

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 IPR2018-00089
Patent No. 8,961,511

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I. INTRODUCTION.....	1
II. OVERVIEW OF THE ‘511 PATENT	3
A. The ‘511 Patent	3
III. CLAIM CONSTRUCTION	6
A. “target tissue”	7
A. “heating”	9
A. “remodeling the therapeutic zone of target tissue”	13
IV. PETITIONER’S GROUNDS ARE IMPROPERLY REDUNDANT	14
V. THE PETITION FAILS TO ESTABLISH A REASONABLE LIKELIHOOD OF PREVAILING ON ANY PROPOSED GROUND FOR ANY CHALLENGED CLAIM	16
A. Ground 1: The Petition Does Not Establish That Edwards in View of Ingle and Mosher Render Claims 43-58 Obvious.....	17
1. Summary of Edwards	17
2. Summary of Mosher	20
3. Summary of Ingle	22
4. The Petition does not establish that the references are properly combinable.....	24
5. Petitioners cannot rebut objective evidence of non-obviousness of the Challenged Claims.....	28
a. RF remodeling of female genital tissue comprising vulva, introitus and vagina tissue has received praise by others.....	28
6. Claims 43-50 are not obvious in view of Edwards, Ingle and Mosher	30

a. “heating the target tissue”	30
b. “wherein the heating includes heating a portion radiating outward from the introitus to Hart’s line”	35
7. Claims 51 is not obvious in view of Edwards, Ingle, and Mosher.....	40
a. The combination of Edwards, Ingle, and Mosher does not disclose or render obvious “wherein the heating includes heating a mucosal surface of the labia minora”	40
B. Ground 2: The Petition Does Not Establish that the Combination of Edwards, Kreuter, Beattie, Smith, and the knowledge of a POSITA Render Claims 43-58 Obvious.....	42
1. Summary of Kreuter	43
2. Summary of Smith.....	46
3. Summary of Beattie	47
4. Kreuter, Smith, and Beattie are Non-analogous Art	48
5. The Petition does not adequately articulate that the references are properly combinable	51
6. Claims 43-50 are not obvious in view of Edwards, Kreuter, Beattie, Smith, and Ordinary Skill in the Art	55
a. “heating the target tissue”	55
b. “wherein the heating includes heating a portion radiating outward from the introitus to Hart's line.”	56
7. Claims 51 is not obvious in view of Edwards and the LS references.....	59
a. The combination of Edwards and the LS references does not disclose or render obvious “wherein the heating includes heating a mucosal surface of the labia minora”	59
VI. CONCLUSION.....	62

TABLE OF AUTHORITIES

Cases

<i>Apple Inc. v. Evolutionary Intelligence, LLC</i> , IPR2014-00079, Paper 8 (P.T.A.B. Apr. 25, 2014)	16
<i>CaptionCall v. Ultrac, Inc.</i> , IPR2013-00549, Paper 20 (P.T.A.B. Apr. 28, 2014)	16, 27
<i>Dell Inc. v. Realtime Data LLC</i> , IPR2016-01002, Paper 71 (P.T.A.B. Oct. 31, 2017).....	16, 24
<i>Polaris Industries, Inc. v. Arctic Cat, Inc.</i> , 2016-1807, 2016-2280, 2018 WL 797462 (Fed. Cir. Feb. 9, 2018) 26, 27, 36, 54	
<i>EMC Corp v. PersonalWeb Techs., LLC</i> , IPR2013-00087, Paper 25 (P.T.A.B. June 5, 2013)	14
<i>Ex Parte Frederick</i> , Appeal 2017-001651 (P.T.A.B. Feb. 7, 2018)	48
<i>Harmonic Inc. v. Avid Tech., Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016)	16
<i>Intellectual Ventures Management, LLC v. Xilinx, Inc.</i> , IPR2012-00019, Paper 33 (P.T.A.B. Feb. 10, 2014).....	6
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	37
<i>Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co.</i> , CBM2012-00003, Paper 7 (P.T.A.B. Oct. 25, 2012)	14, 15
<i>Microsoft Corp. v. Proxyconn, Inc.</i> , 789 F.3d 1292 (Fed. Cir. 2015)	6, 9
<i>Polaris Industries, Inc. v. Arctic Cat, Inc.</i> , 2016-1807, 2016-2280, 2018 WL 797462 (Fed. Cir. Feb. 9, 2018) 26, 27, 36, 54	
<i>PPC Broadband, Inc. v. Corning Optical Commc’ns RF, LLC</i> , 805 F.3d 747 (Fed. Cir. 2016)	6

<i>Samsung Electronics Co. LTD, v. Elm 3DS Innovations, LLC,</i> IPR2016-00687, Paper 42 (P.T.A.B. Aug. 22, 2017).....	27, 54
<i>SciMed Life Sys. v. Advanced Cardiovascular Sys.,</i> 242 F.3d 1337 (Fed. Cir. 2001)	7, 9
<i>World Bottling Cap, LLC v. Crown Packaging Technology, Inc.,</i> IPR2015-01651, Paper 34 (P.T.A.B. Jan. 19, 2017)	29, 34

Statutes

35 U.S.C. § 312(a)(3).....	3
35 U.S.C. § 314(a)	3, 16

Regulations

37 C.F.R. § 42.1(b)	14
37 C.F.R. § 42.100(b)	6
37 C.F.R. § 42.107	1
37 C.F.R. § 42.108	4
37 C.F.R. § 42.108(c).....	16

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.

Thermi first 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 43 or 51. Indeed, the 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 discloses, fairly suggests, or makes obvious this area of treatment whether taken alone or in combination” Ex. 1002 Part 6 at 1352.

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.

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.

In a second ground, Thermi tries to combine Edwards with three secondary references that are non-analogous art. Edwards is directed to a structural condition (incontinence) but these secondary references relate to a skin disease, and the cited treatments would have the opposite effect as the RF treatment in Edwards. A POSITA would not look to these secondary references to improve Edwards, as Petitioner suggests.

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 '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.”

