

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BTL INDUSTRIES, INC.,
Petitioner

v.

INMODE LTD.,
Patent Owner

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

DECLARATION OF JOSEPH BERENHOLZ, M.D.

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BTL EX1003
IPR2024-00703
U.S. Patent No. 8,961,511

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I, Joseph Berenholz, M.D., hereby declare as follows.

I. INTRODUCTION

1. I have been retained as an expert witness on behalf of Petitioner BTL Industries, Inc. (“Petitioner”), for the above-captioned *inter partes* review (IPR). I am being compensated for my time in connection with this IPR at a rate of \$500 per hour. My compensation is not contingent on either my expert opinion or the outcome of this litigation. I have no other interest in this proceeding.

2. I understand that this declaration accompanies a petition for IPR involving U.S. Patent No. 8,961,511 (“the ’511 patent”) (EX1001), which resulted from U.S. Patent Application No. 11/704,067 (“the ’067 application”), filed on February 7, 2007. I understand that the ’511 patent alleges a priority date of February 7, 2006. I refer to this date throughout this declaration.

3. In preparing this declaration, I have reviewed the ’511 patent and each of the documents cited herein, in light of general knowledge in the art before February 7, 2006. In formulating my opinions, I have relied upon my experience, education, and knowledge in the relevant art. In formulating my opinions, I have also considered the viewpoint of a person of ordinary skill in the art (“POSA”) (as defined further below in Section VII.B) prior to February 7, 2006.

II. MY BACKGROUND AND QUALIFICATIONS

4. In forming the opinions in this declaration, I have considered and relied on my education, background, and experience. My experience and education are detailed in my curriculum vitae (“CV”). *See* EX1004.

5. I have been a board-certified obstetrician and gynecologist for over 30 years and have been the Medical Director for the Michigan Center for Women’s Health since 2019. I was the first physician to introduce cosmetic gynecology formally into the Midwest United States when I founded the Laser Vaginal Rejuvenation Institute of Michigan in 2001 and was the first specialty certified physician in Michigan in the field of female cosmetic genital surgery.

6. I obtained my M.D. from the Autonomous University of Guadalajara, Mexico in 1978. I completed one year of transitional Internal Medicine at Deaconess Hospital in St. Louis in 1978 to 1979. I completed one year of general / trauma surgery at Mt. Carmel Mercy Hospital (now known as Sinai-Grace Hospital) in Detroit, MI, in 1979 to 1980. I then completed a residency in Obstetrics and Gynecology at Providence Hospital, Ascension Health System in Southfield, MI from 1981–1985. I am a Diplomate of the American Board of Obstetrics and Gynecology as well as a member of the American Society for Laser Medicine & Surgery, the Michigan State Medical Society, and the Oakland County

Medical Society of Michigan. Additionally, I have been invited to, and am a member of, The Global Exchange of Cosmetic Gynecology.

7. In my clinical practice, I have had experience treating patients using various forms of radiant energy, including radio frequency energy, lasers, and electromagnetic energy. Throughout my over 20 years of practice, I have performed nearly 4000 cosmetic and non-cosmetic gynecologic procedures—including non-invasive vaginal rejuvenation and restoration, vaginoplasties, labiaplasties, mid-urethral slings for incontinence—and helped countless patients who were seeking gynecologic aesthetic and quality of life enhancements.

8. I have conducted research and collaborated with thought leaders in the field of cosmetic gynecology and have co-authored articles in peer-reviewed journals and conference proceedings related to the use of high intensity electromagnetic therapy for urogynecological treatment. I have also served as a spokesperson for numerous corporations relating to the field of urogynecology and cosmetic gynecology, and the devices used within them.

III. SUMMARY OF OPINIONS

9. In forming my opinions about the '511 patent, I have considered the following grounds of unpatentability. Based on my careful review of the references that form the basis of the grounds, it is my opinion that claims 1–58 of the '511

patent would have been obvious to a person of ordinary skill in the art (“POSA”) as of the filing date of the ’511 patent.

Ground	References	Basis	Challenged Claims
1	Edwards, Mosher, and Ingle	§ 103	1–58
2	Edwards, Mosher, Ingle, and Ollivier	§ 103	43–58

10. I have been asked to consider how a POSA would have understood the challenged claims in light of the disclosures of the ’511 patent. I also have been asked to consider how a POSA would have understood the prior-art references Edwards, Mosher, Ingle, and Ollivier. Further, I have been asked to consider and provide my technical review, analysis, insights, and opinions regarding whether a POSA would have understood the combinations of the prior-art references listed in the table above render obvious claims 1–58 of the ’511 patent.

IV. LIST OF MATERIALS CONSIDERED

11. In formulating my opinions, I have relied upon my training, knowledge, and experience that are relevant to the ’511 patent. I have also reviewed and am familiar with the following documents and materials in addition to any other documents cited in this declaration:

Exhibit No.	Description
1001	U.S. Patent No. 8,961,511 to Parmer (“the ’511 patent”)
1002	File History of U.S. Patent No. 8,961,511 (“’511 File History”)
1004	<i>Curriculum Vitae</i> of Dr. Joseph Berenholz

Exhibit No.	Description
1005	U.S. Patent No. 6,463,331 to Edwards (“Edwards”)
1006	U.S. Patent Application Publication No. 2004/0193238 to Mosher et al. (“Mosher”)
1007	U.S. Patent No. 6,216,704 to Ingle et al. (“Ingle”)
1008	Ollivier, D., “Designer Vaginas,” Salon.com, accessed at https://web.archive.org/web/20010124063400/http://www.salon.com/sex/feature/2000/11/14/vagina/print.html (Nov. 14, 2000) (“Ollivier”)
1014	U.S. Patent No. 6,283,987 to Laird et al.
1015	F.H. Netter, “Netter's Atlas of Human Anatomy,” 4 th Ed., Saunders Elsevier, 2006 (“Netter”)
1016	D.J. Goldberg, “Nonablative Laser Technology: Radiofrequency,” <i>Aesthetic Surg J</i> 2004; 24:180–181 (“Goldberg”)
1017	C. Squier and K.A. Brogden, “Human Oral Mucosa: Development, Structure, and Function,” 1 st Ed., Wiley-Blackwell 2011 (“Squier”)
1018	N. Sadick, “Tissue Tightening Technologies: Fact or Fiction,” <i>Aesthetic Surg J</i> 2008; 28:180–188 (“Sadick”)
1019	N.T. Wright and J.D. Humphrey, “Denaturation of Collagen Via Heating: An Irreversible Rate Process,” <i>Annu. Rev. Biomed. Eng.</i> 2002; 4:109–128 (“Wright”)
1020	M. Paul et al., “Three-Dimensional Radiofrequency Tissue Tightening: A Proposed Mechanism and Applications for Body Contouring,” <i>Aesth Plast Surg</i> 35:87-95 (2011) (“Paul”)
1021	J.A. Burns, “Thermage: Monopolar Radiofrequency,” <i>Aesthetic Surgery Journal</i> , 25:638–642 (“Burns”)
1022	Barry E. DiBernardo, “Clinically Relevant Lasers for the Plastic Surgeon,” <i>Aesthetic Surgery Journal</i> (2005)
1025	Alinsod, R.M., “Temperature Controlled Radiofrequency for Vulvovaginal Laxity,” <i>Prime Journal</i> , pp. 16-21 (July/August 2015)
1026	ThermiVa, “Doctors are Weighing in on ThermiVa,” accessed August 20, 2015

12. To the best of my knowledge, the above-mentioned documents and materials are true and accurate copies of what they purport to be. An expert in the field would reasonably rely on them to formulate opinions such as those set forth in this declaration.

V. LEGAL UNDERSTANDING

13. I have also relied upon various legal principles (as explained to me by Petitioner's counsel) in formulating my opinions. My understanding of these principles is summarized below.

14. I have been told the following legal principles apply to analysis of patentability. I also have been told that, in an *inter partes* review proceeding, a patent claim may be deemed unpatentable if it is shown by a preponderance of the evidence that the claim is rendered obvious by one or more prior-art references under 35 U.S.C. § 103.

15. I understand that documents and materials (such as printed publications or patents) that qualify as prior art can be used to render a patent claim obvious.

16. I understand that, once the claims of a patent have been properly construed, the second step in determining invalidity of a patent claim requires a comparison of the properly construed claim language to the prior art on a limitation-by-limitation basis.

A. My Understanding of Claim Construction

17. I understand that during an *inter partes* review proceeding, claims are to be construed in light of the specification as would be read by a POSA at the time of the purported priority date. I also understand that claims in an IPR are construed using the same claim construction standard that would be used to construe the claim in a civil action. I understand that claim terms are given their ordinary and customary meaning as would be understood by a POSA in the context of the entire disclosure. A claim term, however, will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the claim term in the specification. In this case, the claim term will receive the definition set forth in the patent.

B. My understanding of Obviousness

18. I understand that a patent claim is unpatentable if the claimed invention would have been obvious to a POSA at the time of the alleged invention. I understand that this means that even if all of the elements of the claim cannot be found in a single prior-art reference that would anticipate the claim, the claim can still be unpatentable.

19. It is my understanding that, to obtain a patent, a claimed invention must have been, as of its earliest possible priority date, non-obvious in view of the prior art in the field. I understand that a patent claim is obvious when the

differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a POSA at the time the alleged invention was made.

20. When considering the issues of obviousness, I have been told that I am to do the following:

- Determine the scope and content of the prior art;
- Ascertain the differences between the prior art and the claims at issue;
- Resolve the level of ordinary skill in the art; and
- Consider evidence of secondary indicia of non-obviousness (if available).

21. With respect to determining the proper scope of prior art to examine, I understand that for a prior-art reference to be properly used in an obviousness ground under 35 U.S.C. § 103, the prior-art reference must be analogous art to the claimed invention. I have been told that a reference is analogous art to the claimed invention only if: (1) the reference is from the same field of endeavor as the claimed invention; or (2) the reference is reasonably pertinent to the particular problem solved by the inventor.

22. I understand that factors relevant to determining the proper field of endeavor include the inventor's explanations of the subject matter (including the patent specification) and the claimed invention's structure and function. And I

further understand that to be reasonably pertinent to the particular problem solved by the inventor, a prior-art reference must logically commend itself to the inventor's attention in considering his or her problem.

23. I have been told that an analogous reference may be modified or combined with other analogous references or with the POSA's own knowledge if the person would have found the modification or combination obvious. I have also been told that a POSA is presumed to know all relevant, analogous prior art, and the obviousness analysis may take into account the inferences and creative steps that a POSA would employ.

24. In determining whether a prior-art reference would have been combined with another prior-art reference or other information known to a POSA, I have been told that the following principles may be considered:

- A combination of familiar elements according to known methods is likely to be obvious if it yields predictable results;
- The simple substitution of one known element for another is likely to be obvious if it yields predictable results;
- The use of a known technique to improve similar devices, products, or methods in the same way is likely to be obvious if it yields predictable results;

- The application of a known technique to a prior-art reference that is ready for improvement is likely obvious if it yields predictable results;
- Any need or problem known in the field and addressed by the reference can provide a reason for combining the elements in the manner claimed;
- A skilled artisan often will be able to fit the teachings of multiple references together like a puzzle; and
- The proper analysis of obviousness requires a determination of whether a POSA would have a “reasonable expectation of success”—not “absolute predictability” of success—in achieving the claimed invention by combining prior-art references.

25. I understand that whether a prior-art reference renders a claim unpatentable as obvious is determined from the perspective of a POSA. I have also been told that, while there is no requirement for the prior art to contain an express suggestion to combine known elements to achieve the claimed invention, a suggestion to combine known elements to achieve the claimed invention may come from the prior art as a whole or individually, as filtered through the knowledge of one skilled in the art. In addition, I have been told the inferences and creative steps a POSA would employ are also relevant to the determination of obviousness.

26. I also understand that when a work is available in one field, design alternatives and other market forces can prompt variations of it, either in the same field or in another. I have also been told that if a POSA can implement a predictable variation and would see the benefit of doing so, that variation is likely to be obvious. I have been told that in many fields, there may be little discussion of obvious combinations, and in these fields market demand—not scientific literature—may drive design trends. I have been told that, when there is a design need or market pressure and there are a finite number of predictable solutions, a POSA has good reason to pursue those known options.

27. I have been told there is no rigid rule prescribing that a reference or combination of references must contain a “teaching, suggestion, or motivation” to combine references. But I also have been told that the “teaching, suggestion, or motivation” test can be a useful guide in establishing a rationale for combining elements of the prior art. I have been told this test poses the question as to whether there is an express or implied teaching, suggestion, or motivation to combine prior art elements in a way that realizes the claimed invention, and that it seeks to counter impermissible hindsight analysis.

C. A Person of Ordinary Skill in the Art

28. I understand that a POSA is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity—not an automaton.

29. I have been asked to consider the level of ordinary skill in the field that someone would have had at the time the alleged invention was made. In deciding the level of ordinary skill, I considered the following:

- the levels of education and experience of persons working in the field;
- the types of problems encountered in the field; and
- the sophistication of the technology.

30. I understand that the relevant time for considering whether a claim would have been obvious to a POSA is at the time of the alleged invention, which I have assumed to be February 7, 2006.

31. Regardless of whether I use “I” or “POSA” during my technical analysis below, all of my statements and opinions are to be understood to be based on how a POSA would have understood or read a document at the time of the alleged invention.

VI. BACKGROUND CONCEPTS AND TECHNOLOGIES

A. Anatomy of Female Urogenital System

32. The female urogenital system consists of all the organs involved in the formation and release of urine and reproduction. It includes kidneys, ureters, bladder, urethra, uterus, ovaries, fallopian tubes, vagina, and vulva.

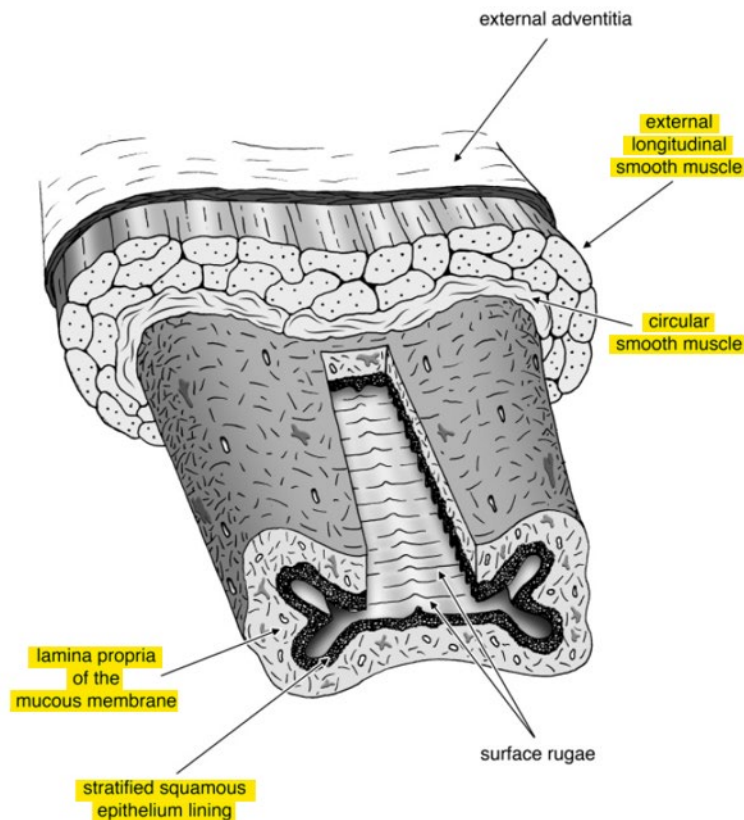
33. The vagina is an elastic, muscular tube that extends from the cervix, which connects the vagina to the uterus, to the vaginal opening, called the introitus. EX1001, 2:3–4 (“...the vagina and its opening, the introitus.”). The ’511 patent describes the vagina as follows, which is consistent with the knowledge of a POSA:

The vagina is a fibromuscular tube, lined with stratified squamous epithelium, that connects the external and internal organs of the female reproductive system. The vagina runs obliquely upwards and backwards at an angle of about 45 degrees between the bladder in front and the rectum and anus behind. In an adult female the anterior wall is about 7.5 cm long and the posterior wall is about 9 cm long. The difference in length is due to the angle of insertion of the cervix through the anterior wall.

EX1001, 11:36–44.

