

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THERMIGEN, LLC AND THERMIAESTHETICS, LLC
Petitioner,

v.

VIVEVE, INC.,
Patent Owner.

Case IPR2018-00089
Patent 8,961,511 B2

Before HYUN J. JUNG, ROBERT A. POLLOCK, and
SCOTT C. MOORE, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION TO INSTITUTE
35 U.S.C. § 314(a)

I. INTRODUCTION

Thermigen, LLC and Thermiaesthetics, LLC (“Petitioner”)¹ filed a Petition for an *inter partes* review of claims 43–58 of U.S. Patent No. 8,961,511 B2 (“the ’511 patent,” Ex. 1001). Paper 2 (“Pet.”). Viveve, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 7 (“Prelim. Resp.”). We review the Petition, Preliminary Response, and accompanying evidence under 35 U.S.C. § 314.

On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst. Inc. v. Iancu*, No. 16-969, 2018 WL 1914661, at *10 (U.S. Apr. 24, 2018). After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least claim 1 of the ’511 patent is unpatentable. Accordingly, we institute an *inter partes* review of claims 43–58.

A. Related Proceedings

According to the parties, the ’511 patent is at issue in *Viveve, Inc. v. ThermiGen, LLC et al.*, Civil Action No. 2:16-cv-1189-JRG (E.D. Tex.). Pet. 2; Paper 3, 2.

In addition to the present proceeding, Petitioner concurrently challenges claims 1–42 of the ’511 patent in IPR2018-00088.

¹ Petitioner further identifies Almirall, S.A. of Barcelona, Spain, as a real party-in-interest. Pet. 2.

B. The '511 Patent

The '511 patent pertains to “treating a loose vagina and introitus” via “corrective or restorative remodeling of the mucosal surfaces of the vagina, introitus, and vulva.” Ex. 1001, 2:17–21. In particular, the patent discloses “apparatus and methods for tightening tissue of the female genitalia by heating targeted connective tissue with radiant energy [typically radiofrequency (RF) energy], while cooling the mucosal epithelial surface over the target tissue to protect it from the heat.” *Id.* Abstract, 4:4–13; *see also id.* at 2:25–28, 4:7–16, 13:16–19, claims 6, 33, 41, and 49 (“heating comprises delivering energy by any of: radiofrequency energy, microwave energy, or ultrasound energy”). According to the Specification, the tightening may be an immediate or near-immediate consequence of thermally denaturing tissue collagen, and/or the result of a longer term healing response involving the deposition of new collagen by cells in the connective tissue. *Id.* Abstract, 4:14–16, 4:63–5:11, 12:39–49.

C. Prosecution History of the '511 patent.

The '511 patent issued to Jonathan B. Parmer from U.S. Application No. 11/704,067, filed February 7, 2007 and claiming the benefit of Provisional Application No. 60/743,247, filed on February 7, 2006.²

As highlighted by both parties, the Examiner rejected then-pending claims over Knowlton.^{3,4} *See* Pet. 6–9; Prelim. Resp. 5. Knowlton discloses

² Petitioner argues, and Patent Owner does not presently contest, that at least independent claims 43 and 51 are not entitled to the filing date of the provisional application. *See* Pet. 4.

³ US 6,350,276 B1, issued Feb. 26, 2002. Ex. 1007.

⁴ Knowlton is cited as background in the '511 patent and incorporated therein by reference. *See* Ex. 1001, 1:47–49, 5:65–26:6.

fluid-cooled apparatus comprising RF electrodes to “appl[y] a mechanical force in combination with the delivery of energy to the skin surface and underlying soft tissue structure, to remodel collagen both esthetically and functionally with minimal thermal damage including cell necrosis.”

Ex. 1007, 13:9–13; 15:25–28, Abstract. In one embodiment, Knowlton discloses treating pre-term cervical dilation by applying RF energy to tighten the dilated cervix. *See* Ex. 1007, 13:35–47 (“The incorporated energy delivery device 18 contracts the native matrix and induces scar collagen. The dilated cervical OS is tightened and the entire cervix is strengthened.”); *see also* Ex. 1003 ¶¶ 66–69, Ex. 1004 ¶¶ 20–21.