A. “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.”

A. “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.

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. *See also Liberty Mut.*, CBM201200003, Paper 7 at 3-4.

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.

Petitioner contends that these claims are (1) obvious in view of Edwards in combination with Ingle and Mosher, and (2) obvious in view of Edwards in combination with Kreuter, Smith, and Beattie. With respect to ground 1, Petitioner asserts that Edwards, Ingle, and Mosher redundantly disclose the same features. Petitioner then presents ground 2, and instead uses Kreuter, Smith, and Beattie to cure the deficiencies of Edwards. Petitioner provides no discussion of the strength or weakness of the theories relative to each other, but merely reiterates the redundancy. 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 PROPOSED GROUND
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). “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, Ingle, and Mosher or Edwards, Kreuter, Beattie and Smith are properly combinable nor that any such a combination would render claims 43-58 unpatentable. The petition therefore fails to establish a reasonable likelihood that Petitioner would prevail with respect to any of the challenged claims, and the Board should deny the petition.

A. Ground 1: The Petition Does Not Establish That Edwards in View of Ingle and Mosher Render Claims 43-58 Obvious

1. Summary of Edwards

Edwards describes systems and methods for treating menorrhagia and female urinary incontinence, which generally apply radiofrequency (RF) energy to tissues “so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition.” Ex. 1008 at Abstract, 1:24-26; 2:34-39. In contrast to the nonablative treatment in the ‘511 patent, Edwards uses RF energy to cause ablative lesions thereby causing 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.” *Id.* 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. 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. 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. 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.

In Edwards’s fourth embodiment, 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.

Edwards further explains that before treating the vaginal wall, “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.

2. 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.

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." *Id.* 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." *Id.* 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. *Id.* at [0056] – [0057], FIG. 2; Ex. 2001 ¶33.

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.

3. 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. 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.

4. The Petition does not establish that the references are properly combinable

The law requires 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 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. *See Polaris Industries, Inc. v. Arctic Cat, Inc.*, 2016-1807, 2016-2280, 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. The Petition merely identifies portions of each reference that allegedly disclose the claimed features. *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 is that Edwards, Mosher, and Ingle were directed generally to treat similar problems regarding incontinence, and a skilled artisan could have looked at all three references to improve upon treatment of urinary 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) (“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 Industries*, 2016-1807, 2016-2280, 2018 WL 797462, at *9.

In view of these deficiencies, the Board should not grant *inter partes* review. *See Captioncall, LLC v. Ultratec, Inc.*, IPR2013-00549, Paper 20 at 6 (P.T.A.B. Apr. 29, 2014).

5. 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 research study and 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 to treat 23 subjects for vaginal laxity. Ex. 2006 at 4. The research article explains that “[t]he labia majora were treated first . . . 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) (citations omitted). 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 led 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*, IPR2015-01651, Paper 34 at 17. 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. Further, Dr. Alisond’s study treated the portion of the genital tissue extending from the introitus externally towards the Hart’s line. Therefore, the strong nexus

between the claims and the Petitioner's own industry praise of the claimed RF treatment weighs against obviousness.

6. Claims 43-50 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. Specifically, Edwards does not teach "heating" without damaging the mucosal surface and Mosher or Ingle are both references are directed to heating the "endopelvic fascia," which is not a target tissue in connection with the '511 patent.

Edwards does not disclose "heating the target tissue," as recited in claim 1. Petitioners 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, Taber’s Cyclopedic Medical Dictionary at 3; Ex. 2001 ¶21 (explaining that Fig. 4 likewise 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. 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-mucosa tissue without damaging the mucosa, Edwards creates “lesions” in the vaginal wall.

Mosher and Ingle cannot remedy the deficiencies of Edwards, 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. Ex. 1009 at Abstract; [0049]

(explaining the negative impacts on continence of a stretched endopelvic fascia).

Ingle, like 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.

Contrary to Petitioner's assertion, 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 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. In relevant part, Mosher explains that:

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* 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].

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.

Accordingly, the combination of Edwards, Mosher, and Ingle does not disclose or render obvious “heating the target tissue,” as recited in claim 43.

Claims 44-50 depend from claim 43 and are not rendered obvious for at least the same reasons.

b. “wherein the heating includes heating a portion radiating outward from the introitus to Hart’s line”

The combination of Edwards, Ingle, and Mosher does not disclose or render obvious “wherein the heating includes heating a portion radiating outward from the introitus to Hart’s line.” Edwards, Mosher, and Ingle are all directed to treating female stress urinary incontinence. For example, Mosher and Ingle disclose heating the anterior vaginal wall adjacent to the bladder to strength and stiffen the endopelvic fascia. These are internal tissues; indeed, deeper tissue than the target tissue in the ‘511 patent. None of these references explicitly or implicitly teach heating vulva tissue extending from the introitus to the Hart’s line.

A POSITA would not be motivated to heat from the introitus to Hart's line, based on the teachings of Edwards, Mosher, and Ingle. Oversimplifying the issue and applying hindsight bias, Petitioner asserts that "[a] POSITA would understand that the recited tissue in the claim is simple squamous epithelial tissue as found on the face and elsewhere in the body and would react to heat in a similar manner." Pet. at 36. The Federal Circuit has recognized that hindsight bias results when "the Board [focuses] on what a skilled artisan would have been *able* to do, rather than what a skilled artisan would have been *motivated* to do at the time of the invention. *Polaris Industries*, 2016-1807, 2016-2280, 2018 WL 797462, at *9. In this case, the genital region radiating outward from the introitus to Hart's line is irrelevant to the common problem that these references was trying to solve: urinary incontinence. Ex. 2001 ¶¶30, 39, 45. A POSITA would understand that heating the region radiating outward from the introitus to Hart's line would provide no additional support to the urethra or bladder, and would affect no improvement of stress urinary incontinence. Ex. 2001 ¶¶30, 39, 45.

