

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THERMIGEN, LLC AND THERMIAESTHETICS, LLC,
Petitioners,

v.

VIVEVE, INC.,
Patent Owner

Case IPR2018-00088
Patent No. 8,961,511

PATENT OWNER'S PRELIMINARY RESPONSE

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I. INTRODUCTION

Patent Owner, Viveve, Inc. (“Viveve”), submits this preliminary response under 37 C.F.R. § 42.107 to the Petition for *Inter Partes* Review of U.S. Patent No. 8,961,511 (“the ‘511 patent”). Petitioner, Thermigen, LLC and Thermiaesthetics, LLC (“Petitioner”) has not demonstrated a reasonable likelihood of prevailing with respect to any challenged claim.

In Court, Petitioner Thermi has acknowledged that the ‘511 patented methods of remodeling certain female genital tissue constitute an improvement over prior art, notably, because they provide non-ablative techniques that do not damage the surface layer of the treatment area—which is referred to as the epithelium in the patent. Specifically, Thermi has said:

This is an innovation and improvement in the field. And the major improvement was being able to remodel this particular tissue without damaging it, scarring it, ablating it, that sort of thing The improvement that was cited is over the prior art which either ablated tissue or it was invasive in order to heat -- to -- to apply heat treatment to this particular tissue [T]he ‘511 patent itself is directed -- is an improvement because you are able to modify this tissue underlying the surface without damaging, without scarring, without burning the tissue.

Ex. 2002 at 23:14-17, 25:12-15, 36:6-9. Despite these clear admissions, Thermi now asks the Board to find that the ‘511 patent does not constitute an improvement over the prior art, based on the Edwards patent, which remodels tissue using ablative RF techniques that leaves the patients with “lesions.” *Infra* at § V.A.1.a.

Thermi seeks to combine the deficient Edwards patent with two secondary references that are also deficient, as they disclose using RF energy *to heat* a deep tissue called endopelvic fascia, which is not within the treatment zone of the ‘511 patent,¹ while *cooling* the intermediate tissue, which is the claimed treatment zone. Petitioner’s conclusory comments on the purported combination do not identify a precise combination of teachings from the reference nor explain why a POSITA would be motivated to make the specific combination in light of relevant differences between the disclosed techniques.

Even in combination, these references do not teach the specific treatment areas recited by independent claims 1 and 35. Indeed, the two secondary references—that Thermi relies on for allegedly teaching the treatment areas—were before the Patent Office during examination of the ‘511 patent, yet the Examiner correctly found that “[n]o other reference has been found which

¹ The ‘511 patent explains “[t]he target zone of embodiments of the invention does not include deeper tissue, such as endopelvic fascia.” Ex. 1001 at 3:47-49.

discloses, fairly suggests, or makes obvious this area of treatment whether taken alone or in combination” Ex. 1002 Part 6 at 1352, Notice of Allowance dated Oct. 20, 2014. Nor does the Petition establish that the combination discloses the additional limitations recited in dependent claims 19-22, 26, and 30.

As recently as 2015, the doctor who developed the Petitioner’s competing system and techniques, Dr. Red Alinsod, stated: “We are really just learning all the things that RF can do for the gynecology, urology, aesthetic, and sexual medicine practice.” Ex. 2007 at 3. Dr. Alinsod also referred to these RF techniques as “game changing and the New Paradigm in Gynecology.” *Id.* These statements made *nine* years after the ‘511 patent’s provisional filing date confirm that the Examiner’s conclusion that treatment of the claimed areas are non-obviousness and that Petitioner’s arguments are based on impermissible hindsight.

For these reasons, as explained more fully below, the Board should deny institution of the *Inter Partes* Review Petition. *See* 35 U.S.C. §§ 312(a)(3), 314(a).

II. OVERVIEW OF THE TECHNOLOGY AND THE ‘511 PATENT

A. The ‘511 Patent

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. Ex. 1001 at claims 1, 35, 43, and 51. Vaginal tissue may

be stretched during child birth, often resulting in decreased sexual pleasure. Ex. 1001 at 2:4-9. Prior to the '511 patent, doctors relied on invasive techniques to treat these conditions, but these approaches often caused scarring and damage. Ex. 1001 at 2:9-12. The '511 patent overcame the problems of the prior art by providing a non-invasive procedure for restorative remodeling of certain female genital tissue that did require surgical incisions, and that did not cause thermal damage to the epithelium.

The '511 patent uses a treatment tip to make optimal contact with the genital epithelial surface for delivery of radiofrequency (RF) energy. Ex. 1001 at 2:53-55. The target tissue of the embodiments of the '511 patent are the lamina propia and muscularis, the tissues that lie immediately beneath the mucosal epithelium of genital tissues. Ex. 1001 at 3:41-45. RF energy heats and denatures collagen located in the collagen-rich lamina propia, resulting in a contraction of the collagen spaces thereby creating a tightening effect. *See* Ex. 1001 at 1:19-20, 35-39. The '511 patent explicitly states that its embodiments are not directed towards deeper tissue, such as endopelvic fascia. Ex. 1001 at 3:47-48.

The use of RF energy to denature collagen for its tightening effect was known and used for other medical purposes prior to the invention of '511 patent. During prosecution of the application eventually granting as the '511 patent, the claims were rejected as anticipated by U.S. Patent No. 6,350,276 to Knowlton et al.

(“Knowlton”). Specifically, the Examiner alleged that “Knowlton discloses a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue (as in the embodiment of figures 13-14 describing the treatment of cervix, see col. 13; 35-37), the method comprising heating the target tissue and remodeling the therapeutic zone of target tissue (see the described treatment and remodeling described from col. 3; 66 through col. 11; 64).” Ex. 1002 Part 4 at 693.

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). Ex. 1002 Part 6 at 1331-1338. 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.” Ex. 1002 Part 6 at 1352, Notice of Allowance. Thus, the Examiner recognized that even though it was known to heat one female genital tissue using RF, this did not fairly suggest or make obvious the heating of other female genital tissues using RF.

III. CLAIM CONSTRUCTION

Petitioner proposes construction of several terms of the ‘511 patent claims. Petitioner has failed to demonstrate a reasonable likelihood that any of the

challenged claims are unpatentable, even if the Board adopts Petitioner's constructions. Viveve, however, disagrees with Petitioner's constructions and reserves the right to offer constructions for additional terms in the event of institution.

In an *inter partes* review proceeding, a claim is given the "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). In *PPC Broadband, Inc. v. Corning Optical Communications RF, LLC*, the Federal Circuit emphasized that the broadest reasonable interpretation in light of the specification does not mean the broadest possible interpretation if it "fails to account for how the claims themselves and the specification inform the ordinary skilled artisan as to precisely which ordinary definition the patentee was using." 815 F.3d 747, 752 (Fed. Cir. 2016). Further, "the Board's construction 'cannot be divorced from the specification and the record evidence.'" *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (citation omitted).

Under the broadest reasonable interpretation, claim terms generally carry their plain and customary meaning. See *Intellectual Ventures Management, LLC v. Xilinx, Inc.*, IPR2012-00019, Paper 33 at 8 (P.T.A.B. Feb. 10, 2014). However, the presumption of a plain and customary meaning can be overcome in certain circumstances. A claim term may be construed contrary to its ordinary meaning where there is clear and unambiguous evidence that the patentee, as lexicographer,

provided a special definition for the claim term, or the patentee otherwise disavowed the full scope of the claim term either in the specification or during prosecution. *Ericsson, Inc. v. Intellectual Ventures I LLC*, IPR2014-00921, Paper 8, at 8 (P.T.A.B. Dec. 16, 2014); *see also Aventis Pharma S.A.v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012); *SciMed Life Sys. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) (“Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent[.]”).

A. “target tissue”

All of the patent claims recite “target tissue.” The broadest reasonable interpretation of “target tissue” is “tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissue, such as endopelvic fascia.” Alternatively, Viveve proposes “tissue immediately beneath the mucosal epithelium of genital tissues.” The intrinsic record does not support Petitioner’s claim construction of “tissue underlying the epithelium,” because other claim language already states that the target tissue includes tissue underlying an epithelium in (“in at least one of the vulva, introitus and vagina”), and the specification explicitly excludes deeper tissues, such as the endopelvic fascia, from “target tissue.”

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.*” Ex. 1001 at 3:43-48 (emphasis added).