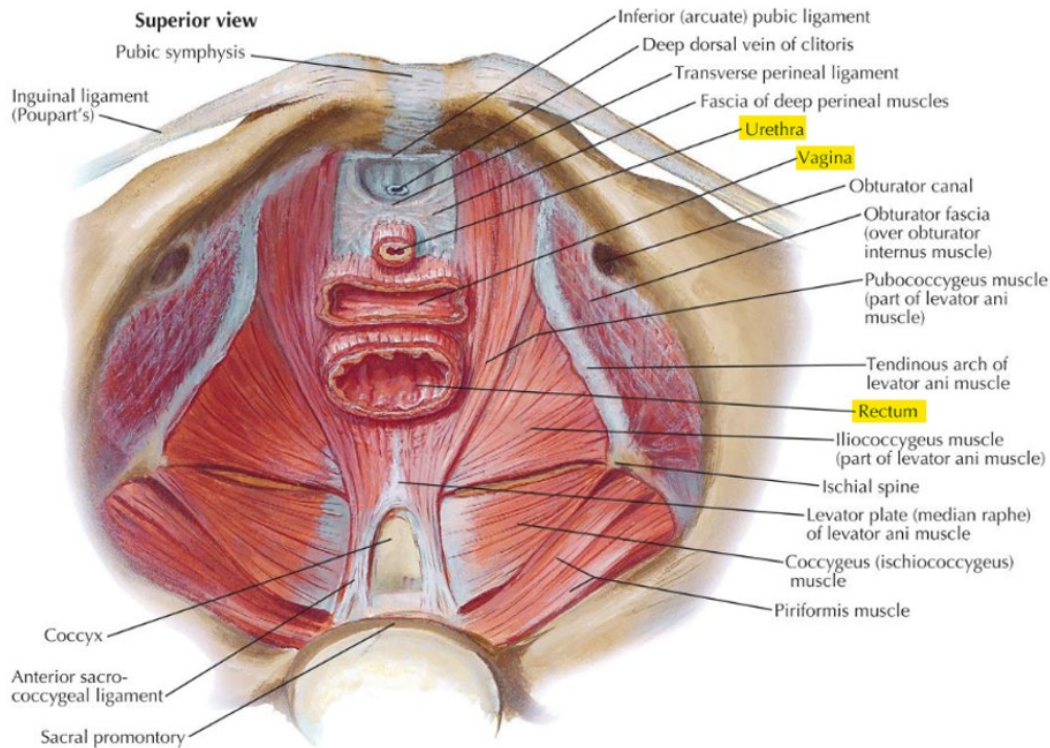
34. The vagina is lined on its inside wall by a layer of stratified squamous epithelium. *See* EX1017, 147 (Section 9.2). The vaginal epithelium, also known as the vaginal mucosa, does not contain keratin and is similar to the inner lining of the

mouth and esophagus as opposed to the surface epithelium found on the outside of the human body. *See* EX1017, 147 (Section 9.2). Under the vaginal mucosa is a layer of tissue known as the lamina propria, or submucosa, which is rich in elastic fibers such as collagen and provides a foundation for the epithelium above. *See* EX1017, 147 (Section 9.2); EX1001, 3:43–47. Beneath the lamina propria is a layer of smooth muscle known as the muscularis, and beneath that is the adventitia, a layer of fibrous connective tissue that anchors the vagina to the surrounding structures. *See* EX1017, 147-148 (Section 9.2, Figure 9.2).



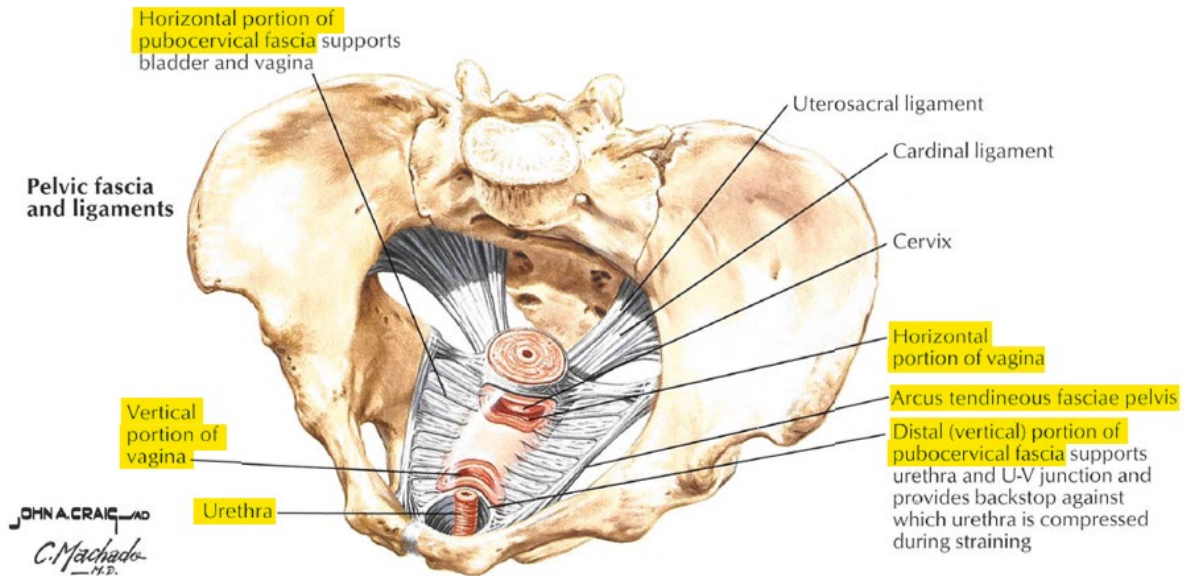
EX1017, FIG. 9.2 (annotated).

35. Immediately anterior to the vagina, adjacent to the anterior vaginal wall, is the urethra, which largely runs parallel to the vagina. Posterior to the vagina and adjacent to the posterior vaginal wall, lies the rectum. *See* EX1015, Plate 356.



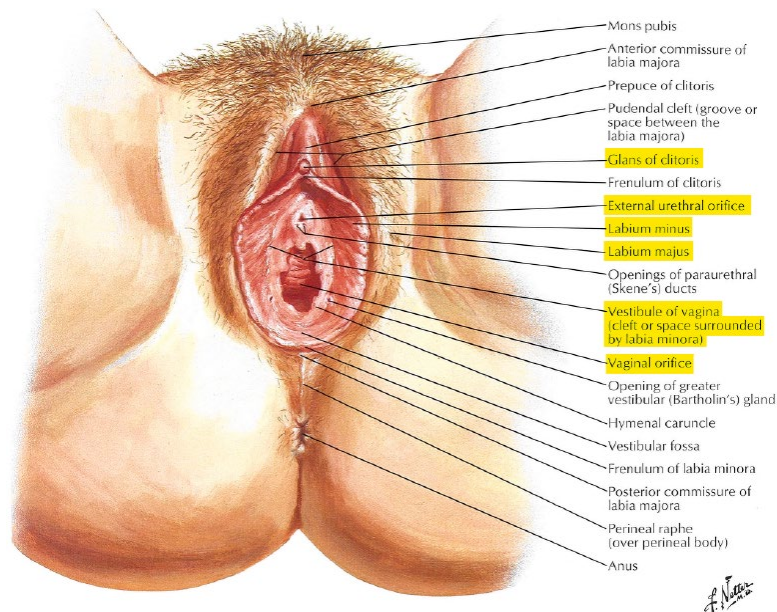
EX1015, Plate 356 (annotated).

36. The vagina is held in place by connective tissue known as the endopelvic fascia, or pubocervical fascia, which “may define a hammock-like structure which extends laterally between the left and right arcus tendinous fasciae pelvic (ATFP).” EX1006, ¶47; *see* EX1015, Plate 372.



EX1015, Plate 372 (annotated).

37. The vulva consists of the female genital structure external to the vaginal opening, known as the introitus, and comprises the mons pubis, labia majora, the labia minora, the clitoris, and the vestibule. *See* EX1015, Plate 377.



EX1015, Plate 377 (annotated).

38. The area of the vulva between the labia minora is known as the vestibule. The outer edge of the vestibule is demarcated by an imaginary boundary, known as Hart's line, and marks the transition between the smooth, non-keratinized epithelium of the vestibule and the keratinized skin of the labia minora. Within the vestibule itself are the introitus and the external opening of the urethra—the urethral meatus. *See* EX1015, Plate 377.

B. Collagen Remodeling

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

Collagen molecules are produced by cells resident in these tissues which synthesize three polypeptide chains that wrap around one another to form a triple helix. Collagen is a major type of fibrous protein that is a basic structural element of connective tissue, tendon, cartilage, and bone. Each of the collagen chains is approximately 1000 amino acid units in length, with glycine recurring regularly every third unit, and with proline and hydroxyproline recurring very frequently. Cross-linking occurs between the sides, not the ends, of collagen molecules and is coupled with the amino acid composition to give collagen its great strength. Collagen tissue tightening takes place in the direction parallel to an axis of collagen fibers.

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

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

¹ Although Sadick (EX1018) was published in 2008, it is a summary and review of studies that, for the most part, were published in, or before, 2006. Therefore, a POSA would have been aware of these techniques and results at the time of the invention. The general mechanism of collagen tissue remodeling also was recognized, for example, in Goldberg (EX1016).

causes an immediately noticeable tightening effect in the tissue. *See* EX1016, 180; EX1021, 639.

41. The denaturation of collagen molecules triggers the body's normal healing response wherein the tissue emit extracellular signals that induce new collagen deposition and fibroplasia—the formation of new collagen molecules and fibers. *See* EX1018, 180, 182; EX1021, 639. This process is known is remodeling, and the formation of new collagen fibers re-establishes the tensile strength and elasticity of the tissue, resulting in long-term tightening of the tissue. EX1018, 180.

42. A POSA would have known that collagen denatures based on a combination of the temperature that it raised to—treatment temperature—and how long it is held at that temperature—treatment time. *See* EX1018, 180; EX1019. A POSA would have understood that they could control either parameter, and that lower treatment temperatures would require longer treatment times and *vice versa*. *See, e.g.*, EX1006, ¶¶64–65, 71, 73, FIGS. 8A, 14, 15. A POSA would have also known that the temperature at which collagen shrinkage occurs is often quoted as 65°C in the literature, but that collagen denaturation is a function of temperature and time, among other things. *See* EX1018, 180 (citing articles from 1999, 2000, and 2003); *see also* EX1020, 87 (citing to seven studies dated 1998–2006 and indicating that “[t]he reported range of temperatures causing collagen shrinkage varies from 60 to 80°C.”).

43. A POSA would have known that collagen contraction occurs at a variety of time-temperature combinations rather than at a specific temperature, but that shrinkage could be obtained with treatment times of several seconds at temperatures of 60°C to 65°C. *See* EX1018, 180 (citing articles from 1999, 2000, and 2003). Furthermore, a POSA would have known that as treatment temperatures increase towards the boiling point of water (100°C), cells and tissue in the human body begin to experience permanent damage, *see* EX1020, 91, and thus treatment at such elevated temperatures, such as 80°C and above, should be avoided.

C. Prior Art Treatments of Female Urogenital Tissue Using Radiant Energy

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

45. Initially, ablative treatments—where the outermost layer of skin or tissue is removed in conjunction with heating of the lower layers of tissue—with CO₂ or erbium-doped yttrium aluminum garnet (Er:YAG) lasers were shown to be effective at causing collagen contraction and remodeling. *See* EX1018, 181;

EX1016, 180. Ablative treatments were commonly used in treating facial and neck skin, where collagen contraction and remodeling can tighten the skin and reduce wrinkles. *See* EX1018, 181. However, they often came with adverse side effects due to the ablative nature of the laser technology, such as infection, changes in skin color, scarring, dermatitis, and long recovery times. *See* EX1018, 181.

46. To combat these side effects, devices that use non-ablative lasers and/or less-focused light were developed. *See* EX1018, 181; EX1016, 180–181. These therapies did not damage the outermost tissue layer and instead focused their energy directly on the lower, collagen-containing layers. *See* EX1018, 181; EX1016, 180–181. Devices such as the Titan² used broad-spectrum infrared light to heat the lower layers of tissue beneath the skin. In order to further reduce unwanted side effects, treatments were performed in multi-second cycles and spread throughout multiple sessions across weeks or months. *See* EX1018, 181. This strategy of delivering repeated, lower levels of energy helped to reduce unwanted tissue damage and minimize patient discomfort. *See* EX1018, 181. Going one step further, the Titan device also used a cooling head to protect the

² Although the studies cited by Sadick (EX1018) in relation to the Titan system are from 2006–2007, the system has been used by clinicians for skin tightening as early as July 2005. *See, e.g.*, EX1022.

outermost skin layer from heat damage. *See* EX1018, 181. Similar to ablative lasers, these non-ablative laser devices were also frequently used in treating the facial and neck skin of patients. *See* EX1018, 181.

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

48. An exemplary system that used RF energy to tighten collagen in the skin was the ThermoCool device. Like the light-based systems, it also employed a mechanism to cool the outer layer, creating a thermal gradient in which the deeper tissue received the most intense heat without affecting the skin surface. *See* EX1018, 182; EX1016, 180. The initial protocol for treating patients was a single pass at the highest energy that the patients could tolerate. *See* EX1018, 182. However, similar to when using light-energy, clinicians found that using multiple passes at lower energies would result in less pain during the treatment and overall better results. *See* EX1018, 182. In addition to treating facial and neck skin like their light-based counterparts, RF-energy systems such as the ThermoCool were also used to treat other areas of the body, such as the legs (including the upper thigh and knee areas) and abdomen. *See* EX1021, 641. The skin-tightening and

wrinkle-reducing effects that were observed in the facial and neck regions were replicated in these new treatment areas as well. *See* EX1021, 641.

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

VII. THE ’511 PATENT

A. Overview of the ’511 Patent

50. The ’511 patent claims a method for remodeling female genital tissue by heating it. EX1001, Abstract, 5:61–64. The ’511 patent purports to solve certain problems related to stretched vaginal tissue, which can occur for example during childbirth, by providing “effective approaches to treating a loose vagina and introitus with a non-invasive procedure.” EX1001, 2:17–18.

51. This is achieved by delivering radiant energy, exemplified as RF energy, through a treatment tip contacting the target tissue. EX1001, 4:4–9. The effect of the heating is to remodel or tighten the tissue, which is caused by the body’s healing response to the stress of heating, including denaturation of existing collagen or deposition of new collagen. EX1001, 4:66–5:5. The ’511 patent’s method of remodeling tissue includes “applying heat to a target tissue underlying the surface mucosal epithelium, while cooling the surface epithelium itself.” EX1001, 11:5–14.

52. The ’511 patent identifies the target tissues as the connective tissue layers beneath the mucosal epithelium—including the lamina propria, or submucosa, and the muscularis. EX1001, 3:43–47. The target does not include deeper tissue, such as the endopelvic fascia. EX1001, 3:47–48. The treatment methods of the ’511 patent can be applied to target tissue found in the vulva, the vagina, and the introitus. EX1001, 13:2–5.

53. The ’511 patent discloses that the target tissue is heated to a therapeutic temperature, which it describes as a temperature that causes remodeling. EX1001, 11:19–23. The “portion of the target tissue which attains the therapeutic temperature, for a sufficient time, is termed the therapeutic zone within the target tissue.” EX1001, 11:23–29. Tissue remodeling may include, for example, “heat-denaturing collagen within collagen-rich areas in the target tissue,”

or “biological healing responses to the stress of heating, [which] may include the deposition of new collagen.” EX1001, 4:58–5:2. In either case, “the effect of remodeling on the tissue is generally one of tissue contraction or tightening.” EX1001, 5:2–5, 12:39-65. Cooling the epithelium protects it from damage and also prevents any remodeling of the epithelium. EX1001, 13:13–26.

54. The “target tissue” is illustrated in Figure 8 (reproduced below):

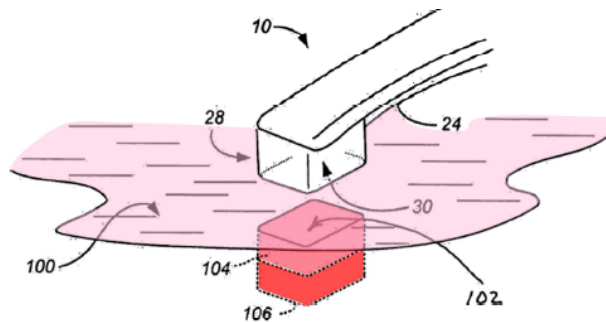


FIG. 8

EX1001, FIG. 8.

