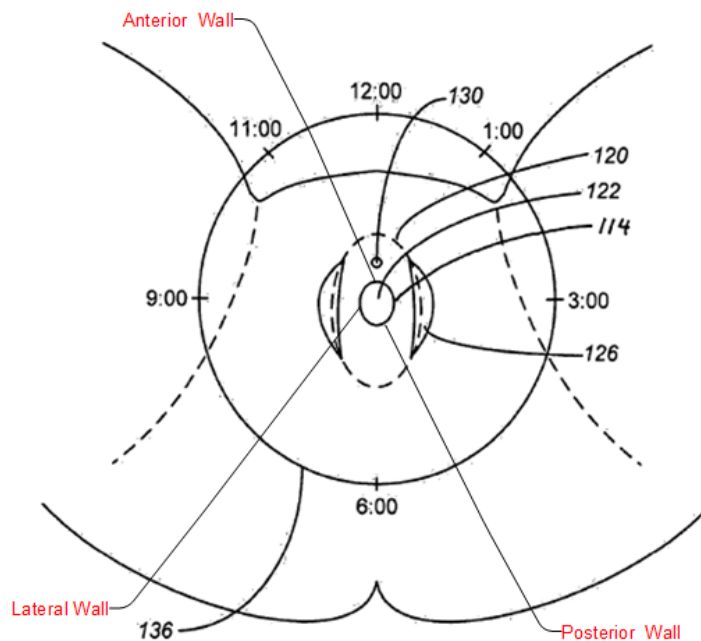
Accordingly, the proposed combination does not render obvious “wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus,” as recited in claim 1.

**E. Claim 35: The Combination does not render obvious “wherein the heating includes heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock, wherein the aspect closest to the urethra is at 12 o’clock”**

Edwards does not suggest heating the vagina *circumferentially* around its wall from 1 o’clock to 11 o’clock, as required by claim 35. Edwards discloses “creat[ing] a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both.” EX1005, 13:14-16, 13:54-56. Neither of these treatment areas meet the claim limitation because the described treatment would, at best,

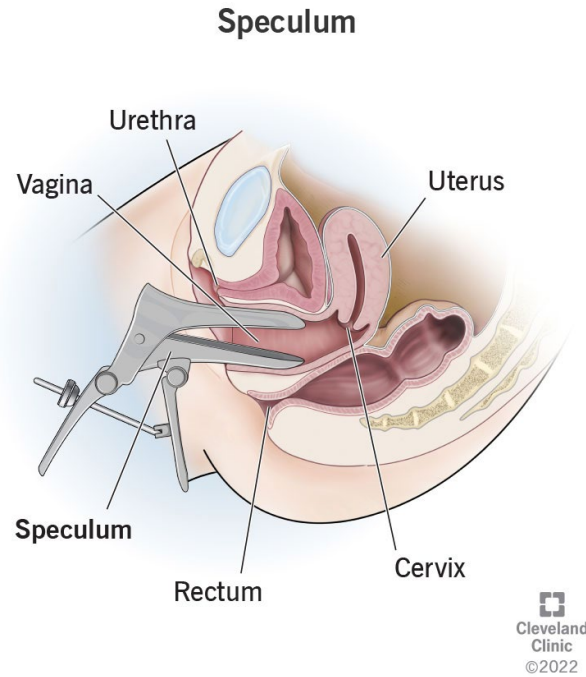
provide single contact treatments that extend in a series longitudinally and not in a circumferential direction in the claimed region.

As shown in FIG. 7 of the '511 patent below, the vaginal wall is oval-shaped. EX1001, FIG. 7; EX2001, ¶112. As shown in the '511 patent (Fig. 7), the anterior and posterior vaginal walls are smaller compared to the lateral vaginal walls. EX2001 ¶112.



EX1001, FIG. 7 (annotated). Nothing in Edwards suggests that its treatment of the anterior wall would be in the claimed region of 1 o'clock to 11 o'clock. EX2001, ¶113. And Edwards potential treatment of the posterior vaginal wall does not extend circumferentially for several reasons.

First, Edwards does not describe (and a POSA would not expect) that the speculum and treatment blade would be rotated within the patient. EX2001, ¶114. As discussed above with reference to Edward FIGS. 4 and 9, the “speculum is inserted in the patient’s vagina” to treat “the posterior wall.” EX1005, 13:38-44; EX2001, ¶114. Blade 420, which has the treatment electrodes, is positioned only after the speculum is in place and is locked in place on the speculum. EX1005, 13:43-49; EX2001, ¶114. Edwards does not describe the speculum being rotated or moved once engaged in place. EX2001, ¶114. Moreover, a POSA would understand that conventional positioning of the speculum is to place the bills against the anterior and posterior vaginal walls. EX2001 ¶117. The conventional position of a speculum can be seen in the diagram below:



EX2010, 2. Further, the patient’s leg would be in the way of the speculum’s rotation, and it would not make sense to rotate the speculum when using irrigation fluids like those described in the Edwards treatment. EX2001, ¶115.

Second, Edwards does not disclose treatments extending in any circumferential direction along the posterior wall. While the Petition refers to a “series of lesions,” those lesions are caused by the electrodes 423 extending along the *length* of the device, as can be seen on blade 420 itself. Pet., 37 (quoting EX1005, 13:14-16); EX1005, Fig. 4 (electrodes 423). This suggests a series of point treatments along the length of the bladder neck, at least because that is the

distribution of electrodes and there is no realistic option to rotate the speculum laterally. EX2001, ¶116.