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

The target tissue of embodiments of this invention include the connective tissue underlying these mucosal epithelial surfaces of the genitalia which, progressing down from the epithelial surface, are known as the lamina propria 102 and the muscularis 104 (FIG. 8), respectively (see, for example, Netter, Atlas of Human Anatomy, 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.

Ex. 1001 at 12:2-16. Thus, the specification makes clear that the “described target tissue layers” include the tissues adjacent the mucosal epithelium, such as the lamina propria and that the deeper tissues including the endopelvic fascia are not

target tissues. Where, as here, “the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent[.]” *SciMed Life Sys. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001).

Petitioner’s proposed claim construction for this term improperly encompasses the deeper tissues underlying the epithelial mucosal surface, such as the endopelvic fascia. Because the Board’s construction “cannot be divorced from the specification and the record evidence,” *Microsoft Corp.*, 789 F.3d at 1298, and in view of the explicit definition of this term in the specification, “tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissue, such as endopelvic fascia.”

B. “heating”

All of the patent claims recite “heating the target tissue.” The ‘511 patent makes clear that this heating step requires “heating without damaging the mucosal epithelial surface.” 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.” Ex. 1001 at 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.” Ex. 1001 at 12:19-21.

The ‘511 patent identifies at least two features that allow the embodiments of the invention to heat the underlying target tissues without ablation: cooling of the epithelium and uniformly-distributed contact between the treatment tip and the epithelium. The ‘511 specification explains that

[a] purpose of the cooling the epithelial surface is to protect it from potentially damaging effects of excess heat that would accumulate in the absence of cooling. The epithelial surface is thus 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.

Ex. 1001 at 13:16-26.

Additionally, the ‘511 specification explains that damage to the epithelium is reduced by uniformly-distributed contact between the energy delivery surface of the treatment tip and the epithelial surface. The specification explains several ways the structure of the treatment tip contributes to uniform energy delivery by promoting optimal contact with the epithelium surface throughout the treatment areas:

[b]y optimal contact is meant a contact that best allows a delivery of energy into the target tissue that is broadly uniform across the surface

of the contact site, notably without significant distortion along the edges of the contact site. Non-uniform delivery of energy does not serve the remodeling process well, and further may risk damage to the mucosal epithelium.

Ex. 1001 at 2:56-62; 8:8-15.

In a related District Court proceeding regarding the ‘511 patent, Petitioner agreed that the intrinsic record did not support the plain and ordinary meaning of the term “heating.” Petitioner asked the District Court for a narrower construction “[b]ecause the plain and ordinary meaning is not the meaning that the skilled artisan would ascertain in reading this record. Without exception, all of the art—the ‘511 patent itself is directed—is an improvement because you are able to modify this tissue underlying the surface without damaging, without scarring, without burning the tissue.” Ex. 2002 at 36:3-9; *see also* 23:14-17, 25:12-15.

Agreeing with the Petitioner’s argument, the District Court determined that under the *Phillips* standard, “heating” should be construed to mean “heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium.” Ex. 2003 at 10. In reaching this claim construction, the 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.” Ex. 2003 at 10-11.

Viveve’s claim construction of “heating” is broader than the District Court’s claim construction under *Phillips*, but still recognizes the critical aspect of the invention as shown by the intrinsic evidence. Viveve’s claim construction represents the broadest reasonable interpretation because the construction is consistent with the intrinsic evidence that the mucosal epithelial surface remains undamaged, but the construction does not unnecessarily narrow the claim to require that the epithelial surface is protected solely by maintaining the epithelium at a lower temperature than the underlying tissue. For example, preventing damage to the mucosal epithelial surface may also be accomplished by uniformly-distributed contact between the energy delivery surface and the mucosal epithelium, and heating to a lower temperature to achieve partial denaturation of collagen. Ex. 1001 at 2:53-62, 4:40-43; Ex. 1003 ¶38.

Thus, “heating without damaging the mucosal epithelial surface” is the broadest reasonable interpretation of “heating the target tissue.”

C. “remodeling the therapeutic zone of target tissue”

All of the ‘511 patent claims recite “remodeling the therapeutic zone of target tissue,” which should be construed to mean “causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic

temperature.” Or alternatively, if the Board finds that it is more appropriate to include the patent’s requirement for avoiding surface damage in the “remodeling” step rather than “heating,” the term should be construed as “causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature without damaging the epithelium.” Just as a demolition of a home constitutes a change that is not considered “remodeling,” the ‘511 patent is clear that certain methods of causing a tissue change (i.e., those “with [] a risk of scarring,” “ablative,” or “invasive procedure[s],”) do not constitute “remodeling” in the context of the invention. Thus, Thermi’s contention that “remodeling . . . is a natural phenomenon that results from the heating of the tissue” (Pet. at 27) is untrue. Although some underlying tissue contraction could take place when high heat is applied to vaginal tissue that burns or destroys the surface, this example clearly falls outside of the scope of the claimed invention. The District Court agreed, rejecting Petitioner’s position that “remodeling” is a natural phenomenon resulting from any heat application, finding instead that “remodeling is a process comprising a doctor’s application of specific concrete steps to specific tissue under particularized conditions, which is simply predicated on the ability of collagen to be physically transformed by heat.” Ex. 2009 at 7.

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

Independent claim 35 recites “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock.” The specification of the ‘511 patent makes clear that this phrase means “heating the vagina circumferentially around its wall from 1 o’clock to 11 o’clock.” Petitioner’s proposed construction of “heating *at least one point of the vaginal wall* between 1 o’clock to 11 o’clock positions in a circumferential view with the urethra at 12 o’clock” (emphasis added) is both unreasonable and inconsistent with the ‘511 specification.

Petitioner attempts to divorce “heating a portion of the vagina” from the remainder of the claim term to support Petitioner’s construction that the claim term only requires heating “at least one point of the vagina.” Pet. at 22. While it is correct that only a portion of the vagina is heated, this claim is clear in light of the specification that the portion that is heated is the circumferential region from 1 o’clock to 11 o’clock, omitting 12 o’clock.

The specification explains that embodiments of the invention “do not include treating the approximately 60 degree arc between 11 o’clock and 10 o’clock because the practice of this invention is not directed toward tissue in the vicinity of the urethra.” Ex. 1001 at 3:66-67, 4:1-3. Thus, these embodiments of the ‘511 patent only treat the portion of the vagina corresponding to “the

approximately 300 degree arc between 1 o'clock and 11 o'clock." Ex. 1001 at 3:65-66.

Indeed, the '511 patent explicitly states "embodiments of the invention comprise treating and remodeling the vagina *over the 300 degree circumferential arc* from about 1 o'clock to about 11 o'clock." Ex. 1001 at 11:56-58. Notably, the specification uses the term "over," a preposition meaning "from one point to another across an intervening space or barrier," further supporting Viveve's construction of this claim term. Ex. 2004 at 3. Petitioner's construction instead asked the Board to ignore the plain language of the specification, and instead read "treating and remodeling the vagina *at some point in* the over 300 degree circumferential arc."

The '511 patent further discloses "with a treatment tip of about 1 cm in width, a series of about 10 contact site *allows completion of an 300 degree arc* of the circumference, between the 1 o'clock and 11 o'clock positions. These dimensional considerations underlie the rationale for an embodiment of the treatment wherein the surface of the energy delivery element has a curvature of about 30 degrees, *each contact site accounting for about 10% of the 300 degree arc.*" Ex. 1001 at 14:37-45 (emphasis added). Thus, the '511 patent makes clear that for these embodiments, the entire 300 degree arc is contacted.

In the context of the ‘511 patent, the broadest reasonable interpretation of this claim term must reflect heating the vagina wall over the entire 300 degree span, and not merely “at least one point” as proposed by Petitioner. Therefore, the Board should adopt “heating the vagina circumferentially around its wall from 1 o’clock to 11 o’clock” as the broadest reasonable interpretation of the term “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock.”

IV. PETITIONER’S GROUNDS ARE IMPROPERLY REDUNDANT

Multiple grounds that are presented in a redundant manner with no meaningful distinction between them are contrary to the regulatory and statutory mandates governing *inter partes* review, and are therefore not entitled to consideration. *See generally Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co.*, CBM2012-00003, Paper 7 (P.T.A.B. Oct. 25, 2012). Presenting multiple redundant grounds places a significant burden on the Board and the patent owner; causes unnecessary delay; and compromises the just, speedy, and inexpensive resolution of the proceeding. *Id.* at 2; 37 C.F.R. § 42.1(b); 42.108. As such, analyzing the petition and eliminating redundant grounds streamlines the proceeding. *Liberty Mut.*, CBM2012-00003, Paper 7 at 2.