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

56. According to the '511 patent, its methods provide “for corrective or restorative remodeling” of tissues of the vagina, introitus, and vulva. EX1001, 2:20–21. The challenged claims, however, merely recite previously known methods for remodeling female genital tissues using radiant energy. EX1001, 2:8–

40, 4:4-13. Each of the independent claims is directed to a “method for remodeling a therapeutic zone within a target tissue” including “heating the target tissue, and remodeling the therapeutic zone of target tissue.” *See* EX1001, 15:46–18:48. The difference between the independent claims is the particular area to which the claimed “heating” step is applied. EX1001, 15:46–18:48.

57. The ’511 patent claims “method[s] for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue.” EX1001, 15:47-18:48. There is nothing new about using a known collagen remodeling technique on a collagen-rich area of the body known to benefit from such remodeling treatments. *See* Section VI.

B. Level of Ordinary Skill in the Art

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

59. The '511 patent envisages that a physician would use the device, and that it would be used in a medical setting. *See, e.g.*, EX1001, 4:47–56, 7:1, 9:38, 14:30–31. The '511 claims are directed to the treatment methods, and not the device itself. Several of the cited references also discuss that these types of devices are intended for physician use. *See* EX1005, 2:40–47, 13:39–31; EX1006, ¶54; EX1007, 18:46–50.

60. I am well qualified to discuss the level of ordinary skill in the art. As I explain in Section II and further show in my CV, I am a medical doctor, specializing in gynecology and have extensive experience related to the treatment of urogenital tissue with radiant energy, both for therapeutic and cosmetic reasons. Throughout my career and the projects that I have been involved in, I have worked with many people having the qualifications of a POSA identified above. My interactions with those people included working with other medical doctors who were POSAs as well as collaborating with persons in industry and academia who were POSAs.

C. Claim Construction

61. I have been informed by Petitioner's counsel that only those claims terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy. As discussed below, it is my opinion that the cited prior art teaches all elements of all claims of the '511 patent when given their ordinary

and customary meaning in view of the '511 patent specification. Accordingly, it is my opinion that no claim terms require an express construction.

62. I also have been informed by Petitioner's counsel that certain claim terms of the '511 patent have been construed in several prior proceedings, including prior IPRs and in district court, and that the parties in the prior proceedings proposed certain constructions not adopted in those proceedings. I address these claim constructions in my invalidity analysis below in the context of the claim element in which the claim term is recited. As I demonstrate below, it is my opinion that the prior art discloses or renders obvious the claim elements under the various prior constructions, including those proposed by Patent Owner that were not adopted by a court or the Board.

VIII. OVERVIEW OF THE PRIOR ART

63. In my opinion, each prior art reference is in the same field as the '511 patent (non-invasive vaginal treatment of uro-gynecological conditions) and is reasonably pertinent to the problems that the '511 patent attempts to address.

A. Edwards

64. Edwards discloses a method for treatment of female uro-genital disorders by application of therapeutic energy, such as RF energy to targeted tissues. EX1005, 2:34–36. This energy is “selectively applied so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition.”

EX1005, 2:37–39. For example, Edwards teaches “circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function.” EX1005, 3:5–13.

65. Edwards’s Figure 9A, reproduced below, describes a method for vaginal remodeling. EX1005, 13:12–13, 3:38-39.

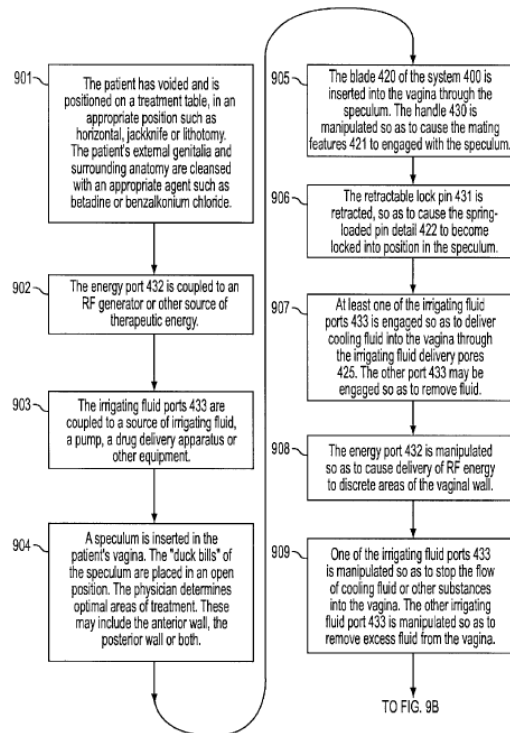


FIG. 9A

EX1005, FIG. 9A

66. In Edwards’s method, energy is delivered to discrete areas of the vaginal wall. EX1005, 13:54–62 (FIG. 9A, step 908). The energy may be RF energy, or may alternatively be microwave, laser, or other therapeutic energies. EX1005, 13:54–59. Cooling fluid is delivered into the vagina before, during, and after the energy delivery in order to minimize thermal damage. EX1005, 7:51–53,

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

67. Edwards teaches that “[t]he physician determines optimal areas of treatment,” which can include the anterior vaginal wall, the posterior vaginal wall, or both, depending on the desired result of treatment. EX1005, 13:14–16, 13:40–42. In particular, Edwards describes that “[r]emodeling of the anterior wall treats incontinence,” and “[r]emodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting [in] physical and psychological improvement in the area of sexual function.” EX1005, 13:16–23.

68. Edwards also discloses “a device that can be used for vaginal remodeling,” shown below in Fig. 4. EX1005, 7:15.

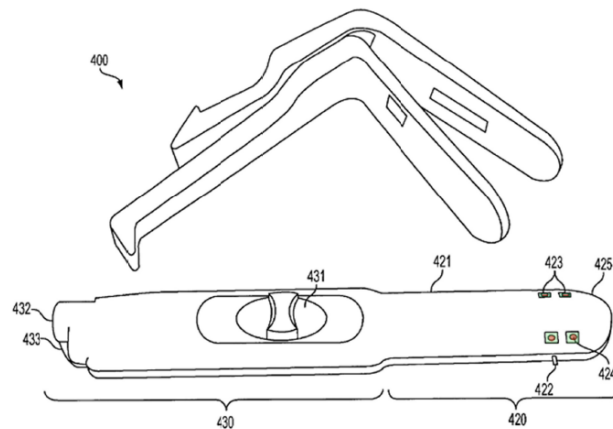


FIG. 4

EX1005, FIG. 4

69. Treatment element 410 of Edwards includes a blade 420 and a handle 430. EX1005, 7:18–28. The blade includes a plurality of electrodes 423 and a

plurality of irrigating fluid delivery pores 425. EX1005, 7:26–28. In performing the method of Figure 9, the distal end of the treatment element 410, i.e., the blade 420 with electrodes 423, is inserted into the vagina. EX1005, 7:18–19, 13:42–43. The electrodes 423 deliver energy (RF or other types of therapeutic energy), and each electrode includes at least one thermocouple 434 used to constantly monitor the temperature. EX1005, 7:37–47. Edwards describes its treatment device as being used with a speculum. EX1005, 13:38–62. A POSA would have understood that, not only could the “blade 420 ... be disengaged and relocked into another position on the speculum,” EX1005, 13:61–62, but also the speculum itself could be rotated to a different position. A POSA also would have understood that in treating areas of the vaginal wall closer to the introitus, a physician would be able to complete the treatment without a speculum.

B. Mosher

70. Mosher discloses methods for treating incontinence by heating collagenous support tissue for a sufficient time to effect substantial collagenous tissue shrinkage. EX1006, ¶9, Abstract. Mosher expressly recognizes, however, that its techniques “will find applications in *a wide variety of therapies*,” EX1006,

¶46, and “may be *directed at a variety of tissue structures* [including] structures of the vagina,” such as the lamina propria. EX1006, ¶48.³

71. As described by Mosher, “techniques of the invention generally involve directing energy from a probe into collagenous tissues of the pelvic support system. The energy will often cause contraction of the collagenous tissue.” EX1006, ¶45. In Mosher, the heating may be provided through the vaginal wall. EX1006, ¶9. For example, Figure 4C, reproduced below, illustrates probe 10 introduced into the vagina. EX1006, ¶54.

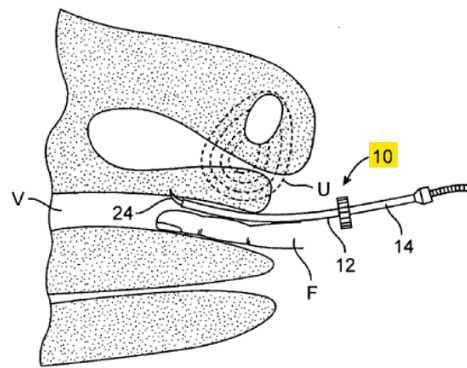


FIG. 4C

EX1006, FIG. 4C (annotated).

72. Similarly, the non-invasive vaginal treatment probe 54 of Figure 6A, reproduced below, also is used for “indirect treatment of tissue” from within the vagina. EX1006, ¶¶58, 67, FIGS. 6, 6A.

³ Emphasis added unless otherwise states.

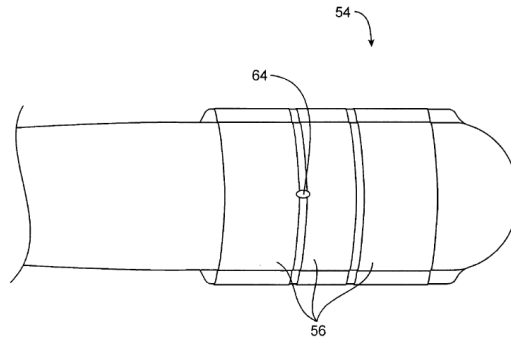


FIG. 6A

EX1006, FIG. 6A

73. In Mosher's treatment method using probe 54, electrodes 56 transmit RF current to heat the target tissue indirectly, through the vaginal wall. EX1006, ¶58. Probe 54 also includes fluid conduits 58, which cool the intervening tissue—here, the vaginal wall—between probe body and the target tissue, both prior to and during heating. EX1006, ¶¶58, 69, FIG. 6.

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

C. Ingle

75. Ingle discloses “methods ... for shrinking of collagenous tissues, particularly for treating urinary incontinence in a noninvasive manner by directing

energy to a patient's own support tissues." EX1007, Abstract. Ingle recognizes that a "wide variety of alternative conditions may also be treated using [its] methods," and that they may also be used, for example, "in cosmetic procedures." EX1007, 17:66–18:7.

76. In particular, the method of Ingle uses "energy [to] heat[] fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues." EX1007, 2:59–61. This is accomplished by applying energy using a large, cooled electrode. EX1007, 2:61–63. The electrode directs the energy through an intermediate tissue, such as the vaginal wall, while the cooling prevents injury thereto. EX1007, 2:63–67, 20:10–18, FIG. 11.

77. Figure 11, reproduced below, illustrates a single probe heating system 80 which can be used to practice Ingle's methods.

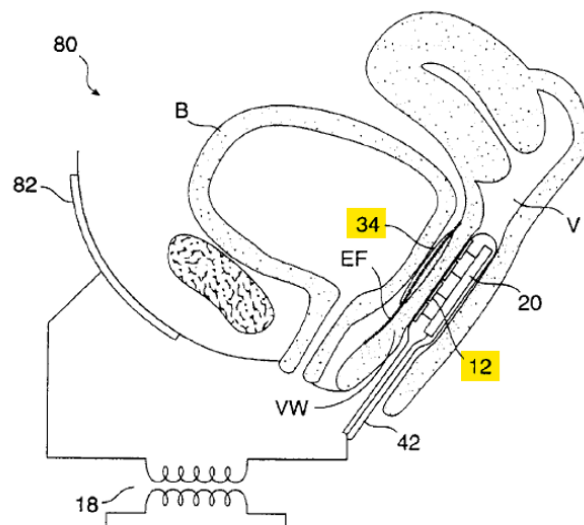


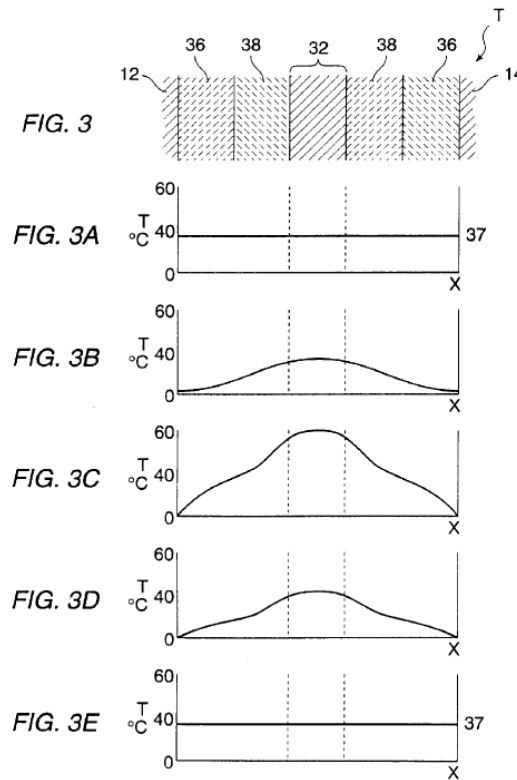
FIG. 11

EX1007, FIG. 11 (annotated).

78. Target zone 34 is heated by RF energy directed through electrode 12.

EX1007, 20:14–16. As noted above, vaginal wall VW is protected by cooling the surface of electrode 12. EX1007, 20:16–18.

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



EX1007, FIGS. 3–3E.

80. Figure 3 illustrates three regions of tissue T—target zone 32, stunned tissue 38, and safely cooled intermediate tissue 36. EX1007, 15:5–26. Ingle describes that “[t]o effect shrinkage of fascia, target zone 32 will typically be

heated to a temperature above about 60 nC, and often to a temperature at or above 70 nC.” EX1007, 15:16–18. Further, the “maximum safe tissue temperature to prevent injury” is “typically ... about 45 nC.” EX1007, 15:12–16. Although Ingle used the notation “nC” throughout the disclosure, a POSA would have understood this to mean “°C,” especially when Ingle discloses that “body temperature” is “approximately 37 nC.”

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

D. Ollivier

82. Ollivier describes techniques for the cosmetic treatment of a women’s vagina and vulva, and more specifically her labia. EX1008. The article describes using “Laser Vaginal Rejuvenation (LVR) to tighten [a patient’s] vagina and ‘enhance sexual gratification’ and Designer Laser Vaginoplasty (DLV) to

‘aesthetically modify’ her labia.” EX1008, 0001. As described in Ollivier, “[b]y reconstructing the ‘optimum structural architecture’ of the vagina – namely, by reconstructing the outer third of the vagina: the orgasmic platform, internal and external vaginal diameter (introitus) and the perineal body – ... women not only are relieved of incontinence, but they also enjoy increased levels of sexual gratification.” EX1008, 0001.

IX. THE COMBINATION OF EDWARDS, MOSHER, AND INGLE RENDERS OBVIOUS CLAIMS 1–58

83. In my opinion, claims 1–58 would have been obvious in view of the combination of Edwards, Mosher, and Ingle.

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

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

collagen-rich tissue. Thus, a POSA would have relied upon Edward, Mosher, and Ingle for their teachings of treatment methods and rationales, and would have further understood that the relevance of these teachings would not have been limited to the specific device(s) disclosed in each reference.

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

86. Applying the treatment details provided in Mosher and Ingle to the treatment method taught in Edwards is simply combining prior art elements according to known methods to yield predictable results. Similarly, the

combination is merely applying known techniques (Mosher/Ingle's treatment methods) to a known method ready for improvement (Edward's treatment method) to yield the predictable result of tightening via collagen denaturation.

87. In particular, Edwards describes a method for vaginal remodeling in order to treat incontinence or to provide improvement in sexual function. EX1005, 13:12-23. In Edwards's method, RF energy is applied to the vaginal wall while delivering cooling fluid to minimize tissue damage. EX1005, 7:14-42. Mosher describes that in order to effect substantial collagenous tissue shrinkage, i.e., remodeling, tissues must be heated for sufficient time and at a sufficient temperature. EX1006, ¶9. A POSA would have looked to Mosher and applied these treatment details to Edwards's treatment method in order to obtain the desired result of vaginal remodeling described in Edwards. Ingle also teaches how to use cooling along with RF treatment for particular times and at particular temperatures in order to control which tissue reaches the treatment temperature and which tissue is protected from treatment. EX1007, Abstract, 11:25-31. A POSA would have looked to Ingle and applied these treatment details to Edwards's treatment method in order to obtain the desired result of vaginal remodeling described in Edwards, without damaging other tissue.