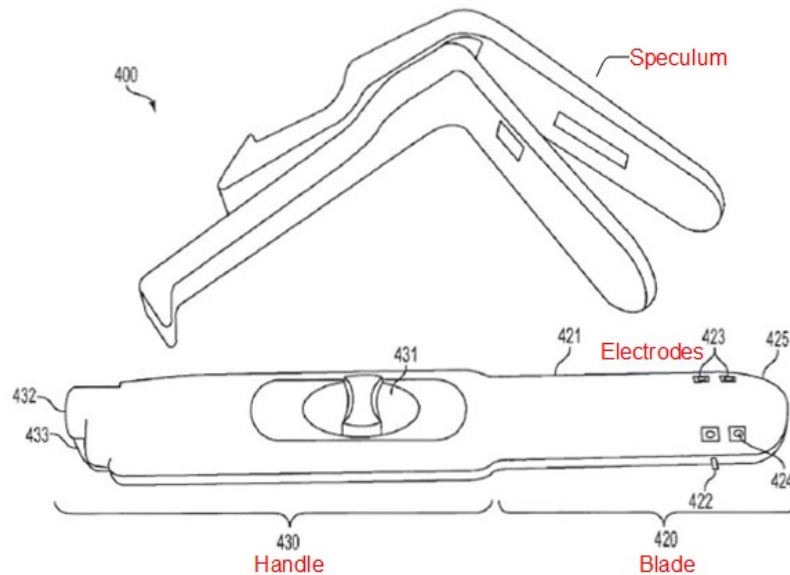


FIG. 4

EX1005, Fig. 4 (annotated). Thus, Edwards’ disclosure of treating the posterior wall describes treatment of a point on the vagina wall and does not teach heating “circumferentially ... from 1 o’clock to 11 o’clock,” as required by claim 35, under any reasonable claim construction. EX2001, ¶117

Mosher does not remedy the deficiencies of Edwards. Like Edwards, Mosher discloses treatment directed towards the endopelvic fascia, i.e., the anterior vaginal wall, at the bladder neck, which is above the vaginal wall between 11 o’clock and 1 o’clock. EX1006, Abstract, ¶[0009]; EX2001, ¶118. Petitioner reasons that because Mosher discloses “distribut[ing] the treatment volume along the patient’s

lateral orientation,” a POSA would be motivated to treat around the circumference of the vagina. Pet., 38 (citing EX1006, ¶[0074]). This significantly mischaracterizes Mosher.

Mosher is clear on its meaning of lateral treatment—namely, that the lateral dimension of the treatment area is greater than the length of the treatment area. EX1006, ¶[0074]. However, Mosher makes clear that this arrangement is achieved through treatment of an area up to 2.5 cm wide, as compared to the 1.5 cm length of the area. EX1006, ¶[0074]. EX2001, ¶119. But Mosher’s limited anterior treatment does not suggest a circumferential treatment in the 1 o’clock to 11 o’clock span. Pet., 67; EX2001, ¶120. At best, a POSA would understand Mosher to potentially hit an insignificant spot inside of the claimed range (e.g., an insignificant spot at 11 o’clock or 1 o’clock), which would not qualify as a *circumferential* portion. EX2001, ¶120. Thus, Mosher does not suggest “heating a portion of the vagina circumferentially” from 1 o’clock and 11 o’clock, as required by claim 35 and Petitioner offers no argument as to why Mosher would be modified in this respect. EX2001, ¶120.

Moreover, Mosher does not “provide an express suggestion to avoid treatment in the 60 degree arc between 11 o’clock and 1 o’clock,” as Petitioner suggests. Pet., 39. Petitioner cites to paragraph [0011] of Mosher describing a

“probe body directly access[ing] the treatment volume ... using *tissue-penetrating electrodes*.” EX1006, ¶[0011]. This disclosure of Mosher describes an embodiment where a needle penetrates tissue to directly heat the fascia, and in that case, 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” that is from being punctured by the tissue penetrating electrode. *Id.*; EX2001, ¶121. But Mosher does not disclose avoiding the bladder neck when applying RF through the vaginal wall. EX2001, ¶121.

Petitioner does not rely upon Ingle for this claim element. Pet., 36-39. In any event, Ingle fails for similar reasons as Mosher. Like Mosher, Ingle discloses treatment directed toward the endopelvic fascia between the bladder neck and the vagina, i.e., the region of the vaginal wall corresponding to the region from 1 o’clock to 11 o’clock. EX1007, 18:46-50; EX2001, ¶122.

Finally, Petitioner fails to sufficiently articulate a specific reason for why a POSA would be motivated to combine Edwards, Mosher, and Ingle to arrive at the specific limitations of claim 35. Petitioner relies on Mosher’s statement of a treatment volume “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.” Pet., 39 (citing EX1006, ¶[0011]). However, as confirmed

by the same paragraph, the offset is needed because the embodiment “us[es] tissue penetrating electrodes having active electrode surfaces that extend from the tissue engaging surface by a distance within a range of about 0 to about 8 mm.” EX1006, ¶[0011]. EX2001, 123. The embodiment of Edwards Petitioner relies upon has no “tissue penetrating electrodes” so there would be no need to consider such an offset. EX2001, 123.

Therefore, the combination of Edwards, Mosher, and Ingle fails to render obvious claim 35.

**F. Claim 43: The Combination does not render obvious “wherein the heating includes heating a portion radiating outward from the introitus to Hart’s line”**

The combination of Edwards, Ingle, and Mosher does not render obvious “wherein the heating includes heating a portion radiating outward from the introitus to Hart’s line.”

As explained above, the Hart’s line is exterior to the introitus (as well as to the opening of the urethra). EX2001, ¶126. As also discussed above, Edwards, Mosher, and Ingle are all directed to treating female SUI, which a POSA would understand (and the references teach) involves treating at the bladder neck and associated structures. EX1005, 2:34-3:9; EX1006 ¶[0006], [0046]; EX2005, 126:2-23; EX2001, ¶126. Petitioner does not appear to dispute this. Pet. 40. Mosher and

Ingle disclose heating the anterior vaginal wall adjacent to the bladder to strengthen and stiffen the endopelvic fascia. EX1006, Abstract, ¶¶[0009], [0058]; EX1007, 2:51-53, 2:59-60. These internal tissues are deeper than the claimed external target tissue between the introitus and Hart's line. EX2001, ¶126. None of these references suggest heating vulva tissue extending from the introitus to the Hart's line.

