

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
Patent No. 8,961,511

DECLARATION OF DR. DENISE POULOS

InMode EX2001
BTL v. InMode
IPR2024-00703

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I, Dr. Denise Poulos, declare as follows:

I. INTRODUCTION

1. I have been retained by Patent Owner InMode Ltd. (“Patent Owner” or “InMode”) as an independent technical expert to provide opinions regarding the subject matter recited in certain claims of U.S. Patent No. 8,961,511 (“the ’511 Patent”). In particular, I have been asked to provide my opinion as to whether a person of ordinary skill in the art at the time of the invention (“POSA”) would have found claims 1 through 58 of the ’511 Patent (“challenged claims”) obvious in view of (i) U.S. Patent No. 6,463,331 (“Edwards”) in view of U.S. Patent Application Publication No. 2004/0193238 (“Mosher”) and U.S. Patent No. 6,216,704 (“Ingle”) and (ii) Edwards in view of Mosher, Ingle, and further in view of an article entitled “Designer vaginas” authored by Debra Ollivier (“Ollivier”) based on the arguments and evidence submitted by BTL Industries, Inc. (“Petitioner” or “BTL”) and its declarant, Dr. Joseph Berenholz.

2. I understand that the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office (“Board”) has instituted an IPR of the patentability of Claims 1 through 58 of the ’511 Patent following the submission of a Petition by BTL. I understand that BTL also submitted a supporting declaration by Dr. Berenholz (EX1003).

3. My analysis and conclusions regarding the '511 Patent and the instituted grounds are set forth below.

4. In connection with forming my opinions, I have considered the references and materials submitted by the parties in this proceeding, as well as the additional materials and information cited and discussed herein. These include the following:

Exhibit	Title
N/A	BTL's Petition
1001	U.S. Patent No. 8,961,511 ("the '511 Patent").
1002	File History of U.S. Patent No. 8,961,511 ("511 File History")
1003	Declaration of Dr. Joseph Berenholz in Support of Petition for Inter Partes Review ("Berenholz Decl.")
1004	Curriculum Vitae of Dr. Joseph Berenholz
1005	U.S. Patent No. 6,463,331 ("Edwards")
1006	U.S. Patent Application Publication No. 2004/0193238 ("Mosher")
1007	U.S. Patent No. 6,216,704 ("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
1015	F.H. Netter, "Netter's Atlas of Human Anatomy," 4th Ed., Saunders Elsevier, 2006 ("Netter")
1016	D.J. Goldberg, "Nonablative Laser Technology: Radiofrequency," Aesthetic Surg J 2004; 24:180–181 ("Goldberg")
1017	C. Squier and K.A. Brogden, "Human Oral Mucosa: Development, Structure, and Function," 1st Ed., Wiley-Blackwell 2011 ("Squier")
1018	N. Sadick, "Tissue Tightening Technologies: Fact or Fiction," Aesthetic Surg J 2008; 28:180–188 ("Sadick")

Exhibit	Title
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)
1024	<i>Viveve, Inc. v. ThermiGen, LLC</i> , 2-16-cv-01189, Claim Construction Order (E.D. Tex. November 13, 2017)
1025	Alinsod, R.M., “Temperature Controlled Radiofrequency for Vulvovaginal Laxity,” <i>Prime Journal</i> , pp. 16-21 (July/August 2015)
1026	ThermiVa, “Doctors are Weighing in on ThermiVa,” (IPR2018-00088, EX2007, accessed August 20, 2015)
2001	Declaration of Denise M. Poulos, M.D.
2002	Curriculum Vitae of Denise M. Poulos, M.D.
2003	Stedman’s Medical Dictionary (28 th Edition), Lippincott Williams & Wilkins (2006)
2004	Stedman’s Medical Dictionary (27 th Edition), Lippincott Williams & Wilkins (2003)
2005	Transcript of Deposition of Dr. Berenholz dated January 9, 2025
2006	<i>Viveve, Inc. v. ThermiGen, LLC</i> , 2-16-cv-01189, Dkt. 130, Summary Judgment Order (E.D. Tex. May 26, 2018)
2007	Merriam-Webster’s Collegiate Dictionary (Tenth Edition), Merriam-Webster (2000)
2008	Taber’s Cyclopedic Medical Dictionary, F.A. Davis Company (2005)
2009	Neurology and Urodynamics (Cover image), Vol. 41, Issue 6 (2022)
2010	Speculum, Cleveland Clinic, available at https://my.clevelandclinic.org/health/drugs/24238-speculum
2011	About Debra Ollivier, available at https://www.debraollivier.com/about
2013	Red Alinsod, “What are the Differences Between ThermiVa

	Radiofrequency and FemiLift/MonaLisa/IntimaLase lasers for use in Aesthetic Vulvovaginal Therapies?” (2015)
2014	M. Bajka, “Detailed Anatomy of the Abdomen and Pelvis of the Visible Human Female,” Clinical Anatomy (2004)
2015	Salon.com, Wikipedia, available at http://en.wikipedia.org/wiki/Salon.com
2016	Thermi Announces Settlement of Patent Infringement Litigation with Viveve, available at https://www.prnewswire.com/news-releases/thermi-announces-settlement-of-patent-infringement-litigation-with-viveve-300659000.html
2017	Y. Sekiguchi, “Laxity of the Vaginal Introitus After Childbirth: Nonsurgical Outpatient Procedure for Vaginal Tissue Restoration and Improved Sexual Satisfaction Using Low-Energy Radiofrequency Thermal Therapy,” Journal of Women’s Health (2013)
2018	L. Millheiser, “Radiofrequency Treatment of Vaginal Laxity after Vaginal Delivery: Nonsurgical Vaginal Tightening,” Journal of Sexual Medicine (2010)

5. My opinions set forth below are based on my personal education, training, experience in the field, and professional judgment, as well as the content of the references considered. My understanding of the relevant law, as discussed below, is based on my discussions with counsel for Signify. I am prepared to testify competently about my analysis and opinions set forth herein.

6. It is my opinion that Petitioner and Dr. Berenholz have not shown that any challenged claim is obvious in view of the grounds set forth in the Petition.

II. PROFESSIONAL BACKGROUND AND COMPENSATION

7. In 1984, I earned a Bachelor of Science in Physiology from the University of Illinois Urbana-Champaign in Urbana, Illinois.

8. In 1988, I earned an M.D. from Rush Medical College in Chicago, Illinois. Then, in 1992, I completed my residency in the Department of Obstetrics and Gynecology at Rush-Presbyterian-St. Luke's Medical Center in Chicago Illinois. Following my residency, I participated in a two-year fellowship training in Urogynecology at the Medical College of Virginia in Richmond, Virginia, under my advisor Dr. J. Andrew Fantl.

9. I am board certified in Obstetrics and Gynecology as of November 1995.

10. Currently, I am also board-certified in Female Pelvic Medicine and Reconstructive Surgery ("FPMRS"; commonly known as Urogynecology), as of June 2013, the first time the board certification in FPMRS was offered. I have been practicing urogynecology since 1994. I am the Medical Director of Women's Health Institute of Illinois, a busy private Urogynecology practice in the suburbs of Chicago.

11. I have been performing incontinence surgeries initially as a resident physician, during my urogynecology fellowship and as an attending urogynecologist since 1994. I have performed many different types of procedures to treat stress incontinence: anterior repairs, open and laparoscopic retropubic urethropexies including Burch and Marshall-Marchetti-Krantz (MMK) procedures, needle suspensions, fascial bladder neck slings, and injection of periurethral

bulking agents. I have performed a variety of surgeries for treatment of pelvic organ prolapse. These include anterior and posterior colporrhaphy, native tissue vault suspension (Sacrospinous ligament fixation and uterosacral suspension), vaginal repair with mesh augmentation, and abdominal sacrocolpopexy- both open and robotically.

12. I have performed over 2,000 synthetic slings since 1998, averaging about 100-150 slings per year. This includes retropubic, obturator and single incision sling approaches. I first began using the TVT in approximately 1998, and began using TVT-O in 2005. I have taught many residents and fellows. I have served as a preceptor for both Ethicon and Boston Scientific in cadaver labs, and as a preceptor in the Operating Room, teaching slings and vaginal mesh procedures to other physicians. In a typical week, I perform numerous incontinence and prolapse surgeries involving mesh and native tissue repairs, in addition to other surgeries. I have also performed revision surgeries following incontinence and prolapse surgeries. I currently perform synthetic slings, including retropubic, transobturator and single incision adjustable slings. Currently, our practice's sling revision rate for either exposure or incomplete bladder emptying is < 2%. I currently perform mesh augmented prolapse surgeries, including sacrocolpopexies as well as vaginal mesh repairs.

13. As part of my practice, I have tested and performed procedures using the SURx Transvaginal System, which I understand was put to market by the Assignee of both the Mosher and Ingle patents.

14. A copy of my curriculum vitae is being submitted herewith as Exhibit 2002, which provides further details about my background and experience, including details regarding my publications, professional awards, and prior testifying experience.

15. I am being compensated by InMode at my standard hourly rate for my work in this proceeding. My compensation is not tied in any way to the substance of my testimony or the outcome of this proceeding. I have no financial interest in the Patent Owner, the '511 Patent, or the outcome of this proceeding.

III. APPLICABLE LAW

16. I am not an attorney. I have been informed by counsel of the following applicable legal standard relating to claims of patent invalidity.

A. Priority

17. I understand that a patentee is entitled to claim the filing date of an earlier application (e.g., the “parent” application) if the later patent (the “child” patent) includes a priority claim to the parent application (e.g., is a continuation or continuation-in-part of the parent application or includes a priority claim to the parent application if the parent is a provisional application) and if the

corresponding disclosure in the parent application supports the later claimed subject matter.

18. I understand that whether a reference is eligible as prior art and whether a reference anticipates or renders obvious a patent claim are two separate questions. I understand that the status of a reference as prior art is a legal question based upon underlying fact issues.

B. Claim Construction

19. I understand that when construing patent claims (if necessary), the Board applies what is termed the “*Phillips* standard,” which requires construing claim language according to its ordinary and customary meaning in the art, consistent with the claims, patent specification and prosecution history.

20. I further understand that the ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. I have further been informed that the patentee may act as his/her own lexicographer through clear statements in the specification.

C. Obviousness

21. I understand that a patent may not issue “if 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 at the time the invention was made to a

person having ordinary skill in the art to which said subject matter pertains.” This has typically been referred to as the “obviousness” inquiry.

22. I understand that obviousness is a question of law based on underlying factual determinations, including: (1) the scope and content of prior art; (2) differences between prior art and claims; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness.

23. I understand that a party asserting that a patent is obvious must demonstrate that a skilled artisan would have had reason to modify the teaching of a prior art reference and/or combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so. This is often referred to as “motivation to combine.”

24. I understand that reasonable expectation of success is assessed as of the date of the invention described in the patent. That the inventors were ultimately successful is irrelevant to whether one of ordinary skill in the art, at the time the invention was made, would have reasonably expected success. I understand that the use of hindsight in the obviousness inquiry is prohibited.

25. I understand that the claimed invention must be considered as a whole in analyzing obviousness or nonobviousness. In determining the differences between the prior art and the claims, the question under the obviousness inquiry is

not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. I understand that it is an improper approach to the obviousness inquiry to try to distill the invention down to a “gist” or “core,” as this superficial mode of analysis disregards elements of the whole.

26. I understand that, as part of determining the scope and content of the prior art, it is appropriate to consider whether there is evidence of a “teaching, suggestion, or motivation” to combine the prior art teachings in the prior art, the nature of the problem or the knowledge of a person having ordinary skill in the art. The question is not simply whether the prior art teaches the particular element of the invention. Knowledge of the goal does not render its achievement obvious.

27. I understand that one indicator of non-obviousness is when prior art “teaches away” from combining certain known elements. A prior art reference teaches away from the patent’s particular combination if it leads in a different direction or discourages that combination, recommends steps that would not likely lead to the patent’s result, or otherwise indicates that a seemingly inoperative device would be produced. Likewise, the fact that elements work together in an “unexpected and fruitful manner” supports the conclusion that an invention is not obvious to those skilled in the art.

28. I understand that a patent claim that is composed of several elements is not made obvious merely because each of those elements was independently known in the prior art. Rather, the useful inquiry is whether there was a reason that would have prompted a person having ordinary skill in the art to combine the elements in the manner of the new invention. Thus, I understand that the challenger must show that at the time of the invention a person of ordinary skill in the art would have been motivated to combine the references, not just that the references could have been combined.

29. I understand that certain objective indicia, with a nexus to the invention claimed in the patent issue, can be important evidence regarding whether a patent is obvious or non-obvious. I understand such indicia include:

- Commercial success;
- Long-felt but unsolved needs in the art for the invention, particularly in the face of prior art later asserted to lead to a solution;
- Failure of others to achieve the results of the invention;
- Unexpected or surprising results;
- Unexpected properties of the claimed invention;
- Licenses showing industry respect for the invention;
- Skepticism of skilled artisans before the invention or accepted wisdom contrary to it;
- Copying of the invention by others in the field;
- Seemingly minor technological differences having practical impact in a crowded field;
- A previously unrecognized problem; and
- Industry acceptance or praise.

30. I understand such indicia are referred to as “objective indicia of nonobviousness” or “secondary considerations,” and that such indicia must be considered when present.

D. Enablement

31. I understand that a reference must necessarily enable the relied-upon portion of its own disclosure. In other words, I understand that a reference must teach a POSA to make or carry out, without undue experimentation, any disclosure relied on to prove obvious. I further understand that factors to consider when determining whether undue experimentation would be required include:

- The quality of experimentation necessary,
- The amount of direction or guidance presented,
- The presence or absence of working examples,
- The nature of the invention
- The state of the prior art
- The relative skill of those in the art
- The predictability or unpredictability of the art, and
- The breadth of the claims.