During prosecution, the Examiner repeatedly rejected claims as anticipated and/or obvious in view of Knowlton. Ex. 1002, 701–704, 748–755, 934–945. According to the Examiner,

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. Ex. 1002, 693; *see also id.* at 759–760 (Final Rejection stating that the cervix is “female genital tissue” and Knowlton discloses treating tissue underlying the cervical epithelium).

To address rejections over Knowlton, applicant amended claim 1 (the only independent method claim then pending) to recite “remodeling a therapeutic zone including at least one of vulva, introitus or vagina” and argued that Knowlton does not disclose treating these tissues. *Id.* at 777–781, 785. Applicant subsequently also amended claim 1 to require that “the heating includes heating a portion of the vagina extending from the introitus

inwardly to a location from 1 cm to 3.5 cm in from the introitus,” thereby excluding the cervix.⁵ *Id.* at 974; Ex. 1003 ¶ 20.

In allowing the claims to issue, the Examiner explained that “Knowlton fails to contemplate the specific areas of treatment set forth in [the] independent claims 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, 1352 (Notice of Allowance). According to Patent Owner, the Examiner, thus, “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.” Prelim. Resp. 5.

D. Illustrative Claims

Petitioner challenges claims 43–58 in this proceeding,⁶ of which claims 43 and 51 are independent (*italicized to highlight differences*).

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

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes *heating a portion radiating outward from the introitus to Hart’s line*.^[7]

⁵ Applicant also re-drafted certain dependent claims in independent format, which subsequently issued as claims 35, 43, and 51. *See id.* at 977.

⁶ Petitioner challenges the remaining claims of the ’511 patent, claims 1–42, of which claims 1 and 35 are independent, in co-pending IPR2018-00088.

⁷ The Specification defines “introitus” as “the opening of the vagina” (Ex. 1001, 2:3–4, 3:51) and “Hart’s line” as the portion of the vulva “where mucosal epithelium gives way to skin on the outer surface of the labia

51. A method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus and vagina tissue, the method comprising:
heating the target tissue, and
remodeling the therapeutic zone of target tissue, wherein the heating includes *heating a mucosal surface of the labia minora*.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 13):

Ground	Claims	Basis	References
1	43–58	§ 103	Edwards, ⁸ Ingle, ⁹ Mosher, ¹⁰ and the knowledge of one of ordinary skill in the art
2	43–58	§ 103	Edwards, Kreuter, ¹¹ Beattie, ¹² Smith, ¹³ and the knowledge of one of ordinary skill in the art

In support of its patentability challenges, Petitioner relies on the Declarations of Dr. Roger Dmochowski, M.D. (Ex. 1003) and Dr. Robert

minora,” i.e., “the boundary where mucosal epithelium and labial skin meet” (*id.* at 3:49–54, 11:59–62).

⁸ US 6,463,331 B1, issued Oct. 8, 2002. Ex. 1008.

⁹ US 6,216,704 B1, issued Apr. 17, 2001. Ex. 1010.

¹⁰ US 2004/0193238 A1, published Sept. 30, 2004. Ex. 1009.

¹¹ Kreuter et al., *Low-dose ultraviolet A1 phototherapy for extragenital lichen sclerosis: Results of a preliminary study*, 46(2) J. Am. Acad. Dermatol. 251–55. Ex. 1012.

¹² Beattie et al., *UVA1 phototherapy for genital lichen sclerosis*, 31 Clin. Exp. Dermatol. 343–47. Ex. 1013.

¹³ Smith and Haefner, *Vulvar Lichen Sclerosus*, 5(2) Am. J. Clin. Dermatol. 105–25. Ex. 1014.

Tucker, Ph.D., M.D. (Ex. 1004). Patent Owner relies on the Declaration of Dr. Lawrence S. Bass, M.D. (Ex. 2001).

II. ANALYSIS

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* at 418. Rather “the test is whether the references, taken as a whole, would have suggested appellant's invention to one of ordinary skill . . . at the time the invention was made.” *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418. “[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show 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.” *In re*

Magnum Oil Tools Int'l, Ltd., 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations and citations omitted).