88. Further still, the '511 patent acknowledges that loose vaginal or vulval tissue was a known problem facing women at the time. EX1001, 1:62-2:21. I agree

that it was a known problem that vaginal tissue is stretched during childbirth, and that this could result in both medical issues and cosmetic concerns. Each of Edwards, Mosher, and Ingle teaches using their method for tightening such tissues, thus a POSA would have looked to these references for solving this known problem. For example, Edwards teaches methods for treating female uro-genital disorders by selectively applying RF energy to tighten, shrink, or reshape tissue in order to correct an unwanted condition. EX1005, 2:34-39. Edwards teaches that its methods can be used for vaginal remodeling in order to treat incontinence or to provide “physical and psychological improvement in the area of sexual function.” EX1005, 13:12-23. Similarly, Mosher teaches methods for treating incontinence by effecting collagenous tissue shrinkage. EX1006, ¶9. Ingle also teaches using its methods for “controlled shrinkage or contraction of a support tissue of the body,” to treat various conditions, such as incontinence, or to provide cosmetic treatment of loose tissue. EX1007, 11:8-11, 17:65-18:7.

89. A POSA further would have had reasonable expectation of success in combining these references, because they all apply known thermal dynamics principles to the treatment of tissue using radiant energy. As described in Goldberg, using RF energy to heat tissue while cooling the surface tissue (as described in each of Edwards, Mosher, and Ingle), results in a “reverse thermal gradient characterized by a higher tissue temperature in the deeper dermis than in

the epidermis and upper dermis.” EX1016, 180. This was known to result in heat-induced collagen contraction due to denaturation of the collagen. EX1016, 180. Each of Edwards, Mosher, and Ingle applies this known principle in its treatment methods.

90. For this reason, a POSA would also have understood that the treatment parameters and techniques disclosed in Mosher/Ingle could be applied to Edwards’s method to result in collagen denaturation and tissue tightening. A POSA would have generally known the range of treatment times and temperatures that could be applied without hurting the patient. And, a POSA would have reasonably expected that applying the times and temperatures described in Mosher and Ingle would have successfully resulted in collagen denaturation and tissue tightening.

B. Independent Claims

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

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

1. Claim 1

- a. [1.P] A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue**

92. I understand that in certain circumstances, the preamble of a claim may be limiting. To the extent the preamble is determined to be limiting, it is my opinion that the combination of Edwards, Mosher, and Ingle teaches this element.

93. Edwards is directed to a method for “the curative treatment of female uro-genital disorders by application of radiofrequency (RF) energy to targeted tissues. Application of this energy is selectively applied so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition.” EX1005,

2:34–39. The disclosed method can be used for “vaginal remodeling” by delivering the RF energy to the anterior and/or posterior regions of the vaginal wall. EX1005, 3:7–10, 13:12–23. This treatment “has the effect of tightening of vaginal walls so as to increase support of the bladder outlet, proximal and mid-urethra,” thereby treating incontinence, and “circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function.” EX1005, 3:9–13, 13:14–23. A POSA would have understood that the “targeted tissues” in Edwards that are remodeled, or tightened, refers to tissue underlying the epithelium of the vagina as those layers have high collagen fiber content and would be responsible for any tightening effect following treatment.

94. Like Edwards, Mosher discloses a method for “directing energy from a probe into collagenous tissues” of the urogenital region. EX1006, ¶45. Mosher provides additional details of the physiological mechanism of tissue remodeling. *See* EX1006, ¶¶66. The RF energy is used to “heat target tissue to temperatures and for which effect a contraction of the collagen within the target tissue and/or enhance stiffening of the support provided by these structures. The supporting collagenous tissues, immediately and/or upon healing, thereby contribute to continence” EX1006, ¶¶55, 66. A POSA would have understood that the contraction of the collagen was a result of heat-induced remodeling. *E.g.*, EX1016, 180.

95. Mosher also includes specific details of what “target tissue” for such RF treatment would include. For example, in describing the vaginal wall as the “intervening tissue” between the “vaginal probe” and the tissue being treated, a POSA would have understood the target tissue as underlying the vaginal epithelium. EX1006, ¶58. Although specific embodiments of Mosher are described with respect to targeting the endopelvic fascia, Mosher’s treatment method expressly “may be directed at a variety of tissue structures” including “structures of the vagina,” and specifically, the “lamina propria—the dense connective tissue layer just under the epithelium.” EX1006, ¶48. In fact, Mosher describes that in certain instances the endopelvic fascia may be damaged or missing, and thus “support of the genitourinary tract is instead provided by a variety of fascial layers, muscular tissues, ligaments and/or tendons within the pelvis.” EX1006, ¶48. A POSA would have understood Mosher’s methods would equally apply to these other disclosed tissue structures, such as the lamina propria. The ’511 patent expressly identifies the lamina propria as an example of target tissue. EX1001, 2:25–28. Because both treatment methods are applying RF energy with surface cooling, a POSA further would have understood that like Mosher, treatment in Edwards also could target lamina propria underlying the epithelium. A POSA would have been motivated to apply the specific details of Mosher’s known

treatment method to Edwards's similarly known method to yield the predictable result of tissue tightening via collagen denaturation.

96. Similarly, Ingle teaches a method of treatment “for shrinking of collagenated tissues” in the urogenital region in a noninvasive manner, for example for the treatment of incontinence. EX1007, 2:51–53, 3:11–25. Ingle teaches that this is achieved by applying energy to the target tissue “from within the vagina of a patient body,” in which the heating energy is transmitted “through the vaginal wall to heat and contract” the target tissue. EX1007, 3:36–45. In Ingle, energy from the probe “heats fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues.” EX1007, 2:59–62. A POSA would have understood that such collagenated support tissues are present underlying the epithelium of the vulva, introitus, and vagina tissue, as claimed. Furthermore, Ingle discloses that the “[t]issue contraction results from controlled heating of the tissue by affecting the collagen molecules of the tissue. Contraction occurs as a result of heat-induced uncoiling and reposition of the collagen β -pleated structure.” EX1007, 11:25–28. A POSA would have understood this effect as being synonymous with remodeling of the target tissue. Because both treatment methods are applying RF energy with surface cooling, a POSA would have understood that like Ingle, treatment in Edwards also targets collagenated support underlying the epithelium. As described in Goldberg, the reverse thermal gradient

resulting from the heating combined with surface cooling targets tissue underlying the epithelium, causing collagen contraction. EX1016, 180. A POSA would have been motivated to apply the specific details of Ingle's known treatment method to Edwards's similarly known method to yield the predictable result of tissue tightening via collagen denaturation.

97. As I discuss in more detail for element [1.2], a POSA would have understood that the "therapeutic zone" is simply the area of the target tissue that is remodeled. *See* Section IX.B.1.c.

98. Accordingly, the combination of Edwards, Mosher, and Ingle teaches *a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue.*

b. [1.1] heating the target tissue

99. I understand that "*heating*" was construed in a prior proceeding as "raising the temperature of the target tissue to no more than about 80 degrees C." In my opinion, the combination of Edwards, Mosher, and Ingle teaches this element both under its ordinary and customary meaning and under this prior construction.

100. Beginning with Edwards, the reference teaches as part of its method for "vaginal remodeling" that "RF energy is delivered to the anterior and posterior

regions of the vaginal wall.” EX1005, 3:7–9, 3:38–39. Edwards teaches, as part of its method, “delivery of RF energy to discrete areas of the vaginal wall.” EX1005, 13:54–56, FIG. 9 (step 908). A POSA would have understood “vaginal remodeling” to mean remodeling of the collagen-containing tissue within the vagina. The goal for the application of this energy in Edwards is to “ablate, tighten, shrink or reshape the tissue.” EX1005, 2:37–39. A POSA would have understood that the applied energy must heat the target tissue in order to reach this goal. This is consistent with the ’511 patent, where the claimed heating encompasses “delivering energy by ... radiofrequency energy,” as taught by Edwards. EX1001, claim 33. Edwards also uses cooling fluid “to minimize thermal damage to tissues,” EX1005, 4:59-61, confirming that the RF energy in Edwards acts to heat tissue.

101. Although Edwards does not specifically disclose the temperature to which the target tissue is heated, a POSA would have understood the appropriate temperatures to which the target tissue would be heated in order to achieve the desired remodeling result. For example, a POSA would have known that in order to achieve vaginal remodeling, the target tissue should be heated to about 65°C to trigger denaturation of the collagen. *See* EX1018, 180 (citing articles from 1999, 2000, and 2003). Furthermore, a POSA would have known that temperatures higher than normal body temperature will cause thermal damage to tissue and thus

would have sought to limit the maximum temperature to the lowest effective therapeutic temperature to minimize this damage. Indeed, the method taught by Edwards includes temperature sensors to prevent the electrodes from “exceed[ing] temperature safety limits” and cooling solutions “so as to minimize thermal damage.” EX1005, 7:43–53. Because a POSA would have known that collagen begins to denature at around 65°C, they would have understood Edwards as teaching to heat the target tissue to a temperature of at least around 65°C but *to no more than about 80 degrees C* in order to avoid thermal damage.

102. Further a POSA would have looked to a similar method such as Mosher and Ingle for express teachings of appropriate temperatures to use. The method of Mosher expressly teaches heating the target tissue to temperatures of “about 65° C. or more,” “about 70° C. or more,” or “about 75° C. or more,” in order “to effect substantial collagenous tissue shrinkage.” EX1006, ¶9; *see also* EX1006, ¶64 (“[T]o obtain a significant percentage of shrinkage in a relatively short treatment time, it is generally advantageous to heat tissues to temperatures of about 70° C. or more.”), ¶65 (“[T]o effect significant, repeatable tissue shrinkage, it is generally desirable to subject the treatment volume to temperatures of at least 70° C. for a time of about 30 seconds or more.”), ¶67, FIG. 10.

103. As I explained above, this is consistent with what a POSA would have known to be the effective temperature range to trigger remodeling of the collagen

found in the target tissue. A POSA would have understood that different combinations of treatment temperatures and treatment times can be used to trigger remodeling and collagenous tissue shrinkage. *See* Section VI.B. They would have known select parameters to balance patient comfort (by limiting treatment duration) and patient safety (by limiting treatment temperatures) in order to provide the most effective treatment. Furthermore, a POSA would have known that at higher temperatures, significant and permanent tissue damage can occur regardless of treatment times. *See* EX1006, ¶65. Consistent with Mosher, a POSA would have understood that it “may be advantageous to (as practicable) limit treatment temperatures toward the lower possible temperatures from which sufficient tissue shrinkage can be provided,” but that adjustments to the treatment time and/or temperature may be necessary. EX1006, ¶65. Such adjustments to the treatment time and/or temperature would have been within the skill of a POSA.

104. Likewise, Ingle discloses a method “for therapeutically heating a target tissue of a patient body through an intermediate tissue.” EX1007, 3:11–13. To effectuate the heating, Ingle discloses “a probe for applying energy to fascia from within the vagina of a patient body” which “is capable of transmitting sufficient heating energy through the vaginal wall to heat and contract the fascia.” EX1007, 3:36–45. Ingle discloses using RF energy to perform its methods. EX1007, 5:11–14. This heat is applied until the treatment tissue “is at or above a

treatment temperature.” EX1007, 16:5–6. Similar to Mosher, and consistent with what a POSA would have understood, Ingle discloses that the target tissue should “be heated to a temperature above about 60 nC, and often to a temperature at or above 70 nC.” EX1007, 15:16–18, 5:53–58.

105. A POSA also would have understood that using the lowest effective temperature would be desired, in order to avoid unnecessary damage to the target tissue and/or surrounding tissue. Mosher, for example, teaches that because “the necrosis sensitivity of the tissue is significantly more dependent on the temperature than on the time for which it is heated, it may be advantageous to (as practicable) limit treatment temperatures toward the lower possible temperatures from which sufficient tissue shrinkage can be provided.” EX1006, ¶65. Ingle, similarly, teaches that “[b]y maintaining the times and temperatures set forth below, significant tissue contraction can be achieved without substantial collateral tissue damage.” EX1007, 11:28–31.

106. It is therefore my opinion that the combination of Edwards, Mosher, and Ingle teaches heating the target tissue, or “raising the temperature of the target tissue to no more than about 80 degrees C.”

107. I have been informed by Petitioner’s counsel that Patent Owner previously argued that the claims require “heating without damaging the mucosal epithelial surface.” The combination of Edwards, Mosher, and Ingle also teaches

heating without damaging the mucosal epithelial surface. Each of Edwards, Mosher, and Ingle teaches cooling the epithelial surface during heating of the target tissue. A POSA would have understood that by cooling the epithelial surface during heating, damage to the epithelial surface is avoided. This is confirmed by each of Edwards, Mosher, and Ingle.

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

109. Mosher also discloses “cooled electrode vaginal probes” where “fluid conduits cool the intervening or intermediate tissue between probe body 54 and the endopelvic fascia EF, such as the vaginal wall.” EX1006, ¶58, FIG. 6. Mosher recognizes that “[a]dvantageously, the pre-cooling can inhibit heating of the intervening tissue to a temperature causing surface lesions within the vagina.” EX1006, ¶58.

110. Ingle discloses the “energy heats fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues.” EX1007, 2:58–61. To achieve this effect, “[t]he electrode surface will generally be

sufficiently flat to direct the current flux through the cooled intermediate tissue and into the target tissue while the cooling system maintains the intermediate tissue at or below a maximum safe tissue temperature.” EX1007, 3:21–25.

111. I further understand from Petitioner’s counsel that in a previous District Court proceeding the court construed the “*heating*” step as “heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium.” As I just discussed, POSA also would have understood that, by cooling the epithelium during treatment, each of Edwards, Mosher, and Ingle maintains the epithelium at a temperature that does not damage or substantially modify the tissue. A POSA would also have understood that the target tissue (i.e., the tissue underlying the epithelium, and which *is* modified) is necessarily heated to a temperature higher than the epithelium, because it is heated to a temperature to effect collagen remodeling. This is achieved, for example, by cooling the epithelium during treatment.

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

112. I have been informed that in prior proceedings, this claim element was construed as reciting the result – contracting or tightening of tissue – of the prior “heating” step. In my opinion, the combination of Edwards, Mosher, and Ingle teaches this element under its ordinary and customary meaning and under this prior construction.

113. As I explain above, Edwards, Mosher, and Ingle teach the heating of “target tissue.” *See* Section IX.B.1.b.

114. The ’511 patent describes the “therapeutic zone” as a “zone of tissue that is heated within the target tissues to a threshold level, i.e., to a therapeutic temperature.” EX1001, 4:14–16. The ’511 patent confirms that “[n]ot all tissue within the target tissue necessarily reaches this threshold level of heat.” EX1001, 4:16–18. This is consistent with how a POSA would have understood the term “therapeutic zone,” as simply the area of the target tissue that is remodeled by the treatment.

115. A POSA would have known which zones of tissue to target based on the desired effect. For example, if the goal was to treat incontinence, a POSA would have selected a zone around the urethra to remodel. On the other hand, for improvements related to sexual function, a circumferential zone of the vagina closest to the introitus would be selected. Each of Edwards, Mosher, and Ingle teaches remodeling at least a portion of the target tissue, i.e., a therapeutic zone.

116. Specifically, Edwards teaches that “radiofrequency (RF) energy is applied to uro-genital tissues so as to cause shrinkage and remodeling.” EX1005, 2:27–30. “Application of this energy is selectively applied so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition.” EX1005, 2:37–39. A POSA would have understood that the application of RF energy

necessarily heats a zone of tissue within the target tissue in order to cause shrinking, tightening, and/or remodeling. This is further evidenced by Edwards's teaching of using cooling fluid "to minimize thermal damage to tissues when the electrodes 225 are deployed," EX1005, 4:59-61, confirming that the energy from the electrodes results in heating of the tissue. More specifically, Edwards teaches "the RF energy is delivered to the anterior and posterior regions of the vaginal wall," which "has the effect of tightening of vaginal walls so as to increase support of the bladder outlet, proximal and mid-urethra. Moreover, circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function." EX1005, 3:8-13; *see also* EX1005, 13:19-22.