Nor is it clear how this would be accomplished. Edwards teaches an applicator that mates with a speculum. By definition, this procedure must take place *interior* to the vagina, not *external* to the vagina, extending from the introitus to the Hart's line. Ex. 2008 at 13:43-46. Nor does the Petition adequately explained a motivation or a modification to Edwards to accomplish the claimed

method. Put simply, Petitioner has failed “to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Unable to find any teaching or motivation in analogous art for treating the was claimed area, Petitioner then asserts that “a POSITA would know that prior art procedures, such as Laser Vaginal Rejuvenation (LVR) described in Olliver were used to tighten a patient’s vagina and enhance sexual gratification, and Designer Laser Vaginoplasty (DVL) was used” to aesthetically modify a patient’s labia, allegedly with similar methods of treatment on the tissue radiating outward from the introitus to Hart’s line. Pet. at 36. But even here, the reference to modifying a patient’s labia relate to “true genital ‘deformities’—extraordinarily long or protruding labia.” *Id.* (citing Ex. 1011, pp. 6-7). None of Edwards, Ingle, or Mosher are focused on treating protruding labia, so there is no reason that a POSITA would look to Dr. Matlock’s LVR technique for guidance.

Petitioner further asserts that “Dr. Matlock’s webpage also describes that LVR can be performed in combination with any of the DLV procedures,” and that it “can sculpture the elongated or unequal labial minora.” Pet. at 21-22. Both LVR and/or DLV, utilize a laser to remove surface vulvar tissues. Ex. 2001, ¶¶ 72-73. These are surgical procedures that require anesthesia, result in patient downtime

and recovery, and can lead to side effects, such as scarring. Ex. 2001 ¶¶ 72-73.

The purpose of the '511 patented methods is to provide a non-invasive proceed that is an improvement over “surgical approaches . . . [that] bring with them a risk of scarring that is entirely counterproductive with regard to the desired result.” Ex. 1001 at 2:9-12. Ollivier and Matlock are thus within the prior art surgical techniques that the '511 Patent methods overcome, and therefore does not provide any evidence of reasonable expectation for success, particularly given the significant differences in wavelength, localization of the radiation, penetration depth, and mechanism(s) of the tissue interaction between UV and RF. Ex. 2001 ¶¶ 63-65.

Additionally, the fact that lasers were allegedly used to tighten a patient's vagina and aesthetically modify a patient's labia does not alter the fact that heating outward from the introitus to Hart's line is irrelevant to the problem faced by the POSITA. Even assuming *arguendo* that a POSITA was so motivated to treat the tissue radiating outward from the introitus to Hart's line, Petitioner provides no evidence that a POSITA would have a reasonable expectation of success in modifying the laser labia treatment by substituting UV energy with RF energy,

given the significant differences between UV energy and RF energy.² Ex. 2001

¶¶63-65. Specifically, differences in wavelength by a factor of more than 100,000, dramatically impacts the localization of the radiation, penetration depth, and mechanism(s) of the tissue interaction. Ex. 2001 ¶63.

Notably, an article authored by Dr. Red Alinsod regarding Petitioner's own ThermiVa RF technology outlines some of the significant differences between LVR/DVL and vaginal RF treatment. For example, Alinsod explains:

In 2005 we were perhaps the first center to provide non-surgical tightening of the vulvar structures using CO2 lasers and later Erbium 2940 lasers. We used ablative settings and non-ablative methods. We were able to get tightening of the labial and internal vaginal skin but at quite a cost in terms of pain and recovery and skin discoloration. The tightening obtained with the most effective CO2 lasers on external vulva were impressive for a short period of time until gravity and aging effects wore out the

² Petitioner's admit that the laser techniques practiced by Matlock are "ablative."

For the reasons described above with reference to Edwards, ablative techniques damage the epithelium surface, and therefore, fall outside of the '511 claims.

Supra at § V.A.1. Likewise, Mosher teaches away from ablative techniques.

Supra at § V.A.2. This is further reason that a POSITA would not be motivated to consider laser techniques for treatment areas to arrive at the claimed invention.

effects in a few months. Using the highest powered CO2 lasers intravaginal, tightening effects were obtained but the downtimes were many many weeks or months.

Ex. 2008 at 1-2; *see also* Ex. 2008 at 6. In view of the differences and disadvantages of laser techniques it would not be obvious to a POSITA to use a laser to heat a portion radiating outward from the introitus to Hart's line nor would a POSITA have had a reasonable expectation of success in modifying RF techniques with the teachings of laser applications.

In sum, Petitioner has not met its burden in establishing a reasonable likelihood that the combination of Edwards, Mosher, and Ingle disclose or render obvious "wherein the heating includes heating a portion radiating outward from the introitus to Hart's line," as recited in claim 43. Claims 44-50 depend from claim 43 and are not rendered obvious for at least the same reasons.

7. Claims 51 is 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 mucosal surface of the labia minora"

The combination of Edwards, Ingle, and Mosher does not disclose or render obvious "wherein the heating includes heating a mucosal surface of the labia minora." As above with respect to the genital area from the introitus to the Hart's line, none of these references explicitly or implicitly teach heating a mucosal

surface of the labia minora, nor would a POSITA be motivated to heat the mucosal surface of the labia minora, based on the teachings of Edwards, Mosher, and Ingle. Petitioner offers the same argument as above that “[a] POSITA would understand that the labia simple [sic] squamous surface tissues and would expect the labia to be remodeled in a similar fashion as the squamous urogenital tissues located throughout the body, including the vagina, cervix, endopelvic fascia, and extra-genital tissue.” Pet. at 44. This hindsight bias should be rejected for the same reasons as presented above with respect to claim 43. In particular, the labia minora is irrelevant to the common problem that these references was trying to solve: urinary incontinence. Ex. 2001 ¶¶30, 39, 45. A POSITA would understand that heating the mucosal surface of the labia minora would provide no additional support to the urethra or bladder, and would affect no improvement of stress urinary incontinence. Ex. 2001 ¶¶30, 39, 45. The labia minora is also external to the vaginal canal, and the Petition does not articulate how (or why) a POSITA would modify Edwards to treat outside the canal.