In *EMC Corp v. PersonalWeb Techs., LLC*, the Board previously explained that grounds may be horizontally or vertically redundant. IPR2013-00087, Paper

25 at 3-4 (P.T.A.B. June 5, 2013). The analysis for both properly focuses on whether the petitioner has articulated a meaningful distinction of the relative strengths and weaknesses of its application of the prior art to one or more claim elements. *Liberty Mut.*, CBM2012-00003, Paper 7 at 3-4.

The instant Petition contains two vertically redundant grounds. The Petitions fail to provide any meaningful distinction between the redundant grounds and, in fact, acknowledges the redundancy in its different theories.

Grounds are vertically redundant if they assert “an additional prior art reference to support another ground of unpatentability when a base ground already has been asserted against the same claim without the additional reference and the Petitioner has not explained what are the relative strength and weakness of each ground.” *Liberty Mut.*, CBM2012-00003, Paper 7 at 12. The grounds of the instant Petition are vertically redundant because they assert several theories directed to overlapping groups of claims without an explanation or rationale as to the respective deficiencies of the separate theories. These grounds should therefore be denied, or if instituted, narrowed to a single theory.

With respect to at least claims 1-10, 13-14, 17, 23-25, and 27-33 of the ‘511 patent, Petitioner contends that these claims are (1) anticipated by Edwards, and (2) obvious over Edwards, Ingle, and Mosher. Petitioner provides no discussion of the strength or weakness of the theories relative to each other, but merely reiterates the

redundancy. (“Edwards discloses this limitation. However, to the extent it is determined that it did not anticipate this limitation, Mosher and Ingle also disclose this limitation.”) Pet. at 40. The Board should therefore deny institution of the redundant grounds or, if instituted, at least narrow institution to a single theory.

**V. THE PETITION FAILS TO ESTABLISH A REASONABLE
LIKELIHOOD OF PREVAILING ON ANY OF ITS PROPOSED
GROUNDS FOR ANY CHALLENGED CLAIM**

The Board may only grant a petition for *inter partes* review where “the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); *see* 37 C.F.R. § 42.108(c). The Board has further clarified that “[i]n an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify ‘with particularity . . . the evidence that supports the grounds for the challenge to each claim’)). “This burden of persuasion never shifts to Patent Owner.” *Dell Inc. v. Realtime Data LLC*, IPR2016-01002, Paper 71 at 5 (P.T.A.B. Oct. 31, 2017).

Further, because the Board is limited to “the information presented in the petition,” a petition that does not stand on its own must be denied. *See, e.g., Apple*

Inc. v. Evolutionary Intelligence, LLC, IPR2014-00079, Paper 8 at 2, 17-19

(P.T.A.B. Apr. 25, 2014). In deciding whether to institute review, the Board does not devise its own theories or arguments by “search[ing] the record and piec[ing] together any evidence or arguments that may support Petitioner’s ultimate conclusion.” *CaptionCall v. Ultrac, Inc.*, IPR2013-00549, Paper 20 at 5 (P.T.A.B. Apr. 28, 2014). The Board should deny the Petition because as shown below, the Petition does not stand on its own because Petitioner fails to provide satisfactory explanation of how the claims are unpatentable under the statutory grounds.

In particular, Petitioner has failed to demonstrate that Edwards anticipates claims 1-10, 13-14, 17, 23-25, 27-33. Petitioner further fails to demonstrate that Edwards, Ingle, and Mosher are properly combinable. Even assuming *arguendo* that Edwards, Ingle, and Mosher were combinable, Petitioner has failed to demonstrate that such a combination would render claims 1-42 unpatentable. Furthermore, Petitioner cannot rebut secondary considerations that support non-obviousness of the challenged claims. The petition therefore fails to establish a reasonable likelihood that Petitioner would prevail with respect to any of the challenged claims under any of the proposed grounds. Accordingly, the Board should deny the petition.

A. Ground 1: The Petition Does Not Establish that Edwards Anticipates Claims 1-10, 13-14, 17, 23-25, 27-33

As discussed below, Petitioner relies on a legally deficient anticipation analysis. “A claim is anticipated if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference.” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor*, 851 F.3d 1270, 1273 (Fed. Cir. 2017). Furthermore, “[a]nticipation requires that a reference disclose ‘not only all of the limitations claimed but also all of the limitations *arranged or combined in the same way* as recited in the claim.’” *Dominion Dealer Solutions, LLC. v. Autoalert, Inc.*, Case IPR2013-00220, Paper 8 at 13 (P.T.A.B. Aug. 15, 2013) (emphasis in original); *Net MoneyIN v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (“[I]t was error for the district court to find anticipation by combining different parts of the [reference] simply because they were found within the four corners of the document[.]”); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001).

1. Edwards does not anticipate claim 1

a. Summary of Edwards

Edwards describes systems and methods for treating menorrhagia and female urinary incontinence. Ex. 1008 at Abstract, 1:24-26. The systems and methods of Edwards generally apply radiofrequency (RF) energy to target tissues “so as to ablate, tighten, shrink or reshape the tissue and thereby correct an

unwanted condition.” Ex. 1008 at 2:34-39. In contrast to the nonablative 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*, Ex. 1008 at 9:66-67, 10:1-4, 11:28-33, 12:47-55, 12:66-67, 13:14-16.

Edwards discloses four embodiments of ablative treatment. Ablation is defined as “removal of a part, pathway, or function by surgery, chemical destruction, electrocautery, or radiofrequency.” Ex. 2005, Taber’s Cyclopedic Medical Dictionary, at 3. Radiofrequency ablation is defined as “ablation in which an electrode delivers a low-voltage, high-frequency current to cauterize and destroy abnormal tissues.” Ex. 2005, Taber’s Cyclopedic Medical Dictionary, at 3. *See also* Ex. 1009 at [0046] (“the term ‘ablation’ of a tissue means that the tissue is substantially removed and/or the function of the tissue is substantially destroyed.”).

The first embodiment inserts a treatment element with needle electrodes into the uterus for intrauterine ablation. Ex. 1008 at 4:15-18, 9:4-7, 9:30-32, 9:66-67, 10:1-2. The second embodiment inserts a treatment element with tissue penetrating electrodes into the urethra to create ablative lesions within the urethral sphincter muscle for the treatment of urinary incontinence. Ex. 1008 at 5:8-9, 10:15-19, 11:30-31. The third embodiment inserts a treatment element with tissue penetrating electrodes into the bladder to create ablative lesions within the bladder outlet to

treat urinary incontinence. Ex. 1008 at 11:45-53, 12:11-18, 12:38-40, 12:47-55.

The fourth embodiment inserts a treatment element into the vagina through a speculum to create ablative lesions in the anterior and posterior vaginal wall to treat urinary incontinence. Ex. 1008 at 13:12-16, 13:43-46; Ex. 2001 ¶¶19-21.

The Petition relies almost exclusively on Edwards' fourth embodiment. 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." Ex. 1008 at 3:6-9. Like other embodiments, Edwards does not disclose any specific energy frequency or temperature for its application. With respect to the fourth embodiment, Edwards explains that "[r]emodeling of the anterior wall treats incontinence based on bladder outlet hypermobility by increasing support for the bladder outlet, as well as the proximal and midurethra." Ex. 1008 at 13:14-19. 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, Ex. 1008 at 3:11-13, Edwards provides no disclosure regarding the specific anatomic tissue structures to heat to provide the result of reducing vaginal circumference or providing a stiffer vagina from a sexual function standpoint. Ex. 2001 ¶¶28-30.

In Edwards's fourth embodiment system, the treatment element is used in conjunction with a speculum. Ex. 1008 at Figure 4, 13:38-40. A speculum is a

device that dilates a vagina. Ex. 2001 ¶25. As shown in Figure 4, Edwards discloses that “[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.*” Ex. 1008 at 7:26-33 (emphasis added). Edwards only ever discloses that the blade 420 locked into position with the speculum during delivery of RF energy to the vaginal wall. See Ex. 1008 at 13:43-62.

A POSITA would understand “simple positioning of the speculum within the vagina” as the conventional positioning of a speculum, with the blades of the speculum against the anterior and posterior vaginal walls. Ex. 2001 ¶25. 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. Ex. 2001 ¶¶26-27.

As shown in Figures 9A and 9B, Edwards further explains 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.”