While Ingle mentions in passing "cosmetic procedures" and treatment of "sagging breasts" (EX1007, 18:1-7, 1:18-23), the same would not suggest to a POSA treating a "portion radiating outward from the introitus to Hart's line." EX2001, ¶127. On this point, Petitioner oversimplifies the issue and applies hindsight bias, by asserting in a conclusory manner that "a POSA would have been motivated to apply the treatments described in Edwards, Mosher, and Ingle to cosmetically enhance the area." Pet., 41. First, the '511 patent acknowledges multiple known references describing use of RF for cosmetic treatments. EX1001, 1:35-61. And the Examiner allowed the claims of the '511 patent over Knowlton and other references describing use of RF treatment for cosmetic procedures. EX1002, 317; EX1013, 6:58-65. The fact that RF treatments were used for cosmetic applications does not render obvious any cosmetic treatment at any anatomical location. *Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG*, 856 F.3d

1019, 1026 (Fed. Cir. 2017) (“it does not necessarily follow from prior-art disclosures of ... general desirability ... that a person of ordinary skill would have been motivated to [achieve the claimed invention].”)

Second, the Federal Circuit has recognized that hindsight bias results when one focuses “on what a skilled artisan would have been *able* to do, rather than what a skilled artisan would have been *motivated* to do at the time of the invention.”

*Polaris Indus. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1068 (Fed. Cir. 2018). Here, Petitioner uses hindsight to argue that passing references to cosmetic treatments elsewhere in the body, such as the face and breasts, would have motivated a POSA to perform a specific procedure to female genital tissue not suggested by the references. Pet., 41. Indeed, Petitioner’s expert confirmed that “all over [one’s] body,” such as the breasts, are squamous epithelium as opposed to mucosal epithelium, which would be found in the claimed treatment site. EX2005, 155:18-20; *see also* EX2001, ¶128. Squamous epithelium requires “different protocols” as compared to mucosal epithelium. EX2005, 155:21-156:7.; *see also* EX2001, ¶128. Also, the genital region radiating outward from the introitus to Hart’s line is irrelevant to the common issue that these references were trying to solve: SUI. EX2001, ¶128. A POSA would have understood that heating the region radiating

outward from the introitus to Hart's line would provide no improvement of SUI inasmuch as Hart's line is even beyond the exit of the urethra. EX2001, ¶128.

Moreover, Petitioner's expert acknowledged that there would be different RF settings, differing times, different use in treating vaginal canal structure versus "external structures" because "tissue response is different externally and in terms of tolerability versus vaginal heating." EX2005, 34:22-35:12; EX2001 ¶130. A POSA would not have understood how to apply the treatments of SUI references to the external introitus to Hart's line region. EX2001 ¶130. Further, the Petition fails to explain how the treatment would be accomplished. As discussed above, Edwards teaches an applicator that mates with a speculum. By definition, this procedure must take place *interior* to the vagina, not *external* to the vagina, extending from the introitus to the Hart's line. EX1005, 13:43-46; EX2001, ¶129. The Petition does not adequately offer any modification to Edwards to accomplish the claimed method. Petitioner's conclusory statement that "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" (Pet., 41) in no way "articulates how [Edwards, Mosher, and Ingle] could be combined, which combination(s) of elements in [Edwards, Mosher, and Ingle] could yield a predictable result, or how any specific combination would operate or read on [heating a portion radiating

outward from the introitus to Hart's line]." *ActiveVideo*, 694 F.3d at 1327-28.

Notably, the only recitation of Hart's line in the relevant portion of the Petition is Petitioner's quotation of the claims and specification of the '511 patent. Pet., 40; EX2001, ¶129. Therefore, Petitioner has not met its burden in establishing that the combination of Edwards, Mosher, and Ingle render obvious "wherein the heating includes heating a portion radiating outward from the introitus to Hart's line," as recited in claim 43.

**G. Claim 51: The Combination does not render obvious "wherein the heating includes heating a mucosal surface of the labia minora"**

The combination of Edwards, Ingle, and Mosher does not render obvious "wherein the heating includes heating a mucosal surface of the labia minora." As explained above, the labia minora is exterior to the introitus.

As addressed above with respect to claim 43, none of the applied references suggest heating a mucosal surface of the labia minora. For claim 51, Petitioner presents the same arguments addressed above with respect to claim 43. Pet., 42. Thus, the application of the references against claim 51 equally fail because the labia minora is also external to the vaginal canal, and the Petition does not establish how (or why) a POSITA would modify Edwards to treat outside the canal. EX2001, ¶133.

Thus, the Petition fails to establish that Edwards, Mosher, and Ingle render obvious “wherein the heating includes heating a mucosal surface of the labia minora,” as recited in claim 51.

**H. All Independent Claims: The Combination does not render obvious “remodeling the therapeutic zone of target tissue”**

The combination of Edwards, Mosher, and Ingle does not render obvious “remodeling the therapeutic zone of target tissue” as recited in each independent claim. Edwards discloses creating “lesions” in and ablating the vaginal wall, which would “substantially affecting the epithelium” and ablate the tissues underlying the epithelium. EX1005, 13:14-16; EX2001, ¶135. Mosher and Ingle also do not teach this element because they only credibly disclose remodeling of the endopelvic fascia, which is excluded deeper tissue, and do not describe remodeling of the “tissue immediately beneath the mucosal epithelium,” as required by the Board’s construction. EX2001, ¶135. As noted above, the intrinsic record establishes (and the ThermiGen IPR panel and *Viveve* district court agreed) that the claimed invention, as recited in each claim, requires that the treatment occur “without substantially affecting the epithelium overlying the target tissue.” EX1009, 15-16; EX1024, 10 (“critical aspect of the invention is the manner in which the target tissue is heated... [which] is important to ensure that the epithelium is not damaged or substantially modified by the method.”); *see also*

EX2005, 105:13-107:8. And “target tissue” properly includes “tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissue, such as endopelvic fascia.” *See supra* Section III.A; EX2001, ¶136.