Further, for all of the reasons presented above with respect to claim 43, a POSITA would not look to laser techniques and certainly would not be motivated to modify the combination of Edwards, Mosher, and Ingle with laser techniques for heating a mucosal surface of the labia minora.

In view of the above, Petitioner has not met its burden in establishing that the combination of Edwards, Mosher, and Ingle disclose or render obvious “wherein the heating includes heating a portion radiating outward from the introitus to Hart’s line,” as recited in claim 51. Claims 52-58 depend from claim 51 and are not rendered obvious for at least the same reasons.

B. Ground 2: The Petition Does Not Establish that the Combination of Edwards, Kreuter, Beattie, Smith, and the knowledge of a POSITA Render Claims 43-58 Obvious

Ground 2 of the Petition is deficient for multiple reasons. First, Kreuter, Beattie, and Smith are non-analogous art and therefore cannot be the basis of a finding of obviousness. These references (collectively, the “LS references”) are not in the same field or endeavor as Edwards, nor are they addressing the same problem as Edwards. Lichen sclerosus (“LS”) is a dermatological disease in which the skin thickens to form plaque-like lesions, typically treated by a dermatologist. Ex. 2001 ¶47, 61. In contrast, stress urinary incontinence (“SUI”)—the focus of Edwards—is a structural urologic condition that is treated by gynecologists and urogynecologists. Ex. 2001 ¶60. In contrast to either SUI or vaginal laxity, LS is not caused by or aggravated by vaginal child birth. Ex. 2001 ¶47.

Second, even if Kreuter, Beattie, and Smith were considered analogous art, Petitioner fails to demonstrate that any of Edwards, Kreuter, Beattie, or Smith teach or suggest the elements of “heating the target tissue” (claims 43-58), “heating

a portion radiating outward from the introitus to Hart's line” (claim 43), or “heating a mucosal surface of the labia minora” (claim 51).

Third, the Petition fails to show the references are properly combinable. Specifically, a POSITA who is looking to improve on Edwards’ ablative RF treatments for SUI would not turn to LS treatments. Even if there was some motivation to look to the LS references (which there is not), there is no rational basis by which a skilled artisan would expect to yield predictable results by modifying the Edwards’ RF techniques for strengthening the internal bladder support (likely by inducing an inflammatory response), with the UV LS treatments, where the objective is to soften by down regulating inflammatory cells that have infiltrated the dermis in affected areas. Ex. 2001 at ¶ 60. For any or all of these bases, Ground 2 also fails.

1. Summary of Kreuter

Kreuter explains that LS is a “chronic inflammatory skin disease characterized by white porcelain-like polygonal plaques and atrophic and/or hypertrophic skin lesions.” Ex. 1012 at 1. Kreuter presents the results of a study performed by dermatologists in which ultraviolet A1 (UVA1) phototherapy was applied to extragenital tissue, such as the shoulder, general body, abdomen, chest, arms, and gluteal areas. Ex. 1012 at 1, 2. As summarized in Table 1, several

participants in the study were males, and “phototherapy of genital LS was not performed.” Ex. 1012 at 2.

Table I. Summary of clinical data of patients with lichen sclerosis (n = 10)

Patient No.	Age (y)/ Sex	Duration (mo)	Localization	Distribution	Treatment before UVA1	Clinical score before tx	Clinical score after tx	Side effects of phototherapy	Relapse (mo)
1	10/F	11	E/G	Shoulder	P, TS	7	1	—	—
2	60/F	164	E	Generalized	P, TE	8	3	—	—
3	57/F	7	E/G	Abdomen	TS	7	3	—	—
4	72/F	8	E/G	Abdomen, chest	TS, TE	8	2	—	—
5	80/F	14	E	Shoulder	TS	6	4	—	—
6	21/M	84	E	Shoulder, R arm	P	9	2	—	—
7	40/F	17	E	Shoulder, abdomen	SR, SS, TS	8	2	—	1
8	64/F	26	E/G	Abdomen	TS, TE	8	1	Pruritus	—
9	60/M	72	E	Gluteal	TS, OP	8	2	—	—
10	63/F	9	E/G	Chest	TS, OP	7	3	—	2
Mean						7.6	2.3		
Standard deviation						0.84	0.95		

E, Extragenital; *G*, genital; *OP*, surgical excision; *P*, penicillin; *R*, right; *SR*, systemic retinoid; *SS*, systemic corticosteroid; *TE*, topical estrogen; *TS*, topical corticosteroid; *tx*, therapy.

Ex. 1012 at 3.

During the Kreuter treatments, patients were exposed to UVA1 radiation at wavelengths of 340 to 400 nm. Ex. 1012 at 2. To apply 20 J/cm², patients were treated for 15 minutes. Ex. 1012 at 2. Patients received “40 sessions of UVA1 at a dose of 20 J/cm² per session, resulting in a cumulative dose of 800 J/cm².” Ex. 1012 at 2.

While providing some detail on the energy settings of the UVA1 device, Kreuter does not describe any specific layers of tissue that were heated by the UVA1 radiation. Ex. 2001 ¶50. That is because UVA1 phototherapy, as applied in Kreuter, is not used to heat the tissue. Ex. 2001 at ¶65. Rather, UVA1 phototherapy is used to suppress DNA synthesis to produce an immunomodulatory

effect in the cells of the LS affected area. Ex. 2001 at ¶65. In fact, UVA1 radiation does not heat tissue beyond an incidental amount, and certainly not to a level that would denature collagen. Ex. 2001 ¶65.

Kreuter also differs significantly from Edwards. For one, LS affected regions exhibit surface hyperkeratosis and inflammatory cells infiltrated the dermis, resulting in thick plaques forming on the skin. Ex. 2001 ¶60. The goal of the treatments in Kreuter is “softening and repigmentation of former affected skin [i.e., porcelain-like white patches]. . . [and] softening of sclerotic plaques.” Ex. 1012 at 2. In other words, Kreuter aims to downregulate inflammatory cells so the skin becomes softer. Ex. 2001 ¶ 60. The goal of the Edwards treatment is the opposite: stiffening structural support by likely stimulating collagen production.