A. Person of Ordinary Skill in the Art

Petitioner proposes that one of ordinary skill in the art “is a medical doctor practicing in the field of plastic surgery and in particular, in urogynecology or a similar field” or “a medical doctor who has at least ten years of knowledge and experience in the treatment or research regarding treatment of tissue with radiant energy.” Pet. 25. Petitioner’s experts, however, propose definitions indicating experience in both plastic surgery involving female genitalia and the clinical application of radiant energy to human tissue and/or experience performing electrosurgical procedures. See Ex. 1003 ¶ 8; Ex. 1004 ¶ 14. Petitioner’s experts do not opine on number of years’ experience required. See *id.* Although Patent Owner does not propose an alternative definition in the Preliminary Response, Patent Owner’s expert similarly states that such a person would have “a medical degree plus at least two years of experience in a field such [] as gynecology, urogynecology, [sic] or plastic surgery, with clinical experience in application of radiant energy to human tissue and experience involving female genital anatomy.” Ex. 2001 ¶ 14.

In considering the testimony of the parties’ experts, the field of the ’511 patent, and the relevant art, we determine that one of ordinary skill in the art would have a medical degree plus at least two years of experience in a field such as gynecology, urogynecology, or plastic surgery involving female genital anatomy, with clinical experience in the application of radiant energy to female genital tissue.

B. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).

Under that standard, we presume that a claim term carries its “ordinary and customary meaning,” which “is the meaning that the term would have to a person of ordinary skill in the art in question” at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) (“Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history.”). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Limitations, however, may not be read from the specification into the claims (*In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993)), nor may the Board “construe claims during [an *inter partes* review] so broadly that its constructions are *unreasonable* under general claim construction principles” (*Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (overruled on other grounds by *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017))).

We address below terms identified by the parties as in need of construction. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (instructing that claim terms need only be construed to the extent necessary to resolve the controversy).

1. “target tissue”

The independent claims before us recite “method[s] for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue.” Within the body of the claims, “target tissue” is also the subject of “heating” and “remodeling.” Petitioner proposes that we construe the term “target tissue” as “tissue underlying the epithelium.” Pet. 26–27 (citing Ex. 1001, 2:25–28, 3:41–47, 11:11–14, 12:2–13).

Patent Owner contends that Petitioner’s proposed definition is overly broad as it includes deeper tissue layers expressly excluded in the Specification. Prelim. Resp. 7–9. In accord with Patent Owner’s position, column 3, lines 41–48 of the Specification states:

Embodiments of the invention include methods for remodeling a therapeutic zone of tissue within a target tissue of female genitalia. 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.

Similarly, column 12, lines 2 through 16 of the Specification states:

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 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.

“Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly

disclaim[s] the broader definition.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). In particular, patentee must “demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.” *Id.* at 1366. On the present record, we agree with Patent Owner that the passages identified in the Specification comprise a “clear and unmistakable” disclaimer of the scope of target tissue. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366–67 (Fed. Cir. 2012). We also note that there is no evidence in the record that the term “target tissue” has an ordinary and customary meaning in the art to which the ’511 patent pertains that encompasses the endopelvic fascia. Thus, even though we find a clear and unmistakable disclaimer here, this is not a situation where a disclaimer is necessary in order to depart from the plain and ordinary meaning of a claim term. Rather, the construction we adopt here is a definition set forth in the specification of a term that has not been shown to have an ordinary and customary meaning outside the scope of the ’511 patent.

On this record, we construe “target tissue” as used in the claims of the ’511 patent to mean tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissues, such as the endopelvic fascia.

2. “heating”

All independent claims of the ’511 patent recite the step “heating the target tissue.” Patent Owner proposes that we do not apply the plain and ordinary meaning to “heating” as used therein. Prelim. Resp. 9–13. Patent Owner points out that in applying the *Phillips* standard, the District Court construed “heating” to mean “heating the tissue underlying the epithelium to

a temperature that is higher than the temperature of the epithelium.” *Id.* at 11. Patent Owner also rejects this construction, arguing instead that the Specification “makes clear that this heating step requires ‘heating without damaging the mucosal epithelial surface.’” Prelim. Resp. 9.