Ex. 1008 at 13:43-46 (emphasis added). Thus a POSITA 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). Ex. 2001 ¶¶26-28.

Edwards discloses delivery of a cooling or irrigation fluid into the vagina through pores 425 on blade 420. Ex. 1008 at 13:50-53. Notably, Edwards does not disclose any specific provisions indicative of protection of the mucosal epithelium from ablation, such as heat dissipating gel, adjusting the energies used, adjusting the interval of exposure, turning the exposure on and off (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. Ex. 2001 ¶23.

b. Edwards does not disclose “heating the target tissue”

Edwards does not disclose “heating the target tissue,” as recited in all challenged claims. Petitioner previously confirmed that the claimed methods heat target tissue without causing surface tissue damage, as would be the case with ablative techniques:

- This is an innovation and improvement in the field. And the major improvement was being able to remodel this particular tissue *without damaging it, scarring it, ablating it*, that sort of thing.

- The improvement that was cited is over *the prior art which either ablated tissue or it was invasive in order to heat -- to -- to apply heat treatment to this particular tissue.*
- [T]he ‘511 patent itself is directed -- is an improvement because *you are able to modify this tissue underlying the surface without damaging, without scarring, without burning the tissue.*

Ex. 2002 at 23:14-17, 25:12-15, 36:6-9 (emphasis added).

Unlike the claimed invention, Edwards does not disclose heating without damaging the mucosal epithelial surface, as required by the claim. Instead, Edwards discloses that, “[a] method 900 is performed to create a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both.” Ex. 1008 at 13:14-16. This is consistent with Edwards’ teaching of ablative RF techniques, that a POSITA would understand “deliver[] a low-voltage, high-frequency current to cauterize and destroy abnormal tissues.” Ex. 2005 at 3; Ex. 2001 ¶21 (explaining that Fig. 4 confirms that this embodiment uses ablative techniques based on the electrode size which is consistent with a high heating effect that is intended to produce an ablative, destructive action).

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 bladder neck, and not to protect the epithelial mucosa. Ex. 2001 ¶22. In particular, Edwards does not describe any specific provisions for protecting the mucosal epithelium in the area that is being treated. Ex. 2001 ¶23. This is because a POSITA 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. Ex. 2001 ¶23. 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. Ex. 2001 ¶23. A POSITA 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. Ex. 2001 ¶22. In fact, Edwards confirms that its cooling fluid “prevents collateral thermal damage to the urethral wall and associated structures,” (Ex. 1008 at 11:5-7)—thus confirming that Edwards causes damage to the contacted tissue and that the cooling fluid is for protecting non-target tissue.

Unlike the claimed invention which heats sub-mucosal tissue without damaging the mucosa, Edwards creates “lesions” in the vaginal wall. Thus, Edwards does not disclose “heating the target tissue,” as recited in the claims.

c. Edwards does not disclose “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

Edwards does not disclose “wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus,” as recited in claim 1. Edwards merely discloses that “[a] method 900 is performed to create a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both.” Ex. 1008 at 13:14-16. Edwards does not disclose the depth within the vagina on the anterior that is being treated. Therefore, Edwards does not explicitly disclose “wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus,” as recited in claim 1.

Furthermore, Edwards does not inherently disclose “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.” To establish inherency, Petitioner must show that the limitation must necessarily be present in the recited reference. *Cont’l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) (“Inherency . . . may not be established by probabilities or possibilities.

The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”). Petitioner has not met this burden. In an adult female, the anterior vaginal wall is about 7.5 cm long and the posterior vaginal wall is about 9 cm long. Ex. 1001 at 11:41-42. Thus, more than half of the length of the anterior vaginal wall, and almost two-thirds of the length of the posterior vaginal wall do not fall within the claimed range.

In fact, Edwards more likely excludes the portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus. In particular, Edwards discloses that “[r]emodeling the anterior wall treats incontinence based on bladder outlet hypermobility by increasing support for the bladder outlet, as well as the proximal and mid-urethra.” Ex. 1008 at 13:16-19. The region of the vaginal wall that is adjacent to the bladder outlet and the proximal and mid-urethra is beyond 3.5 cm inward from the introitus. Ex. 2001 ¶¶28-29.

Additionally, Edwards discloses “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.” Ex. 1008 at 13:43-46 (emphasis added). Thus a POSITA 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., further from the vaginal opening) at a location beyond 3.5 cm from the introitus. Ex. 2001 ¶¶26-28. Furthermore, because 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, the treatable area along the posterior and anterior vaginal walls is restricted to the area past the speculum. Ex. 2001 ¶¶26-28. Edwards does not disclose any configuration in which RF energy is delivered to the vagina without the blade 420 locked into position relative to the speculum, and likely cannot treat the region from the introitus to a region 3.5 cm from the introitus due to the presence and positioning of the speculum. Ex. 2001 ¶27.

To remedy the deficiencies of Edwards, Petitioner apparently relies on the alleged knowledge of a person of ordinary skill in the art, stating “[a] POSITA would know that the mean length from cervix to introitus along the anterior wall in an unaroused vagina of a woman of child-bearing age is approximately 6.5 cm. Therefore, the treatment of the anterior wall of the vagina, as contemplated by Edwards would necessarily entail the treatment of the portion of the vagina from the introitus to at least an inward position of 2 cm.” Pet. at 29. However, the Federal Circuit has made clear that a claim is anticipated only if each and every limitation is found either expressly or inherently in a single prior art reference, and that the Board is not permitted to “fill in missing limitations simply because a skilled artisan would immediately envision them.” *Nidec Motor Corp.*, 851 F.3d at 1274-75. Petitioner additionally provides no explanation to support its assertion

that the region from the introitus to at least an inward position of 2 cm is necessarily treated, rather than the region starting from 3.5 cm from the introitus to the cervix.

Therefore, Edwards does not expressly or inherently disclose “wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus,” as recited in claim 1.

2. Edwards does not anticipate claims 2-10, 13-14, 17, 23-25, 27-33

Claims 2-10, 13-14, 17, 23-25, 27-33 ultimately depend from independent claim 1, and accordingly are not anticipated by Edwards for at least the same reasons discussed above for claim 1.

3. Edwards does not anticipate claims 2-4

Edwards does not expressly disclose temperature ranges, nor are they inherent in the disclosure of Edwards. In particular, Petitioner’s own expert identifies that certain genital tissue, including endopelvic fascia may be heated to up to 140°C. Ex. 1003 ¶ 52.

To establish inherency, Petitioner must show that the limitation must necessarily be present in the recited reference. *Cont’l Can Co. USA*, 948 F.2d at 1268-69 (“Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is

not sufficient.”). In light of the large possible temperature range outside of the claimed ranges, Petitioner can provide no evidence that the system of Edwards necessarily uses the claimed temperature ranges, instead relying on what would be obvious to a POSITA. *See* Pet. at 29-30. Therefore, Edwards does not expressly or inherently disclose the features of claims 2-4. Accordingly, Edwards does not anticipate claims 2-4 for at least these additional reasons.

4. Edwards does not anticipate claim 23

Petitioner alleges that claim 23 is anticipated by Edwards. *See* Pet. at 35. Petitioner appears to admit, however, that Edwards does not explicitly disclose heating “submucosa and muscularis below a mucosal epithelium.” Rather, Edwards merely discloses “delivery of RF energy to discrete areas of the vaginal wall,” but Edwards provides no disclosure as to what specific tissues are heated. Nor does Petitioner explain with factual support any reason that these particular tissues would be heated by Edwards’ techniques. Therefore, Petitioner has not met its burden in establishing a reasonable likelihood that Edwards anticipates claim 23.

5. Edwards does not anticipate claim 24

Petitioner alleges that claim 24 is anticipated by Edwards. *See* Pet. at 13, 24. However, in its claim-by-claim analysis, Petitioner failed to identify any aspects of Edwards that allegedly disclose, either explicitly or inherently, that “heating does

not modify a mucosal epithelium,” as recited in claim 24. Nor could it since Edwards teaches an ablative technique that “create[s] a series of lesions in either the anterior wall, the posterior wall, or both.” Ex. 1008 at 13:14-16. Indeed, this omission in its claim-by-claim analysis is telling, impliedly conceding that Edwards teaches damage to the surface tissue, unlike the claimed invention. Therefore, Petitioner has not met its burden in establishing a reasonable likelihood that Edwards anticipates claim 24.