In further contrast, Edwards discloses application of ablative radiofrequency energy to the vaginal walls, uterus, and urethra of female patients to achieve a thermal inflammatory response. *See* Ex. 1008 at 9:66-67, 10:1-4, 11:28-33, 12:47-55, 12: 66-67, 13:14-16; Ex. 2001 ¶65. Kreuter describes a different form of radiation—low dose UVA1 irradiation—on male and female non-genital tissue to affect the DNA/RNA of the diseased tissue to halt production of inflammatory cells via a photochemical response. Ex. 2001 ¶65.

2. Summary of Smith

Smith describes the pathophysiology of and various treatment methodologies for vulvar LS. Ex. 1014 at 1. Smith notes that LS can appear in the “labial, perineal, and anal areas.” Ex. 1014 at 2. For example, the affected area may include a “single area to the entire vulva,” from the clitoris to the anus. Ex. 1014 at 2. LS may present in various conditions, such as fusion of the labia minora. Ex. 1014 at 2. In certain cases, the “vaginal opening may become smaller, interfering with intercourse.” Ex. 1014 at 2. Smith suggests various treatments for these symptoms including topical testosterone, topical corticosteroids, and surgery. Ex. 1014 at 9-15. Among the surgical treatments, Smith cites vulvectomy, laser surgery, and cryosurgery. Ex. 1014 at 13-15. Nowhere does Smith discuss non-ablative heating of female genital tissue. Ex. 1014 at 13-15. Instead, Smith describes surgery and laser surgery techniques. The ablative laser surgery described in Smith vaporizes the skin removing the entire epidermis and in certain cases a portion of the dermis. Ex. 2001 ¶55. Such ablative surgical techniques are identified in the ‘511 patent as “bring[ing] with them a risk of scarring that is entirely counterproductive with regard to the desired result” of vaginal tightening. Ex. 1001 at 2:11-12.

Because Smith, like Kreuter, is focused exclusively on LS, a dermatological disease, it differs significantly from the teachings of Edwards, which is directed to

treatment of “female urinary incontinence” which is a structural urologic condition, Ex. 1008 at 1:24-30, Ex. 2001 ¶60, and the treatments described and claimed in the ‘511 Patent. Ex. 2001 ¶55.

3. Summary of Beattie

Beattie describes a study investigating the use of UVA1 therapy in which seven women “underwent UVA1 therapy for severe genital LS.” Ex. 1013 at 2. In the Beattie study, “two patients had two courses of treatment to the perineum, one had 33 and 29 exposures over a 12-month period.” Ex. 1013 at 2. “A high-output, 2-kW, filtered metal halide source . . . with an emission spectrum of 340-440 nm was used for perineal irradiation.” Ex. 1013 at 2. Patients were positioned in stirrups exposing the labia and vulva, and “light [was] deliver[ed] to the perineum.” Ex. 1013 at 2-3. As illustrated in the table below, Beattie only describes application of the light to the perineum—the area between the anus and vulva. Ex. 2001 ¶58.

Table 1 Patient characteristics, treatment schedule and response to treatment.

Patient no.	Age (years)	Duration (years)	Skin type	MED (J/cm ²)	Starting dose (J/cm ²)	Maximum dose (J/cm ²)	Total no. of treatments (course)	Treatment frequency no./week	Total dose (J/cm ²)	Improvement (course)	Adverse effect
1	66	22	II	40	7 (P)	60.2	1) 33 2) 29	5	1465	1) Moderate 2) Minimal	Erythema
					15 (WB)	30	1) 32 2) 31	5	1422	1) Very good 2) Moderate	
2	53	10	II	20	10 (P)	31.9	15	3	253	None	—
3	62	9	I	10	3.5 (P)	19.2	20	3	228	None	—
4	50	15	II	14	5 (P)	79.5	32	5	868	Minimal	—
5	48	6	II	7	3.5 (P)	60.2	30	5	845	Moderate	—
6	78	47	II	4	3 (P)	26.6	16	5	192	Moderate	—
7	74	27	III	40	15 (P)	130	1) 16 2) 30	4	2212	1) Minimal 2) Moderate	—
							1) 16	4	2168	1) Minimal	
							2) 14			2) Moderate	
							3) 20			3) Moderate	
							4) 15			4) Very good	

P, perineum; WB, whole body.

Ex. 1013 at 3 (“P, perineum”). The perineum includes epithelial tissue, not mucosal epithelium tissue. Ex. 2001 ¶58. Beattie thus does not disclose application of radiant energy to mucosal epithelial tissue, such as the vulva. The treatments described in Beattie resulted in “[t]hree of the seven patients obtain[ing] moderate improvement in their perineal disease severity after one course of therapy.” Ex. 1013 at 3.

4. Kreuter, Smith, and Beattie are Non-analogous Art

An invention cannot be found obvious in view of prior art that is not analogous. Prior art is only analogous if “it is from the same field of endeavor or if it is reasonably pertinent to the particular problem the inventor is trying to solve.” *Ex Parte Frederick*, Appeal 2017-001651 at 5 (P.T.A.B. Feb. 7, 2018) (citing *Circuit Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1335 (Fed. Cir. 2015)). In determining whether prior art is analogous, “[t]he question is not whether simple

concepts . . . are within the knowledge of lay people or even within the knowledge of a person of ordinary skill in the art. Rather, the question is whether an inventor would look to this particular art to solve the particular problem at hand.” *Id.*

The LS references are directed to a different field of endeavor from Edwards. Edwards describes systems and methods of applying RF energy to treat stress urinary incontinence. Ex. 1008 at Abstract. Stress urinary incontinence is a structural urologic condition that is typically treated by urogynecologists and gynecologists. Ex. 2001 ¶¶60-61. Conversely, the LS references are directed to the treatment of LS, a dermatological disease that is typically treated by dermatologists. Ex. 2001 ¶¶61. Indeed, the Edwards patent was assigned to SURx a developer of RF devices for treatment of stress urinary incontinence, Ex. 1003 ¶43, and the LS references were published in dermatology publications and/or authored by dermatologists. Exs. 1012, 1013, 1014.