**1. Edwards does not teach remodeling “without substantially affecting the epithelium”**

Edwards (and, in particular, the embodiment relied upon by Petitioner) discloses that “[a] 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. Indeed, Edwards teaches “deliver[ing] a low-voltage, high-frequency current to cauterize and destroy abnormal tissues.” EX2008, 6; EX2001, ¶137-139 (explaining that the relevant embodiment uses ablative techniques based on the electrode size being consistent with a high heating effect intended to produce destructive action). Lesions in the vaginal wall will result in “thermal injury of some kind” and “cellular breakdown.” EX2005, 103:7-12; EX2001, ¶ 138.

While Edwards discloses that “at least one of the irrigating fluid ports 433 is engaged so as to deliver cooling fluid into the vagina through the irrigating fluid delivery pores 425” (EX1005, 13:50-53), this type of cooling would be understood to protect non-target areas, not epithelial mucosa at the target site. EX2001 ¶140. In fact, Edwards does not apply irrigating fluid where the electrodes are located on

the blade, as the irrigating pores are not located adjacent to, or on the same surface as, the electrodes. EX2001 ¶140.

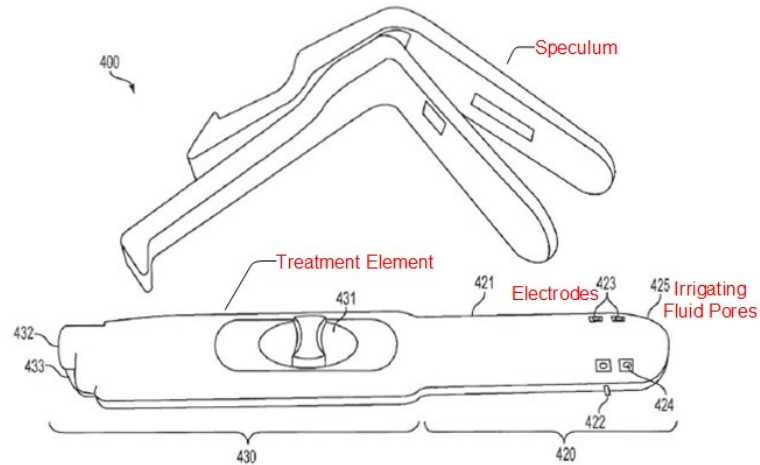


FIG. 4

EX1005, Fig. 4 (annotated).

Edwards does not describe any specific provisions for protecting the mucosal epithelium in the area that is being treated. EX2001, ¶141. Edwards also does not describe any provisions indicative of protection of the mucosal epithelium from ablation, such as heat dissipating gel, adjusting the energies used, adjusting the interval of exposure, turning the exposure on and off (pulsing), insulating the energy applicator, cooling of the entire electrode assembly, or other cooling elements that directly targets tissue in contact with the applicator. EX2001, ¶141. Instead, Edwards notes the treatments “require [] local or regional anesthesia,”

which would only be necessary if tissue is ablated. EX1005, 2:22-27; EX2001, ¶141.

Edwards' disclosure of "irrigating fluid" is merely consistent with clearing away blood and other fluids during an ablative procedure. EX2001 ¶142.

Irrigating fluid may also be used to protect tissue in non-target areas, rather than protecting different layers within the target area, such as the surface mucosa. EX2001 ¶142. In fact, Edwards makes clear that "[t]his cooling fluid lowers the relative temperature of the targeted tissues and prevents *collateral* thermal damage of the uterine walls and associated tissues." EX1005, 9:42-48. This terminology suggests preventing damage of non-targeted areas. EX2001 ¶142.

Thus, unlike the claimed invention, which remodels sub-mucosal tissue without substantially affecting the epithelium, Edwards creates "lesions" in the vaginal wall and, therefore, fails to teach the claimed "remodeling." EX2001, ¶143

## **2. Mosher does not teach remodeling "tissue immediately beneath the mucosal epithelium"**

Mosher is directed to treating the "endopelvic fascia," which is not a target tissue in connection with the '511 patent. EX2001 ¶144. The ThermiGen IPR construction of target tissue includes "tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissue, such as endopelvic fascia." See *supra* Section III.A. The target tissues of the '511 patent thus include "the

lamina propria and the muscularis, underlying the mucosal epithelium of a female genital tissue.” EX1001, 2:25-28. The mucosa which includes the epithelium and lamina propria is thin, in the range of 0.2 mm. EX2001, ¶145. The muscularis is 0.8 mm or thicker. EX2001, ¶145. And the deep fascia, such as the endopelvic fascia is outside the vaginal wall proper.

Mosher discloses heating and remodeling the endopelvic fascia to treat bladder outlet hypermobility. EX1006, Abstract; *see also id.*, ¶[0009]; ¶¶[0045]-[0050]; EX2001, ¶146. Mosher is thus focused on remodeling the endopelvic fascia, and not the tissue immediately beneath the mucosal epithelium. Mosher explains that:

FIG. 9 illustrates the 2-D orientation of collagen fibers in the deep fascia, and preferred target tissue for incontinence treatments. The structure of tissues between a vaginal treatment probe and this deep fascia collagen of the endopelvic fascia includes typically about 0.04 mm of epithelium along the surface of the vaginal wall. Below the epithelium is between 0.04 mm and 0.7 mm of submucosa, typically comprising loosely packed thin collagen fibers. Below the submucosa lies a layer of superficial fascia, at a depth of between 0.7 mm to about 2.0 mm. This superficial fascia contains much smaller collagen bundles which are loosely packed and appear interlacing. *The deep fascia illustrated in FIG. 9 typically lies throughout a depth of between about 2.0 and 4.0 mm*, and includes larger, elongated

collagen bundles having a distinct horizontal or 2-D distribution. This deep fascia provides an exemplary target for greater heat-induced changes, including contraction or shrinkage, stiffening, and/or the like.