IV. PERSON OF ORDINARY SKILL IN THE ART

32. I understand that claim construction and patentability is generally analyzed from the perspective of a person of ordinary skill in the art at the time of the invention (“POSA”).

33. I understand that a POSA is a hypothetical person that is considered to have the normal skills and knowledge of a person in a certain technical field, as of the time of the invention at issue. I understand that factors that may be considered

in determining the level of ordinary skill in the art include: (1) the education level of the inventor; (2) the types of problems encountered in the art; (3) the prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the education level of active workers in the field.

34. The '511 Patent issued from U.S. Provisional Application No. 60/743,247 ("247 Provisional"), filed February 7, 2006.

35. I understand that in his declaration, Dr. Berenholz applied the following definition of a POSA:

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

EX1003, ¶ 58.

36. While I had at least the qualifications of a POSA under the above definition at all relevant times including the February 7, 2006, filing date of the '247 Provisional, I believe this standard is over-credentialed. As of February 2006, there were not many individuals that would fit under this definition. Indeed, similar to Dr. Berenholz, I was only aware of a handful of doctors practicing in the field of

cosmetic gynecology in 2006. EX2005, 55:5-17. Further, I agree with Dr. Berenholz that “any board-certified physician, urogynecologist, gynecologist, or obstetrician would have had a general understanding or ordinary skill related to the technology of the ’511 patent.” *Id.*, 57:17-58:19.

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

one of ordinary skill in the art a medical degree plus at least two years of experience in a field such as gynecology, urogynecology, or plastic surgery involving female genital anatomy, with clinical experience in the application of radiant energy to female genital tissue.

EX1009, 8-9.

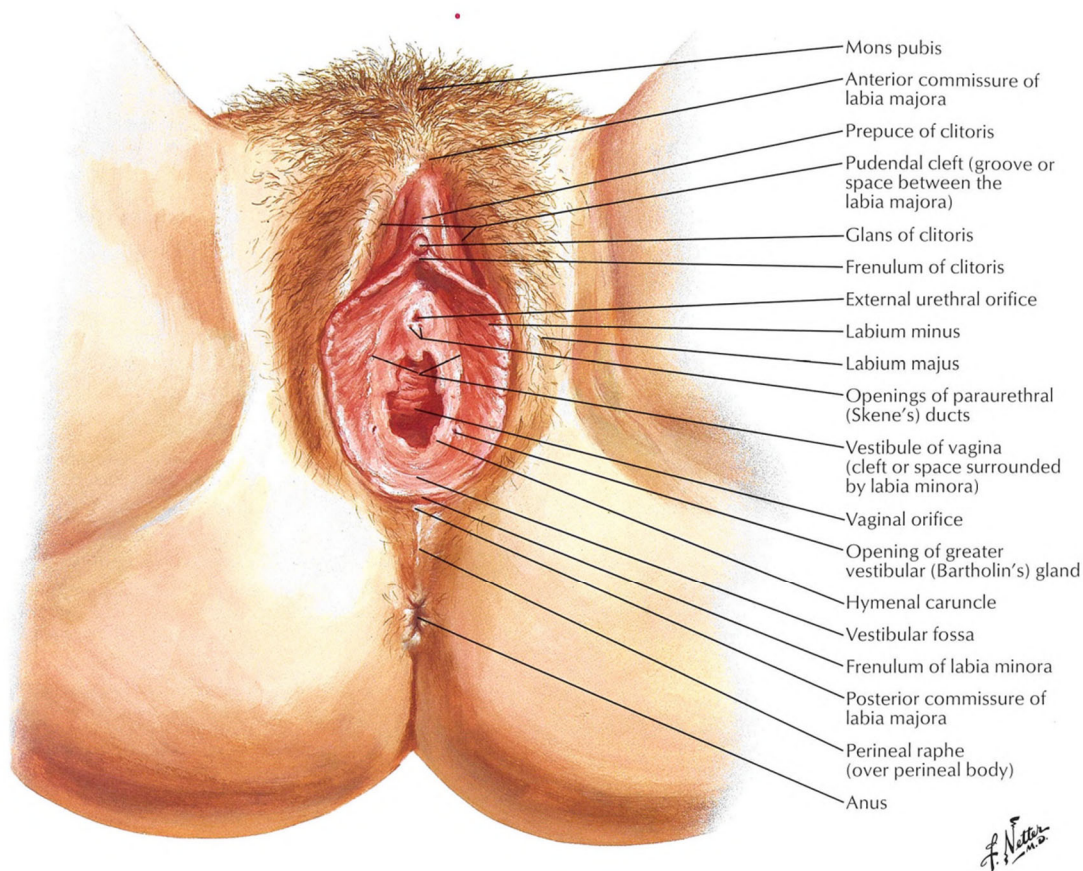
38. I had at least the qualifications of a POSA under the above definition at all relevant times including the February 7, 2006, filing date of the ’247 Provisional.

39. For purposes of this proceeding only, I have applied both definitions of a POSA when analyzing the materials discussed herein. And my opinions in this declaration are the same under both definitions of a POSA (i.e., BTL’s proposed definition and the ThermiGen IPR definition) and are unchanged by the definition ultimately adopted by the panel.

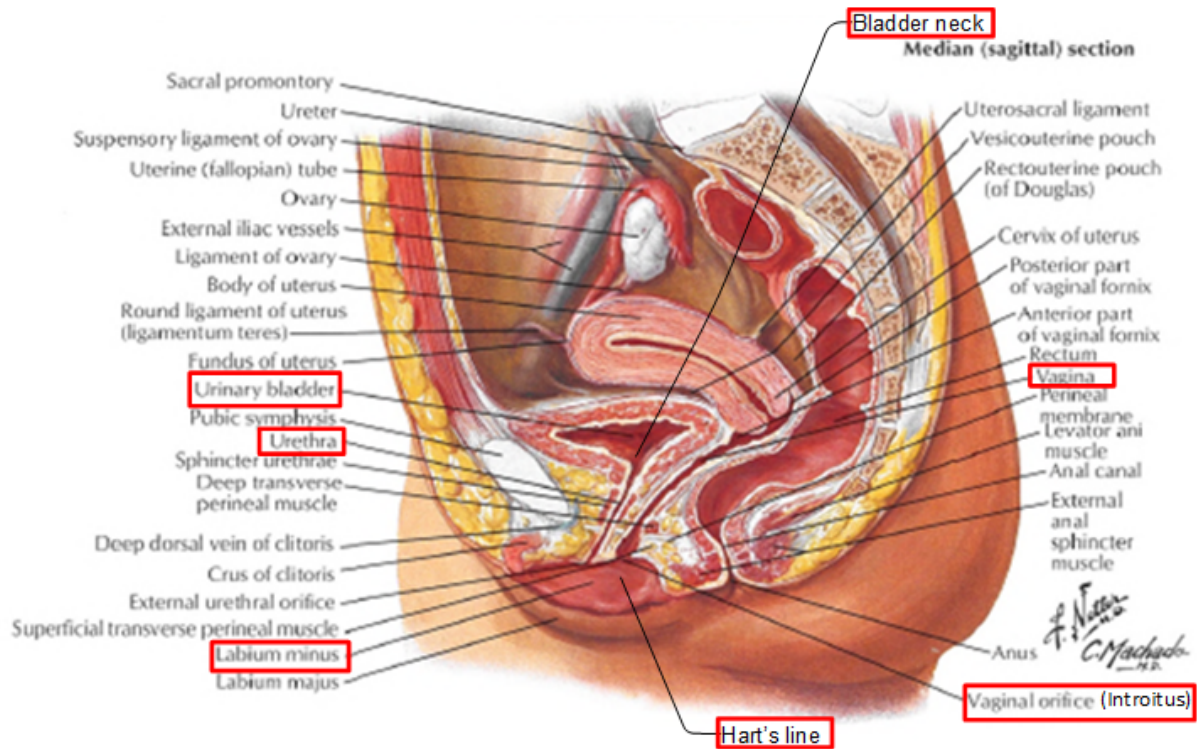
V. TECHNICAL BACKGROUND OF THE '511 PATENT

A. Anatomy of The Female Genitourinary System

40. At its most basic, the female genitourinary system includes the female genitals, the reproductive system, and the urinary system. The reproductive system includes the vulva, the vagina, and the uterus, among other organs. The urinary system includes, the urethra and the bladder, among other organs. These organs are located within the female pelvis. The organs can generally be seen in the below figures:

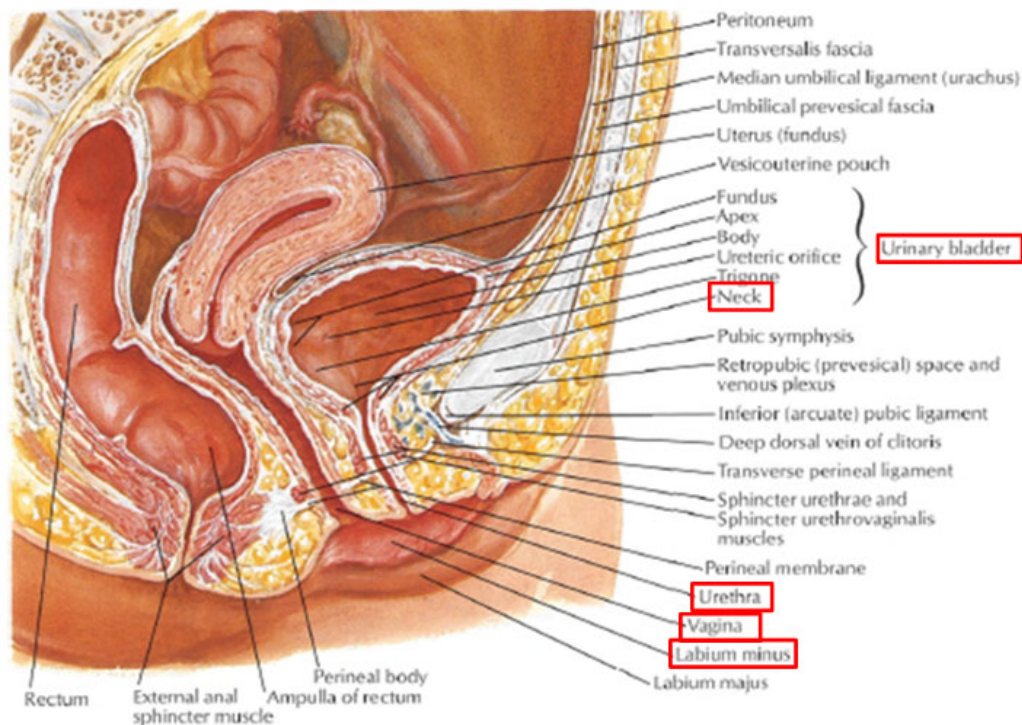


EX1015, Plate 377.



EX1015, Plate 360 (annotated).

Female: midsagittal section



EX1015, Plate 365 (annotated).

41. Starting with the female reproductive system, the vulva is the external female genitalia. The external female genitalia consists of the labia majora, labia minora, vaginal orifice (or introitus), urethral orifice, and clitoris. The vulva also includes the vulva vestibule, which is a surface of the vulva that begins superiorly just below the clitoris and ends inferiorly at the posterior commissure of the labia minora, with its borders formed from the edge of the labia minora. This border, or outer edge of the vestibule, is also known as Hart's line. Within the vulva vestibule is the introitus and the urethral orifice. The introitus is the entrance to the vagina (or the distal most portion of the vagina). Immediately within the introitus is the vaginal canal, which is around 9 cm on average. *See* EX2009. In other words, the introitus is around 9 cm on average from the distal end of the vaginal canal. The tissue lining the vaginal canal is generally known as the vaginal wall. When stretched, the vaginal canal becomes tube-like, but the circumferential wall is still described as having an anterior wall, posterior wall, and two lateral walls.

42. Turning next to the urinary system, as described above, within the vulva vestibule, and adjacent to the introitus is the urethral orifice. Immediately within the urethral orifice is the urethra, which is about 4 cm in length on average. EX2003, 2072 ("about 4 cm long passing from the bladder . . . opening in the vestibule of the vagina."); EX2004, 1672. On the other, proximal, end of the urethra is the bladder. Acting as a valve that controls the flow of urine from the

bladder into the urethra is the bladder neck. The bladder neck is a group of muscles opening at the base of the bladder where it connects to the urethra. The bladder neck holds urine in place and controls release of urine from the bladder. The bladder neck extends for roughly 1-1.5 cm. The urethra runs roughly in the same sagittal plane as the vagina, but diverges from the vagina in a curving manner.

EX2003, 2072; EX2004, 1672.

B. '511 Patent Background and Disclosure

43. The '511 patent claims recite methods of remodeling tissue immediately underlying a surface layer of female genital tissue, by heating specific areas of tissue around the vulva, the vagina, and the introitus (the opening of the vagina), to a therapeutic temperature. EX1001, claims 1, 35, 43, and 51. In most of the claims of the '511 patent, the claimed treatment locations are close to or outside the introitus (or opening of the vagina). The '511 patent's methods restore vaginal tissue, which often becomes stretched during childbirth and stretches increasingly over time (and also occurs in women who have not delivered a child), resulting in decreased sexual pleasure. EX1001, 2:4-9. Prior to the '511 patent, doctors relied on invasive techniques, such as surgery, to treat these conditions, but these approaches often caused scarring, resulted in damage, and required prolonged recovery. EX1001, 2:9-12. The inventive techniques claimed in the '511 patent overcame the problems of the prior art by providing a non-invasive

procedure for restorative treatment and remodeling of certain female genital tissue that did not require surgical incisions, that did not require surgical incisions, did not cause thermal damage to the epithelium, and did not result in patient down time.