The Edwards techniques would be performed by an urogynecologist, gynecologist, or possibly a plastic surgeon. Ex. 2001 ¶¶61. These specialists may be familiar with the disease LS, but their departments would likely not have the UVA1 phototherapy devices described in the LS references and they would not be performing these specialty treatments. Ex. 2001 ¶¶61. An urogynecologist, gynecologist, or plastic surgeon—would likely refer a case of LS to a dermatologist, who would be more likely to have a UVA1 phototherapy system.

Ex. 2001 ¶61. Treatment of LS thus would not be within the field of a POSITA relative to the '511 patent.

Further, the LS references are not reasonably pertinent to the problem faced by Edwards. Edwards discloses techniques to strengthen the bladder support. Ex. 1008 at Abstract, 13:12-19. In contrast, with LS, the living epithelium thins with surface hyperkeratosis and inflammatory cells infiltrate the dermis resulting in thick plaques forming on the skin. Ex. 2001 ¶60. Kreuter and Beattie apply UVA1 phototherapy to down regulate inflammatory cells and suppress collagen synthesis, thereby softening the plaques and returning the skin to a normal state. Ex. 1012; Ex. 1013; Ex. 2001 ¶60.

The lack of pertinence of the LS references to the ablative RF energy techniques of Edwards is also highlighted by the disparate physical and histological properties of the RF energy and UVA1 phototherapy treatments. A POSITA would understand that UV and RF energies are generated differently, delivered to the target tissue differently, interact with tissues of the body differently, and have effects modulated differently. Ex. 2001 ¶¶61-63. RF energy is used to generate an electro-thermal response—heating tissue to the point of collagen denaturation. Ex. 2001 ¶65. UVA1 phototherapy, in contrast, is not used to heat tissue but rather to affect the DNA/RNA of the diseased tissue to stop the over production of collagen via a photochemical response. Ex. 2001 ¶65. UVA1

phototherapy thus does not heat tissue to a level required to denature collagen or remodel collagen as described in the '511 patent. Ex. 2001 ¶65. These differences in the physical properties highlight the incompatibility of UV radiation to RF energy therapies.

The LS references thus fail to qualify as analogous art under either criterion. Accordingly, the '511 patent cannot be rendered obvious in view of Edwards, Kreuter, Smith, and Beattie. Therefore, Petitioner is unable to establish a *prima facie* case of obviousness.

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

Applying the standards set forth in § V.A.4, the Petition fails to show that the references are properly combinable.

Assuming *arguendo* that the references are analogous, as to “[1] how specific references could be combined,” Petitioner does not adequately articulate how Edwards could be combined with Kreuter, Beattie, or Smith. Petitioner does not address how Edwards, which creates ablative lesions in the vaginal wall via insertion of an RF applicator through a speculum, could be combined with UVA1 phototherapy, which in relevant part is used to reduce collagen and remove surface lesions, to areas outside the vaginal canal (including extra-genital areas) as disclosed in the LS references. For example, Petitioner is silent as to what modifications to the Edwards device would be made to apply RF energy to areas

outside of the vaginal canal, without the use of a speculum. Nor does the Petition explain what wavelengths would be applied, the temperature of the applied heat, the duration of treatment, or any other specifics. The LS references use UVA1 phototherapy, which does not heat the tissue beyond that of a shower or bath, and does not heat tissue enough to denature collagen. Ex. 2001 ¶65. The LS references do not identify any specific sub-epithelial tissue layers heated during UVA1 phototherapy, whether therapeutic temperatures are achieved, or any other details regarding heating of tissue. And the Petition does not suggest which layers of tissue would be heated using a combination of Edwards, Kreuter, Beattie, and Smith.

As to “[2] which combination(s) of elements in specific references could yield a predictable result,” the Petition does not address why a POSITA would have a reasonable expectation of success in modifying Edwards, which uses RF to create ablative lesions in the mucosal vaginal wall to induce inflammation and collagen denaturation, with Kreuter and Beattie, which disclose application of UVA1 phototherapy to suppress inflammatory cells and reduce collagen synthesis. Ex. 1012 at 5; Ex. 1013 at 4. For example, Petitioner does not identify any instance where UVA1 phototherapy and ablative radiofrequency techniques have been successfully combined to achieve predictable results. Indeed, the Petition does not address how any combination of multiple radiant energy devices could be

combined in a treatment to achieve a predictable result, especially given that the significant differences in wavelength by a factor of more than 100,000 dramatically impacts the localization of the radiation, penetration depth, and mechanism(s) of the tissue interaction. Ex. 2001 ¶¶63-65.

In addition, the Beattie study included a range of 15 to 65 total exposures of UVA1 phototherapy. Ex. 1013 at 2. More than half the patients reported minimal or no improvement. Ex. 1013 at Table 1. In spite of the many treatments, Beattie noted that the “results for genital LS are not as impressive as those reported for extragenital.” Ex. 1013 at 4. Given the high number of treatments and mediocre results reported, a POSITA would have a low expectation of success in evaluating Beattie for application to other treatment techniques, such as SUI.

The Petition does not attempt to address “[3] how any specific combination would operate or read on the asserted claims.” As discussed above, the disparate physical properties and tissue effects of the Edwards RF energy and Kreuter, Beattie, and Smith UVA1 phototherapy treatments would make combination unlikely. And more importantly, Petitioner does not cite to any teachings in Kreuter, Beattie, and Smith that disclose heating tissue specifically in the area between the introitus and the Hart’s line (claim 43) or the labia minora (claim 51) so as to create remodeling.