6. Edwards does not anticipate claim 26

Petitioner alleges that claim 26 is anticipated by Edwards, which requires “tightening the introitus.” See Pet. at 36. The introitus is the opening where the vagina exits the body. Petitioner appears to admit that Edwards does not explicitly disclose this limitation. Rather, Edwards merely discloses “vaginal wall tightening” but Edwards provides no disclosure as to what specific area along the length of the vagina is tightened. Nor does Petitioner explain with factual support any reason that a POSITA would understand that the introitus is necessarily tightened using Edwards’ techniques. Indeed, because Edwards teaches using an RF applicator in combination with a speculum for entry to the vagina, it is more likely that Edwards is not treating the introitus. Ex. 2001 ¶¶27-28. Therefore, Petitioner has not met its burden in establishing a reasonable likelihood that Edwards anticipates claim 26.

7. Edwards does not anticipate claim 30

Petitioner alleges that Claim 30 is anticipated by Edwards. However, Petitioner fails to identify any aspects of Edwards that allegedly disclose, either explicitly or inherently, “wherein at least some of the remodeling occurs during the heating.” With respect to claim 28, the Petition alleges that “the mechanism of the remodeling of the target tissue is a natural phenomenon that necessarily occurs based on the application of energy to the target tissue and this element is necessarily met by the method taught by Edwards.” Pet. at 37.

However, as acknowledged by the Petition, Edwards discloses that “[t]he tiny cites of treated muscle resorb, remodel and shrink *in the weeks that follow treatment . . .*” Pet. at 26; Ex. 1008 at 2:53-56 (emphasis added). Therefore, Petitioner has not met its burden in establishing a reasonable likelihood that Edwards anticipates claim 30.

B. Ground 2: The Petition Does Not Establish That Edwards in View of Ingle and Mosher Render Claims 1-42 Obvious

Obviousness requires that “each and every limitation of the claim is described or suggested by the combination of prior art references or would have been obvious based on the knowledge of those of ordinary skill in the art.” *Ex Parte Von Hollen*, Appeal 2017-005071, at 4 (P.T.A.B. Jan. 19, 2018) (citing *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988)). The Federal Circuit has explained that in order to demonstrate that the challenged claims are obvious, petitioner must

articulate “[1] how specific references could be combined, [2] which combination(s) of elements in specific references could yield a predictable result, or [3] how any specific combination would operate or read on the asserted claims.” *Dell Inc. v. Realtime Data LLC*, IPR2016-01002, Paper 71 at 10 (P.T.A.B. Oct. 31, 2017) (citing *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1327-28 (Fed. Cir. 2012)). Moreover, to invalidate a claim based on obviousness, petitioner must demonstrate “that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Id.*

1. Summary of Mosher

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 discloses several embodiments, for example “[i]n some embodiments, 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.” Ex. 1009 at [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." Ex. 1009 at [0057]. Mosher also discloses a number of tissue-penetrating electrode tips, "with each tip having a sharpened distal end suitable for penetrating into tissue, particularly for transmucosal penetration through the vaginal wall and into the tissue structures which support the urethra, urinary sphincter, bladder neck, and the like." Ex. 1009 at [0052].

The above described embodiments (i.e., "direct access" embodiments) differ from the '511 patent and Edwards in that they are minimally invasive—they require a surgical technique, such as laparoscope inserted near the patient's belly button or surgically cut flap in the vaginal wall—to access the surface of the endopelvic fascia. Ex. 1009 at [0056] – [0057], FIG. 2; Ex. 2001 ¶33. The disclosed methods are also different in that they focus on treatment of the deeper tissues, such as endopelvic fascia.

Mosher further discloses a non-invasive embodiment in which the probe body may be separated from the endopelvic fascia, with heating provided through (for example) the vaginal wall. Ex. 1009 at [0009]. Yet even here, Mosher also differs from Edwards in that, in that "[i]n many embodiments, these treatments will

be performed so as to *inhibit ablation* of the target collagenous tissues.” Ex. 1009 at [0046] (emphasis added). Thus, Mosher teaches away from a combination with Edwards, which relies on ablative techniques.

Mosher provides a laundry list of tissues that Mosher purports may be the target of treatment using Mosher’s disclosed system and method. Ex. 1009 at [0011]. However, Mosher does not provide any detail as to how its techniques would be adapted—if at all—to treat any of these other tissues, nor any coherent teaching as to which specific tissues would actually replace the support lost due to damage to the endopelvic fascia. Ex. 2001 ¶32. In fact, many of these structures are irrelevant to the treatment of stress urinary incontinence because they are located either too lateral or too posterior to provide any support to the urethra or bladder. Ex. 2001 ¶32. Furthermore, at least one structure listed in Mosher’s laundry list is not found in female anatomy. Ex. 2001 ¶32. Therefore, a POSITA would understand that Mosher’s laundry list recitation of anatomy as not encompassing the possible treatment areas for female urinary stress incontinence. Ex. 2001 ¶32.

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

2. Summary of Ingle

Ingle describes systems and methods for treating fascia for treating incontinence. Ex. 1010 at 2:51-53, 2:59-60. Specifically, Ingle aims to stiffen the endopelvic fascia “[u]sing gentle resistive heating between bipolar electrodes, [so that] the endopelvic fascia EF and arcus tendineus fascia pelvis ATFP are controllably contracted to shrink them and re-elevate the bladder toward its original position.” Ex. 1010 at 17:30-34; *see also* at 17:50-59.

Ingle discloses several embodiments in which “a first electrode having a first electrode surface which is engagable 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.” Ex. 1010 at 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.” Ex. 1010 at 7:54-61; *see also* Ex. 1010 at 8:24-27 (“[t]he method comprises clamping a target tissue between a plurality of electrode surfaces...”).

While Ingle generically discloses 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.*, Ex. 1010 at Figs. 6, 11, 12, 12K, and 13. In particular, Ingle discloses 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.” Ex. 1010 at 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.* at 18:46-50, or as shown in Figure 18A, Ingle discloses a two probe device 250 that “includes both a transvaginal probe 252 and a transrectal probe 254.” *Id.* at 29:66-67, 30:1-2.

Ingle’s embodiments differ from the ‘511 patent and the other references in that they require a parallel electrode on the opposite side of the vaginal wall, inserted into another orifice or on the abdomen. This configuration limits the regions of the vaginal wall available for treatment. *See* Ex. 2001 ¶44.

Ingle was considered by the Examiner during the prosecution of the ‘511 patent, but was not applied as the basis of a rejection.

3. Petition does not adequately articulate that the references are properly combinable

The Federal Circuit has explained that a party who petitions the Board for a determination of obviousness must articulate “[1] how specific references could be combined, [2] which combination(s) of elements in specific references could yield

a predictable result, or [3] how any specific combination would operate or read on the asserted claims.” *Dell Inc. v. Realtime Data LLC*, IPR2016-01002, Paper 71 at 10 (P.T.A.B. Oct. 31, 2017) (citing *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1327-28 (Fed. Cir. 2012)). Moreover, to invalidate a claim based on obviousness, petitioner must demonstrate “that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Id.*

As to “[1] how specific references could be combined,” Petitioner does not adequately articulate how, or even whether, the specific references could be combined. For example, Edwards discloses a treatment element in conjunction with a speculum, in which 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, thereby restricting the areas along the posterior and anterior vaginal walls that are treatable using this method. Ex. 1008 at Figure 4, 13:38-40. In light of this disclosure, the Petition does not address how this embodiment of Edwards can be combined with Mosher (which teaches “tissue-penetrating electrodes may be inserted from the probe body so as to heat the endopelvic fascia,” Ex. 1009 at Abstract) and Ingle (which teaches “clamping a target tissue between a plurality of electrode surfaces,” Ex. 1010 at 8:24-27).

Indeed, although Petitioner relies on the fact that all three references “describe methods of cooling the intermediate tissue,” this suggests there would be no reason to look beyond Edwards to Mosher or Ingle—Edwards already incorporated an irrigation port, and Petitioner cites to no specific deficiency with Edwards that Mosher or Ingle would cure, let alone how they would cure it.