44. The '511 patent uses a treatment tip to make optimal contact with the genital epithelial surface for delivery of radiofrequency (RF) energy. EX1001, 2:53-55. The target tissues of the embodiments of the '511 patent are the tissues that lie immediately beneath the mucosal epithelium of genital tissues, the lamina propria and muscularis. EX1001, 3:41-45. RF energy heats and denatures collagen located in the collagen-rich lamina propria, resulting in a contraction of the collagen spaces thereby creating a tightening effect. See EX1001, 1:19-20, 35-39. The '511 patent explicitly states that its embodiments exclude deeper tissue, such as endopelvic fascia. EX1001, 3:47-48.

45. Some invasive surgical techniques, including those using lasers, ablative RF, and scalpels, were used to treat conditions in the female genital region prior to the invention of the '511 patent; however, there were adverse effects. For example, these procedures would ablate and destroy the epithelium, often required significant recovery time, requiring time off work, bleeding, scarring, and increased pain.

46. Unlike the prior invasive surgical techniques, the claimed treatment of the '511 patent uses heating without ablation to remodel the female genitalia. Applying such treatments to the anatomical areas at issue in the present claims was not known prior to the '511 patent.

C. Prosecution History of the '511 Patent

47. I understand that during prosecution of the application eventually granting as the '511 patent, the claims were rejected in view of U.S. Patent No. 6,350,276 to Knowlton et al. ("Knowlton"). EX1002, 82. However, the prosecution history explains that Knowlton's treatments specifically related to "modifying skin surfaces and underlying tissue" including the cervix (among other parts of the body) rather than the claimed female genital tissue. EX1013, 1:16-29, 6:49-57, 13:35-37.

48. The independent claims were amended to specify heating of specific areas of female genital tissue, including introitus (claims 1 and 43), vagina (claim 35), and vulva (claim 51). EX1002, 234-244. In the Notice of Allowance, the Examiner explained "Knowlton fails to contemplate the specific areas of treatment set forth in independent claims [1, 35, 42, and 51]. No other reference has been found which discloses, fairly suggests, or makes obvious this area of treatment whether taken alone or in combination with the Knowlton reference." EX1002, 317.

49. I understand that in 2017, a prior petitioner, ThermiGen, LLC, filed two petitions for Inter Partes Review against the '511 Patent. IPR2018-00088; IPR2018-00089 (the “ThermiGen IPRs”). These petitions asserted grounds based on Edwards, Mosher, and Ingle, and the Ollivier reference. EX1009, 6; EX1012, 59-60.

D. State of the Field

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

51. Subsequent to 2006, the industry acknowledged the benefits of the low temperature, non-ablative treatment of vaginal tissue described in the '511 patent. For example, in a 2015 article entitled “Temperature Controlled Radiofrequency for Vulvovaginal Laxity,” which reports on a clinical study funded by ThermiAesthetics, Dr. Alinsod states that vulvovaginal rejuvenation using RF energy “is a fairly new concept with real potential for success.” EX1025, 18. That article highlights the importance of features of the claims of the '511 patent,

including treatment starting at the introitus and extending inward (EX1025, 16 (left column), 19 (right column)), treatment of the using treatment temperatures below 80° C (EX1025, 18 (right column)), and avoiding damage to the epithelium (EX1025, 20 (left column)). The article explains that the results of the study showed that the treatment resulted in “pronounced improvement,” measured on two different pre-existing measurement scales. *Id.*, 20 (“Results” section). As discussed in more detail below, the article describes as “landmark” the prior study of the Viveve treatment, which I understand is the original owner of the ’511 patent.

52. Notably, these praised treatment aspects are missing from the prior art discussed below.

E. Claims of the ’511 Patent

53. The ’511 Patent contains 58 total claims. Claims 1, 35, 43, and 51 are independent claims, where claims 2 through 34 depend from claim 1, claims 36 through 42 depend from claim 35, claims 44 through 50 depend from claim 43, and claims 52 through 58 depend from claim 51. Independent claims 1, 35, 43, and 51 are reproduced below:

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

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus.

35. A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock.

43. A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes heating a portion radiating outward from the introitus to Hart's line.

51. A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:

heating the target tissue, and

remodeling the therapeutic zone of target tissue,
wherein the heating includes heating a mucosa! surface
of the labia minora.

EX1001, claims 1, 35, 43, and 51.

VI. CLAIM CONSTRUCTION

54. I understand that in his declaration, Dr. Berenholz states that it is his opinion that no claim term requires construction but acknowledges that certain claim terms of the '511 Patent were construed in previous proceedings such as the *Viveve v. ThermiGen* district court litigation (“*Viveve* litigation”) and the ThermiGen IPR. A POSA would understand that the constructions from the ThermiGen IPR are proper constructions. Therefore, it is my opinion that the constructions from the ThermiGen IPR should be adopted as modified below.

A. “target tissue”

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

[o]n the present record, we agree with Patent Owner that the passages identified in the Specification comprise a “clear and unmistakable” disclaimer of the scope of target tissue. *See Thorner v. Sony Computer*

Entm't Am. LLC, 669 F.3d 1362, 1366–67 (Fed. Cir. 2012). We also note that there is no evidence in the record that the term “target tissue” has an ordinary and customary meaning in the art to which the ’511 patent pertains that encompasses the endopelvic fascia.

EX1009, 11.

56. A POSA would understand that this is the proper construction.

Therefore, in my opinion the panel should adopt ThermiGen IPR panel construction of “target tissue” in full.

57. The specification explicitly defines the term target tissue: “The target tissue lies immediately beneath the mucosal epithelium of genital tissues, and includes the lamina propria, a connective tissue that includes collagen in the extracellular space, and the muscularis, which includes smooth muscle. The target zone of embodiments of the invention ***does not include deeper tissue, such as endopelvic fascia.***” EX1001, 3:43-48 (emphasis added).

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

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

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

EX1001, 12:2-16.

59. I understand that when the specification describes the features of the “present invention” as a whole, this description limits the scope of the invention. The specification makes clear that the “described target tissue layers” include the tissues adjacent the mucosal epithelium, such as the lamina propria and that the deeper tissues including the endopelvic fascia are not target tissues. I further understand that where, as here, the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent.

60. In my opinion, Petitioner’s proposed claim construction for this term improperly encompasses the deeper tissues underlying the epithelial mucosal surface, such as the endopelvic fascia, which is outside the scope of the ’511 patent’s “present invention.”

B. “remodeling”

61. In my opinion, panel should also adopt the ThermiGen IPR construction of “remodeling the therapeutic zone of target tissue” defined as “the result of raising the temperature of target tissue to no more than about 80 degrees C without substantially affecting the epithelium overlying the target tissue, wherein that result includes a tightening or contraction of the target tissue.” EX1009, 14-16;

EX1011, 14-15. The '511 patent states a requirement for avoiding surface damage. EX1001, 12:17-21.

62. I understand that in the ThermiGen IPR, the panel found that the “[s]pecification makes clear . . . that ‘remodeling of the connective tissue underlying the mucosal epithelial surfaces does not substantially affect the epithelium itself. The method and apparatus, as provided by embodiments of the invention are non-invasive and substantially non[-]ablative of genital tissue.’” EX1009, 15 (citing EX1001, 12:17–21). In my opinion, this construction is supported by the intrinsic record. In my opinion, the '511 patent is clear that the claimed method is performed without “damaging” or “substantially affecting the epithelium overlying the target tissue.” The abstract indicates that “[t]his invention relates generally to apparatus and methods for tightening tissue of the female genitalia by heating targeted connective tissue with radiant energy, while cooling the mucosal epithelial surface over the target tissue to protect it from the heat.” EX1001, Abstract. The specification further explains that “[t]he method and apparatus, as provided by embodiments of the invention are non-invasive and substantially non ablative of genital [t]issue.” EX1001, 12:19-21, 13:19-23 (“[t]he epithelial surface is [] a conduit for energy passing through to underlying layers, but the energy does not manifest in the form of increased temperature at the

epithelial surface. As such, the epithelium itself is not damaged or substantially modified by the method.”).

63. I understand that this panel’s Institution Decision “for simplicity” provisionally adopts the *Viveve* court construction. Institution Decision, 14. However, a POSA would not find that construction consistent with the plain and ordinary meaning of the term as used in the ’511 patent.

64. A POSA would understand that the *Viveve* court’s “remodeling” construction does not capture the non-ablative aspect (“without substantially affecting the epithelium overlying the target tissue”) of the claimed invention. Notably, both the *Viveve* court and the panel in the ThermiGen IPR acknowledged. Specifically, the *Viveve* court agreed that the invention requires this understanding, but incorporated the understanding into its “heating” construction. EX1024, 11-12. For its “heating” construction, the *Viveve* court found that “the intrinsic evidence indicates that a critical aspect of the invention is the manner in which the target tissue is heated. Specifically, the intrinsic evidence indicates that maintaining the epithelium at a temperature lower than the underlying tissue is important *to ensure that the epithelium is not damaged or substantially modified by the method.*” EX1024, 10-11. A POSA would understand that to ensure that the claims properly reflect that meaning of the term as used in the ’511 patent, the “remodeling” term should be understood to mean “without substantially affecting the epithelium

overlying the target tissue,” as adopted by the panel in the ThermiGen IPR. EX1009, 14-16; EX1011, 14-15.

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

C. “heating”

66. I understand that the panel’s Institution Decision adopts the definition of “heating” in the ThermiGen IPRs, which construed “heating” as “raising the temperature of target tissue to no more than about 80 degrees C.” EX1009, 14. In my opinion, this construction would be proper to the extent that the panel also adopts the ThermiGen IPR construction for the “remodeling” term.

67. However, should the panel adopt the *Viveve* court construction of “remodeling,” it is my opinion that the heating term should be construed as “raising the temperature of target tissue to no more than about 80 degrees C without substantially affecting the epithelium overlying the target tissue,” so as to include the patent’s requirement for avoiding surface damage. EX1001, Abstract; 2:56-62; 8:8-15; 12:17-21.

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

68. Independent claim 35 recites “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock,” and in my opinion, this term should be construed as “heating multiple, contiguous contact sites in the 300 degree arc extending from 1 o’clock to 11 o’clock along the vaginal wall.” EX1009, 18. I understand that the panel in the ThermiGen IPRs preliminarily construed the term as “heating *at least one contact site* in the 300 degree arc extending from 1 o’clock to 11 o’clock along the vaginal wall.” EX1009, 18 (emphasis added). The ThermiGen IPR construction reads the “circumferentially” term out of the claim. EX1009, 16-18.

69. I understand that the ThermiGen IPR panel acknowledged the importance of the “circumferentially” language noting that the plain language of the claim “requires heating . . . over a defined arc, and thus excludes the ‘at least one point’” language that was proposed by ThermiGen. EX1009, 17. I also understand that the ThermiGen panel noted that a “contact site” extends around the curvature of the vaginal wall accounting for “accounting for about 10% of the 300 degree arc.” EX1009, 17 (citing EX1001, 14:35-45. But the intrinsic record and anatomy of the vagina demonstrate that a contact site as used in the ThermiGen IPR construction is equivalent to a point of the vaginal wall.

70. The Specification states the circumference of the vagina “is approximately 12 cm.” EX1001, 14:35-37. Therefore, a contact site, which covers 10% of the 300 degree arc in the vagina, would be roughly 1 cm. And the specification also states that an exemplary treatment tip is “about 1 cm in width.” EX1001, 14:37-40. Given that the treatment tip is 1 cm and the contact site is the same width, heating “at least one contact site” is equivalent to heating “at least one point.”

71. Further, when considering a treatment such as those of the ’511 patent, a POSA would treat the target area roughly uniform over the entire treatment area. A POSA would understand that you would not treat discrete contact sites of the vaginal wall to create the tightening effect of the ’511 patent. Rather, a POSA would further understand that to achieve this roughly uniform treatment, one would need to treat several sequential contact sites over substantially all of the treatment area. I agree with Dr. Berenholz that a POSA would “want [the contact points] to be as close to contiguous as possible.” EX2005, 117:9-118:1. The exact number of contact sites would depend on the size of the intensity of RF energy used, but a POSA evaluating the specification and claim language would understand that a circumferential treatment includes at least six contact sites, with

at least one contact site on each wall of the vagina.¹ Indeed, by analogy to the elastic band on, for example, a pair of sweatpants. If one were to make the elastic tighter on just one or two non-contiguous locations (e.g., sites) around the elastic waistline, no circumferential tightening of the waste band would occur. Rather, to achieve circumferential tightening, you would need tighten (shrink) roughly six or more locations (every 60 degrees) around the elastic waistline.

72. This understanding is further supported by the known issues with many invasive surgical treatments. Surgical treatments in and before 2006 frequently only tightened the anterior wall (from around 11 o'clock to 1 o'clock) and the posterior wall (from around 5 o'clock to 7 o'clock) but not the lateral walls. Only treating the anterior and posterior walls, but not the lateral walls, can create "gaping" on the sides, which would lead to undesirable issues with sexual function. Therefore, a POSA would understand that you want the heating to be roughly uniform over the vaginal wall from 1 o'clock to 11 o'clock.