As Patent Owner points out, the ’511 patent teaches optimal contact of an energy delivery device and active cooling of the epithelial surface over the target tissue such that “the epithelium itself is not damaged or substantially modified by the method.” *Id.* at 9–11 (citing Ex. 1001, Abstract, 12:19–21, 13:16–26, 2:56–62, 8:8–15). But the plain language of the independent claims makes no express mention of protecting the epithelial layer from damage or modification, whether through a configuration of the energy delivery device, by cooling the epithelial layer, or by creating a temperature gradient as indicated under the District Court’s construction under *Phillips*. Each of these elements is, however, recited in one or more independent claims, suggesting that the independent claims encompass, but are not necessarily limited to those elements. Depending from claim 1, for example, claim 24 includes the limitation “wherein the heating does not modify a mucosal epithelium of the genital tissue”; claims 5–8, 10, and 17–22 relate to the configuration of an energy delivery device; claim 9 and its dependent claims include the step of “cooling the epithelium”; and claim 15 and its dependent claims state that the step of cooling the epithelium results in “a reverse thermal gradient from the epithelium to the target tissue.” See *Nazomi Commc’ns, Inc. v. Arm Holdings, PLC.*, 403 F.3d 1364, 1370 (Fed. Cir. 2005) (“The concept of claim differentiation ‘normally means that limitations stated in dependent claims are not to be read into the independent claim from which they

depend.’”) (quoting *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971–72 (Fed. Cir.1999)).

Applying the broadest reasonable construction consistent with the specification, we do not limit the term “heating” as did the District Court, nor as Patent Owner proposes.¹⁴ See *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (“Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.”).

Although we generally apply the ordinary meaning to the term “heating,” we also note that the ’511 patent places an upper limit on the temperature to which target tissue is heated. According to the Specification, in heating the target tissue, the “[t]emperature is raised to a level that is therapeutic, i.e., to a temperature that causes remodeling.” Ex. 1001 11:21–23. In particular, “[t]he therapeutic temperature . . . may be . . . as high as 45 degrees C., or as high as 80 degrees C. The inventive method, therefore includes heating target tissue to as high as 80 degrees C.” *Id.* at 11:25–29;

¹⁴ When a claim term has previously been construed by a district court, the Board must “assess whether [the court’s] interpretation [is] consistent with the broadest reasonable construction of the term.” *Power Integrations, Inc. v. Lee*, 797 F.3d 1318, 1324–27 (Fed. Cir. 2015). The broadest reasonable interpretation of disputed claim terms is “a different claim construction standard than that applied by a district court” (*id.*), and may sometimes produce a different result.

see also id. at 4:34–40 (indicating a temperature of “about 80 degrees C. in the target tissue”). Accordingly, we construe “heating” as used in the claims of the ’511 patent as raising the temperature of target tissue to no more than about 80 degrees C.

3. “remodeling”

Patent Owner proposes that we construe “remodeling” as used in the claims of the ’511 patent as “causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature,” with or without the additional requirement, “without damaging the epithelium.” Prelim. Resp. 13–14. Patent Owner also notes that the District Court defined “remodeling” under the *Phillips* standard as “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.” Prelim. Resp. 13–14 (citing Ex. 2009, 7). Although we do not disagree with the thrust of these constructions, in the context of the claims as a whole, they appear to render the “heating” step redundant. In this respect, we agree with Petitioner that the term refers to “a natural phenomenon that results from the heating of the tissue,” i.e., “the *result* caused when heated tissue reaches a sufficient temperature.” Pet. 32 (citing Ex. 1001, 4:15–16, 5:2–5, 11:22).

The independent claims of the ’511 patent recite “method[s] for remodeling a therapeutic zone of a target tissue . . . comprising: heating the target tissue, and remodeling the therapeutic zone of target tissue.” Considering the overall structure of these claims and the use of the term in the context of the Specification, “remodeling” in the body of the independent claims refers to the result obtained by heating the target tissue

to a therapeutic temperature—i.e., the result obtained by raising the temperature of target tissue to no more than about 80 degrees C. *See* section II(B)(2) above.