As to “[2] which combination(s) of elements in specific references could yield a predictable result,” Petitioner does not articulate any evidence to support a finding that a POSITA would have a reasonable expectation of success in combining Edwards, Mosher, and Ingle. In particular, Petitioner does not address why a POSITA would have a reasonable expectation of success in modifying Edwards, which aims to create ablative lesions, with Mosher and Ingle, which purport to inhibit ablation. Likewise, although Edwards mentions that other forms of energy besides RF could be used, Petitioner provides no rationale basis that one would expect success in combining the RF technique and tip of Edwards with “the ultrasound vaginal probe embodiment described in Ingle ‘704.” Pet. at 46. See *Polaris Indus., Inc. v. Arctic Cat, Inc.*, No. 2016-1807, 2018 WL 797462, at *9 (Fed. Cir. Feb. 9, 2018) (“by completely disregarding certain teachings as ill-defined ‘subjective preferences,’ the Board’s approach invited the ‘distortion caused by hindsight bias’ into the fold. We have observed that ‘the prejudice of

hindsight bias’ often overlooks that the ‘genius of invention is often a combination of known elements which in hindsight seems preordained.’” (citations omitted).

Even assuming that the references can be combined, as to “[3] how any specific combination would operate or read on the asserted claims,” the Petition still does not articulate the specific combination it is relying on to read on the asserted claims. Regarding each claim element, the Petition merely identifies portions of each reference that allegedly disclose the claimed feature. *See, e.g.*, Pet. at 42. (“Edwards disclose this limitation. However, to the extent it is determined that it did not anticipate this limitation, Mosher and Ingle ‘704 also disclose this limitation.”).

The crux of Petitioner’s obviousness argument apparently is that Edwards, Mosher, and Ingle were directed generally to similar devices to treat similar problems regarding incontinence, and a skilled artisan could have looked at all three references to improve upon treatment of urinary stress incontinence. *See generally* Pet. 44-46. The Board has determined that such an assertion is not enough for a finding of obviousness. *See Samsung Electronics Co. LTD, v. Elm 3DS Innovations, LLC*, IPR2016-00687, Paper 42 at 35 (P.T.A.B. Aug. 22, 2017) (“We understand Petitioner’s position to be that Bertin ‘754 and Leedy ‘695 were directed to similar general goals and problems in the semiconductor fabrication arts, and a skilled artisan would have looked at both references to improve upon

fabrication processes. However, based on the complete record here, Petitioner’s ‘reasoning seems to say no more than that a skilled artisan, once presented with the two references, would have understood that they could be combined. And that is not enough: it does not imply a motivation to pick out those two references and combine them to arrive at the claimed invention.’”) (citing *Pers. Web Techs., LLC v. Apple Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017)). The Federal Circuit has repeatedly held that it is error for the Board 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.” *Polaris Indus., Inc. v. Arctic Cat, Inc.*, No. 2016-1807, 2018 WL 797462, at *9 (Fed. Cir. Feb. 9, 2018).

Petitioner has the burden of showing, in its petition, a reasonable likelihood that it would prevail. 35 U.S.C. § 314(a). The Board measures the reasonable likelihood by considering the analysis offered by Petitioner. 37 C.F.R. § 42.104(b) (setting forth the requirements of a petition, including specificity and identification of support). “The Board considers the reasons *articulated by Petitioner*; Petitioner should not expect the Board to search the record and piece together additional evidence that may support Petitioner’s position, or to insert its own reason for combination.” *Captioncall, LLC v. Ultratec, Inc.*, IPR2013-00549, Paper 20 at 6 (P.T.A.B. Apr. 29, 2014) (emphasis in original) (holding that the Board did not abuse its discretion when declining to institute *inter partes* review when “[t]he

reason articulated by Petitioner (that the references share a ‘basic concept’) was determined to be insufficient by the Board”). In view of at least the above identified deficiencies, the Board should not grant *inter partes* review on this ground.

4. Petitioners cannot rebut objective evidence of non-obviousness of the Challenged Claims

a. RF remodeling of female genital tissue comprising vulva, introitus and vagina tissue has received praise by others

Although Petitioners now urge the Board to find that RF application for remodeling vaginal tissue was known or obvious for decades, Petitioner recently funded a study and research article entitled “Temperature Controlled Radiofrequency for Vulvovaginal Laxity,” by Dr. Red Alinsod. Ex. 2006 at 1. Dr. Alinsod, the research investigator, states that vulvovaginal rejuvenation using RF energy “is a fairly new concept with real potential for success.” Ex. 2006 at 3. Like the ‘511 patent reported many years before, there have been few options for treatment of vaginal laxity other than ineffective Kegel exercises or surgical intervention. *Id.* Dr. Alinsod’s study used the ThermiVa, Petitioner’s own RF device for treating vaginal laxity, to treat 23 subjects. Ex. 2006 at 4. The research article explains that “[t]he labia majora were treated first . . . This was followed by treatment of the mucosal surface of the vaginal introitus starting at the hymenal ring and advanced to approximately 4 to 9 cm into the cavity for each zone of the

vaginal wall (ventral, dorsal, left and right).” Ex. 2006 at 4. The article further describes that “[t]here were no burns, blisters or major complications during or after treatments, which were described as pleasant and comfortable.” Ex. 2006 at 5.

The Board has held that “industry praise provides probative and cogent evidence that one of ordinary skill in the art would not have reasonably expected the claimed invention.” when there is a nexus between the claimed invention and the industry praise. *World Bottling Cap, LLC v. Crown Packaging Technology, Inc.*, IPR2015-01651, Paper 34 at 22 (P.T.A.B. Jan. 19, 2017) (citing *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013)). Notably, the above article cites two Viveve studies, the Millheiser and Sekiguchi studies, which the article describes as “landmark.” Ex. 2006 at 3. Furthermore, on Dr. Alinsod’s website, www.thermiva.org, nearly a decade after the filing of the application which lead to the ‘511 patent, Dr. Alinsod asserts that “[w]e are really just learning all the things that RF can do for the gynecology, urology, aesthetic, and sexual medicine practice and it is just amazing the stuff you and the other docs are discovering,” and that “RF is game changing and the New Paradigm in Gynecology.” Ex. 2007 at 3.

There is a presumption of nexus when the patentee shows that the asserted objective evidence is tied to a specific product and that product is the invention disclosed and claimed. *World Bottling Cap, LLC v. Crown Packaging Technology*,

Inc., IPR2015-01651, Paper 34 at 17 (P.T.A.B. Jan. 19, 2017) (*citing WBIP, LLC v. Kohler Co.*, 829 F.3d 1317 (Fed. Cir. 2016)). Here, there is a strong nexus between the objective evidence and the claimed invention. As indicated in the research article, Dr. Alisond's study heated tissue underlying an epithelium of female genital tissue without damaging the mucosal epithelium ("[t]here were no burns, blisters or major complications during or after treatments, which were described as pleasant and comfortable"). Further, Dr. Alisond's study treated the portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus as well as externally towards the Hart's line.

Therefore, the strong nexus between the claims and the industry praise of RF treatment of the vulva, introitus, and vagina tissue, as shown by Petitioner's own research article and by Petitioner's Research Investigator, weighs against obviousness.

5. Claims 1-34 are not obvious in view of Edwards, Ingle and Mosher

a. "heating the target tissue"

The combination of Edwards, Mosher, and Ingle does not disclose or render obvious "heating the target tissue" as recited by the '511 patent. But Edwards does not teach this limitation for the reasons presented above. Nor do Mosher or Ingle, as both references are directed to heating the "endopelvic fascia," which is not a target tissue in connection with the '511 patent.

Mosher discloses heating the endopelvic fascia to treat bladder outlet hypermobility. Mosher's aim is "heating between about 100 and about 800 cubic millimeters of endopelvic fascia for sufficient time to effect substantial collagenous tissue shrinkage." Ex. 1009 at 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." Ex. 1009 at [0049].

Ingle, like Edwards and Mosher, is also directed to heating the endopelvic fascia to treat bladder outlet hypermobility. Ingle explains that:

The pelvic support which generally maintain the position of the urinary bladder B are illustrated in FIG. 4. Of particular importance for the method of the present invention, endopelvic fascia EF defines a hammock-like structure which extends between the arcus tendineus fascia pelvis ATFP. These latter structure extend between the anterior and posterior portions of the pelvic bone, so that the endopelvic fascia EF largely defines the pelvic floor. In women with urinary stress incontinence due to bladder neck hypermobility, the bladder has typically dropped

between about 1.0 cm and 1.5 cm (or more) below its nominal position . . . Using gentle resistive heating between bipolar electrodes, the endopelvic fascia EF and arcus tendineus fascia pelvis ATFP are controllably contracted to shrink them and re-elevate the bladder toward its original position.

Ex. 1010 at 17:1-34, Fig. 4.