¹ As will be discussed further later, Petitioner's and Dr. Berenholz's assertion that a POSA would understand that there are only two walls of the vagina, the anterior wall (from 9 o'clock to 3 o'clock, passing through 12 o'clock) and the posterior wall (from 3 o'clock to 9 o'clock, passing through 6 o'clock) is simply incorrect. Petition, 37; Ex. 1003, 129. As Dr. Berenholz seemed to admit in his deposition, a POSA would understand that the vaginal canal comprises four walls, the anterior wall, posterior wall, and two lateral walls. EX2005, 118:21-22 ("lateral walls and anterior walls don't go together.")

73. As a result, it is my opinion that to properly capture the “circumferentially” language, the claim term should be defined as “heating multiple contiguous contact sites in the 300 degree arc.”

VII. THE GROUNDS ADVANCED AGAINST THE ’511 PATENT

74. I address below the grounds set forth in the Petition and discussed in Dr. Berenholz’s declaration. *See* Petition, 22-67 (Ground 1), 67-68 (Ground 2); EX1003, ¶¶83-270 (Ground 1), ¶¶271-277 (Ground 2). I note that the ’511 Patent includes four independent claims: claim 1, claim 35, claim 43, and claim 51.

75. I present below exemplary reasons demonstrating why Dr. Berenholz (and Petitioner) fail to demonstrate any of the challenged claims are unpatentable. In doing so, I do not represent or concede that any of the unaddressed claims or limitations are necessarily present or obvious—rather, it is my opinion that for at least the reasons set forth below, Dr. Berenholz (and Petitioner) fails to demonstrate any of the challenged claims are unpatentable, and therefore any remaining claims or limitations need not also be addressed.

A. Ground 1: The Combination of Edwards, Mosher, and Ingle Does not Render Obvious the Claims of the ’511 Patent

76. Dr. Berenholz opines that Edwards, Ingle, and Mosher render obvious claims each of the claims of the ’511 Patent. EX1003, ¶83. I disagree. Not only has Dr. Berenholz (and Petitioner) failed to demonstrate that Edwards, Ingle, and Mosher render obvious the “remodeling” element and the required treatment areas

recited in independent claims 1, 35, 43, and 51, but Dr. Berenholz (and Petitioner) has also failed to demonstrate that the references are properly combinable.

1. Overview of the Alleged Prior Art

a. Overview of Edwards

77. Edwards describes systems and methods for treating menorrhagia and female urinary incontinence. EX1005, Abstract, 1:24-51. The purported “advantage[]” of the Edwards treatments is they “require only local or regional anesthesia.” EX1005, 2:22-27. In contrast to the non-ablative treatment described in the ‘511 patent, Edwards explains that in the various embodiments the RF energy causes ablative lesions which causes the affected area to shrink and be relatively strengthened. *See*, EX1005, 13:14-16 (“to create a series of lesions”), 9:66-10:7 (“repeat ... so as to selectively ablate other areas”), 11:28-33 (“so as to create more areas of ablation lesions”), 12:47-55 (“more areas of ablation lesions”), 12:66-67.

78. A POSA would understand that ablation is the “removal of a part, pathway, or function by surgery, chemical destruction, electrocautery, or radiofrequency.” EX2008, 6. And radiofrequency ablation is defined as “ablation in which an electrode delivers a low-voltage, high-frequency current to cauterize and destroy abnormal tissues.” EX2008, 6; *see also* EX1006, ¶[0046] (“the term

‘ablation’ of a tissue means that the tissue is substantially removed and/or the function of the tissue is substantially destroyed.”).

79. Edwards describes four embodiments of ablative treatment. The first, second and third embodiments are directed to inserting needle electrodes into (i) the uterus for intrauterine ablation “to coagulate the entire endometrium and upper layers of the myometrium” (EX1005, 2:40-47, 4:15-31, 9:4-7, 9:30-32, 9:66-67, 10:1-2), (ii) the urethra to create ablative lesions within the urethral sphincter muscle for the treatment of urinary incontinence (*id.*, 2:48-58, 5:8-9, 10:15-19, 11:30-31), and (iii) the bladder to create ablative lesions to treat urinary incontinence (*id.*, 2:59-4, 11:45-53, 12:11-18, 12:38-40, 12:47-55). The fourth embodiment inserts a speculum that mounts an electrode device thereon to create ablative lesions in the anterior and posterior vaginal wall to treat urinary incontinence. EX1005, 2:5-13, 13:43-46.

80. Dr. Berenholz (and Petitioner) relies almost exclusively on Edwards’ fourth embodiment. *See, e.g.*, EX1003, ¶¶64-69, 120-123. Edwards explains that “[t]he difference between this embodiment and the other embodiments is that the RF energy is delivered to the anterior and posterior regions of the vaginal wall.” EX1005, 3:6-9. Although Edwards mentions in passing that treating both the anterior wall and posterior wall may provide physical and psychological improvement in the area of sexual function (EX1005, 3:11-13) Edwards provides

no disclosure regarding the specific anatomic tissue structures to heat to provide the result of reducing vaginal circumference or improving sexual function. A POSA would also understand that Edwards does not suggest adjusting the location of its ablative treatment further distally (toward the introitus) than the mid vaginal canal (about 4.5 centimeters from the introitus).

81. In contrast to the '511 patent, Edwards describes ablative treatments for menorrhagia and urinary incontinence. Because, as noted above, Edwards explains that the only difference between the fourth embodiment and the other three ablative embodiments is that RF is instead delivered to the vaginal wall, EX1005, 3:6-7, a POSA would understand that the treatment of the fourth embodiment would also cause ablation on the surface of the vaginal wall.

b. Overview of Mosher

82. Mosher describes systems and methods to treat incontinence by “heating between about 100 and about 800 cubic millimeters of endopelvic fascia for sufficient time to effect substantial collagenous tissue shrinkage.” Mosher at Abstract. Mosher describes that “a probe body may directly engage the endopelvic fascia, such as by introducing an endoscopic probe into the body adjacent the endopelvic fascia, or by surgically displacing a flap from the vaginal wall.” EX1006, ¶[0009]. Mosher further explains that “[d]irect probe 42 will may optionally be used in a laparoscope procedure using a superior approach, typically

under the direction of a laparoscope 50 inserted near the patient's mid-line (for example, adjacent the belly button) . . . Alternative surgical methods for use of related probes may access the endopelvic fascia using an inferior approach, preferably with a small transvaginal incision as illustrated in FIG. 2.” EX1006, ¶ [0057].

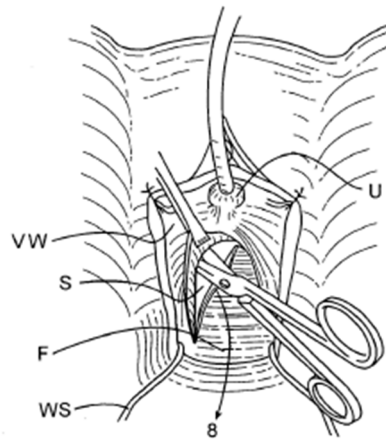


FIG. 2

83. Mosher also describes a number of tissue-penetrating electrode tips for treating the bladder and bladder neck. EX1006, ¶[0055] (“penetration of electrode tips 24”); Fig. 4C.

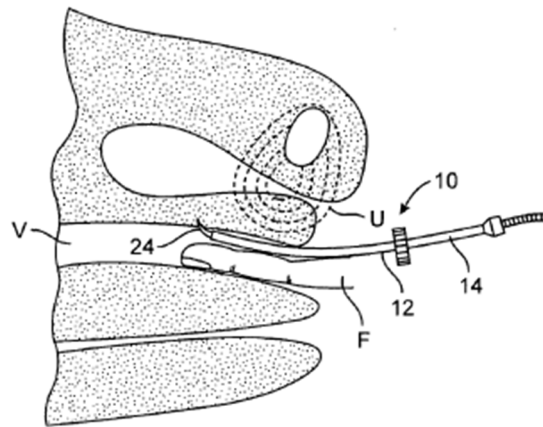


FIG. 4C

84. The above-described embodiments (i.e., “direct access” embodiments) differ from the ’511 patent and Edwards in that they are invasive—they require a surgical technique, such as laparoscope inserted near the patient’s umbilical region or surgically cut flap in the vaginal wall—to access the surface of the endopelvic fascia. EX1006, ¶ [0056]-[0057], FIG. 2. These procedures would require anesthetic including at a minimum local anesthetic and in most cases some form of sedation. In several embodiments, Mosher teaches surgically opening the tissue planes with incisions through the perineal skin or surgical incisions into the vagina. EX1006, Figs. 2, 5A. Opening the tissue planes allows for entry of an energy delivery application to access the endopelvic fascia directly. Mosher also describes several embodiments using various tissue-penetrating electrodes, for example needle electrodes having various shapes and diameters that can penetrate tissue to a depth of 8 mm. The tissue-penetrating electrodes, similar to opening of the tissue planes, provides direct access to the deeper tissues such as the endopelvic fascia.

These embodiments would be considered invasive or minimally invasive. The described methods are also different in that they focus on treatment of the deeper tissues, such as endopelvic fascia.

85. Mosher further describes a non-invasive embodiment in which heating may be provided through (for example) the vaginal wall. EX1006, ¶ [0009].

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

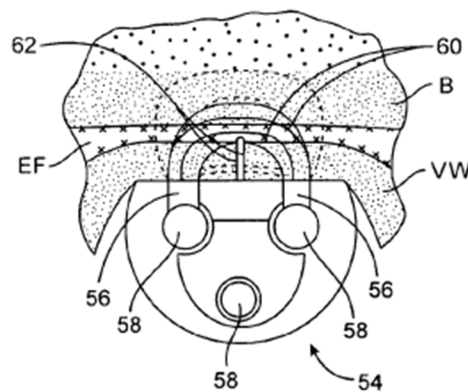


FIG. 6

EX1006, FIG. 6.

86. While being directed to treating stress urinary incontinence through therapy directed at the bladder neck, Mosher provides a laundry list of tissues that Mosher purports may be the target of treatment using Mosher’s described system

and method. EX1006, ¶[0048]. However, that laundry list would not guide a POSA. Indeed, the list includes anatomic structures such as puboprostatic ligaments and posterior puboprostatic ligaments, which are male anatomic structures not found in female anatomy. EX1006, ¶[0048]. Thus, a POSA would not see this list as credible or instructive. Also, Mosher does not provide any detail as to how its techniques would be adapted—if at all—to treat any of these other tissues. Therefore, a POSA would understand that Mosher’s laundry list recitation of anatomy as not encompassing the possible treatment areas for female urinary stress incontinence. In fact, while Mosher catalogs a laundry list of various pelvic connective tissue, fascia and ligamentous structures, he provides no coherent teaching of which structures in combination would provide an intact sling or support spanning across the pelvis to replace the support lost as a result of damage to the endopelvic fascia from whatever cause. A POSA would not know which structures need be targeted in combination to obtain such support. All of the specific embodiments presented by Mosher relate to exposure of endopelvic fascia and not these other structures.

c. Overview of Ingle

87. Ingle describes systems and methods for treating fascia for treating incontinence. EX1007, 2:51-53, 2:59-60. Specifically, Ingle aims to heat the endopelvic fascia so that “the endopelvic fascia EF and arcus tendineus fascia

pelvis ATPF are controllably contracted to shrink them and re-elevate the bladder toward its original position.” EX1007, 17:30-34; *see also* 17:50-59.

88. Ingle describes embodiments in which “a first electrode having a first electrode surface which is engageable against the tissue. A second electrode has a second electrode surface which can be aligned substantially parallel to the first electrode surface, with the tissue positioned therebetween.” EX1007, 4:33-37.

Ingle explains that “the electrodes will generally be mechanically coupled to each other, ideally using a clamp structure which allows the target tissue to be compressed between the electrode surfaces. Compressing the tissues can enhance the uniformity of the heating, particularly when the tissue is compressed between the electrode surfaces so that the surfaces are separated by less than their widths.” EX107, 7:54-61; *see also* EX107, 8:24-27 (“[t]he method comprises clamping a target tissue between a plurality of electrode surfaces...”).

89. While Ingle generically describes several tissue structures that may be responsible in some manner for control of urination, Ingle’s embodiments are drawn to treatment of the endopelvic fascia adjacent the bladder wall. *See, e.g.*, EX1007, Figs. 6, 11, 12, 12K, and 13. In particular, Ingle describes that “one electrode structure may be disposed within a large body cavity such as the rectum or vagina, while the other is placed in an adjacent cavity, or on the skin so that the region to be treated is between the electrode surfaces.” EX1007, 14:63-67. For

example, as shown in Figure 6, “the endopelvic fascia will preferably be disposed between the electrodes of the urethral probe 44 and the vaginal probe 42.” *Id.* , 18:46-50, 29:66-67, 30:1-2.

90. A POSA would understand that Ingle’s embodiments differ from the ‘511 patent and the other references in that they require a parallel electrode on the opposite side of the vaginal wall, inserted into another orifice or on the abdomen. This configuration limits the regions of the vaginal wall available for treatment.