EX1006, ¶[0066].

Petitioner relies on Mosher's description of "cooled electrode vaginal probes" in FIGS. 6 and 6A. Pet., 31-32 (citing EX1006 ¶[0058], FIG. 6). With reference to FIG. 6, Mosher describes "cool[ing] the intervening or *intermediate tissue between probe body 54 and the endopelvic fascia EF*, such as the vaginal wall VW as seen in FIG. 6." EX1006 ¶[0058]. As shown in FIG. 6 of Mosher, the vaginal wall includes the epithelium as well as "the tissue immediately beneath the mucosal epithelium," including the lamina propria and muscularis. EX2001 ¶147; EX1006, FIG. 6. Mosher describes cooling this "intervening or intermediate tissue" of the vaginal wall, which a POSA would understand from Mosher's disclosure includes the lamina propria and muscularis. EX1006, ¶[0058]; EX2001, ¶147. Mosher thus discloses cooling the target tissues of the '511 patent ("the tissue immediately beneath the mucosal epithelium"), which would not result in the claimed treatment. EX2001, ¶147.

Petitioner argues that Mosher identifies lamina propria as a potential target tissue. Pet., 27. As discussed above (supra Section IV.B), Mosher only mentions

the lamina propria in a laundry list disclosure that includes *male anatomical features*. EX1006, ¶[0048]. Given the clearly flawed laundry list disclosure and the fact that Mosher does not describe how its treatment would be applied to other structures from that laundry list, a POSA would not have found any particular treatment obvious in view of the same. EX2001, ¶148. For example, Mosher does not describe the RF settings necessary to treat, e.g., the lamina propria, the amount of time to apply RF heating, how to cool the nearby epithelium so as to avoid damage thereto, or the other parameters necessary to achieve remodeling of the lamina propria. EX2001, ¶148. Nor is there any credible reason to select from the laundry list for use with Edwards SUI treatment.

Mosher thus does not teach “remodeling ... target tissue,” the tissue immediately beneath the mucosal epithelium.

### **3. Ingle does not teach remodeling “tissue immediately beneath the mucosal epithelium”**

Ingle, like Mosher, is also directed to heating the endopelvic fascia to treat bladder outlet hypermobility. Ingle explains that “the present invention directs energy to a patient’s own support tissues. This energy heats [endopelvic] fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues.” EX1007, 2:51-3:10; *see also id.*, 3:11-20, 3:36-50, 17:1-34, 17:41-64, 18:8-13, Fig. 4. Ingle disclosure of endopelvic fascia and “other

collagenated support structures” does not teach or suggest treatment of “tissue immediately beneath the mucosal epithelium of genital tissues.” EX2001 ¶150. Indeed, Ingle defines “collagenated tissue [] as fascia, ligament, or the like.” EX1007, 11:8-11; EX2001, ¶150.

Ingle discloses that “[t]he target tissue is *separated from a tissue surface* by an intermediate tissue.” EX1007, 7:16-21. Thus, Ingle explicitly differentiates the intermediate tissue between the surface and the target fascia, which would include tissue immediately beneath the mucosal epithelium (i.e., surface). *See* EX1007, 15:19-25; EX2001, ¶151.

Accordingly, the combination of Edwards, Mosher, and Ingle does not render obvious “remodeling the therapeutic zone of target tissue,” as recited in independent claims 1, 35, 43, and 51.

**I. Claim 26: The Combination does not render obvious “tightening the introitus”**

Petitioner cites only to Edwards for claim 26 and states that it is relying upon “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.”” Pet., 63-64. Petitioner then states, in a conclusory manner, that Edwards’ treatment would result in “tightening the introitus.” *Id.* Not so. EX2001, ¶154.

As established above, the introitus is the opening of the vagina at the body's exterior. As also established above, (i) the treatment area in Edwards (related to the bladder neck position) is not at or near the introitus and (ii) Edwards' speculum device would not permit its electrodes to contact the introitus when positioned in the patient. *See supra* Sections IV.A, IV.D. Indeed, because Edwards teaches using an RF applicator in combination with a speculum for entry into the vagina, Edwards is not treating the introitus and, consequently, there is nothing to suggest that its treatment would have any effect on the introitus. *Id.*, EX2001, ¶¶155.

Moreover, Petitioner does not explain how a POSA would modify Edwards' device and/or treatment to affect the introitus. Nor does Petitioner cite to Mosher or Ingle for this element. Therefore, in view of the above, Petitioner has not met its burden in establishing that Edwards, Mosher, and Ingle render obvious claim 26. EX2001, ¶156.

**J. The Combination does not render obvious claims 2-34, 36-42, 44-50, and 52-58**

Claims 2-34, 36-42, 44-50, and 52-58 ultimately depend from independent claims 1, 35, 43, and 51 and accordingly are not rendered obvious by the combination of Edwards, Ingle, and Mosher for at least the same reasons discussed above for the independent claims. EX2001, ¶157.

**V. GROUND 2: PETITIONER’S COMBINATION OF EDWARDS, MOSHER, INGLE, AND OLLIVIER FAILS**

For the reasons articulated above and with respect to claims 43 and 51, the combination of Edwards, Mosher, and Ingle does not render obvious the challenged claims because none of the references disclose “heating a portion radiating outward from the introitus to Hart’s line” or “heating a mucosal surface of the labia minora.” Indeed, Edwards, Mosher, and Ingle do not disclose treating outside of the vaginal canal. *See* EX2001 ¶159. Likely recognizing this deficiency of Ground 1, Petitioner relies upon Ollivier for Ground 2. However, Ollivier does not suggest the relevant claim features and, more fundamentally, is not an enabling disclosure. EX2001, ¶159.