117. Mosher also discloses "directing energy from a probe into collagenous tissues of the pelvic support system," which "will often cause contraction of the collagenous tissue." EX1006, ¶45. Mosher expressly teaches heating the target tissue to temperatures of "about 65° C. or more," "about 70° C. or more," or "about 75° C. or more." EX1006, ¶9. Mosher explains that the "heat-induced changes" caused by the directed energy include "contraction or shrinkage, stiffening, and/or the like" and that these changes are "through tissue remodeling resulting from the healing process." EX1006, ¶66. Mosher describes the remodeling in more detail:

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

EX1006, ¶66.

118. Similarly, Ingle also discloses that its “method comprises directing energy from a probe, through the intermediate tissue, and into the target tissue. The energy heats the target tissue so that the target tissue contracts.” EX1007, 3:53–56. Ingle, consistent with Mosher and the knowledge of a POSA, further explains that the “[t]issue contraction results from controlled heating of the tissue by affecting the collagen molecules of the tissue. Contraction occurs as a result of heat-induced uncoiling and repositioning of the collagen B-pleated structure.” EX1007, 11:25–31. This is consistent with a POSA’s understanding of tissue remodeling due to collagen denaturation.

119. It is therefore my opinion that the combination of Edwards, Mosher, and Ingle teaches remodeling the therapeutic zone of target tissue.

- d. [1.3] wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus.**

120. As previously explained, the vagina is an elastic, muscular tube with one end at the cervix leading into the uterus and the other end terminating at the vagina's external opening, also known as the introitus. *See* Section VI.A. A POSA would have understood this claim element as 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). In my opinion, the combination of Edwards and Mosher teaches heating this claimed treatment area.

121. Edwards teaches performing its method “to create a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both. Remodeling of the anterior wall treats incontinence based on bladder outlet hypermobility by increasing support for the bladder outlet, as well as the proximal and mid-urethra. Remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting physical and psychological improvement in the area of sexual function.” EX1005, 13:14–22.

122. A POSA, based on Edwards's teachings of improvement of sexual function, would have understood Edwards's teachings to include treatment near the opening of the vagina. Specifically, Edwards teaches “circumferential tightening of the vaginal wall” to “provide physical and physiological improvement in the area

of sexual function.” EX1005, 3:11–13. A POSA would have understood that in order to achieve these improvements of sexual function, the treatment area must include the region near the opening of the vagina. *See, e.g.*, EX1008, 0001.

123. Although Edwards does not expressly disclose the distance between the treatment area and the opening of the vagina, Mosher further confirms that a POSA would have been motivated to focus treatment nearer the opening of the vagina, in order to avoid damage to nerves in the bladder neck region and in the antero-lateral vaginal wall. EX1006, ¶74. For example, Mosher describes using non-invasive vaginal probe 54 to provide treatment. EX1006, ¶¶58, 75, FIGS. 6, 6A. Mosher describes the safety advantages of using an “enhanced treatment width” or “laterally elongate treatment region,” including when performing treatment with non-invasive vaginal probe 54. EX1006, ¶¶74, 75. Mosher describes the preferred treatment region as “significantly wider (along the medial-lateral orientation) than its urethral length, ideally having a width of about 25 mm and a length of about 15 mm.” EX1006, ¶74. Despite the reference to “urethral length” in this description, a POSA would have understood this treatment region to apply to non-invasive treatment within the vagina, because it is discussed in relation to using a non-invasive vaginal probe device. Indeed, Mosher describes several electrode configurations for its vaginal probe 54 to provide this “enhanced treatment width.” EX1006, ¶75.

124. Mosher discloses that it would be beneficial to have a treatment region having “a length about 15 mm,” or about 1.5 cm. EX1006, ¶74. Mosher teaches that it is beneficial to “limit the length of the treatment along the axis of the patient’s urethra,” in order to “minimize exposure of the bladder neck and antero-lateral vaginal wall nerves to RF energy.” EX1006, ¶74. In the case of performing treatment with a vaginal probe, a POSA would have understood Mosher’s treatment length of about 15 mm (1.5 cm) to refer to the length of the treatment region extending along the vagina. A POSA would have understood that the vaginal axis largely runs parallel to the urethral axis. *See* EX1007, FIG. 6. A POSA would have thus understood Mosher’s teaching of a 1.5 cm treatment length as a teaching to focus treatment on the area around the opening of the vagina. Therefore, a POSA would have been motivated to focus heating on the portion of the vagina extending from the introitus inwardly to a location of about 1.5 cm in order to avoid treatment too close to the bladder neck and other nerves.

125. It is therefore my opinion that the combination of Edwards, Mosher, and Ingle teaches *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.*

2. Claim 35

126. Similar to claim 1, claim 35 is directed to a “*method for remodeling a therapeutic zone within a target tissue*” and includes the same “*heating the target*

tissue” and “*remodeling the therapeutic zone of target tissue*” steps found in claim

1. For the same reasons I discuss above, it is my opinion that the combination of Edwards, Mosher, and Ingle teaches elements [35.P], [35.1], and [35.2]. *See* Sections IX.B.1.a–IX.B.1.c.

127. The only difference is that element [35.3] further recites that “*the heating includes heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock, wherein the aspect closest to the urethra is at 12 o’clock.*”

128. I have been informed by Petitioner’s counsel that in a prior proceeding this element was construed as: “heating at least one contact site in the 300 degree arc extending from 1 o’clock to 11 o’clock along the vaginal wall.” In my opinion, the combination of Edwards and Mosher teaches element [35.3] under this construction.

129. Edward teaches that its disclosed method “create[s] a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both.” EX1005, 13:14–16. A POSA would have understood that the “anterior vaginal wall” is the portion of the wall closest to the urethra and corresponds to semicircle formed between 9 o’clock and 3 o’clock, passing through 12 o’clock on the ’511 patent’s reference clock dial found in Figure 7. A POSA would have also understood that the “posterior vaginal wall” corresponds to the complementary semicircle formed

between 3 o'clock and 9 o'clock, passing through 6 o'clock on the reference clock dial. A POSA would have understood that treating any portion of the posterior wall would necessarily fall within the recited 300 degree arc. Thus, by teaching treatment of the posterior wall, Edwards teaches 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.

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

131. Additionally, Mosher teaches that "it may be advantageous to distribute the treatment volume *along the patient's lateral orientation* while limiting the length of treatment along the axis of the patient's urethra. ... Such a laterally elongate treatment region ... will preferably be significantly wider (along the medial-lateral orientation) than its urethral length." EX1006, ¶74. Based on

Mosher's teachings of distributing the treatment volume along a lateral orientation, a POSA would have further been motivated to treat more locations around the circumference of the vagina, in order to expand the treatment area.

132. Thus, it is my opinion that the combination of Edwards and Mosher teaches heating along the entire 300 degree arc.

133. I have been informed by Petitioner's counsel that the claims of the '511 patent do not require the exclusion of treatment in the 60 degree arc between 11 o'clock and 1 o'clock. Mosher, however, suggests it may be beneficial to avoid this region. Mosher teaches that the "treatment volume will preferably be separated from a urethra of a patient by at least about 1 cm to inhibit injury to nerves along the urethra," where the treatment volume is "offset laterally from the urethra to a right side of the patient" and "another treatment volume [is] similarly offset laterally from the urethra to a left side of the patient." EX1006, ¶11. A POSA would have understood that a 1 cm offset from each side of the urethra would equate to approximately 11 o'clock and 1 o'clock on the reference clock. This is also confirmed by the '511 patent, as it discloses that "with a treatment tip of about 1 cm in width, a series of about 10 contact sites allows completion of an 300 degree arc of the circumference, between the 1 o'clock and 11 o'clock positions." EX1001, 14:37–40. Given a treatment tip of about 1 cm in width, 10 contact sites would equate to roughly 10 cm as the length of the 300 degree arc of the

circumference. From there, a POSA would understand that each centimeter corresponds to approximately a 30 degree arc of the circumference and therefore a 1 cm offset would exclude 30 degrees in each direction.

134. A POSA reading both Edwards and Mosher would have been motivated to provide “circumferential tightening of the vaginal wall” in order to “provide physical and physiological improvement in the area of sexual function” but limit the treatment to the *300 degree arc of the circumference, between the 1 o’clock and 11 o’clock positions*, thereby limiting potential injury to nerves along the urethra.

135. Thus, it is my opinion that the combination of Edwards and Mosher further teaches avoiding treatment in the 60 degree arc between 11 o’clock and 1 o’clock.

3. Claim 43

136. Similar to claim 1, claim 43 is directed to a “*method for remodeling a therapeutic zone within a target tissue*” and includes the same “*heating the target tissue*” and “*remodeling the therapeutic zone of target tissue*” steps found in claim 1. For the same reasons I discuss above, it is my opinion that the combination of Edwards, Mosher, and Ingle teaches elements [43.P], [43.1], and [43.2]. *See* Sections IX.B.1.a–IX.B.1.c.

137. The only difference is that element [43.3] further recites that “*the heating includes heating a portion radiating outward from the introitus to Hart’s line.*” In my opinion, the combination of Edwards, Mosher, and Ingle teaches element [43.3].

138. A POSA would have understood that the “*portion radiating outward from the introitus to Hart’s line*” refers to the part of the vulva known as the vulval vestibule. Like the tissue of the vaginal wall, the epithelium that covers the vulval vestibule is a non-keratinized mucosal type. *See* Section VI.A. Beneath the vestibular epithelium also lies the collagen-rich lamina propria and smooth muscle layer further below, again, just like in the vaginal wall. *See* Section VI.A. Consistent with a POSA’s understanding, the ’511 patent, describes that the “vulva includes tissue radiating outward from the introitus to Hart’s line, where mucosal epithelium gives way to skin on the outer surface of the labia minora.” EX1001, 3:51–54.

139. At the time of invention, a POSA would have known that using RF treatment to heat and remodel tissue high in collagen content is beneficial in a wide number of applications, ranging from therapeutic to cosmetic uses. *See* EX1016; EX1018; EX1021.

140. Indeed, each of Edwards, Mosher, and Ingle disclose heating a variety of tissues, also confirming that it was known that RF treatment was widely

beneficial. For example, Edwards describes the application of RF energy to the interior of the uterus, the circular external urethral sphincter muscle, the submucosal bladder outlet musculature and connective tissue, and the anterior and posterior regions of the vaginal wall. EX1005, 2:34–3:13. Similarly, Mosher lists numerous tissue structures appropriate for treatment with its methods, including structures defining the pelvic floor and/or diaphragm, structures of the bladder and urethra, structures of the vagina, structures of the uterus, and structures of the bowel. EX1006, ¶48.

141. Ingle also teaches that its methods may also be used to treat a “wide variety of alternative conditions,” such as “selective shrinkage of fascia may effectively treat cystocele, hiatal, and inguinal hernias” EX1007, 17:66–18:3. Consistent with what a POSA would understand, Ingle also discloses that its methods are not limited to therapeutic treatments as they “may even be used in cosmetic procedures such as abdominoplasty (through selectively shrinking of the abdominal wall), to remove wrinkles by shrinking the collagenated skin tissues, or to lift sagging breasts by shrinking their support ligaments.” EX1007, 18:1–7, 1:18-23. As confirmed by Ingle, a POSA would have known that radiant energy treatments were known to be used to treat other tissues, e.g., face, breasts, for cosmetic purposes.

142. At the time of the invention, POSA would also have known that there was patient demand for reconstructive treatment of the vulva, including the introitus, vulval vestibule, and labia for cosmetic purposes. *See* EX1008; Section VI.C. Procedures such as laser vaginal rejuvenation were performed with an aim at tightening the treated tissue. *See* Section VI.C. Combined with the knowledge that the application of radiant energy, and specifically RF energy, would be beneficial for tightening, shrinking, and/or smoothing collagen-containing tissue throughout the body, a POSA would have been motivated to apply the RF treatments described in Edwards, Mosher, and Ingle to the vulval vestibule region described in element [43.3]. *See* Sections VI.B–VI.C. A POSA also would have had a reasonable expectation of success in doing so because the mucosal epithelium of the vulval vestibule is the same as that of vaginal mucosal epithelium, with the same underlying collagen-rich layers, as described in Edwards, Mosher, and Ingle.

143. Thus, it is my opinion that the combination of Edwards and Mosher further teaches *heating a portion radiating outward from the introitus to Hart’s line*.

4. Claim 51

144. Similar to claim 1, claim 51 is directed to a “method for remodeling a therapeutic zone within a target tissue” and includes the same “heating the target tissue” and “remodeling the therapeutic zone of target tissue” steps found in

claim 1. For the same reasons I discuss above, it is my opinion that the combination of Edwards, Mosher, and Ingle teaches elements [51.P], [51.1], and [51.2]. *See* Sections IX.B.1.a–IX.B.1.c.

145. The only difference is that element [51.3] further recites that “*the heating includes heating a mucosal surface of the labia minora.*” The ’511 patent discloses that:

The mucosal epithelium of vulvar tissue outside the vagina and the introitus includes the labia minora, or that portion of the vulva extending outward from the introitus to Hart’s line, the boundary where mucosal epithelium and labial skin meet (FIG. 7). The mucosal epithelium and the skin, while contiguous, are embryologically and histologically distinct. The portion of the female genitalia that are covered by epithelium is also substantially defined by the bounds of the vestibule, which extends outward or down from the hymenal ring at the top of the vagina, radially beyond the introitus, including the portion of labia minora located within Hart’s line.

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

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

146. For all the reasons discussed above for element [43.3], a POSA would have been motivated to apply the RF treatments described in Edwards, Mosher, and Ingle to the inner surfaces of the labia minora as described in element [51.3]. *See* Section IX.B.3. A POSA would have known that radiant energy treatments were known to be used to treat other tissues, e.g., face, breasts, for cosmetic purposes. A POSA also would have known that treating the vulva (including the labia) was often done for cosmetic purposes. *See* EX1008. A POSA also would have had a reasonable expectation of success in doing so because the mucosal epithelium of the labia minora is the same as that of vaginal mucosal epithelium, with the same underlying collagen-rich layers, as described in Edwards, Mosher, and Ingle.

147. Thus it is my opinion that the combination of Edwards, Mosher, and Ingle teaches *heating a mucosal surface of the labia minora*.

C. Dependent Claims

1. Claims 2, 36, 44, and 52

148. Claims 2, 36, 44, and 52 depend from claims 1, 35, 43, and 51, respectively. Claims 2, 36, 44, and 52 recite, “*wherein heating the target tissue comprises heating it to a temperature between 45 degrees C. and 80 degrees C.*” As discussed above, the cited art teaches “heating” when construed as “raising the temperature of the target tissue to no more than about 80 degrees C.” EX1001, 19–21. The only additional element added in claims 2, 36, 44, and 52 is the lower temperature threshold of 45°C. *See* Section IX.B.1.b. In my opinion, Mosher and Ingle teach heating the target tissue to above 45°C.

149. A POSA would have understood that collagen denatures at around 65°C, causing it to contract and tighten. *See* Section VI.B. Therefore, in order to achieve the desired remodeling result, a POSA would have known to heat the target tissue to at least this temperature in order to cause denaturation. This is supported by the teachings of Mosher, where it is disclosed that “it is generally desirable to subject the treatment volume to temperatures of at least 70° C” in order “to effect significant, repeatable tissue shrinkage.” EX1006, ¶65 (“[T]o effect significant, repeatable tissue shrinkage, it is generally desirable to subject the

treatment volume to temperatures of at least 70° C. for a time of about 30 seconds or more”). Additionally, Ingle also teaches that to cause collagenated tissue to contract, the tissue should be heated to a temperature that is “preferably between about 60 nC and 80 nC,” which results in the tissue contracting. EX1007, 12:64–13:2.

150. Ingle also confirms that temperatures lower than 60°C would be unlikely to cause remodeling. It discloses that the tissue not being treated should be maintained at a temperature “below a maximum safe tissue temperature, typically being below about 45 nC.” EX1007, 13:13–15. A POSA reading Ingle would understand this passage to mean that temperatures of below 45°C would not cause any damage to the tissue. Consequently, without any heat damage breaking apart the intramolecular hydrogen bonds in collagen, no denaturation and thus no remodeling would occur. Because of this, a POSA would have known that the target tissue to be treated must be raised to a temperature above 45°C.