2. Independent Claims

a. Claim 1: The Combination of Edwards, Ingle, and Mosher does not render obvious “wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus”

91. While Ground 1 relies on to combination of Edwards, Ingle, and Mosher to allegedly render claim 1 obvious, the Petition relies only on Edwards and Mosher for this particular element of claim 1. Pet., 35-36. Dr. Berenholz (along with Petitioner) essentially argues that because Edwards and Mosher teach treating *a* portion of the vagina, they must teach treating *the* portion of the vagina most distal to the introitus. EX1003, ¶¶120-25. I disagree. Not only do Edwards and Mosher not teach treating the portion of the vagina most distal to the introitus, but both references specifically target the opposite end of the vagina and the device in Edwards is unable to treat the introitus. EX2005, 126:2-23. Therefore, in my

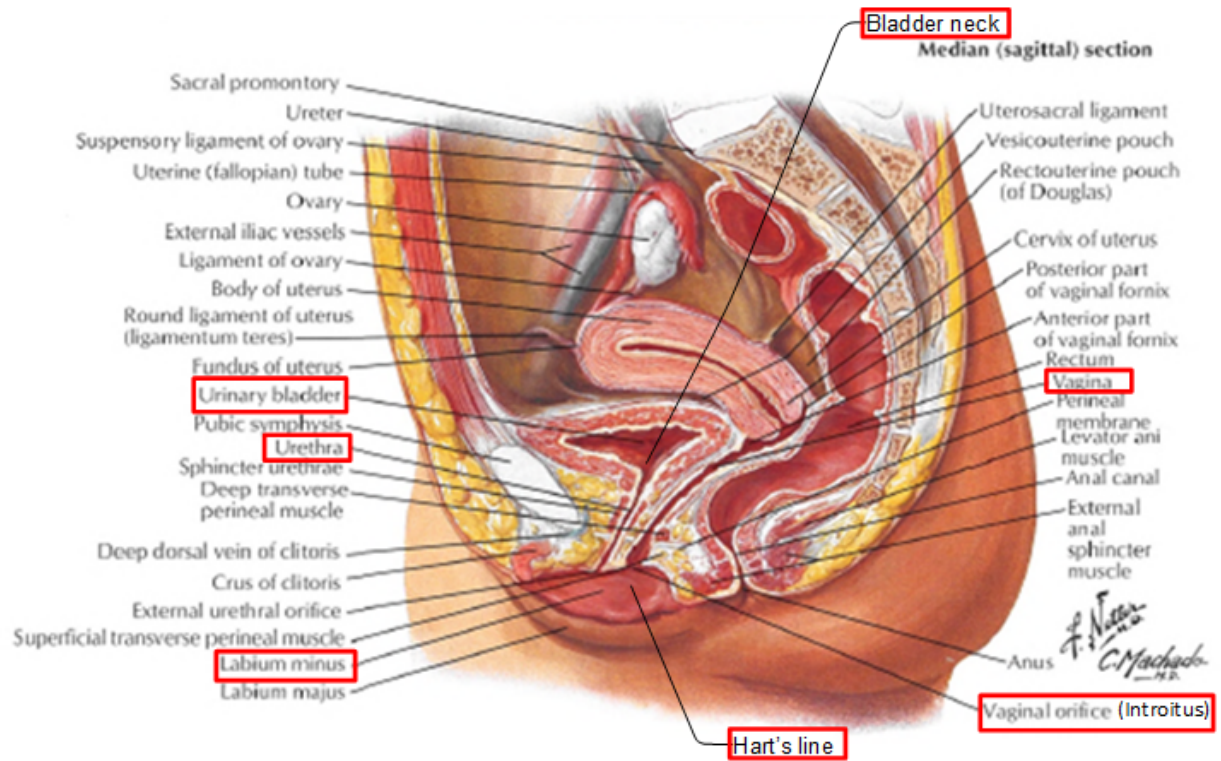
opinion, the combination of Edwards, Mosher, and Ingle does not teach treating the portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus.

92. As an initial matter, Dr. Berenholz’s (and Petitioner’s) arguments seem to be based on a misunderstanding of the claim language. Dr. Berenholz (and Petitioner) states that “A POSA would have understood this treatment area includes heating a portion of the vagina starting 1 cm from the opening and extending a further 2.5 cm back towards the cervix (i.e., 3.5 cm from the introitus).” EX1003, 120; Petition, 35. I disagree—this reading of the claim language is flawed. A POSA would understand that the plain reading of this limitation requires the treating of at least the introitus and the first 1 cm of the vaginal (up to 3.5 cm in from the introitus).

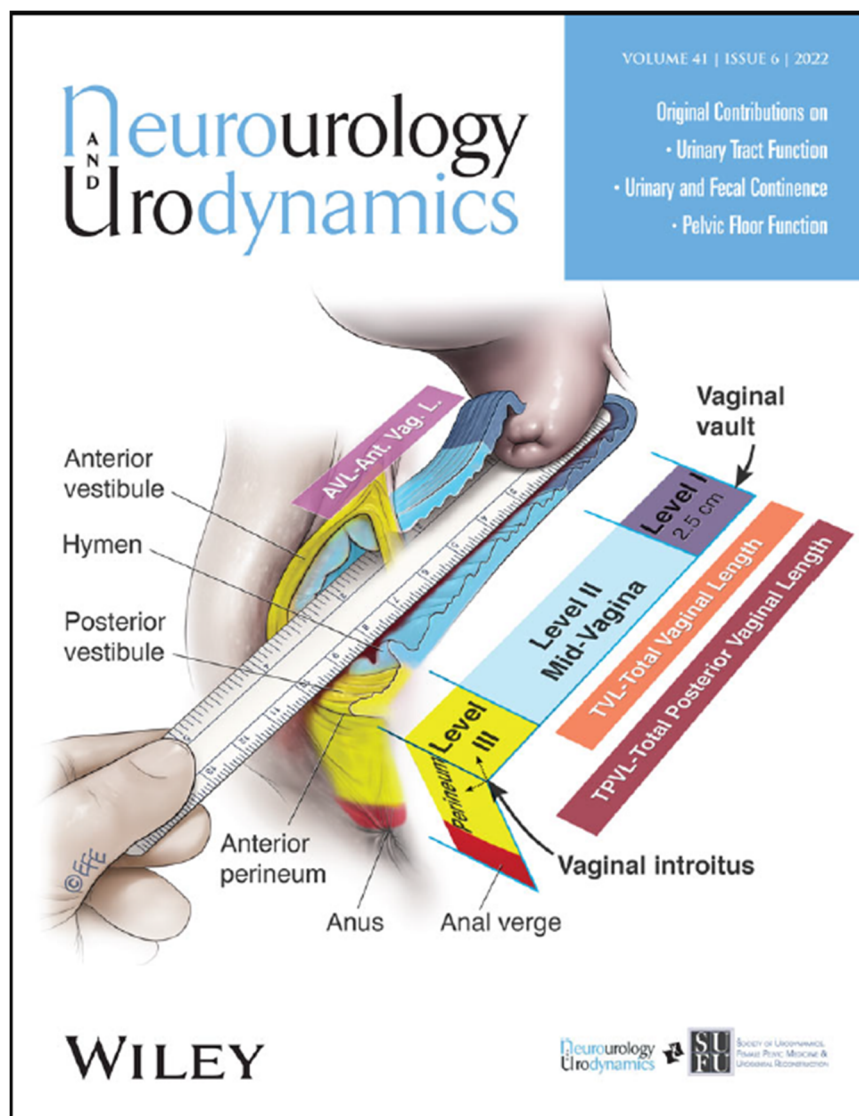
93. As explained above, the introitus is the external opening of the vagina at the distal end. *Supra* Section V.A. A POSA would understand that the primary structures targeted to treat SUI, as in Edwards and Mosher, are the bladder neck and supportive tissues, which are located at the proximal end of the urethra. *Supra* Section V.A; EX1005, 2:1-5 (“bladder[]neck”); EX1006, [0006], [0046]. Dr. Berenholz appears to agree by stating that expert agreed Edwards and Mosher address stress urinary incontinence by “strengthening the tissues surrounding . . . [the bladder] neck.” EX2005, 126:2-23. When treating a patient for SUI, using

Edwards and Mosher's techniques, a POSA would understand that one would treat the portion of the vaginal canal proximal to the target structure—the bladder neck—which is not near the introitus. *Supra* V.A.

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



EX1015, Plate 360 (annotated).



EX2009.

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

96. Accordingly, Edwards does not suggest treating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus. Specifically, Edwards is treating the posterior and anterior vaginal walls opposite the bladder outlet: “A method 900 is performed to create a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both.” EX1005, Fig. 8A (“proximate to the bladder outlet”), 3:9-11, 6:20, 11:48-53.

97. A POSA would not understand these treatment areas to be at the introitus. Further, as explained above, the introitus is the external opening of the vagina (i.e., at the distal end of the vaginal canal). The primary structure targeted to treat SUI is the bladder neck. Supra Section V.A. Therefore, when treating a patient for SUI, a POSA would understand that one would treat the proximal end of the vaginal canal—opposite the introitus.

98. The Edwards device includes a speculum and a blade:

In a step 904, a speculum is inserted in the patient's vagina. The blades of the speculum are placed in an open position. The physician determines optimal areas of treatment. These may include the anterior wall, the posterior wall or both.

In a step 905, the blade 420 of the system 400 is inserted into the vagina through the speculum. The handle 430 is manipulated so as to cause the mating features 421 to engaged with the speculum.

EX1005, 13:23-46.

99. The speculum and blade are depicted in Figure 4:

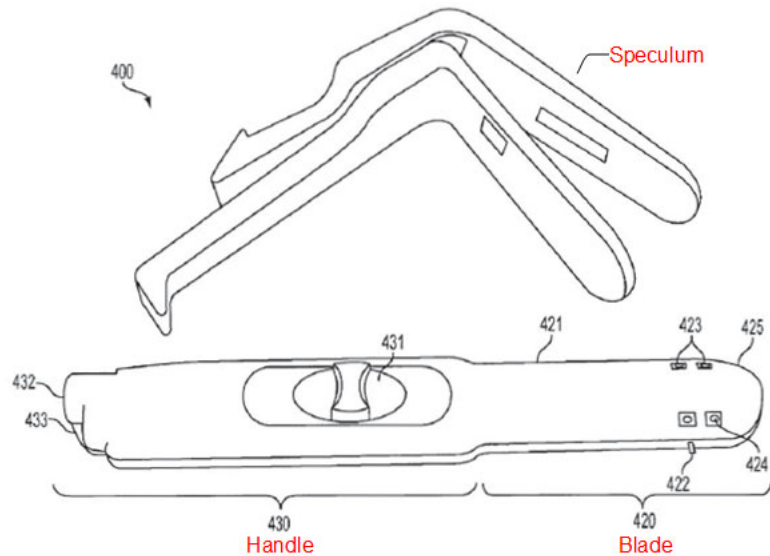


FIG. 4

EX1005, Fig. 4

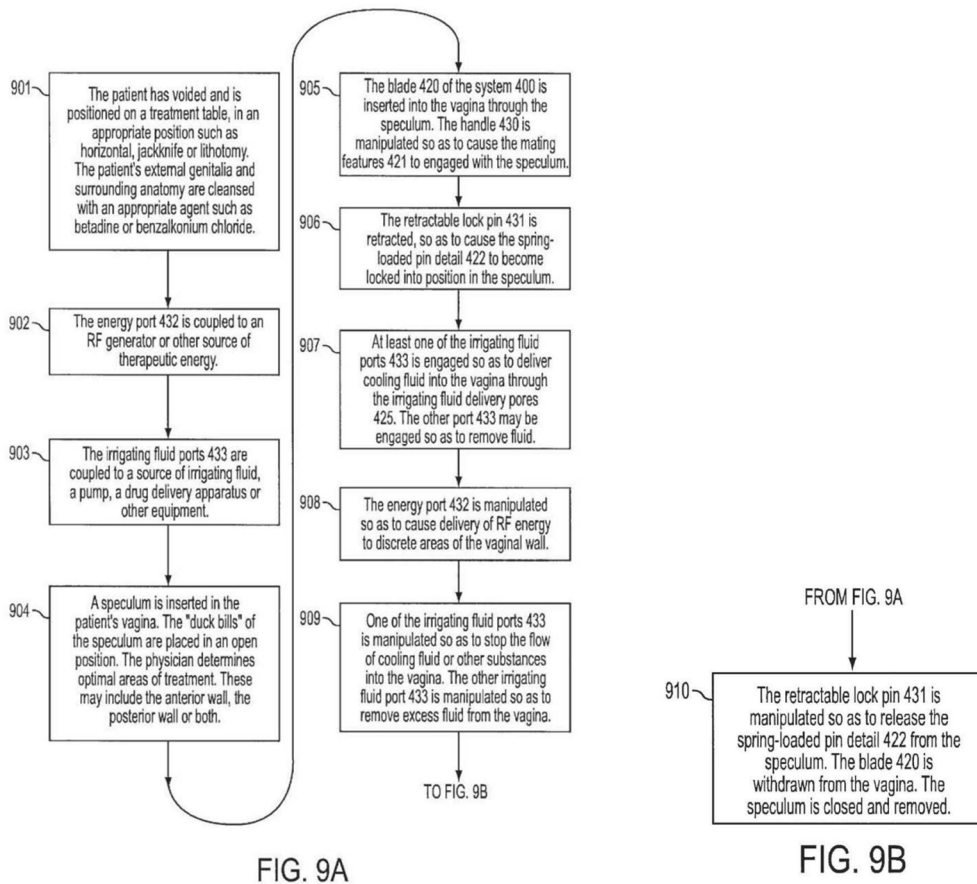
100. Thus, a POSA would understand that because the blade 420 is passed through the speculum, the blade treats the anterior or posterior vaginal walls deeper into the vagina (i.e., away from the vaginal opening). A speculum is a well-known device that dilates a vagina. A POSA would understand that in Edwards, the blade is not used until it has been mounted on the speculum which has already been inserted into a vagina. *See, e.g.,* EX1005, Fig. 9A. As shown in Figure 4, “[t]he blade 420 includes mating features 421, a spring-loaded pin detail 422, a plurality of relatively flat electrodes 423 and a plurality of irrigating fluid delivery pores 425. The mating features 421 are constructed to engage with features in the speculum following simple positioning of the speculum within the vagina. The spring-loaded pin detail 422 *locks the blade 420 into the correct position in the*

inserted speculum.” EX1005, 7:26-33 (emphasis added). Edwards only ever suggests that the blade 420 is locked into position with the speculum during delivery of RF energy to the vaginal wall. *See* EX1005, 13:43-62.