In its conclusory five-paragraph argument, Petitioner appears to rely simply on the idea that Ollivier mentions cosmetic treatments to vulvar tissues to suggest modifications to the references in Ground 1. The argument fails for multiple reasons: (1) Ollivier was not sufficiently accessible to the public interested in the art; (2) Ollivier’s high-level discussion reporting that one doctor was conducting (undisclosed) laser treatments does not provide a sufficient, enabling disclosure; (3) Ollivier never mentions the target tissues of claims 43 and 51; and (4) Petitioner has not sufficiently explained how the references would be combined.

**A. Ollivier is not an enabling reference or qualifying printed publication**

Ollivier appears to be an article entitled “Designer vaginas” that purportedly appeared on a website called Salon.com. Salon.com is described as a “politically progressive and liberal news and opinion website” that provides “provocative (if predictably liberal) political commentary and lots of sex.” EX2015. Salon.com is not a medical or technical publication. The author does not have a medical or technical background. EX1008, 1; EX2011. EX2001, ¶¶160-161

First, Petitioner has not demonstrated that Ollivier “was made ‘sufficiently accessible to the public interested in the art’ before the critical date.” *Voter Verified, Inc. v. Premier Election Sols., Inc.*, 698 F.3d 1374, 1380 (Fed. Cir. 2012). Indeed, Petitioner provides no evidence that a medical doctor as of 2006 would access or be aware of Salon.com, let alone the Ollivier article. In fact, Petitioner’s own expert testified during his deposition that he was “not aware of Salon.com ***until two minutes ago.***” EX2005, 158:5-12 (“Q. Are you aware of the Salon.com website? A. Not at all.”). Dr. Berenholz further testified, that he was not aware of any doctors that read Salon.com. *Id.*; EX2001, ¶162. InMode’s expert was also unaware of Salon.com before this case. Notably, the Petition asserts that “interested persons would have known of or been able to locate Salon.com,” and that the article could be located using “Salon.com’s search functionality.” Pet. 12-

13. But Petitioner’s expert contradicts that unsupported assertion. Moreover, whether a person could search for the article at Salon.com’s website is irrelevant if an “interested researcher” would not have known of that website or have been drawn to its content in the first place. *See Verified, Inc.*, 698 F.3d at 1380-81. Nor has Petitioner established what search, if any, would have resulted in the article being found (*see* EX1029) or how the cited to “Audience Profile” (*see* EX1023) would capture the relevant population at issue.

Second, regarding enablement, Petitioner’s expert admits that Ollivier does not provide any specifics regarding the procedure or laser being used. EX2005, 160:6-10 (acknowledging that he obtained knowledge of the procedure through personal experience because he “was trained by Dr. Matlock”); EX2001, ¶163 *Raytheon Techs. Corp. v. GE*, 993 F.3d 1374, 1381 (Fed. Cir. 2021) (“reference must necessarily enable the relied-upon portion of its own disclosure”). Ollivier is an article that merely indicates that there was a single doctor—Dr. Matlock—performing an invasive procedure using laser to cut away tissue, with no real description of the actual procedure. EX1008.

As to the actual treatment alluded to in Ollivier, Petitioner’s expert’s understanding of the procedure was not obtained through Ollivier’s disclosure, but through training with Dr. Matlock. Moreover, for the training, Dr. Matlock

required participating doctors to sign a non-disclosure agreement, as the procedure was kept secret. EX2005, 162:3-6 (agreeing that Dr. Matlock “keeps the specifics ... of the treatment confidential”), 162:23-163:4 (describing Dr. Matlock’s “contract about ... not divulging treatment, surgical techniques, et cetera. ... it was confidential.”), 165:23-166:1 (Dr. Matlock’s procedures still confidential). InMode’s expert confirms that Dr. Matlock still requires a non-disclosure agreement to explain the procedure. EX2001, ¶164.

Due to the secrecy of the procedure, Ollivier reports on Dr. Matlock’s treatments at a high-level, referring to, e.g., “Laser Vaginal Rejuvenation.” EX1008, 1, 2 (stating that Dr. Matlock has not “published any scientific material relating to his work”). Ollivier makes reference to Dr. Matlock’s “antiseptic trimmings and surgical prunings of a trusty laser” to remove tissues, without providing any details on the procedure. EX1008, 1. The reference “trimmings” and “surgical pruning” suggests only that Matlock is using a surgical laser instead of a scalpel to surgically remove tissue. EX2001, ¶ 165. Indeed, Ollivier identifies the risks associated with laser vaginal surgery, including “hemorrhage, infection, loss of sensitivity, lingering pain from nerve damage,” which are associated with invasive procedures. EX1008, 2; EX2001, ¶ 165. As established above, the remodeling techniques of the ’511 patent are non-invasive procedures intended to

avoid these effects. EX1001, 2:9-16 (“surgical approaches are not highly popular because of the risks associated with an invasive procedure, in a sensitive area, especially when such procedures are considered medically optional.”); EX2001, ¶166. Given the invasive procedure suggested by Ollivier and the lack of details, because the treatment was maintained as a secret, there is no enabling disclosure of a treatment to be combined with the other references.

**B. Claims 43 and 51 are not obvious in view of Edwards, Mosher, Ingle, and Ollivier**

**1. Claim 43: Edwards, Mosher, Ingle, and Ollivier do not render obvious “heating a portion radiating outward from the introitus to Hart's line”**

Ollivier does not describe heating between the introitus and Hart’s line. Ollivier vaguely describes invasive surgical techniques where “labia [are] modified, vulvae reconfigured,” and labium are “trim[ed] back.” EX1008, 1. But Ollivier does not teach or suggest treatment of the portion of the vagina from introitus to the Hart’s line, nor does Ollivier disclose treating in an area “radiating outward” from the introitus. Rather, in the treatment described by Ollivier, portions of external vaginal tissue are removed entirely, which may even remove the Hart’s line. EX1008, 1; EX2001, ¶167. Thus, there is no suggestion of the specific treatment claimed. Indeed, a POSA reading Ollivier would not know to

heat target tissue underlying a portion of the vulva radiating outward from the introitus to the Hart's line. EX2001, ¶167.