151. In my opinion, Mosher and Ingle teach heating the target tissue to a temperature that is within the recited range of claims 2, 36, 44, and 52.

152. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 2, 36, 44, 52.

2. Claims 3 and 4

153. Claim 3 recites: “*wherein heating the target tissue comprises heating it to a temperature between 50 degrees C. and 75 degrees C.*”

154. Claim 4 recites: “*wherein heating the target tissue comprises heating it to a temperature between 55 degrees C. and 70 degrees C.*”

155. As indicated previously, Mosher, discloses that “it is generally desirable to subject the treatment volume to temperatures of at least 70° C.” in order “to effect significant, repeatable tissue shrinkage.” EX1006, ¶65. Ingle also teaches that to cause collagenated tissue to contract, the tissue should be heated to a temperature that is “preferably between about 60 nC and 80 nC.” EX1007, 12:64–13:2. In my opinion, Mosher and Ingle teach heating the target tissue *to a temperature that is between 50 and 75 °C.*

156. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 3 and 4.

3. Claims 5, 37, 45, and 53

157. Claims 5, 37, 45, and 53 depend from claims 3, 35, 43, and 51, respectively. Claims 5, 37, 45, and 53 recite: “*wherein heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.*” In my opinion, each of Edwards, Mosher, and Ingle teaches the recited element.

158. Edwards discloses a method for vaginal remodeling that uses a device containing a “treatment element 410 that includes a blade 420 and a handle 430.” EX1005, 7:20–21, FIG. 4. Although “treatment element 410” is not labeled in Figure 4, a POSA would have understood that the depicted device is the treatment element as it is comprised of the elements 420 and 430.

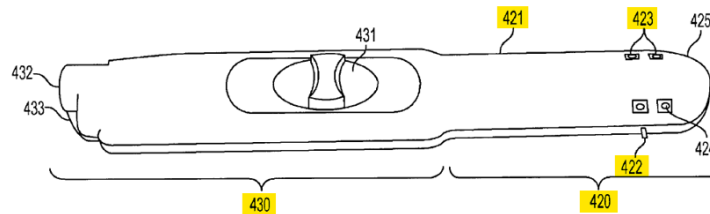


FIG. 4

EX1005, FIG. 4 (excerpt) (annotated).

159. Edwards also discloses “[t]he blade 420 of the system 400 is inserted into the vagina” and “RF energy [is delivered] to discrete areas of the vaginal wall.” EX1005, 13:43–44, 13:56–56, FIG. 9A (step 908). Additionally, Edwards discloses that the blade includes a “plurality of relatively flat electrodes 423” which are “disposed to deliver RF energy.” EX1005, 7:26–39. A POSA would have understood the blade to be a *treatment tip*, and the RF electrodes to be an *energy delivery element*. Edwards teaches a method involving inserting a speculum into the vagina, inserting the *treatment tip* into the vagina through the speculum, and then locking the *treatment tip* into place through “mating features 421” and a “spring-loaded pin detail 422.” EX1005, 13:43–49. A POSA would have understood that by using the device as illustrated in the manner described, the

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

160. Likewise, Mosher’s disclosed method also uses a device containing the recited elements. Mosher teaches “a vaginal probe body 54 includes a plurality of electrodes 56” that allows for “RF current” to be transmitted through them. EX1006, ¶58. A POSA would have understood that the end of the vaginal probe that includes the plurality of electrodes is *a treatment tip* because it is this portion of the probe that is used to provide treatment. A POSA also would have understood the plurality of RF electrodes are *an energy delivery element*. Mosher also discloses that the electrodes contain a “relatively flat tissue-engaging electrode surface,” which a POSA would understand to mean that the *treatment tip* is *contacting the epithelium*. EX1006, ¶58.

161. In Ingle’s disclosed method, a “vaginal probe 42” is used to heat the target tissue by “RF energy selectively directed through the segments of electrode 12.” EX1007, 20:14–17, FIG. 11. A POSA would have understood the distal portion of the vaginal probe to be *a treatment tip*, and the RF directing electrodes to be *an energy delivery element*. Like in Mosher, the electrodes in Ingle are

“substantially flat” and “engagable against the intermediate tissue.” EX1007, 3:13–

16. Even more expressly, Ingle discloses that its method “comprises coupling an electrode of a probe to the tissue surface.” EX1007, 7:19–20. Therefore, the *treatment tip* disclosed by Ingle is also *contacting the epithelium*.

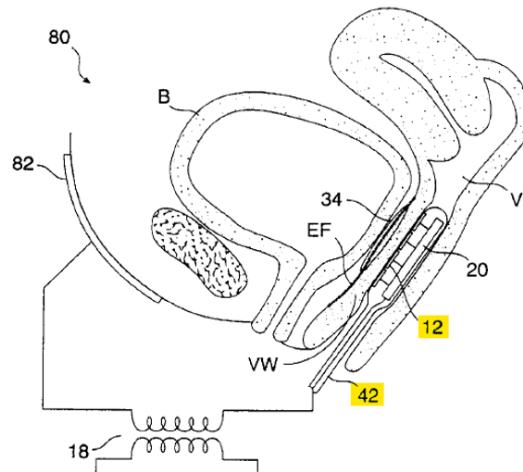


FIG. 11

EX1007, FIG. 11 (annotated).

162. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 5, 37, 45, and 53.

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

163. Claim 6 depends from claim 5, and claims 33, 41, 49, and 57 depend from claims 1, 35, 43, and 51, respectively. Claim 6 recites: “*wherein the energy includes any of radiofrequency energy, microwave energy, or ultrasound energy.*” Claims 33, 41, 49, and 57 similarly recite: “*wherein heating comprises delivering energy by any of: radiofrequency energy, microwave energy, or ultrasound*

energy.” In my opinion, each of Edwards, Mosher, and Ingle teaches the recited elements.

164. Edwards teaches a method using “electrodes 423 [that] are disposed to deliver *RF energy*,” but the electrodes can be configured to “also deliver *microwave energy*, ELF (extremely low frequency range energy), laser and other forms of therapeutic energy.” EX1005, 7:37–42.

165. Mosher discloses “*RF energy* can then be applied through the probe in order to heat the target tissue.” EX1006, ¶55.

166. Ingle teaches that the “target zone 34 is heated by *RF energy* selectively directed through the segments of electrode 12.” EX1007, 20:14–16. Additionally, Ingle discloses that “probes which heat the target tissue using *ultrasound*, *RF energy*, *microwave*, or any other energy transmitting mechanism” can be used. EX1007, 25:54–56.

167. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 6, 33, 41, 49, and 57.

5. Claims 7, 38, 46, and 54

168. Claims 7, 38, 46, and 52 depend from claims 1, 35, 43, and 51 respectively. Claims 7, 38, 46, and 52 recite: “*wherein the heating is controlled by a feedback control, such that temperature does not go higher than a predetermined*

temperature.” In my opinion, each of Edwards, Mosher, and Ingle teaches the recited element.

169. Edwards teaches that “[e]ach electrode 423 includes at least one thermocouple 424 that is used to monitor the temperature of each electrode 423,” and that the purpose of this monitoring is to “disengage,” or shut down any electrodes that “exceeds temperature safety limits.” EX1005, 7:43–50.

170. Mosher discloses that feedback on “heating temperatures may be provided by needle-mounted temperature sensors 62.” EX1006, ¶58; EX1006, ¶68 (discussing the temperature sensor being “used in a feedback loop to control the RF energy applied by the probe.”). This “feedback loop” is used by Mosher to maintain the treatment temperature. EX1006, ¶73. A POSA would have understood that using a feedback loop to maintain a treatment temperature ensures *that temperature does not go higher than a predetermined temperature.*

171. Ingle teaches a “control system ... coupled to the electrode surface segments” of Ingle’s probe, to “selectively energize the electrode surface segments so as to heat the target tissue to a treatment temperature while the cooling system maintains the intermediate tissue ... at or below a maximum safe tissue temperature.” EX1007, 4:61–67. In Ingle’s method, “needle mounted temperature sensors will ideally provide direct feedback of the tissue temperature so that selected treatment zone is heated to about 60 nC or more while heating the tissues

adjacent the electrodes is limited to about 45 nC or less.” EX1007, 7:11–14; *see also* EX1007, 12:37-45, 23:50-65. A POSA would have understood that in order to limit the heating of the tissue adjacent to the electrodes, the feedback control must also limit the temperature in the treatment zone such that the *temperature does not go higher than a predetermined temperature*.

172. A POSA would have understood that regulating the treatment temperature is desired in order to prevent tissue damage.

173. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 7, 38, 46, 54.

6. Claim 8

174. Claim 8 depends from claim 7, and recites: “*wherein the feedback control is provided by one or more thermal sensors.*” In my opinion, each of Edwards, Mosher, and Ingle teaches the recited element.

175. Edwards teaches that “at least one thermocouple 424 that is used to monitor the temperature of each electrode 423.” EX1005, 7:43–54. Mosher discloses that feedback on “heating temperatures may be provided by needle-mounted temperature sensors 62.” EX1006, ¶58. Ingle teaches “needle mounted temperature sensors will ideally provide direct feedback of the tissue temperature.” EX1007, 7:10-15, 12:37-45, 23:50-65.

176. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 8.

7. Claims 9, 39, 47, and 55

177. Claims 9, 39, 47, and 55 depend from claims 1, 35, 43, and 51 respectively. Claims 9, 39, 47, and 55 recite: “*wherein the method further comprises cooling the epithelium.*” In my opinion, each of Edwards, Mosher, and Ingle teaches the recited element.

178. Edwards teaches a method including the “delivery [of] cooling fluid into the vagina through the irrigating fluid delivery pores 425.” EX1005, 13:50–52. Because Edwards discloses that the reason cooling fluid is delivered is “to minimize thermal damage to tissues,” a POSA would have understood that it is the epithelium being cooled. EX1005, 4:60–61; *see also* EX1005, 7:51–53. Additionally, because the irrigating fluid delivery pores 425 that deliver the cooling fluid is located on the blade, or *treatment tip*, a POSA would have understood that any cooling fluid released would inherently cool the epithelium. EX1005, 4:26–28.

179. Mosher discloses a method in which “fluid conduits cool the intervening or intermediate tissue” between the *treatment tip* and the target tissue, “such as the vaginal wall.” EX1006, ¶58. A POSA would have understood the

“intervening or intermediate tissue,” and especially when exemplified as “the vaginal wall” to refer to the epithelium of the vagina.

180. The method disclosed by Ingle also comprises “cooling the intermediate tissue with the probe.” EX1007, 7:18–20. Specifically, Ingle discloses that “the vaginal mucosa adjacent probe 84 is protected by the cooled probe” and a POSA would have understood the “vaginal mucosa” to be synonymous with vaginal epithelium. EX1007, 20:61–63. *See also* EX1007, 3:43–58 (“The transmitting element is capable of transmitting sufficient heating energy through the vaginal wall to heat and contract the fascia. A *cooling system* is disposed adjacent to the transmitting element. The cooling system is capable of *maintaining the vaginal wall adjacent the probe below a maximum safe temperature* when the fascia is heated by the transmitting element.”).

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

182. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 9, 39, 47, and 55.

8. Claim 10

183. Claim 10 depends from claim 9, and recites: “*wherein cooling is by contacting the epithelium with a treatment tip, the tip including a cooling*

mechanism.” In my opinion, each of Edwards, Mosher, and Ingle teaches the recited element.

184. As discussed above in claim 5, each of Edwards, Mosher, and Ingle disclose *contacting the epithelium with a treatment tip*. See Section IX.C.3. Further, a POSA would have understood that for the treatment tip to cool the epithelium, physical contact is necessary.

185. Edwards additionally discloses that the “blade 420,” or *treatment tip*, also features “a plurality of irrigating fluid delivery pores 425” that are “disposed to deliver cooling liquids so as to minimize thermal damage.” EX1005, 7:26–53. A POSA would have understood that the plurality of irrigating fluid delivery pores that deliver cooling liquids is *a cooling mechanism*.

186. The electrodes located on the vaginal probe, or *treatment tip*, used in the method disclosed by Mosher “are cooled by fluid conduits 58.” EX1006, ¶58, FIG. 6. A POSA would have understood that these fluid conduits located in the *treatment tip* are a type of *cooling mechanism*. See also EX1014, 5:54–67 (teaching that the surfaces of electrodes are cooled by a cooling system, “typically includ[ing] a conduit through the electrode for the circulation of a cooling fluid.”).

187. Ingle discloses that the electrodes in the *treatment tip* “will generally be actively cooled” and that the disclosed “method comprises coupling an electrode of a probe to the tissue surface and cooling the intermediate tissue with

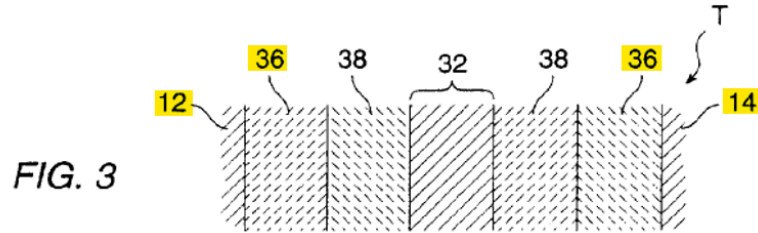
the probe.” EX1007, 7:8–23; EX1007, 20:14-19, FIG. 11. A POSA would have known that unlike passive cooling, which is achieved without any external energy input, in order for the electrodes of Ingle to be “actively cooled,” energy must be imparted into them and thus *a cooling mechanism* must be present in the *treatment tip*.

188. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 10.

9. Claim 11

189. Claim 11 depends from claim 9, and recites: “*wherein cooling the epithelium comprises cooling it to a temperature between 0 degrees C. and 10 degrees C.*” In my opinion, Ingle teaches the recited element.

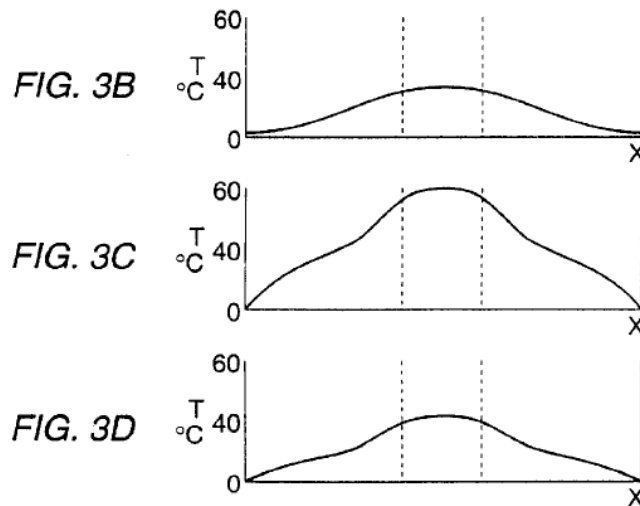
190. Ingle discloses that the epithelium in contact with the electrodes of the *treatment tip* “will preferably be pre-cooled by the surfaces of electrodes 12, 14 generally using an electrode surface temperature of at or above 0 °C” which “will substantially decrease the temperature of intermediate tissues 36.” EX1007, 15:31–35. Looking at Figure 3, a POSA would have understood that the “intermediate tissues 36” is the epithelium as they are in direct contact with “electrodes 12, 14.” EX1007, 15:31–35.



EX1007, FIG. 3 (annotated).

191. Additionally, a POSA would have known that cooling the epithelium that is in direct contact with an electrode having a surface temperature of around 0°C would also cool the epithelium to a temperature of near 0°C. This understanding is confirmed by Ingle as it is shown in Figures 3B–3D that the temperature of the immediate tissues—the epithelium—remain consistently near, but above, 0°C throughout the entire treatment process while cooling is applied.

EX1007, 15:40–16:15.



EX1007, FIGS. 3B-3D.

192. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 11.

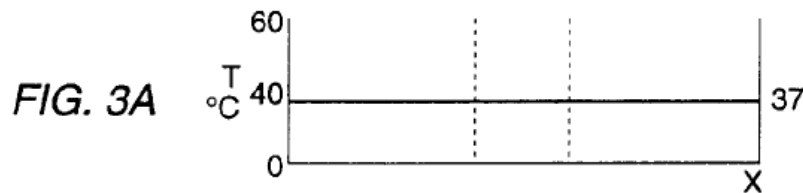
10. Claim 12

193. Claim 12 depends from claim 9, and recites: “*wherein the method further comprises cooling of at least some of the target tissue, the cooling of the target tissue having an effect on the therapeutic zone.*” In my opinion, the combination of Edwards, Mosher, and Ingle teaches the recited limitation.