In sum, a POSITA would not be motivated to combine Edwards with the LS references. Stretching to manufacture a motivation to combine, Petitioner argues without citation that a “POSITA would have been motivated to look to the treatments for conditions which were improved by the induction of new collagen in the target tissue and/or treatments relating to the appearance of genital tissue as abnormal or deformed.” Pet. at 62. A nebulous directive to look to treatments “relating to the appearance of genital tissue as abnormal” is hardly a rational basis to combine Edwards with the LS references. As noted above, the Board has determined that such an assertion is not enough for a finding of obviousness. See *Samsung Electronics*, IPR2016-00687, Paper 42 at 35. If anything, the LS references teach away from the combination because UVA1 irradiation induces collagenase activity, leading to the *suppression* of collagen synthesis. Ex. 1012 at 5 (“UVA1 irradiation may suppress collagen synthesis and induce collagenase activity”); Ex. 1013 at 4 (“the mechanism of action of UVA1 is immunomodulation via T-cell apoptosis and hence regulation of pro-inflammatory cytokines . . . which stimulate collagenase . . . UVA1 irradiation has also been shown to induce collagenase mRNA”). Because the LS references teach suppressing collagen to soften skin, a POSITA looking to modify Edwards “would be discouraged from following the path set out in the [LS] reference[s].” *Polaris Industries*, 2016-1807, 2016-2280, 2018 WL 797462, at *9. In view of at least the

above identified deficiencies, the cited references are not combinable and the Board should deny *inter partes* review on this ground.

6. Claims 43-50 are not obvious in view of Edwards, Kreuter, Beattie, Smith, and Ordinary Skill in the Art

a. “heating the target tissue”

The combination of Edwards, Kreuter, Beattie, Smith, and ordinary skill in the art does not disclose or render obvious “heating the target tissue” as recited by the ‘511 patent. As discussed above in § V.A.6.a, Edwards does not disclose or teach the “heating the target tissue” element. Specifically, Edwards does not raise the temperature of tissue immediately beneath the mucosal epithelium of genital tissue, exclusive of deeper tissue, without damaging the mucosal surface.

It appears that the Petition does not rely on the secondary references for meeting this claim element, nor could it. Kreuter discloses application of UVA1 phototherapy to non-genital tissues. But “phototherapy of genital LS was not performed.” Ex. 1012 at 2. Kreuter also fails to identify any specific layers of tissue that were heated. This is likely because UVA1 does not heat the surface tissue beyond an incidental amount, well short of heating required to denature collagen or to have any collagen remodeling effect. Ex. 2001 ¶65. Because LS primarily affects only the epithelial tissue layers, a POSITA would understand Kreuter to only treat epithelium tissue, consistent with the UVA1 wavelengths. Ex. 2001 ¶¶47, 60, 63.

Beattie discloses “light delivery to the perineum,” which includes epithelial tissue between the vulva and anus. Ex. 1013 at 2-3, Ex. 2001 ¶58. While the patients in the Beattie study were “positioned in stirrups in the lithotomy position to expose the inner labia and vulva on an adjustable gynecological examination couch,” mucosal epithelial tissue was not treated. Ex. 1013 at 2-3. Beattie thus does not disclose application of heat to tissue immediately beneath the mucosal epithelium of genital tissues. Beattie, like Kreuter, also fails to identify any specific layers of tissue that were heated. Because LS affects epithelial tissue layers, a POSITA would understand Beattie to only treat epithelium tissue. Ex. 2001 ¶¶60-63.

Petitioners do not allege that Smith discloses this element. In sum, none of the cited references disclose “heating the target tissue,” as in the challenged claims.

b. “wherein the heating includes heating a portion radiating outward from the introitus to Hart’s line.”

The combination of Edwards, Kreuter, Beattie, Smith, and ordinary skill in the art does not disclose or render obvious this feature because they do not disclose treating a portion radiating outward from the introitus to Hart’s line. As discussed above, in the cited embodiments, Petitioner acknowledges that Edwards does not disclose treating outside of the vaginal canal. In particular, Edwards is treating the “anterior vaginal wall, the posterior vaginal wall or both.” See Ex. 1008 at 13:16-19; Ex. 2001 ¶19.

Smith notes that LS can result in fusion of the labia minora or result in the “vaginal opening . . . becom[ing] smaller, interfering with intercourse.” Smith at 2. But Smith does not disclose gently heating tissue in any of these areas. Ex. 1014 at 2, Ex. 2001 ¶69. Instead, Smith outlines vulva treatment options as laser ablation surgery, surgical vulvectomy, and cryosurgery treatments. Ex. 1014 at 13. Smith also references Kreuter’s non-genital UVA1 phototherapy treatment of LS in non-genital tissues. Ex. 1014 at 15. Smith, however, does not disclose “heating a portion radiating outward from the introitus to Hart’s line.”

Beattie describes treatments where UVA1 phototherapy was applied to the perineum. Ex. 1013 at 2. Petitioners argue that the description of the setup for treatment of perineum equates to disclosure of heating the vulva. Not so. Beattie states that the “the patient was positioned in stirrups in the lithotomy position to expose the inner labia and vulva,” but these tissues were not treated. Ex. 1013 at 2-3. UVA1 was only applied to the perineum, which includes epithelium tissue located between the vagina and the anus.

Petitioner does not assert that Kreuter discloses “heating a portion radiating outward from the introitus to Hart's line.” Instead, Petitioner asserts that “it would have been obvious to a POSITA that Krueter itself taught . . . ‘radiating outward from the introitus to Hart’s line’ given that it was well known that application of radiant energy [could be used] to heat and remodel any target tissue underlying a

simple squamous epithelial tissue.” Pet. at 60. This impermissible hindsight bias that is contradicted by Petitioner’s references. Kreuter did not apply UVA1 phototherapy to vulvar tissue, and Beattie, which Petitioners identify as “expand[ing] on Kreuter,” also did not apply ultraviolet radiation to vulvar tissue. Pet. at 57.