More fundamentally, Petitioner fails to explain how Ollivier's vague description of vaginas "being redesigned, labia modified, vulvae reconfigured," using an undisclosed type of laser, to cut away vaginal tissue would suggest to a POSA how the RF techniques of the SUI references could be used to treat the region "radiating outward from the introitus to Hart's line." EX2001, ¶168.

Petitioner provides no disclosure regarding how the SUI references could be used to perform the "antiseptic trimmings and surgical prunings" of the laser described in Ollivier. EX1008, 1; EX2001, ¶168. Indeed, as Petitioner's expert admits, the laser treatments of Ollivier "us[e] a laser as a scalpel" to "sculpt[]" and "cut" the tissue, while RF treatments like in the SUI treatments do not. EX2005, 31:16-21, 159:24-160:5; EX2001, ¶168.

**2. Claim 51: Edwards, Mosher, Ingle, and Ollivier do not render obvious "heating a mucosal surface of the labia minora"**

Ollivier also does not disclose heating a mucosal surface of the labia minora. Rather, Ollivier vaguely describes invasive surgical techniques where "labia [are] modified" or "trimm[ed] back." EX1008, 1. From the little that can be discerned of the treatment alluded to in Ollivier, portions of external vaginal tissue are

removed entirely. EX1008, 1; EX2001, ¶169. The '511 patent is clear that these “surgical approaches” are associated with “a risk of scarring that is entirely counterproductive with regard to the desired result.” EX1001, 2:13-16; EX2001, ¶169. Further, Ollivier does not describe treating the “mucosal surface of the labia minora,” as opposed to the labia majora.

As with claim 43, Petitioner also fails to explain how Ollivier’s vague description lasers cutting away vaginal tissue would suggest to a POSA how the RF techniques of the SUI references could be used to treat the region “mucosal surface of the labia minora.”. EX2001, ¶170.

### **3. Claims 43 and 51: No motivation to combine Ollivier with Edwards, Mosher, and Ingle**

There is no motivation to combine the laser surgical procedures referenced in Ollivier with the SUI procedures of Edwards, Mosher, and Ingle (the “SUI references”). For one, Ollivier identifies the risks associated with laser vaginal surgery, including “hemorrhage, infection, loss of sensitivity, lingering pain from nerve damage.” EX1008, 2. And Petitioner’s expert acknowledges that these side effects can occur with laser surgical techniques. EX2001, ¶171; EX2025, 163:19-13.

Also, Ollivier acknowledges that others in the field did not even believe Dr. Matlock’s procedure was safe or effective. Indeed, Ollivier quotes another medical

doctor who explains that the procedure “‘is a way of preying on vulnerable women.’” EX1008, 2 (“‘Run away. Run away. Run away.’”). EX2001, ¶172

Moreover, a doctor treating SUI (which is generally focused on strengthening the internal support for the bladder region) would not look to methods for improving the look of exterior genitalia or treating “‘true genital ‘deformities’.” EX1008, 6-7; EX2001, ¶173. Treating external genitalia has no effect on SUI. EX2001, ¶173.

Petitioner also provides no explanation as to how the SUI references would be modified to incorporate the vague teachings of Ollivier. Indeed, the Edwards energy applicator is a blade that mates with a speculum, thus confirming it is intended for internal usage. EX1005, 13:38-42, FIG. 4; EX2001, ¶174. Similarly, Mosher discloses “vaginal probes” with “needle mounted temperature sensors.” EX1006, ¶[0058]. Likewise, Ingle discloses “clamping a target tissue between a plurality of electrode surfaces...” for example, by placing one electrode surface in the vagina and a second electrode surface in the rectum. EX1007, 8:24-27.

Petitioner does not explain how these applicators would be modified to treat the external vulva tissues.

Finally, Dr. Matlock was allegedly advertising and performing ablative laser treatments on the vagina since at least the late nineties. EX1008, 1-2. Yet, prior to

the present invention, no one suggested the specific non-invasive procedures, on specific anatomical structures, claimed in the '511 patent. EX2001, ¶175

**C. The Combination of Edwards, Ingle, Mosher, and Ollivier does not render obvious claims 2-34, 36-42, 44-50, and 52-58**

Claims 2-34, 36-42, 44-50, and 52-58 ultimately depend from independent claims 1, 35, 43, and 51 and accordingly are not rendered obvious by the combination of Edwards, Ingle, Mosher, and Ollivier for at least the same reasons discussed above for the independent claims. EX2001, ¶176

**VI. OBJECTIVE INDICIA**

While he is now attacking the '511 patent, Dr. Berenholz's former employer, Thermi, and mentor, Dr. Alinsod, recently praised the '511 patent treatments as "landmark." EX1025, 18; EX1004, 2; EX2005, 44:12-20. Specifically, Dr. Alinsod and Thermi published a paper in which Dr. Alinsod describes a study of Viveve's (the original assignee of the '511 patent) treatment as a "landmark study" that reported "notable improvement to sexual function." EX1025, 18, 21. The "landmark study" describes treatments corresponding to claims 1, 26, and 35, as discussed below. *See* EX2018; EX2001, ¶177. Dr. Alinsod's paper also praises a second study of Viveve's device and treatment, which device and treatment also corresponds to claims 1, 26, and 35. EX1025, 18, 21; EX2017.

“[I]ndustry praise ... provides probative and cogent evidence that one of ordinary skill in the art would not have reasonably expected” the claimed invention. *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013). “[T]here is presumption of nexus ... when the patentee shows that the asserted objective evidence is tied to the a specific product and that product ‘is the invention disclosed an claimed.’” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016).