194. As discussed above for claims 5 and 10, the combination of Edwards, Mosher, and Ingle teaches *cooling the epithelium wherein cooling is by contacting the epithelium with a treatment tip. See Sections, IX.C.3, IX.C.8.* A POSA would have understood that by contacting a tissue, such as epithelium, with a cooled treatment tip, the tissue being contacted will necessarily be cooled by conductive heat transfer. A POSA would have further understood that as the outermost layers of tissue are cooled, they would in turn cool the deeper layers of tissue, again, because of conductive heat transfer. A POSA would have known that cooling the epithelium by direct contact with a cooled treatment tip would necessarily result in cooling of the tissue immediately beneath it as well, or in other words, would result in a cooling of the target tissue. *See Section IX.C.8.* Furthermore, as a POSA would have known that different temperatures affect how collagen degrades, a POSA would have known that cooling the tissue would have *an effect on the therapeutic zone* as its temperature is being changed along a gradient. *See Section IX.C.8.*

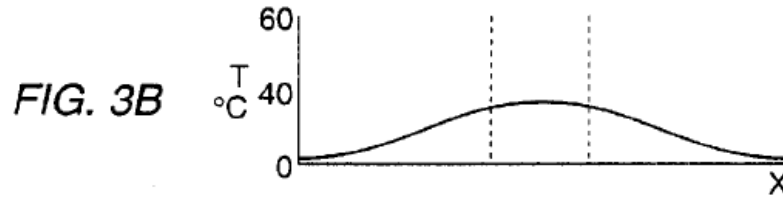
195. The POSA's understanding of conductive heat transfer is confirmed by Ingle. Figures 3A–3E show the temperature of a volume of tissue being treated. *See* EX1007, 15:28–30. It is showing temperature (on the y-axis) as a function of distance from the electrode (on the x-axis, where 0 represents the location of the electrode). The set of dotted vertical lines near the center of the graph represent the *therapeutic zone* of the *target tissue* that is under the electrode and being treated. *See* EX1007, 15:28–15:15, FIGS. 3A–3E.

196. In Figure 3A, no cooling has been applied and the temperature is consistent throughout the tissue layers at normal body temperature—37°C. *See* EX1007, 15:28–30, FIG. 3A.



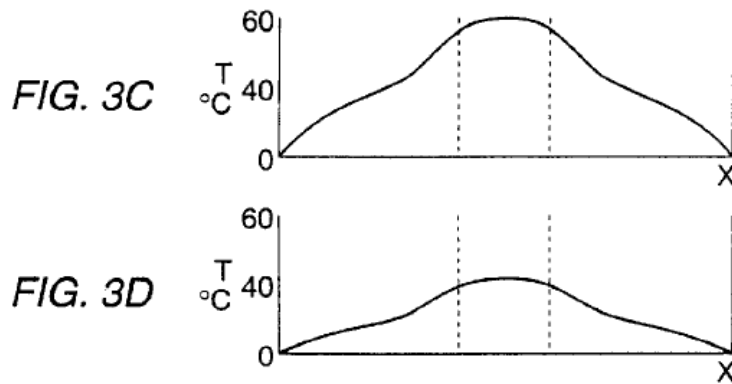
EX1007, FIG. 3A.

197. As soon as cooling is engaged on the treatment tip, the temperature of the epithelium drops down to near 0°C , and as a result of conductive heat transfer, the deeper tissue further from the treatment tip are cooled as well. *See* EX1007, 15:45–49, FIG. 3B. This includes a portion of the tissue in between the dotted vertical lines—the treatment zone.



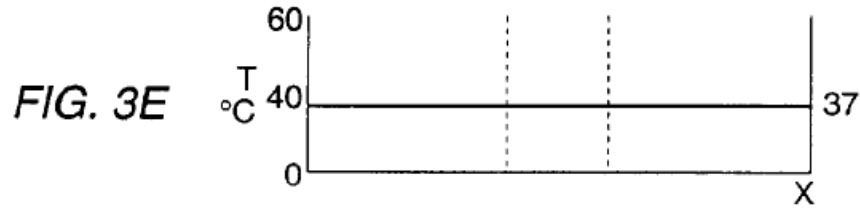
EX1007, FIG. 3B.

198. Even when heating is applied, and then subsequently stopped, Ingle shows that the cooling provided by the treatment tip has an effect on the treatment zone and not allowing it to reach a constant, flat temperature. *See* EX1007, 15:58–16:13, FIGS. 3C–3D.



EX1007, FIGS. 3C-D.

199. As a final confirmation that the difference in temperature are the results of the cooling provided by the treatment top, Ingle discloses that once cooling is stopped, all tissue returns to normal body temperature. *See* EX1007, 16:13–16:15, FIG. 3E.



EX1007, FIG. 3E.

200. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 12.

11. Claims 13 and 14

201. Claims 13 and 14 depend from claim 9. Claim 13 recites: “*wherein the cooling precedes the heating, and continues during the heating.*” Claim 14 recites: “*wherein the cooling is during the heating, and continues after heating.*” In my opinion, the combination of Edwards, Mosher, and Ingle teaches these recited elements.

202. In the method disclosed by Edwards, “the irrigating fluid ports 433 is engaged so as to delivery [sic] cooling fluid into the vagina through the irrigating fluid delivery pores 425” during “step 907.” EX1005, 13:50–52. Then, in “step 908, the energy port 432 is manipulated so as to cause delivery of RF energy to discrete areas of the vaginal wall.” EX1005, 13:54–56. It is only after the RF energy is delivered—the *heating*—that in “step 909, one of the irrigating fluid ports 433 is manipulated so as to stop the flow of cooling fluid.” EX1005, 13:63–65. A POSA would have understood that because the cooling fluid is started before

RF energy is delivered and is not stopped until after, that cooling must have been occurring during the heating of the tissue. Therefore, Edwards teaches *the cooling precedes the heating, is during the heating, and continues after heating*.

203. Mosher explicitly teaches “cooling prior to and during RF energy application.” EX1006, ¶69. A POSA would have understood “RF energy application” to mean heating the target tissue.

204. Ingle expressly discloses that “the tissue will preferably be cooled before and after energizing of the electrodes.” EX1007, 15:5–7. A POSA would have understood that “energizing of the electrodes” refers to *the heating* step, or when “RF current is directed through the tissue between the electrodes to heat the tissue.” EX1007, 15: 5–7, 15:58–60. Additionally, Ingle teaches that “the electrode surfaces are often cooled throughout the heating process.” EX1007, 15:64–65. Because the cooled electrodes are the source of cooling in the method of Ingle, a POSA would have known that continued cooling of the electrode surfaces during the heating process means that the epithelium is also cooled *during the heating*. See EX1007, 20:52–58. Ingle further teaches that “[t]o minimize collateral damage to the adjacent tissues . . . the cooling system continues to circulate cold fluid through the electrode, and to remove heat from the tissue, after the heating radiofrequency energy is halted.” EX1007, 16:7–10.

205. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 13 and 14.

12. Claims 15 and 16

206. Claim 15 depends from claim 9, and claim 16 depends from claim 15. Claim 15 recites: “*wherein the combination of cooling the epithelium and heating the target tissue creates a reverse thermal gradient from the epithelium to the target tissue.*” Claim 16 recites: “*wherein the reverse thermal gradient ranges from a low temperature of 0 degrees C. to 10 degrees C. at the epithelium to a high temperature of 45 degrees C. to 80 degrees C. in the underlying target tissue.*” In my opinion, the combination of Mosher and Ingle teaches the recited elements.

207. A POSA would have understood a *thermal gradient* created by *cooling the epithelium and heating the target tissue* to mean an increase in the observed temperature of the tissue when measuring past the epithelium and through to the target tissue. For example, Goldberg describes: “This combination of volumetric heating with contact cooling leads to a reverse thermal gradient characterized by a higher tissue temperature in the deeper dermis than in the epidermis and upper dermis.” EX1016, 180. This understanding is consistent with the ’511 patent, which confirms that in “a reverse thermal gradient” there is “a lower temperature at the mucosal epithelium, and a higher temperature in the underlying tissue.” EX1001, 13:43–45.

208. As explained above for claim 2, Mosher and Ingle specifically disclose heating the target tissue *to a temperature of 45 degrees C. to 80 degrees C.* See Section IX.C.1. And as explained for claim 11, Ingle specifically discloses cooling the epithelium *to a temperature of 0 degrees C. to 10 degrees C.* See Section IX.C.9. A POSA would have known that a *reverse thermal gradient* inherently forms when the target tissue is heated and the epithelium is cooled due to conductive heat transfer. This effect is illustrated in Ingle, which explains: “intermediate tissue 36 exhibits a substantial temperature differential as compared to [the] target tissue 32. . . . [A]s compared to the tissues at uniform body temperature, the temperature differential between the target and intermediate tissues can now be used to help enhance selective heating of the target tissue while minimizing collateral damage to the adjacent tissue.” EX1007, 15:45–57, FIGS. 3B–3D.

209. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 15 and 16.

13. Claims 17, 40, 48, and 56

210. Claims 17, 40, 48, and 56 depend from claims 1, 35, 43, and 51, respectively. Claims 17, 40, 48, and 56 recite: “*wherein the method comprises contacting the epithelium with a treatment tip at a one or more contact sites during a procedure, the tip comprising an energy delivery element adapted to heat the*

target tissue.” As discussed above for claim 5, Edwards, Mosher, and Ingle already teach: *heating comprises delivering energy by contacting the epithelium with a treatment tip, the tip including an energy delivery element.* See Section IX.C.3. In my opinion, Edwards and Mosher teach the additional recited element of “*contacting. . . one or more contact sites.*”

211. A POSA would have understood that given the size of the electrodes disclosed in Edwards and Mosher in relation to the size of the treatment area—e.g., *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 treatment tip must contact *one or more* treatment sites in order to achieve the desired result. Through visual inspection of Figure 4, a POSA would have understood that electrodes disclosed by Edwards are located at the very distal end of the *treatment tip* and small in size compared to the tip. See EX1005, FIG. 4.

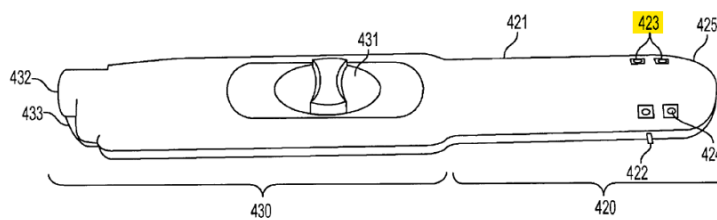


FIG. 4

EX1005, FIG. 4 (excerpt) (annotated).

212. In order to achieve the goal of providing “physical and psychological improvement in the area of sexual function,” Edwards discloses that

“circumferential tightening of the vaginal wall” is required. EX1005, 3:11–13. A POSA would have known that in order to achieve circumferential tightening of the vaginal wall using the device as disclosed in Figure 4, the treatment tip must be moved around and contact multiple treatment sites. This understanding is expressly confirmed by Edwards, who discloses that “blade 420 may be disengaged and relocked into another position in the speculum, so as to deliver energy to another area of the vagina.” EX1005, 13:60–62.

213. In the method disclosed by Mosher, an exemplified electrode size was disclosed as having “a width of at least 20 mm and a length of less than 8 mm.” Like with Edwards, a POSA would have known that to achieve therapeutic results, namely having a length of 15 mm as described in Mosher, an electrode of the disclosed size must contact multiple treatment sites. Again, this understanding is expressly confirmed by Mosher as it teaches “heat[ing] a treatment surface with a ‘paint’ tip movement pattern.” EX1006, ¶71, FIG. 12A.

214. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 17, 40, 48, and 56.

14. Claim 18

215. Claim 18 depends from claim 17, and recites: “*wherein the method is performed during a procedure, and wherein the contacting of any one or more*

contact sites is repeated one or more times during a procedure.” In my opinion, Mosher and Ingle teach the recited limitation.

216. As discussed above, a POSA would have known to perform the procedure over the *contact sites* in multiple passes, or *repeated one or more times*, as opposed to a single pass. *See* Section VI.C. Multiple passes allows for the use of a lower treatment temperature in each pass instead of one pass using the highest tolerable temperature. A POSA would have understood that this is beneficial as the lower treatment temperature reduces patient discomfort while at the same time showing more consistent, and improved, clinical tightening results. *See* Section VI.C; *see also* EX1021, 639 (“multiple passes at lower energy levels appear to elicit a more substantial tissue effect than a single pass at higher energy levels”), FIG. 1.

217. A POSA’s understanding is confirmed by Ingle, which discloses that “the electrode may be energized for 15 secs. and turned off for 15 secs. repeatedly during a heating session.” EX1007, 7:25–26. A POSA would have understood that energizing an electrode and turning it off in 15 second cycles produces the same results as contacting the site with the tip for 15 seconds, removing contact for 15 seconds, and repeating.

218. Similarly, Mosher teaches “heat[ing] a treatment surface with a ‘paint’ tip movement pattern as shown in FIG. 12A . . . Arrow 37 indicates a tip

movement pattern of five passes in the treatment zone.” EX1006, ¶71, claim 19, FIG. 12A. At the disclosed “tip movement speeds of about 0.4 cm/sec. for a treatment of 140 seconds and tip movement speeds of about 1.1 cm/sec. for a treatment period of 90 seconds,” the tip travels a total distance of 56 cm and 99 cm, respectively, along a 14 cm path. EX1006, ¶71, FIG. 12A. A POSA would have understood this to teach repeating contact at the sites several times during the procedure.

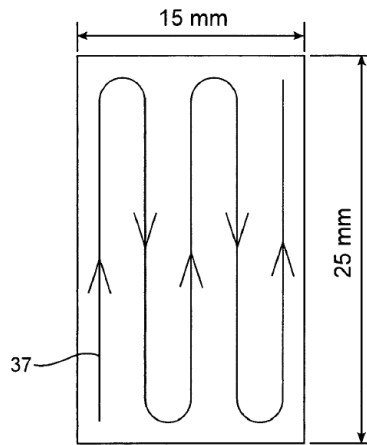


FIG. 12A

EX1006, FIG. 12A.

219. Further still, a POSA would have understood that it was typical to contact each particular contact site more than once during a procedure, because moving the device allows for more even distribution of the thermal energy resulting in a more uniform effect on the tissue. This included moving the *treatment tip* in a linear, or axial, motion as well as in a rotational movement circumferentially in order to distribute the energy throughout the treatment area. A

POSA would have known to keep the *treatment tip* in constant motion instead of holding it in one location for a prolonged period as such a method would result in more uniform RF energy distribution, and thus would heat all of the target tissue to a therapeutic temperature evenly, increasing patient comfort and producing more consistent results.

220. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 18.

15. Claim 19

221. Claim 19 depends from claim 17, and recites: “*wherein the method includes contacting the tip to the epithelium at a plurality of contact sites during a procedure, moving the tip from site to site, the combined contact sites comprising a treatment area.*” In my opinion, Edwards and Mosher both teach the recited element.

222. As discussed above for claims 5 and 17, the combination of Edwards, Mosher, and Ingle teaches *contacting the tip to the epithelium at a plurality of contact sites during a procedure*, as well as *moving the tip from site to site*. A POSA would have understood that contacting a plurality of contact sites would create a combined treatment area comprised of the target tissue treated at each contact site.

223. Edwards teaches a method in which the treatment site can be “either the anterior vaginal wall, the posterior vaginal wall, or both.” EX1005, 13:14–22; EX1005, 13:60-62. A POSA would have understood the anterior vaginal wall as one *contact site* and the posterior vaginal wall to be a separate *contact site*, and thus treating both the anterior and posterior vaginal walls would necessitate the treatment of *a plurality of contact sites during a procedure*, for example to result in circumferential vaginal tightening.

224. Mosher expressly discloses *moving the tip from site to site* as it teaches “heat[ing] a treatment surface with a ‘paint’ tip movement pattern as shown in FIG. 12A,” and recognizes that total treatment volume is dependent on the speed of tip movement. EX1006, ¶¶13, 71, FIG. 12A.