101. Thus, Edwards makes clear that the blade 420 of the treatment element mates with the speculum, with the spring-loaded pin detail locking the blade 420 into position relative to the speculum, and thereby restricting the treatable area along the posterior and anterior vaginal walls. And in a female patient with stress urinary incontinence (SUI), who would have looser tissue structure relative to a patient without SUI, at least two inches of the speculum bills must be in contact with the vaginal wall (i.e., the anterior and posterior walls) to maintain the speculum in place during treatment. When engaged with the speculum, the blade 420 appears to extend at least an inch forward (into the vagina) from the end of the speculum bill. The electrodes would contact the vaginal wall at least an inch forward (into the vagina) from the end of the speculum bill.

102. The positioning of the blade 420 into the speculum inhibits treatment of the area from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus. Indeed, the speculum dilates the introitus and moves the introitus out of the way so that deeper structures of the vagina can be treated.

103. As shown in Figures 9A and 9B, Edwards confirms that before treating the anterior and/or posterior wall of the vagina, “the blade 420 of the system 400 is inserted into the vagina *through the speculum*. The handle 430 is manipulated so as to cause the mating features 421 to engage with the speculum.” EX1005, 13:43-46 (emphasis added).



Id., Figs. 9A-9B.

104. Thus, Edwards device would not provide for treatment of the area from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus.

In fact, a POSA would understand that the speculum dilates the introitus and moves it out of the way so that deeper structures of the vagina can be treated.

105. It is my opinion that Mosher does not remedy the deficiencies of Edwards. Mosher is directed to treating the endopelvic fascia, which supports and is located adjacent to the bladder. Mosher explains injury to the nerves in the bladder neck should be avoided:

To avoid injury to nerves in the bladder neck region while providing sufficient treatment volume along the endopelvic fascia, it may be advantageous to distribute the treatment volume along the patient's lateral orientation while ***limiting the length of treatment along the axis of the patient's urethra***. This may minimize exposure of the bladder neck and antero-lateral vaginal wall nerves to RF energy. Such a laterally elongate treatment region of the endopelvic fascia will preferably be significantly wider (along the medial-lateral orientation) than its urethral length, ideally having a width of about 25mm and a length of about 15 mm. Treatment depths will preferably be at least about 2mm, optionally being as much as 6 mm.

EX1006, ¶[0074] (emphasis added).

106. Contrary to Dr. Berenholz's opinion, a POSA would not understand this disclosure to reference the region from vagina from the introitus to 3.5 cm inward. A POSA would understand that while Mosher merely suggests a rectangular treatment ***area*** of 25 mm by 15 mm, Mosher does not explicitly state where the rectangular treatment area is located within the vagina. Also, Mosher would not suggest treating the first 2.5 cm of the vagina in from the introitus

inasmuch as a POSA would understand that treating this region does not help the conditions Mosher looks to treat.

107. Moreover, Mosher teaches a treatment area having a width of about 25 mm and a length of about 15 mm, to avoid treating laterally down the urethral length (i.e., towards the introitus) in order to limit the exposure to the bladder neck and the urethra. EX1006, [0074]. The region of the anterior vaginal wall that is adjacent to the endopelvic fascia at the bladder neck is beyond the region extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus, therefore Mosher does not suggest a shallow treatment area. Indeed, with Mosher's limited treatment length, a POSA would understand that the introitus—which is spaced more than about 4 cm from the bladder neck—would not be treated.

108. While Dr. Berenholz (and Petitioner) do not rely upon Ingle for this claim element, it is my opinion that Ingle suffers from the same deficiencies. Ingle is directed to treating incontinence at the bladder neck, as opposed to treating the introitus. EX1007, 17:30-34, Figs. 6, 11, 12, 12K, and 13.

109. Further, while Dr. Berenholz (and Petitioner) provides a general discussion regarding why a POSA would have been motivated to combine Edwards, Mosher, and Ingle (*see* EX1003, ¶¶84-90), these arguments do not explain how the references would be combined to read on this limitation. In fact, as

explained above, Dr. Berenholz's statement that "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 nerve in the bladder neck region and in the antero-lateral vaginal wall" (*id.*, ¶123) is incorrect.

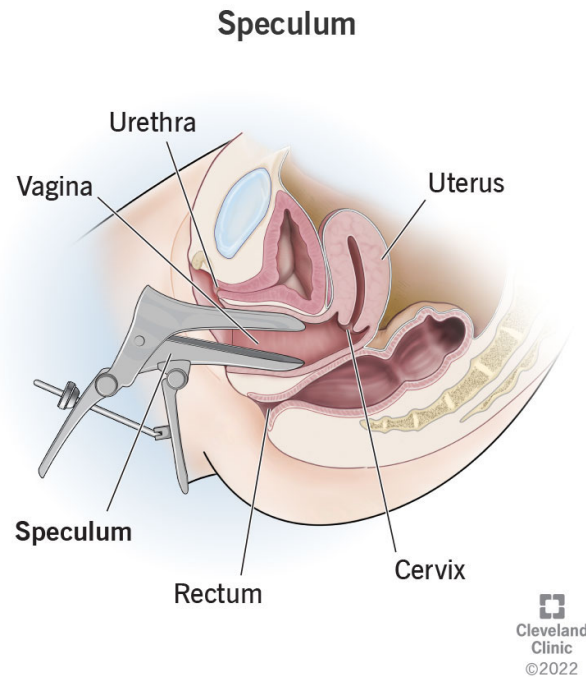
110. Therefore, in my opinion, a POSA would not understand Edwards, Mosher, and Ingle as suggesting the features of claims 1-34.

b. Claim 35: The Combination of Edwards, Ingle, and Mosher Does Not Render Obvious "wherein the heating includes heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock, wherein the aspect closest to the urethra is at 12 o'clock"

111. In my opinion, the combination of Edwards, Mosher, and Ingle does not teach treating the 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.

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

being rotated or moved once engaged in place. Moreover, a POSA would understand that conventional positioning of the speculum is to place the bills against the anterior and posterior vaginal walls. The conventional position of a speculum can be seen in the diagram below:

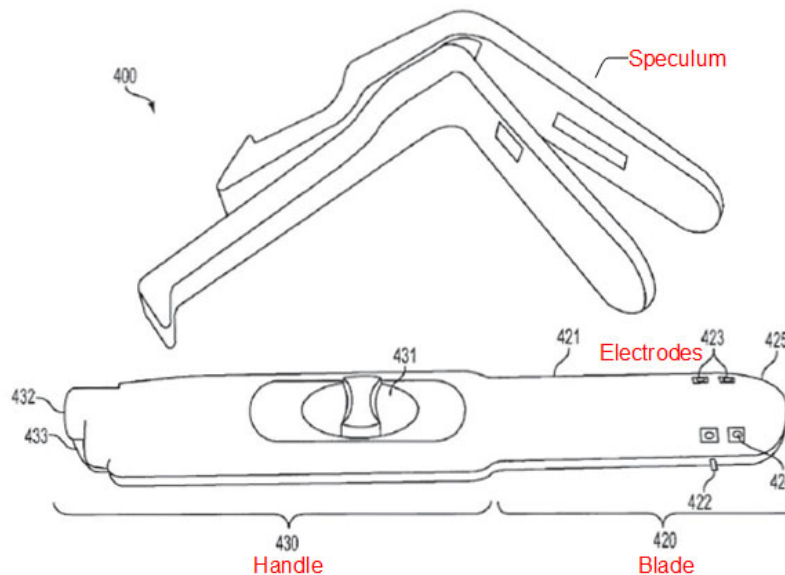


EX2010, 2.

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

116. Second, Edwards does not disclose treatments extending in any circumferential direction along the posterior wall. While the Petition refers to a "series of lesions," those lesions are caused by the electrodes 423 extending along the *length* of the device, as can be seen on blade 420 itself. Petition, 37 (quoting

EX1005, 13:14-16); EX1005, Fig. 4 (electrodes 423). A POSA would understand that this suggests a series of point treatments along the length of the bladder neck, at least because that is the distribution of electrodes and there is no realistic option to rotate the speculum laterally.



EX1005, Fig. 4 (annotated).

117. Thus, Edwards’ description of treating the posterior wall suggests treatment of a point on the vagina wall and does not suggest heating “circumferentially ... from 1 o’clock to 11 o’clock,” as required by claim 35.

118. In my opinion, Mosher does not remedy the deficiencies of Edwards. Mosher fails to suggest heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock. Like Edwards, Mosher describes treatment

directed towards the endopelvic fascia, i.e., the anterior vaginal wall corresponding to the region between 11 o'clock and 1 o'clock. *See* EX1006, Abstract, ¶[0009].

Petitioner reasons that because Mosher discloses “distribut[ing] the treatment volume along the patient’s lateral orientation,” a POSA would be motivated to treat around the circumference of the vagina. Pet., 38 (citing EX1006, ¶74). I disagree.

119. A POSA would understand that Mosher is clear on its meaning of lateral treatment—namely that the lateral dimension of the treatment area is greater than the length of the treatment area. EX1006, ¶[0074]. However, Mosher makes clear that this arrangement is achieved through treatment of an area up to 2.5 cm wide and 1.5 cm long. EX1006, ¶[0074].

120. However, Mosher’s limited anterior treatment does not suggest a circumferential treatment in the 1 o'clock to 11 o'clock span. Petition, 67. At best, a POSA would understand Mosher to potentially hit an insignificant spot inside of the claimed range (e.g., an insignificant spot at 11 o'clock or 1 o'clock), which would not qualify as a *circumferential* portion. Thus, Mosher does not suggest “heating a portion of the vagina circumferentially” from 1 o'clock and 11 o'clock, as required by claim 35 and Petitioner offers no argument as to why Mosher would be modified in this respect.

121. Moreover, Mosher does not “provide an express suggestion to avoid treatment in the 60 degree arc between 11 o'clock and 1 o'clock,” as Petitioner

suggests. Pet., 39. Petitioner cites to paragraph [0011] of Mosher describing a “probe body directly access[ing] the treatment volume . . . by using tissue-penetrating electrodes.” EX1006 ¶[0011]. A POSA would understand that this disclosure of Mosher describes an embodiment where a needle penetrates tissue to directly heat the fascia, and in that case, the “treatment volume will preferably be separated from a urethra of a patient by at least about 1 cm to inhibit injury to nerves along the urethra” that is from being punctured by the tissue penetrating electrode. *Id.* But Mosher does not suggest avoiding the bladder neck when applying RF through the vaginal wall. Indeed, the bladder neck is the target.

122. While Petitioner does not rely upon Ingle for this claim element (Pet., 36-39), Ingle fails for similar reasons as Mosher. A POSA would understand that like Mosher, Ingle teaches treatment directed toward the endopelvic fascia between the urethra and the vagina, i.e., the region of the vaginal wall falling within 1 o’clock to 11 o’clock. EX1007, 18:46-50.

123. Further, a POSA would not be motivated to combine Edwards, Mosher, and Ingle to arrive at the specific limitations of claims 35. Dr. Berenholz (and Petitioner) relies on Mosher’s statement of a treatment volume “offset laterally from the urethra to a right side of the patient” and “another treatment volume [is] similarly offset laterally from the urethra to a left side of the patient.” EX1003, ¶133 (citing EX1006, ¶[0011]). However, as confirmed by the same

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

124. Therefore, in my opinion, the combination of Edwards, Mosher, and Ingle does not suggest the features of claims 35-42.

c. Claim 43: The Combination of Edwards, Ingle, and Mosher Does Not Render Obvious “wherein the heating includes heating a portion radiating outward from the introitus to Hart’s line”

125. In my opinion, the combination of Edwards, Mosher, and Ingle does not suggest treating the portion radiating outward from the introitus to Hart's line.

126. A POSA would understand that the Hart’s line is exterior to the introitus and the opening of the urethra. A POSA would also readily understand that Edwards, Mosher, and Ingle are all directed to treating female stress urinary incontinence. As Dr. Berenholz (and Petitioner) admits, Edwards describes ablation of the uterus, bladder, and vaginal wall. Pet. 40; EX1005, 2:34-3:13. Likewise, Mosher and Ingle teach heating the anterior vaginal wall adjacent to the bladder to strength and stiffen the endopelvic fascia. EX1006, Abstract, ¶[0009], [0058]; EX1007, 2:51-53, 2:59-60. Contrary to the external, vulvar target tissue

claimed by claim 35, these are internal tissues; indeed, deeper tissue than the target tissue in the ‘511 patent.

127. Only one of Edwards, Mosher, and Ingle mentions external tissue. However, Ingle’s passing reference to “cosmetic procedures” and treatment of “sagging breasts” (EX1007, 18:1-7, 1:18-23) would not motivate a POSA treat a “portion radiating outward from the introitus to Hart’s line.” Indeed, a POSA would understand that there is significant difference between the dense innervation and vasculature of the tissue of the breast, abdominal wall, and face described in Ingle compared to that of the vaginal, vulvar, and introital tissue. Therefore, a POSA would not make the jump to use RF energy to treat these latter tissues cosmetically. In my opinion, Dr. Berenholz oversimplifies the issue and applies hindsight bias by asserting that “a POSA would have been motivated to apply the RF treatments described in Edwards, Mosher, and Ingle to the vulval vestibule region described in [this limitation].” EX1003, ¶142. However, the fact that RF treatments were used for certain other cosmetic applications would not mean that a POSA would have been motivated to apply RF heating to the claimed region.