Moreover, a POSITA would not be motivated to heat from the introitus to Hart’s line, based on the teachings of Edwards, Kreuter, Beattie, and Smith. None of the references discuss any benefit of tightening and contracting vulvar tissue. Ex. 2001 ¶¶52, 55, 58-59, 69. The region of the vagina radiating outward from the introitus to Hart’s line is irrelevant to urinary incontinence and sexual function, as treated by Edwards. Ex. 2001 ¶¶28-30. And a POSITA would not be motivated to combine the non-mucosal epithelial UVA1 phototherapy techniques of the LS references with the mucosal epithelium ablative techniques of Edwards to tighten vulvar tissues, an objective that is not disclosed in any of the references.

Petitioner has not met its burden in establishing a reasonable likelihood that the combination of Edwards, Kreuter, Beattie, Smith, and ordinary skill in the art do not disclose or render obvious “wherein the heating includes heating a portion radiating outward from the introitus to Hart’s line,” as recited in claim 43. Claims 44-50 depend from claim 43 and are not rendered obvious for at least the same reasons.

7. Claims 51 is not obvious in view of Edwards and the LS references**a. The combination of Edwards and the LS references does not disclose or render obvious “wherein the heating includes heating a mucosal surface of the labia minora”**

For many of the reasons articulated above and with respect to claim 43, the combination of Edwards, Kreuter, Beattie, Smith, and ordinary skill in the art does not disclose or render obvious this feature because none of the references disclose “heating a mucosal surface of the labia minora.” Edwards does not disclose treating outside of the vaginal canal. See Ex. 1008 at 13:16-19; Ex. 2001 ¶20.

Petitioner declares without citation to any specific passage that Beattie “expressly discloses treatment of the labia minor[a] [sic].” Pet. at 64. This is not true. Beattie describes treatments where UVA1 phototherapy was applied to the perineum, not the labia minora. Ex. 1013 at 2-3. In Beattie, “the patient was positioned in stirrups in the lithotomy position to expose the inner labia and vulva,” but these tissues were not treated. Ex. 1013 at 2-3.

Contrary to Petitioner’s assertion, treatment of the labia minora would not have been obvious to a POSITA in light of Kreuter at least because “phototherapy of genital LS was not performed” in Kreuter. Ex. 1012 at 2. And Beattie and Smith, which allegedly build on Kreuter, also did not apply phototherapy to vulvar tissue. Ex. 1013 at 2-3; Ex. 1014 at 13-15.

Petitioner cites to Ollivier as describing use of lasers in performing electrosurgery on female genital tissue. Pet. 64. As Petitioner admits, Ollivier

describes use of lasers to surgically modify tissue, including the labia. Ollivier describes laser vaginal rejuvenation (LVR) and Designer Laser Vaginoplasty (DLV), which are either laser surgery procedures, or are ablative treatments, in which a laser is used to remove surface vulvar tissues. Ex. 2001 ¶72. These are surgical procedures that require anesthesia, result in patient downtime and recovery, and can lead to side effects, such as scarring. Ex. 2001 ¶72. The purpose of the '511 patented methods is to provide a non-invasive proceed that is an improvement over "surgical approaches . . . [that] bring with them a risk of scarring that is entirely counterproductive with regard to the desired result." Ex. 1001 at 2:9-12. Ollivier is thus within the prior art surgical techniques that the '511 Patent methods overcome, and therefore does not provide any evidence of reasonable expectation for success. And the Petition still fails to address how the laser electrosurgery described by Ollivier could be combined with any of the references of record to achieve a predictable result. As noted above, there are significant differences in wavelength, localization of the radiation, penetration depth, and mechanism(s) of the tissue interaction between UV and RF. Ex. 2001 ¶¶63-65. There also significant differences between ablative CO₂ and erbium lasers used by Matlock and the UVA1 phototherapy systems described in Kreuter, Beattie, and Smith. Ex. 2001 ¶64. Ollivier and Matlock thus do not cure any of the above discussed deficiencies of Edwards, Kreuter, Beattie, or Smith.

Petitioner argues that “a POSITA would have understood that during the performance of these ablative female genital tissue electrosurgeries, thermal affects were necessarily occurring in the areas surrounding the ablated tissue.” Pet. at 64 (citing verbatim Ex. 1004 ¶86). Petitioner cites no evidence in support of this proposition, which is a verbatim quote from Petitioner’s Expert Dr. Tucker’s declaration. Ex. 1004 ¶86. The Ollivier and Matlock references describe laser ablative vaginal rejuvenation procedures at a high level but do not identify thermal effects in areas surrounding the ablated tissues. *See, e.g.*, Ex. 1011 at 1-2; Ex. 1015 at 18.

Petitioner also argues that “A POSITA would have understood that the application of heat to sub-surface, dermal tissue throughout the body to induce collagen growth – one component of remodeling – and further suggested its curative properties when applied to the vulva.” Pet. at 65. This assertion is belied by the lack of any teaching in Edwards, Kreuter, Beattie, and Smith as well as Mosher and Ingle of applying non-ablative radiant energy to vulvar tissues.

Petitioner has not met its burden in establishing a reasonable likelihood that the combination of Edwards, Kreuter, Beattie, Smith, and ordinary skill in the art do not disclose or render obvious “wherein the heating includes heating a mucosal surface of the labia minora,” as recited in claim 51. Claims 52-58 depend from claim 51 and are not rendered obvious for at least the same reasons.

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

/Megan S. Woodworth/

Frank C. Cimino, Jr.
Reg. No. 39,945
Lead Counsel for Patent Owner

Megan S. Woodworth
Reg. No. 53,655
First Backup Counsel for Patent
Owner

Michele V. Frank
Reg. No. 37,028
Backup Counsel for Patent Owner

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 13,934 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

/Megan S. Woodworth/
Megan S. Woodworth
Reg. No. 53,655
First Backup Counsel for Patent
Owner

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:

James Trainor
Dimitrios T. Drivas
White & Case LLP
1221 Avenue of the Americas
New York, NY 10020
jtrainor@whitecase.com
ddrivas@whitecase.com

Dated: February 14, 2018

/Megan S. Woodworth/
Megan S. Woodworth
Reg. No. 53,655
First Backup Counsel for Patent
Owner

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.