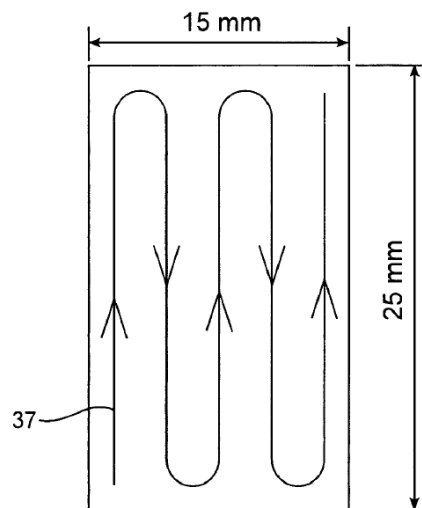


FIG. 12A

EX1006, FIG. 12A.

225. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 19.

16. Claim 20

226. Claim 20 depends from claim 19, and recites: “*wherein any one of the contact sites is contacted one or more times during a procedure.*”

227. In my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 20 for the same reasons discussed above for claim 18. *See* Section IX.C.14.

17. Claim 21

228. Claim 21 depends from claim 19, and recites: “*the method further comprising repeating the procedure one or more times.*” In my opinion, Mosher teaches the recited element.

229. As discussed above, a POSA would have known that repeating the treatment procedure multiple times allows for the compounding of the treatment effects from each individual procedure, thereby increasing the tightening of the target tissue. *See* Section IX.C.14. This understanding is confirmed by Mosher who teaches that its techniques are “effective for controllably and *repeatably enhancing* the structural support of a wide variety of fascia and other collagenous tissues.”
EX1006, ¶46.

230. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 21.

18. Claim 22

231. Claim 22 depends from claim 21, and recites: “*wherein the treatment areas of the one or more procedures may be any of the same treatment area, different treatment areas, or overlapping treatment areas.*” In my opinion, the combination of Edwards, Mosher, and Ingle teaches the recited element.

232. As discussed above for claim 21, a POSA would have understood that repeating the treatment procedure across multiple sessions would be beneficial. *See* Section IX.C.17. When repeating the treatment procedure, a POSA would aim to target the same treatment area to reinforce the treatment effects. This would result in the treatment *of the same treatment area and of overlapping treatment areas.* However, it would be nearly impossible for a POSA to treat the exact same treatment area from procedure to procedure, without either overshooting or undershooting the boundary. As a result, *different treatment areas* will also necessarily be treated in the repeated procedures. A POSA would also be motivated to treat different treatment areas in order to provide an expanded combined treatment area.

233. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 22.

19. Claim 23

234. Claim 23 depends from claim 1, and recites: “*wherein the target tissue heating includes heating submucosa and muscularis below a mucosal epithelium.*”

In my opinion, Edwards and Mosher teach the recited element.

235. As explained above, a POSA would have known that the vaginal is comprised of multiple layers of varying tissue composition with the outermost layer (that is exposed to the vaginal canal) comprising the mucosal epithelium. *See* Section VI.A. Below the mucosal epithelium is a layer of tissue known as the lamina propria, or submucosa, which is rich in elastic fibers such as collagen and provides a foundation for the epithelium above. *See* Section VI.A. Beneath the lamina propria is a layer of smooth muscle known as the muscularis, and below that is the adventitia, a layer of fibrous connective tissue that anchors the vagina to the surrounding structures. *See* Section VI.A. This understanding is confirmed by the '511 patent which describes the tissue “immediately beneath the mucosal epithelium of genital tissues” as including “the lamina propria, a connective tissue that includes collagen in the extracellular space, and the muscularis, which includes smooth muscle.” EX1001, 3:43–47.

236. Furthermore, a POSA would have understood that in treating tissue with radiant energy, and specifically RF energy, the heating occurs mostly in the tissue just beneath the electrode, up to a depth of around 5 mm. *See* Section VI.C.

Additionally, a POSA would have known that the mucosal epithelium is a very thin layer of tissue, with a thickness of approximately 0.04 mm. *See* EX1006, ¶66. Therefore, when Edwards discloses a method using “RF energy” to treat “the anterior and posterior regions of the vaginal wall,” a POSA would have understood that the RF energy penetrates the thin mucosal epithelium of the vaginal wall to heat the *submucosa and muscularis below*. EX1005, 3:8–9.

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

238. Additionally, a POSA would have understood that different treatment results can be achieved by treating different layers of tissue. A POSA would have also understood that target treatment depth can be controlled by the intensity of the RF energy used—with increasing energy needed to target deeper layers of tissue. EX1006, ¶85, FIG. 23.

239. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 23.

20. Claim 24

240. Claim 24 depends from claim 1, and recites: “*wherein the heating does not modify a mucosal epithelium of the genital tissue.*” In my opinion, each of Edwards, Mosher, and Ingle teaches the recited element.

241. As described above for claims 9–16, each of Edwards, Mosher, and Ingle teaches cooling the epithelial surface during heating of the target tissue. *See* Sections IX.C.7–IX.C.12. Additionally, Edwards discloses the purpose of the cooling is “to minimize thermal damage to tissues” during heating. EX1005, 4:59–61. A POSA would have understood that because the method of Edwards directly cools with the *treatment tip*, the tissue being cooled is the *mucosal epithelium*, which is in direct contact with the tip. *See* Section IX.C.8.

242. Mosher discloses the “cooling the intermediate tissue” in order “to inhibit necrosis of any intermediate tissue.” EX1006, ¶13. A POSA would have understood the intermediate tissue to refer to the mucosal epithelium as it was exemplified to be the “vaginal wall.” EX1006, ¶58.

243. Ingle discloses a method in which “the cooling system continues to circulate cold fluid through the electrode, and to remove heat from the tissue” so as to “minimize collateral damage to the adjacent tissues 36.” EX1007, 16:5–11. A POSA would have understood that adjacent tissues refers to the tissue adjacent to,

and in contact with, the electrode, which is the mucosal epithelium. *See* EX1007, FIG. 3.

244. A POSA would have understood that because of the cooling provided Edwards, Mosher, and Ingle, aimed at minimizing and preventing thermal damage, the heating does not affect the *mucosal epithelium of the genital tissue*. This understanding is confirmed by Ingle's teaching that the epithelium should be cooled *to a temperature between 0 degrees C. and 10 degrees C.* *See* Section IX.C.9. A POSA would have known that this is well below the temperature that remodeling occurs, and would have known that the heating taught by Edwards, Mosher, and Ingle *does not modify the mucosal epithelium*. *See* Section VI.B.

245. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 24.

21. Claim 25

246. Claim 25 depends from claim 1, and recites: "*wherein remodeling comprises contracting target tissue.*" In my opinion, the combination of Edwards, Mosher, and Ingle teaches the recited element.

247. As I discuss above for element [1.2], a POSA would have understood the combination of Edwards, Mosher and Ingle as teaching *remodeling the therapeutic zone of target tissue*. *See* Section IX.B.1.c. Because *remodeling*

already includes the requirement of *a tightening or contracting of the target tissue*, the combination of Edwards, Mosher, and Ingle teaches claim 25 as well.

22. Claim 26

248. Claim 26 depends from claim 1, and recites: “*wherein remodeling comprises tightening the introitus.*” In my opinion, Edwards teaches the recited limitation.

249. Edwards discloses a method “of tightening of vaginal walls,” where the “circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function.” EX1005, 3:9–12. Additionally, as discussed above for claim element [1.3], Edwards also teaches treatment and tightening “*a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus.*” See Section IX.B.1.d. Therefore, a POSA would have understood Edward’s disclosure of circumferential tightening of the vaginal wall starting at *a portion of the vagina extending from the introitus* to include *tightening the introitus* itself.

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

251. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 26.

23. Claim 27

252. Claim 27 depends from claim 1, and recites: “*wherein remodeling comprises tightening the vagina.*” In my opinion, each of Edwards, Mosher, and Ingle teaches the recited element.

253. Edwards expressly teaches a method for “circumferential tightening of the vaginal wall.” EX1005, 3:11–12, 13:19–22. Mosher discloses that the method of “treatment of the present invention may be directed at . . . structures of the vagina.” EX1006, ¶48. Ingle similarly discloses a method for tightening tissue “separated from the vagina by a vaginal wall.” EX1007, 3:36–39.

254. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 27.

24. Claim 28

255. Claim 28 depends from claim 1, and recites: “*wherein remodeling comprises denaturing collagen.*” In my opinion, Mosher and Ingle teach the recited element.

256. As explained above, a POSA would have understood that when collagen is heated, its intramolecular hydrogen bonds break, causing its triple-helical structure to unwind. *See* Section VI.B. This natural phenomenon would have been known to a POSA as denaturation. *See* Section VI.B. A POSA’s understanding is confirmed by Mosher, which discloses that “[w]ithin the first 24

hours of the heating treatment, fibroblasts will move in to begin repair. Over about two weeks, type III collagen will replace the denatured collagen.” EX1006, ¶66.

Ingle additionally confirms that “[t]issue contraction results from controlled heating of the tissue by affecting the collagen molecules of the tissue. Contraction occurs as a result of heat-induced uncoiling and repositioning of the collagen β -pleated structure.” EX1007, 11:25–28.

257. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 28.

25. Claim 29

258. Claim 29 depends from claim 1, and recites: “*wherein remodeling comprises tightening collagen-rich sites in the target tissue.*” In my opinion, the combination of Edwards, Mosher, and Ingle teaches the recited element.

259. As explained above, a POSA would have understood that remodeling occurs because of the tightening of collagen fibers in tissue. *See* Section VI.B. This is caused either by: (1) the shortening of collagen fibers due to the breaking of intramolecular hydrogen bonds in; and (2) the deposition of new collagen molecules and formation of new collagen fibers. *See* Section VI.B. Because both of these tightening effects are the result of heating collagen in the target tissue, a POSA would have understood that Edwards, Mosher, and Ingle teach that *remodeling comprises tightening collagen-rich sites in the target tissue.* A POSA

would have thus been motivated to treat collagen-rich sites, to achieve a tightening effect through the natural process of denaturing collagen.

260. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 29.

26. Claims 30 and 31

261. Claims 30 and 31 depend from claim 1. Claim 30 recites: “*wherein at least some of the remodeling occurs during the heating.*” Claim 31 recites: “*wherein at least some of the remodeling occurs after the heating.*” In my opinion, Mosher teaches the recited elements.

262. As explained above, a POSA would have understood that collagen remodeling occurs in two stages: (1) an immediately noticeable tightening effect in the tissue caused by the breaking of the collagen’s intramolecular hydrogen bonds, resulting in the shortening of the collagen fibers; and (2) delayed, and long-term tightening effects caused by fibroplasia and new collagen depositions in response to the body’s healing response. *See* Section VI.B. Further, a POSA would have known that the immediate effect occurs *during the heating* of the collagen fibers as the heat is breaking the intramolecular hydrogen bonds and that the delayed effects occur *after the heating* is completed as it takes the body time to heal, deposit new collagen, and form new collagen fibers.

263. A POSA's understanding is confirmed by Mosher, who teaches that "RF heating will typically induce collagen shrinkage," which a POSA would understand as the immediate shortening of collagen fibers. EX1006, ¶66. Mosher additionally confirms that "[w]ithin the first 24 hours of the heating treatment," the RF heating will "provid[e] increased stiffness through tissue remodeling resulting from the healing process," which a POSA would understand as delayed remodeling caused by fibroplasia and new collagen deposits. EX1006, ¶66; *see also* EX1006, ¶55 (discussing that the collagenous tissues subject to RF energy provide support "immediately and/or upon healing"), ¶64, FIG. 8A.

264. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 30 and 31.

27. Claim 32

265. Claim 32 depends from claim 31, and recites: "*wherein the remodeling after the heating is by a depositing of collagen in the target tissue.*" In my opinion, Mosher teaches the recited element.

266. As discussed above, a POSA would have known that heating collagen-containing tissues causes remodeling, which results from new collagen deposition. *See* Section VI.B. A POSA would have recognized this collagen deposition as part of the normal tissue healing process.

267. A POSA's understanding of collagen remodeling is confirmed by Mosher, who teaches that heating collagen-containing tissue "provid[es] increased stiffness through tissue remodeling resulting from the healing process. Within the first 24 hours of the heating treatment, fibroblasts will move in to begin repair. Over about two weeks, type III collagen will replace the denatured collagen." EX1006, ¶66. A POSA would have understood that type III collagen replacing denatured collagen is the same as *depositing of collagen in the target tissue*.

268. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claim 32.

28. Claims 34, 42, 50, and 58

269. Claims 34, 42, 50, and 58 depend from claim 1, 35, 43, and 51, respectively. Claims 34, 42, 50, and 58 recite: "*wherein heating comprises delivering energy by ultrasound energy*." As discussed above for claim 6, Edwards and Ingle each disclose the recited element. *See* Section 162.

270. Thus, in my opinion, the combination of Edwards, Mosher, and Ingle teaches claims 34, 42, 50, and 58.

X. THE COMBINATION OF EDWARDS, MOSHER, INGLE, AND OLLIVIER RENDERS OBVIOUS CLAIMS 43–58

271. In my opinion, claims 43-58 would have been obvious in view Edwards, Mosher, Ingle, and Ollivier.

272. As I discussed above, a POSA would have known that treating the vulva, including areas specifically recited in claims 43 and 51, is often done for cosmetic purposes. *See* Sections IX.B.3, IX.B.4. Ollivier provides an express suggestion to do so. *See generally* EX1008.

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

274. A POSA would have been motivated to use the treatment method of the Edwards-Mosher-Ingle combination, which teaches treating at least the vagina and introitus, to also treat the vulvar vestibule and labia minora, in order to achieve the desired aesthetic modification expressly described in Ollivier. EX1008, 0001. Ollivier teaches using earlier laser techniques to provide cosmetic treatment to these vulvar tissues as recited in claims 43 and 51, and adds that lasers have “fallen out of favor” and there are “more sophisticated tools that do the same thing.” EX1008, 0003. As I discuss above, at the time of invention, a POSA would have known that using RF treatment to heat and remodel tissue high in collagen content

is beneficial in a wide number of applications, ranging from therapeutic to cosmetic uses. *See* EX1016; EX1018; EX1021.

275. A POSA also would have had a reasonable expectation of success in doing so because the vulval region comprises similar mucosal epithelium, with the same underlying collagen-rich layers as in the vagina.

276. Accordingly, the combination of Edwards, Mosher, Ingle, and Ollivier teaches all elements of claims 43 and 51.

277. Likewise, Edwards, Mosher, and Ingle teach the further elements of dependent claims 44-50 and 52-58 for the same reasons I discuss above. Thus, the combination of Edwards, Mosher, Ingle, and Ollivier also teaches claims 44-50 and 52-58.

XI. OBJECTIVE INDICIA DO NOT SUPPORT PATENTABILITY

278. I understand that the obviousness analysis includes considering evidence of secondary considerations, sometimes called objective indicia, of non-obviousness (if available). I understand that any secondary considerations of non-obviousness must have a nexus, or a close connection, to the novel aspects of the claimed invention. I understand that secondary considerations of non-obviousness include the following: commercial success, long-felt but unmet need, failure of others, copying, praise in the industry, and unexpectedly superior results as compared with the closest prior art.

279. I have been advised by Petitioner's counsel that in the prior IPRs, the Patent Owner argued that Dr. Alinsod's 2015 article (EX1025) and website (EX1026) demonstrate that there was industry praise for vulvovaginal rejuvenation using RF energy, quoting Dr. Alinsod's statement that it "is a fairly new concept with real potential for success" and that "RF is game changing." I have considered the article and website but they do not alter, in any way, my opinions above that the claims would have been obvious based on the prior-art references Edwards, Mosher, Ingle, and Ollivier. In the article and on his website Dr. Alinsod is discussing a specific device, the ThermiVa. He is not discussing the use of RF energy for vulvovaginal rejuvenation generally.

280. And, as I discuss in detail above, RF treatment of vulva, introitus, and vagina tissues was known in the art prior to the '511 patent. Dr. Alinsod's statements made in the context of promoting a particular device cannot negate the strong evidence that a POSA would have been motivated to provide RF energy treatment to vulva, introitus, and vagina tissues at least as early as February 2006.

XII. CONCLUSION

281. In signing this declaration, I recognize that the declaration will be filed as evidence in an *inter partes* review before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will

take place within the United States. If cross-examination is required, I will appear for cross-examination within the United States during the time allotted.

282. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on this 8th day of APRIL 2024, in FARMINGTON HILLS, Michigan.

A handwritten signature in cursive script, reading "J Berenholz MD", written over a horizontal line.

Joseph Berenholz, M.D.