128. Therefore, a POSA would simply not be motivated to heat from the introitus to Hart’s line, based on the teachings of Edwards, Mosher, and Ingle. Further, I understand that it is improper to focus on what a skilled artisan would have been *able* to do, rather than what a skilled artisan would have been *motivated*

to do at the time of the invention.. In my opinion it is unquestionable that a POSA would not have been motivated to use the treatments described in Edwards, Mosher, and Ingle to cosmetically enhance the genital region radiating outward from the introitus to Hart's line. First, that region is irrelevant to the common problem that these references were trying to solve: urinary incontinence. Second, a POSA would understand that heating the region radiating outward from the introitus to Hart's line would provide no additional support to the bladder or bladder neck, and would not result in improvement of stress urinary incontinence since Hart's line is even beyond the opening of the urethra.

129. Additionally, it is not clear how treating the region radiating outward from the introitus to Hart's line would be accomplished. Edwards teaches an applicator that mates with a speculum. A POSA would undoubtedly understand that by definition, this procedure must take place *interior* to the vagina, not *external* to the vagina, extending from the introitus to the Hart's line. EX1005, 13:43-46. In my opinion, Dr. Berenholz (and Petitioner) has not adequately explained a motivation or a modification to Edwards to accomplish the claimed method it physically cannot accomplish. Notably, the only recitation of Hart's line in the relevant portion of Dr. Berenholz's declaration is his quotation of the claims and specification of the '511 patent. EX1003, ¶¶136-142.

130. Further, I agree with Dr. Berenholz that there would be different RF settings, differing times, different uses in treating vaginal canal structure versus “external structures” because “tissue response is different externally and in terms of tolerability versus vaginal heating.” EX2005, 34:22-35:12.

131. Therefore, in my opinion, the combination of Edwards, Mosher, and Ingle does not suggest the features of claims 43-50.

d. Claim 51: The Combination of Edwards, Ingle, and Mosher Does Not Render Obvious “wherein the heating includes heating a mucosal surface of the labia minora”

132. In my opinion, the combination of Edwards, Ingle, and Mosher does not render obvious “wherein the heating includes heating a mucosal surface of the labia minora.”

133. As discussed above with respect to the portion from the introitus to the Hart’s line, none of these references suggest heating a mucosal surface of the labia minora. Further, a POSA would not be motivated to heat the mucosal surface of the labia minora (outside the vaginal canal), based on the teachings of Edwards, Mosher, and Ingle.

134. Therefore, in my opinion, the combination of Edwards, Mosher, and Ingle does not render obvious the features of claims 51-58.

e. All Independent Claims: The Combination of Edwards, Ingle, and Mosher Does Not Render Obvious “remodeling the therapeutic zone of target tissue”

135. In my opinion, the combination of Edwards, Ingle, and Mosher does not render obvious “remodeling the therapeutic zone of target tissue” as recited by each of the independent claims of the ’511 patent. Edwards discloses creating “lesions” in and ablating the vaginal wall, which would “substantially affecting the epithelium” and ablate the tissues underlying the epithelium. EX1005, 13:14-16. Mosher and Ingle also do not teach this element because they only credibly teach remodeling of the endopelvic fascia, which is excluded deeper tissue, and do not describe remodeling of the “tissue immediately beneath the mucosal epithelium,” as required by the Board’s construction.

136. And “target tissue” properly includes “tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissue, such as endopelvic fascia.” *See supra* Section VI.A.

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

137. First, it is my opinion that under proper construction of the claims, Edwards does not describe remodeling the therapeutic zone of target tissue because, unlike the claimed invention, Edwards does not disclose remodeling without substantially affecting the epithelium. Rather, Edwards discloses that its

techniques are ablative: “A method 900 is performed to create a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both.” EX1005, 13:14-16. The method 900 is performed using sterile technique. EX1005, 13:22-23.

138. Consistent with this disclosure, a POSA would understand that ablative RF techniques “deliver[ing] a low-voltage, high-frequency current to cauterize and destroy abnormal tissues.” EX2008, 6. A POSA would understand that lesions in the vaginal wall would result in thermal injury and cellular breakdown.

139. A POSA would understand that the Edwards’ fourth embodiment would also cause ablation on the surface of the vaginal wall based on the figures. Specifically, in Figure 4, the size of the electrodes 423 are very small in relation to the blade and even in relation to the thermocouples 424. EX1005, Fig. 4. The size of these electrodes would suggest to a POSA that Edwards uses a pinpoint RF application. A POSA would understand that such a pinpoint electrode would have a high heating effect intended to produce destructive action.

140. In my opinion, while Edwards discloses that “at least one of the irrigating fluid ports 433 is engaged so as to deliver cooling fluid into the vagina through the irrigating fluid delivery pores 425,” this type of cooling without other provisions would serve to protect a non-target area, such as the upper vagina, a

distance remote from the electrodes, but not to protect the epithelial mucosa at the heat treatment site. This is supported by the fact that Edwards does not apply irrigating fluid where the electrodes are located on the blade.

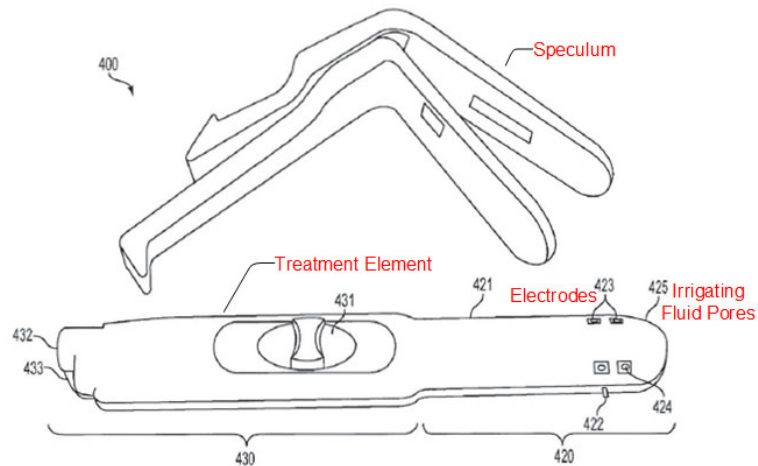


FIG. 4

EX1005, Fig. 4 (annotated).

141. In particular, Edwards does not describe any specific provisions for protecting the mucosal epithelium in the area that is being treated. This is because a POSA would understand that once the target tissue is heated to a coagulation point, as Edwards is doing, other provisions would be necessary to prevent mucosal damage, such as heat dissipating gel, adjusting the energies used, adjusting the interval of exposure, turning the exposure on and off (for example, pulsing), insulating the energy applicator, cooling of the entire electrode assembly or other cooling elements that specifically targets tissue in contact with the applicator. Furthermore, Edwards does not teach a specific technique or motion to

be used with treatment, which would also be necessary to prevent damage to the mucosal epithelium. Instead, Edwards notes the treatments “require [] local or regional anesthesia,” which a POSA would understand would only be necessary if tissue is ablated. EX1005, 2:22-27.

142. A POSA would also understand that Edwards’ disclosure of “irrigating fluid” is merely consistent with clearing away blood and other fluids during an ablative procedure. A POSA would interpret the use of an irrigation fluid for cooling in Edwards as consistent with attempting to protect non-target tissue, rather than stratifying the heat effect to protect the surface layer. In fact, Edwards confirms that its cooling fluid “prevents collateral thermal damage to the urethral wall and associated structures,” (EX1005, 9:42-48)—thus confirming that Edwards causes damage to the contacted tissue and that the cooling fluid is for protecting non-target tissue.

143. Unlike the claimed invention, which remodels sub-mucosal tissue without substantially affecting the epithelium, Edwards creates “lesions” in the vaginal wall. Therefore, in my opinion, a POSA would not understand Edwards as teaching “remodeling,” as recited in the claims.

ii. Mosher does not teach remodeling “tissue immediately beneath the mucosal epithelium”

144. Mosher is directed to remodeling the “endopelvic fascia,” which is not a target tissue in connection with the ‘511 patent.

145. A POSA would understand that, as construed by the ThermiGen IPR panel, “tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissue, such as endopelvic fascia.” *See supra* Section VI.A. Therefore, the target tissues of the ’511 patent include “the lamina propria and the muscularis, underlying the mucosal epithelium of a female genital tissue.” EX1001, 2:25-28. A POSA would understand that the mucosa which includes the epithelium and lamina propria is thin, in the range of 0.2 mm. A POSA would further understand that the muscularis is 0.8 mm or thicker. The deep fascia, such as the endopelvic fascia is outside the vaginal wall proper. Mosher and Ingle are directed to treating tissues deeper than the lamina propria, the muscularis, and the vaginal wall proper.

146. Mosher discloses heating and remodeling the endopelvic fascia to treat bladder outlet hypermobility. EX1006, Abstract. Mosher further explains that: “When the endopelvic fascia has excessive length or stretches excessively under a load, the fluid pressure within the bladder advanced into the bladder neck and down the urethra more readily. Leakage may result in part because the endopelvic fascia allows the bladder, bladder neck, and/or urethra to drop below its desired position, at which fluid pressure within the bladder may actually help to seal the bladder neck. Stretching of the endopelvic fascia may also alter the timing of pressure pulse transmission to the urethra.” EX1006, ¶[0049]; *see also id.*, ¶¶

[0009], [0045]-[0059]. Mosher is therefore focused on remodeling the endopelvic fascia, and not the tissue immediately beneath the mucosal epithelium. Mosher explains that:

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

EX1006, ¶[0066].

147. Petitioner relies on Mosher's description of "cooled electrode vaginal probes" in FIGS. 6 and 6A. Pet., 31-32 (citing EX1006, ¶[0058], FIG. 6). With reference to FIG. 6, Mosher describes "cool the intervening or intermediate tissue between probe body 54 and the endopelvic fascia EF, such as the vaginal wall VW as seen in FIG. 6." EX1006, ¶[0058]. A POSA would understand that, as shown in FIG. 6 of Mosher, the vaginal wall includes the epithelium as well as "the tissue immediately beneath the mucosal epithelium," including the lamina propria and

muscularis. EX1006, FIG. 6. Mosher describes cooling this “intervening or intermediate tissue” of the vaginal wall, and a POSA would understand Mosher’s disclosure as cooling the entire vaginal wall including the lamina propria and muscularis. EX1006, ¶[0058]. Mosher therefore discloses cooling the target tissues of the ’511 patent, “the tissue immediately beneath the mucosal epithelium.”

148. Petitioner argues that Mosher identifies lamina propria as a potential target tissue. Pet., 27. As discussed above (supra Section VII.A.1.b), Mosher only mentions the lamina propria in a laundry list of tissues, including male anatomical features. EX1006, ¶[0048]. But Mosher does not describe how the disclosed treatment would be applied to the lamina propria. Therefore, for that reason and in view of the flawed laundry list, a POSA would not have found any particular treatment obvious. For example, Mosher does not describe the RF settings necessary to treat, for example, the lamina propria, the amount of time to apply RF heating, how to cool the nearby epithelium to avoid damage to the epithelium, or the other parameters a POSA would understand are necessary to achieve remodeling of the lamina propria.

149. Therefore, in my opinion, a POSA would not understand Mosher as teaching “remodeling . . . target tissue,” the tissue immediately beneath the mucosal epithelium.

iii. Ingle does not teach remodeling “tissue immediately beneath the mucosal epithelium”

150. Ingle, like Mosher, is also directed to heating the endopelvic fascia to treat bladder outlet hypermobility. Ingle explains that “the present invention directs energy to a patient’s own support tissues. This energy heats [endopelvic] fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues.” EX1007, 2:51-3:10; *see also id.*, 3:11-20, 3:36-50, 17:1-34, 17:41-64, 18:8-13, Fig. 4. A POSA would understand that Ingle’s disclosure of endopelvic fascia and “other collagenated support structures” does not teach or suggest treatment of “tissue immediately beneath the mucosal epithelium of genital tissues” because Ingle defines the relevant “collagenated tissue [] as fascia, ligament, or the like.” EX1007, 11:8-11.

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

152. Accordingly, it is my opinion that Edwards, Mosher, and Ingle do not suggest “remodeling the therapeutic zone of target tissue,” as recited in independent claims 1, 35, 43, and 51.

3. Dependent Claims

a. The Combination of Edwards, Ingle, and Mosher does not render obvious claim 26

153. In my opinion, the combination of Edwards, Ingle, and Mosher does not render obvious claim 26, which further requires “tightening the introitus.”

154. Dr. Berenholz (and Petitioner) alleges that Edwards discloses “tightening the introitus.” *See* EX1003, ¶¶248-251. Notably, though, while Dr. Berenholz (and Petitioner) seems to admit that Edwards does not explicitly disclose this limitation, Dr. Berenholz (and Petitioner) nonetheless argues that a POSA would recognize that “circumferential tightening” deeper into the vaginal canal would result in “tightening the introitus.” *Id.* I disagree.

155. A POSA would understand the introitus is the opening where the vagina exits the body. Further, as discussed above, a POSA would understand that the treatment area in Edwards is not at or near the introitus (it is near the bladder neck) and that Edwards’ speculum would not permit the electrodes to contact the introitus when positioned in the patient’s vagina. Nor does Petitioner explain with factual support any reason that a POSA would understand that the introitus is necessarily tightened using Edwards’ techniques. Indeed, as explained above, because Edwards teaches using an RF applicator in combination with a speculum for entry to the vagina, Edwards cannot treat the introitus. Therefore, A POSA

would understand that Edwards does not suggest that its treatment would have any effect on the introitus.