Therefore, even if one combined Edwards with the teachings of Mosher and Ingle, the tissue that would be heated would be the endopelvic fascia, which is not the “target tissue” as in the claims.

To the extent that the Board construes “target tissue” as “tissue immediately beneath the mucosal epithelium of genital tissues,” the combination of Edwards, Mosher, and Ingle still fail to disclose or render obvious this feature. Contrary to Petitioner’s assertion, Ingle does not disclose heating the tissue immediately beneath the mucosal epithelium. Petitioner’s expert opines that “the ‘therapeutic zone’ would include fascia supporting the urethra or bladder, including at least the endopelvic fascia, that the ‘intermediate tissue’ is the mucosal epithelium of the anterior vaginal wall, and that the ‘stunned tissue’ is the muscularis and/or the submucosa of the dermal vaginal tissue.” Ex. 1003 ¶50. However, this position is contrary to the explicit disclosure in Ingle. Ingle discloses that “[t]he target tissue is *separated from a tissue surface* by an intermediate tissue. The method comprises coupling an electrode of a probe to the tissue surface and cooling the intermediate

tissue with the probe.” Ex. 1010 at 7:16-21. Thus, Ingle explicitly differentiates the tissue surface (i.e., mucosal epithelium) from the intermediate tissue. Ingle therefore suggests that the tissue separating the tissue surface from the target tissue is the tissue immediately beneath the mucosal epithelium, and that this intermediate tissue is “safely cooled.” See Ex. 1010 at 15:19-25.

Similarly, Mosher discloses heating the endopelvic fascia, and not the tissue immediately beneath the mucosal epithelium. Petitioner’s expert opines that “A person of skill in the art would understand that Mosher’s described treatment depth of between 2-6 mm would include remodeling of the muscularis, as the distance from the vaginal wall to the muscularis is typically about 3 mm in depth.” Ex. 1003 ¶61. However, this assertion is both unsupported and contrary to the explicit teachings of Mosher. 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. RF heating will typically induce collagen shrinkage so as to provide physical elevation of the urethra by shrinkage of the endopelvic fascia.

Ex. 1009 at [0066].

The disclosure of the references themselves clarify that the tissue being heated is the deep tissue, the endopelvic fascia, and not the submucosa.

Accordingly, the combination of Edwards, Mosher, and Ingle does not disclose or render obvious “heating the target tissue,” as recited in claim 1. Claims 2-34 depend from claim 1 and are not rendered obvious for at least the same reasons.

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

The combination of Edwards, Mosher, and Ingle does not disclose or render obvious this feature because Edwards, Mosher, and Ingle do not treat the portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus. As discussed above, Edwards does not disclose 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. In particular, Edwards is treating the anterior vaginal wall opposite the bladder outlet and proximal and mid-urethra. *See* Ex. 1008 at 13:16-19; Ex. 2001 ¶28.

Neither Mosher nor Ingle remedy the deficiencies of Edwards. Ingle discloses treating the endopelvic fascia transvaginally “[u]sing gentle resistive heating between bipolar electrodes, [so that] the endopelvic fascia EF and arcus tendineus fascia pelvis ATFP are controllably contracted to shrink them and re-elevate the bladder toward its original position.” Ex. 1010 at 17:30-34. As explained by Ingle and shown in, for example, Figures 6, 11, 12, 12K, and 13, treatment is directed to the endopelvic fascia located between the vaginal wall and the bladder wall. *See, e.g.*, Ex. 1010 at 20:19-25 (“Bladder B (and the other tissues opposite endopelvic fascia EF relative to the vaginal probe 42) are heated significantly less than endopelvic fascia EF”). Therefore, Ingle does not disclose or render obvious this feature.

Mosher does not remedy the deficiencies of Edwards and Ingle. Like Ingle, Mosher is directed to treating the endopelvic fascia, which supports and is located adjacent to the bladder. Ex. 2001 ¶¶32, 36-38. Mosher explains that “[t]o avoid injury to nerves in the bladder neck region while providing sufficient treatment volume along the endopelvic fascia, it may be advantageous to distribute the treatment volume along the patient’s lateral orientation while *limiting the length of*

treatment along the axis of the patient's urethra." Ex. 1009 at [0074]. Mosher further discloses that "such a laterally elongate treatment region of the endopelvic fascia will preferably be significantly wider (along the medial-lateral orientation) than its urethral length, ideally having a width of about 25 mm and a length of about 15 mm." Ex. 1009 at [0074].

A POSITA would understand that to treat the endopelvic fascia transvaginally, the treatment region refers to the region of the anterior vaginal wall adjacent to the bladder. Ex. 2001 ¶¶36-38. A POSITA would further understand that Mosher teaches away from treating the region extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus. 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. Ex. 1009 at [0074]. The region of the anterior vaginal wall that is adjacent to the endopelvic fascia 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 disclose or render obvious this feature.

Accordingly, the combination of Edwards, Mosher, and Ingle does not disclose or render obvious "wherein the heating includes heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in

from the introitus,” as recited in claim 1. Claims 2-34 depend from claim 1 and are not rendered obvious for at least the same reasons. Therefore, Petitioner has not met its burden in establishing a reasonable likelihood that the combination of Edwards, Mosher, and Ingle disclose or render obvious the features of claims 1-34.

a. Claims 19-22

Petitioner alleges that claims 19-22 are obvious in view of Edwards, Mosher, and Ingle. Pet. at 13. However, Petitioner failed to identify the aspects of Edwards that allegedly disclose or render obvious the features of claim 19, as the Petition does not address claim 19 under Ground I. Specifically, the Petition fails to identify which aspects of Edwards disclose or render obvious “wherein the method includes contacting the tip to the epithelium at a plurality of contact sites during a procedure, moving the tip from site to site, the combined contact sites comprising a treatment area,” as recited in claim 19. Furthermore, the Petition fails to articulate the combination that it relies upon to allegedly render obvious the features of claim 19. Claims 20-22 depend from claim 19 and are not rendered obvious for at least the same reasons. Accordingly, Petitioner has not met its burden in establishing a reasonable likelihood that the combination of Edwards, Mosher, and Ingle disclose or render obvious the features of claim 19. *See Lam Research Corp. v. Flamm*, IPR2015-01766, Paper 7 at 19 (P.T.A.B. Feb. 24, 2016) (denying institution for insufficient demonstration of a reasonable likelihood of

success in showing a claim obvious because “[i]t is Petitioner’s responsibility to explain specific evidence that support its arguments, not the Board’s responsibility to search the record and piece together what may support Petitioner’s arguments.”).

b. Claim 26

The combination of Edwards, Ingle, and Mosher does not disclose or render obvious “wherein remodeling comprises tightening the introitus,” as recited in claim 26. As discussed above, neither Edwards, Ingle, nor Mosher disclose treating the introitus. Petitioner alleges that “a POSITA would have understood that Ingle ‘704’s method could be used to tighten the introitus. Mosher also describes that its methods can be used to heat a variety of tissues including the submucosa and muscularis below a mucosal epithelium.” Pet. at 64. However, Petitioner provides no articulable reason why a POSITA would treat the introitus, given that this region is irrelevant for the treatment of urinary incontinence. Ex. 2001 ¶¶28-30, 37-39, 43-44. To the extent that these references disclose application of RF energy in vaginal tissues, the application is focused on the area near the bladder and bladder outlet, which is the opposite end of the vaginal canal as the introitus. The Board has held that “obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.” *Samsung Electronics Co. Ltd. v. Elm 3DS Innovations, LLC*, IPR2016-00687, paper 42 at 35-36

(P.T.A.B. Aug. 22, 2017) (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)). Furthermore, a showing of obviousness requires “an articulated reason with a rational underpinning to combine specific teachings in the references in a particular manner to arrive at the claimed invention[.]” *Dominion Dealer Solutions, LLC v. AutoAlert, Inc.*, Case IPR2013-00220, Paper 8 at 22 (P.T.A.B. Aug. 15, 2013) (citing *KSR Int’l Co.*, 550 U.S. at 418). Arguing merely that references are analogous to the invention of the patent at issue or to each other is insufficient. *Id.*

Petitioner merely asserts that “tissue underlying non-mucosal epithelial layers are also susceptible to RF modeling,” but provides no reason why a POSITA would be motivated to heat the introitus. Pet. at 64. Particularly where the stated motivation is that the patents are all devoted toward urinary incontinence, it is not clear what specific motivation a POSITA would have for targeting the introitus. Therefore, claim 26 is not rendered obvious for at least this additional reason. As such, Petitioner has not met its burden in establishing a reasonable likelihood that the combination of Edwards, Mosher, and Ingle disclose or render obvious the features of claim 26.

c. Claim 30

Petitioner alleges that Claim 30 is rendered obvious by Edwards, Mosher, and Ingle. However, as discussed above, Edwards discloses that “[t]he tiny cites of

treated muscle resorb, remodel and shrink *in the weeks that follow treatment*”

Pet. at 26; Ex. 1008 at 2:53-56 (emphasis added). Therefore Edwards does not disclose or render obvious “wherein at least some of the remodeling occurs during the heating.”