Here, claim 1 recites “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.” EX1001, claim 1. Claim 26 recites “tightening the introitus.” EX1001, claim 26. Claim 35 recites “heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock.” EX1001, claim 35. Both of the studies praised by Dr. Alinsod describe heating and remodeling vaginal tissue by applying an RF “treatment tip ... to the mucosal surface of the vaginal *introitus* starting at the hymenal ring and [treating] the entire area *from the 1:00 o'clock to 11:00 o'clock position* ... with RF energy pulses.” EX2018, 3; EX2017, 777; EX2001, ¶179. Moreover, the specific device being used was the Viveve device. EX2018, 3 (left column); EX2017, 776-77. The treatment was performed to heat tissue “beneath the surface” and while using cryogen so as not to affect the surface tissue. EX2018,

3 (right column); EX2017, 779, 780 (“nonablative”); EX2001, ¶179. Also, the treatment area extended from the hymenal ring (which forms a portion of circumference of the introitus) to about 1.6 cm from the introitus. EX2001, ¶179; EX2018, 3 (describing a 20 cm<sup>2</sup> treatment area over a 12 cm circumference (left column)). This treatment is commensurate in scope with the treatment of claim 1—“introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus”—and claim 26—“tightening the introitus.” EX2001, ¶179; EX1001, claims 1, 26. Also treating the area from “the 1:00 o’clock to 11:00 o’clock position ... moving the tip in a clockwise direction” is commensurate in scope with claim 35’s treatment of “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock.” EX2018, 3 (right column); EX2017, 777; EX1001, claim 35; EX2001, ¶179. These treatment areas in claims 1 and 35 were the “specific areas of treatment” that the Examiner identified as novel and non-obvious during prosecution of the ’511 patent. EX1002, 317.

Dr. Alinsod even performed his own study that provided “confirmation” of the studies of the Viveve treatment and concluded that such evidence “is a boon to successful treatment and may represent a key advance in the emerging field of vulvovaginal rejuvenation.” EX1025, 21 (also praising the lack of “downtime” or “risks” to the patients); EX2001, ¶180. Dr. Alinsod contrasted this benefit to prior

treatments that resulted in significant patient downtime. EX2013, 3, 5, 6. This praise from Dr. Alinsod, who Petitioner's expert described as "a very good physician," regarding the specific treatments of the '511 patent claims 1, 26, and 35 forms a strong objective indicium of non-obviousness. EX2005, 42:23-44:3.

## **VII. PETITIONER'S EXPERT'S DECLARATION SHOULD BE GIVEN LITTLE WEIGHT**

According to the declaration, the expert supposedly, "[i]n formulating [his] opinions, [he] ... considered the viewpoint of a person of ordinary skill in the art" and "relied on [his] education, background, and experience." EX1003, ¶3-4.

However, Dr. Berenholz testified that he did not prepare his declaration. Instead, "[i]t was drafted by the attorneys who represent [him]." EX2005, 166:24-167:5. Not only did Dr. Berenholz not prepare his declaration, but he did not edit or change "any portion of the declaration." *Id.*, 168:18-20. Dr. Berenholz further testified that he did not even know what his contribution to the declaration was. *Id.*, 167:19-168:4 ("I'm not sure where [my expertise in thermal energy and non-invasive vaginal rejuvenation] was utilized in the declaration."). Dr. Berenholz also did not know where the Ollivier reference, which Petitioner relies on as the basis for Ground 2, came from. *Id.*, 157:24-158:11.

Additionally, despite both of Petitioner's grounds being based on obviousness combinations, Dr. Berenholz did not even know what the doctrine of

obviousness is. *Id.*, 119:20-120:1 (“Q. Okay. What’s your understanding of ... the doctrine of obviousness in patent law? A. “Are you referring to claim structure? Or what are you referring to?”).

Finally, despite supposedly considering the viewpoint of a POSA, Petitioner’s expert repeatedly testified that he was ***not*** able to testify as to general knowledge in the field and could only speak to his specific experience. *Id.*, 142:9-13 (“Q. But for a non-surgical procedure would you use betadine? A. I haven’t with my device, but I’m sure others have with theirs. ***I just can’t speak to it. I can only offer you my experience.***”). However, Petitioner’s expert—Dr. Berenholz—is not a POSA, but a doctor who began performing cosmetic gynecological treatments in 1995-1996, giving him years of experience more than the POSA. *Id.*, 49:18-50:3.

For these reasons, the declaration should not be given weight.

## **VIII. CONCLUSION**

For the foregoing reasons, Petitioner’s grounds fail.

Respectfully submitted,

/Justin J. Oliver/

Justin J. Oliver

VENABLE LLP

600 Massachusetts Avenue, NW

Washington, D.C. 20001

Telephone: 202-721-5423

Facsimile: 202-344-8300

Email: JOliver@Venable.com

## **CERTIFICATE OF COMPLIANCE**

Pursuant to 37 C.F.R. § 42.24, I hereby certify that the foregoing paper contains 13,959 words as measured by the word processing software used to prepare the document, excluding the cover page, signature block, and portions exempted under 37 C.F.R. § 42.24.

Respectfully submitted,

July 1, 2025

/Justin J. Oliver/  
Justin J. Oliver (Reg. No. 44,986)  
Venable LLP  
Tel: (202) 721-5423

## **CERTIFICATE OF SERVICE**

I certify that a copy of Patent Owner's Corrected Patent Owner Response was served to Petitioner by causing it to be sent by email to counsel for Petitioner at the following email address:

rbemben-PTAB@sternekessler.com,  
jchagnon-PTAB@sternekessler.com,  
rcoller-PTAB@sternekessler.com,  
cvira-PTAB@sternekessler.com, and  
PTAB@sternekessler.com

Respectfully submitted,

July 1, 2025

/Justin J. Oliver/  
Justin J. Oliver (Reg. No. 44,986)  
Venable LLP  
Tel: (202) 721-5423