156. Further, not only does Dr. Berenholz (or petitioner) not cite Mosher or Ingle for this claim, but he does not explain how a POSA would modify Edwards' treatment to affect the introitus.

b. The Combination of Edwards, Ingle, and Mosher Does Not Render Obvious Claims 2-34, 36-42, 44-50, and 52-58 of the '511 Patent

157. I understand that because claims 2-34, 36-42, 44-50, and 52-58 ultimately depend from independent claims 1, 35, 43, and 51, they cannot be rendered obvious by the combination of Edwards, Ingle, and Mosher for at least the same reasons discussed above for the independent claims.

B. Ground 2: The Combination of Edwards, Mosher, Ingle and Ollivier Does nNt Render Obvious Claims 43 through 58 of the '511 Patent

158. Dr. Berenholz opines that combination Edwards, Ingle, and Mosher further in view of Ollivier renders obvious claims 43-58 of the '511 patent.

159. However, as explained above, the combination of Edwards, Mosher, and Ingle does not render obvious claims 43-58 because none of the references disclose "heating a portion radiating outward from the introitus to Hart's line" or "heating a mucosal surface of the labia minora." In fact, as explained above, Edwards, Mosher, and Ingle are limited to internal treatments and do not disclose

treating outside of the vaginal canal. In my opinion, Ollivier does not cure this deficiency as it does not suggest these claim elements and a POSA would not have considered Ollivier.

1. Overview of Ollivier

160. Ollivier appears to be an article entitled “Designer vaginas” authored by Debra Ollivier that purportedly appeared on a website called Salon.com. The Ollivier reference is Salon.com intrigue piece written by Debra Ollivier.

161. Ollivier discusses gynecological surgery, including two ablative surgical treatments: Laser Vaginal Rejuvenation (LVR) and Designer Laser Vaginoplasty (DLV) supposedly performed by Dr. David Matlock. EX1008, 1. Ollivier describes Dr. David Matlock’s “antiseptic trimmings and surgical prunings of a trusty laser” to remove vulvar tissues. EX1008, 1. “Antiseptic trimmings and surgical pruning” demonstrates that Matlock is using a surgical laser instead of a scalpel to remove excess vulvar tissue. Ollivier identifies the risks associated with laser vaginal surgery, including “hemorrhage, infection, loss of sensitivity, lingering pain from nerve damage.” EX1008, 2. These side effects are common with laser surgical techniques. The remodeling techniques of the ‘511 patent are intended to avoid these side effects. EX1001, 2:9-16 (“surgical approaches can bring with them a risk of scarring that is entirely counterproductive with regard to the desired result” and “surgical approaches are not highly popular because of the

risks associated with an invasive procedure, in a sensitive area, especially when such procedures are considered medically optional.”)

2. Ollivier Does Not Enable a POSA to Implement the Described Procedures

162. Salon.com is described as a “politically progressive and liberal news and opinion website” that provides “provocative (if predictably liberal) political commentary and lots of sex.” EX2015. A POSA would understand that Salon.com is not a medical or technical publication. The author does not have a medical or technical background. EX1008, 1; EX2011. I was not aware of Salon.com before this case.

163. A POSA would understand that Ollivier does not provide any specifics regarding the procedure or laser being used because Ollivier is an article that merely indicates that there was a single doctor—Dr. Matlock—performing an invasive procedure using laser to cut away tissue, with no real description of the actual procedure. EX1008. The article does not appear to be directed to the medical community.

164. As to the actual treatment mentioned in Ollivier, it was known in the field that, for training, Dr. Matlock required participating doctors to sign a non-disclosure agreement, as the procedure was kept secret. *See* EX2005, 162:3-6 (agreeing that Dr. Matlock “keeps the specifics ... of the treatment confidential”), 162:23-163: 4 (describing Dr. Matlock’s “contract about ... not divulging

treatment, surgical techniques, et cetera. ... it was confidential.”), 165:23-166:1 (Dr. Matlock’s procedures still confidential). I understand that Dr. Matlock still requires a non-disclosure agreement to explain the procedure.

165. Ollivier makes reference to Dr. Matlock’s “antiseptic trimmings and surgical prunings of a trusty laser” to remove tissues. However, Ollivier does not provide any details on the procedure. EX1008, 1. Ollivier’s reference to “trimmings” and “surgical pruning” would suggest to a POSA only that Matlock is using a surgical laser instead of a scalpel to surgically remove tissue. Indeed, Ollivier identifies the risks associated with laser vaginal surgery, including “hemorrhage, infection, loss of sensitivity, lingering pain from nerve damage,” which are associated with invasive procedures. EX1008, 2. As discussed above, the remodeling techniques of the ’511 patent are non-invasive procedures intended to avoid these effects. EX1001, 2:9-16 (“surgical approaches are not highly popular because of the risks associated with an invasive procedure, in a sensitive area, especially when such procedures are considered medically optional.”). Therefore, given the invasive procedure suggested by Ollivier and the lack of details, because the treatment was maintained as a secret, a POSA would understand that there is no disclosure that would allow a POSA to understand the specifics of the treatment so as to be able to perform the same, or to combine aspects of the treatment with the other teachings (such as Edwards, Mosher, and Ingle).

166. Further, because Ollivier merely generally discusses Dr. Matlock's use of lasers, a POSA who is seeking to use non-ablative techniques that do not damage the surface of the treatment area would not look to ablative laser-related teachings, because the entire process by which these techniques work is by complete destruction of the surface layer of the treatment area. Ablative laser treatments are at the opposite end of the energy application spectrum of the non-ablative techniques of the '511 patent.

3. Claims 43 and 51 Are Not Obvious in View of Edwards, Mosher, Ingle, and Ollivier

a. Edwards, Mosher, Ingle, and Ollivier Do Not Render Obvious "heating a portion radiating outward from the introitus to Hart's line"

167. Ollivier does not suggest heating between the introitus and Hart's line. Ollivier vaguely describes invasive surgical techniques where "labia [are] modified, vulvae reconfigured," and labium are "trim[ed] back." EX1008, 1. But Ollivier does not teach or suggest treatment of the portion of the vagina from introitus to the Hart's line, nor does Ollivier disclose treating in an area "radiating outward" from the introitus. Treatment of these specific portions are integral to the goal of the '511 patented method: "treating a loose vagina and introitus with a non-invasive procedure . . . for corrective or restorative remodeling." EX1001, 2:17-21. Rather, in the treatment described by Ollivier, portions of the external vaginal tissue are removed entirely which may even remove the Hart's line. EX1008, 1.

Indeed, a POSA reading Ollivier would not know to heat target tissue underlying a portion of the vulva radiating outward from the introitus to the Hart's line.

168. Further, Dr. Berenholz (and Petitioner) fails to explain how Ollivier's vague description of vaginas "being redesigned, labia modified, vulvae reconfigured," using an undisclosed type of laser, to cut away vaginal tissue would suggest to a POSA how the RF techniques of the SUI references could be used to treat the region "radiating outward from the introitus to Hart's line." Dr. Berenholz (and Petitioner) provides no disclosure regarding how the SUI references could be used to perform the "antiseptic trimmings and surgical prunings" of the laser described in Ollivier. EX1008, 1. Indeed, I agree with Dr. Berenholz that, the laser treatments of Ollivier "us[e] a laser as a scalpel" to "sculpt[]" and "cut" the tissue, while RF treatments like in the stress urinary incontinence treatments do not. EX2005, 31:16-21, 159:24-160:5.

b. Claim 51: Edwards, Mosher, Ingle, and Ollivier do not disclose "heating a mucosal surface of the labia minora"

169. Ollivier also does not suggest heating the mucosal surface of the labia minora. Rather, Ollivier vaguely describes invasive surgical techniques where "labia [are] modified" or "trimm[ed] back." EX1008, 1. The '511 patent is clear that these "surgical approaches" are associated with "a risk of scarring that is entirely counterproductive with regard to the desired result." EX1001, 2:13-16.

Nor does Ollivier describe treating the “mucosal surface of the labia minora,” as opposed the labia majora.

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

4. A POSA Would Not Be Motivated to Combine Ollivier with Edwards, Mosher, and Ingle

171. A POSA would not be motivated to combine the laser surgical procedures referenced in Ollivier with the SUI procedures of Edwards, Mosher, and Ingle (the “SUI references”). As an initial matter, Ollivier identifies the risks associated with laser vaginal surgery, including “hemorrhage, infection, loss of sensitivity, lingering pain from nerve damage.” EX1008, 2. A POSA would understand that these side effects can occur with laser surgical techniques. EX2025, 163:19-13.

172. Additionally, Ollivier itself acknowledges that others in the field did not even believe Dr. Matlock’s procedure was safe or effective. Indeed, Ollivier quotes another medical doctor who explains that the procedure “is a way of preying on vulnerable women.” EX1008, 2. That same doctor said of Dr. Matlock’s treatment: “Run away. Run away. Run away.” EX1008, 2

173. Moreover, a POSA would understand that when treating stress urinary incontinence (which is generally focused on strengthening the internal support for the bladder region) there would be no reason to look to methods for improving the look of exterior genitalia or treating “true genital ‘deformities’—extraordinarily long or protruding labia.” EX1008, 6-7. This is because a POSA would understand that treating external genitalia has no effect on SUI.

174. Dr. Berenholz (and Petitioner) also provides no explanation as to how the SUI references would be modified to incorporate the vague teachings of Ollivier. Indeed, a POSA would understand that the Edwards energy applicator is a blade that mates with a speculum, thus confirming it is intended for internal usage. EX1005, 13:38-42, FIG. 4. Similarly, Mosher discloses “vaginal probes” with “needle mounted temperature sensors”—also intended for internal usage. EX1006, ¶¶0058]. Likewise, Ingle discloses “clamping a target tissue between a plurality of electrode surfaces...” for example, by placing one electrode surface in the vagina and a second electrode surface in the rectum—also intended for internal usage. EX1007, 8:24-27. In my opinion, Dr. Berenholz (and Petitioner) does not explain how these applicators would be modified to treat the external vulva tissues.

175. Finally, while Dr. Matlock was allegedly advertising and performing ablative laser treatments on the vagina since at least the late nineties (EX1008, 1-

2), prior to the '511 patent, no one suggested the specific non-invasive procedures, on specific anatomical structures, claimed in the '511 patent.

5. Dependent Claims

c. The Combination of Edwards, Ingle, Mosher and Ollivier Does Not Render Obvious Claims 44-50 and 52-58 of the '511 Patent

176. I understand that because claims 44-50 and 52-58 ultimately depend from independent claims 43 and 51, they cannot be rendered obvious by the combination of Edwards, Ingle, Mosher, and Ollivier for at least the same reasons discussed above for the independent claims.

VIII. OBJECTIVE INDICIA

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

178. I understand that industry praise provides probative and cogent evidence that one of ordinary skill in the art would not have reasonably expected the claimed invention. I also understand that the praise should be directed to novel elements of the claims (including of the product/treatment that meets/performs such elements).

179. Here, claim 1 recites “heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus.” EX1001, claim 1. Claim 26 further recites “tightening the introitus.” EX1001, claim 26. Claim 35 recites “heating a portion of the vagina circumferentially around its wall from 1 o'clock to 11 o'clock.” EX1001, claim 35. Both of the studies praised by Dr. Alinsod describe heating and remodeling vaginal tissue by applying an RF “treatment tip . . . to the mucosal surface of the vaginal *introitus* starting at the hymenal ring and [treating] the entire area *from the 1:00 o'clock to 11:00 o'clock position* . . . with RF energy pulses.” EX2018, 3; EX2017, 777. A POSA would understand that this described treatment corresponds to the limitations of claims 1, 26, and 35. Moreover, the specific device being used was the Viveve device. EX2018, 3 (left column); EX2017, 776-77. The treatment was further performed to heat tissue “beneath the surface” and while using cryogen so as not to affect the surface tissue. EX2018, 3 (right column), EX2017, 779, 780 (“nonablative”). Also, a POSA would understand that the treatment area extended

from the hymenal ring (which forms a portion of circumference of the introitus) to about 1.6 cm from the introitus. EX2018, 3 (describing a 20 cm² treatment area over a 12 cm circumference (left column)). This treatment is commensurate with the treatments of claim 1—“introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus”—and claim 26—“tightening the introitus.” EX1001, claims 1, 26. Also treating the area from “the 1:00 o’clock to 11:00 o’clock position . . . moving the tip in a clockwise direction” is commensurate in scope with claim 35’s treatment of “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock.” EX2018, 3 (right column); EX2017, 777; EX1001, claim 35.

180. Dr. Berenholz’s mentor, Dr. Alinsod, even performed his own study that provided “confirmation” of the studies of the Viveve treatment and concluded that such evidence “is a boon to successful treatment and may represent a key advance in the emerging field of vulvovaginal rejuvenation.” EX1025, 21 (also praising the lack of “downtime” or “risks” to the patients). Dr. Alinsod contrasted this benefit to prior treatments that resulted in significant patient downtime. EX2013, 3, 5, 6.

IX. CONCLUSION

181. In conclusion, it is my opinion that a POSA would not have understood any of claims 1 through 58 of the ’511 Patent to be obvious based on

the combination of references from the grounds set forth in the Petition and Dr. Berenholz's declaration.

182. I hereby declare that all statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. Further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the application or any patent issuing thereon. I declare under penalty of perjury that the foregoing is true and correct.

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1/22/2025
Date

Denise Poulos MD
Dr. Denise Poulos