Mosher and Ingle do not remedy the deficiencies of Edwards. As acknowledged by the Petition, Mosher discloses that “RF heating will typically induce collagen shrinkage . . . [o]ver about two weeks, type III collagen will replace the denatured collagen” Pet. at 65; Ex. 1009 at [0066] (emphasis added). Ingle is silent with respect to when the remodeling occurs with respect to the heating time.

The combination of Edwards, Mosher, and Ingle does not disclose or render obvious “wherein at least some of the remodeling occurs during the heating,” as recited in claim 30 for at least this additional reason. Accordingly, Petitioner has not met its burden in establishing a reasonable likelihood that the combination of Edwards, Mosher, and Ingle disclose or render obvious the features of claim 30.

7. Claims 35-42 are not obvious in view of Edwards, Ingle, and Mosher

- a. The combination of Edwards, Ingle, and Mosher does not disclose or render obvious “wherein the heating includes heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock, wherein the aspect closest to the urethra is at 12 o’clock,”**

Edwards does not disclose this feature because Edwards does not disclose heating the vagina circumferentially around its wall from 1 o’clock to 11 o’clock, as required by the claim. As discussed above, Edwards discloses treating “discrete areas of the vaginal wall, namely on either the anterior or posterior wall.” Ex. 1008 at 3:11-13. The anterior vaginal wall corresponds to the region between 11 o’clock and 1 o’clock, while the posterior vaginal wall corresponds to the region between 5 o’clock to 7 o’clock, as it is described in the claim. Ex. 2001 ¶44. The vaginal walls from 1 o’clock to the 5 o’clock and 7 o’clock to 11 o’clock would be considered the lateral vaginal walls. Ex. 2001 ¶44. Edwards therefore does not disclose this feature.

Mosher and Ingle do not remedy the deficiencies of Edwards. Mosher fails to disclose or render obvious heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock. Like Edwards, Mosher only discloses 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 Ex. 1009 at Abstract, [0009].

The Petition reasons that because Mosher discloses treating a width of 2.5 cm and the 60 degree portion between 11 o'clock and 1 o'clock is approximately 2 cm wide, Mosher discloses treating 0.5 centimeters within the 1 o'clock to 11 o'clock span. Pet. at 67. However, 0.5 cm does not span the entire circumference of the vaginal wall between 1 o'clock and 11 o'clock, as required by claim 35.

Ingle fails for similar reasons as Mosher. Similar to Mosher, Ingle discloses treatment directed toward the endopelvic fascia between the urethra and the vagina, i.e., the region of the vaginal wall corresponding to the region from 1 o'clock to 11 o'clock. Ex. 1010 at 18:46-50.

Petitioner uses the flawed reasoning that because Ingle discloses that a rectal probe "may help to stabilize the location and direction of the vaginal probe so that it can provide heating to the deep tissues above and to the sides of the vagina" that Ingle discloses treating the 3 o'clock and 9 o'clock regions of the vaginal wall.

As an initial matter, Edwards and Ingle cannot be combined as suggested by Petitioner. As discussed above, Edwards uses a treatment element in conjunction with a speculum, in which 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. Ex. 1008 at Fig. 4, 13:38-40. A speculum is positioned with the blades of the speculum against the anterior and posterior walls

of the vaginal. Ex. 2001 ¶25. Edwards does not disclose moving the speculum during treatment such that the blades of the speculum are instead against the lateral vaginal walls. However, even if rotating the speculum of Edwards 90 degrees were possible, rotation of the vaginal probe including the rectal probe of Ingle is not possible because the rectal probe would be obstructed by the patient's leg.

Additionally, Ingle discloses that the rectal probe combined with the vaginal probe provides a clamping structure “to decrease the separation distance 264, and to clamp the target tissue between electrodes 266, 268.” Ex. 1010 at 30:45-50. Ingle explains that “[c]lamping of the tissue will help ensure firm engagement between the electrodes and the tissue surfaces, and will also promote even heating by minimizing the ratio between separation distance 264 and electrode widths 284.” Ex. 1010 at 30:53-56. Further, “[t]he rectal probe may optionally include a balloon to apply pressure to the vaginal probe, thus squeezing the two probes together.” Ex. 1010 at 31:31-33. Thus, a POSITA would understand that attachment of the probe to the speculum in lieu of the rectal probe of Ingle would not adequately provide the opposing pressure on the opposite side of the vaginal wall, nor the firm engagement between the electrodes and the tissue surface, that the rectal probe provides, as taught by Ingle. Therefore, Edwards and Ingle are not combinable with a reasonable expectation of success.

Nor would a POSITA be motivated to modify Edwards as to treat the entire circumference from 1 o'clock to 11 o'clock. Each time Edwards blade treats a new discrete area, the blade must be "disengaged and relocked in another position in the speculum." Ex. 1008 at 13:60-62. Doing that throughout the circumference of 1 o'clock to 11 o'clock would be time-consuming and uncomfortable for the patient. Ex. 2001 ¶27. Therefore, even if Mosher or Ingle did teach this full breadth of the treatment (which they do not), a POSITA would not be motivated to modify Edwards technique in this way.

However, even assuming *arguendo* that Edwards, Mosher, and Ingle are combinable as suggested by Petitioner, the combination of Edwards (11 o'clock to 1 o'clock and 5 o'clock to 7 o'clock), Mosher (11 o'clock to 1 o'clock) and Ingle ("deep tissues above and to the sides of the vagina") still fails to span the entire circumference of the vaginal wall between 1 o'clock and 11 o'clock, as required by claim 35.

Therefore the combination of Edwards, Mosher, and Ingle fails to disclose or render obvious claim 34. Claims 35-42 depend from claim 34 and are not rendered obvious for at least the same reasons. Accordingly, Petitioner has not met its burden in establishing a reasonable likelihood that the combination of Edwards, Mosher, and Ingle disclose or render obvious the features of claims 34-42.

VI. CONCLUSION

For at least the reasons provided above, the Petition should be denied and trial should not be instituted.

Respectfully submitted,

Dated: February 14, 2018

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(a)(1)(i), the undersigned hereby certifies that the foregoing PATENT OWNER'S PRELIMINARY RESPONSE contains 13,794 words, excluding a table of contents, a table of authorities, mandatory notices under 37 C.F.R. § 42.8, a certificate of service or word count, or appendix of exhibits or claim listings, as measured by the word-processing system used to prepare this paper.

Dated: February 14, 2018

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing PATENT OWNER'S PRELIMINARY RESPONSE and accompanying exhibits were served electronically on February 14, 2018, on counsel of record for the Petitioner as follows:

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PATENT OWNER'S EXHIBITS

Exhibit	Description
2001	Declaration of Lawrence S. Bass, M.D.
2002	Claim Construction Hearing Transcript in District Court Litigation 2:16-CV-1189-JRG (E.D. Tex. July 18, 2017)
2003	Claim Construction Memorandum Opinion and Order in District Court Litigation 2:16-CV-1189-JRG (E.D. Tex. Nov. 13, 2017)
2004	Webster's Third New International Dictionary, Merriam-Webster (2002)
2005	Taber's Cyclopedic Medical Dictionary, F.A. Davis Company (2005)
2006	Red M. Alinsod, "Temperature Controlled Radiofrequency for Vulvovaginal Laxity," Prime Journal 16 (2015)
2007	www.thermiva.org website
2008	Red Alinsod, "What are the Differences Between ThermiVa Radiofrequency and FemiLift/MonaLisa/IntimaLase lasers for use in Aesthetic Vulvovaginal Therapies?" (2015)
2009	Memorandum Opinion and Order in District Court Litigation 2:16-CV-1189-JRG (E.D.Tex. Apr. 20, 2017)
2010	C.V. of Lawrence S. Bass, M.D.