Further, the Specification teaches that the result obtained by heating the target tissue “may include a melting or denaturing of preexisting collagen in the tissue,” and/or “a healing process in which there is an increase in the rate of cellular production and deposition [of collagen] into the extracellular space. Both types of responses . . . contribute to an overall tightening of the target tissue.” Ex. 1001, 12:50–65; *see id.* at 12:39–49; 13:2–5 (“Remodeling of genital tissue, as practiced by embodiments of this invention, may be understood variously as contracting or tightening of tissue, this may apply to the vulva, the vagina, and the introitus.”).

The Specification makes clear, however, that “remodeling of the connective tissue underlying the mucosal epithelial surfaces does not substantially affect the epithelium itself. The method and apparatus, as provided by embodiments of the invention are non-invasive and substantially non[-]ablative of genital tissue.” *Id.* at 12:17–21.

In view of the above, we construe “remodeling” as used in the body of the independent claims of the ’511 patent to refer to the result of raising the temperature of target tissue to no more than about 80 degrees C without substantially affecting the epithelium overlying the target tissue, wherein that result includes a tightening or contraction of the target tissue.

C. Ground 1: Obviousness in view of Edwards, Ingle, and Mosher
Petitioner challenges claims 43–58 as obvious in view of Edwards, Ingle, and Mosher. Pet. 28–55. Patent Owner opposes. Prelim. Resp. 17–42. We begin with an overview of Edwards, Ingle, and Mosher.

1. Overview of Edwards (Ex. 1008)

Edwards “provides a method and system for the curative treatment of female uro-genital disorders by application of radiofrequency (RF) energy to targeted tissues. Application of this energy is selectively applied so as to ablate, tighten, shrink or reshape the tissue and thereby correct an unwanted condition.” Ex. 1008, 2:33–38. “In alternative embodiments, other forms of energy may be delivered, such as microwave, laser, ELF (extremely low frequency) and other therapeutic energies.” *Id.* at 13:57-59.

Edwards discloses four embodiments of the invention. *Id.* at 2:40–3:13. In the fourth embodiment, “RF energy is delivered to the anterior and posterior regions of the vaginal wall. This has the effect of tightening of vaginal walls so as to increase support of the bladder outlet, proximal and mid-urethra.” *Id.* at 3:5–11.

Figure 4 of Edwards is reproduced below.

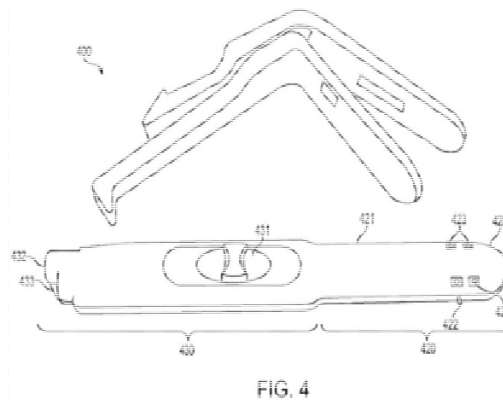


Figure 4 illustrates the distal end of a system 400 that can be used for vaginal remodeling in accord with the fourth embodiment. *Id.* at 3:25–27, 7:14–8:5. Briefly, the system comprises a treatment element coupled to an RF generator. *Id.* at 7:14–15. “The distal end of the treatment element . . . is inserted into a vagina using a speculum.” *Id.* at 7:18–19. A plurality of relatively flat electrodes 423 are disposed on the distal end of the treatment

unit. *Id.* at 7:34–39. “Each electrode 423 includes at least one thermocouple 424 that is used to monitor the temperature of each electrode 423. . . . If one of the electrodes 423 exceeds temperature safety limits, that particular one of the electrodes 423 can be disengaged without aborting the entire procedure.” *Id.* at 7:43–50. Also on the distal end of the treatment element, “irrigating fluid delivery pores 425 . . . are disposed to deliver cooling liquids so as to minimize thermal damage.” *Id.* at 7:51–55, 7:66–8:5.

Figure 9A of Edwards is reproduced below.

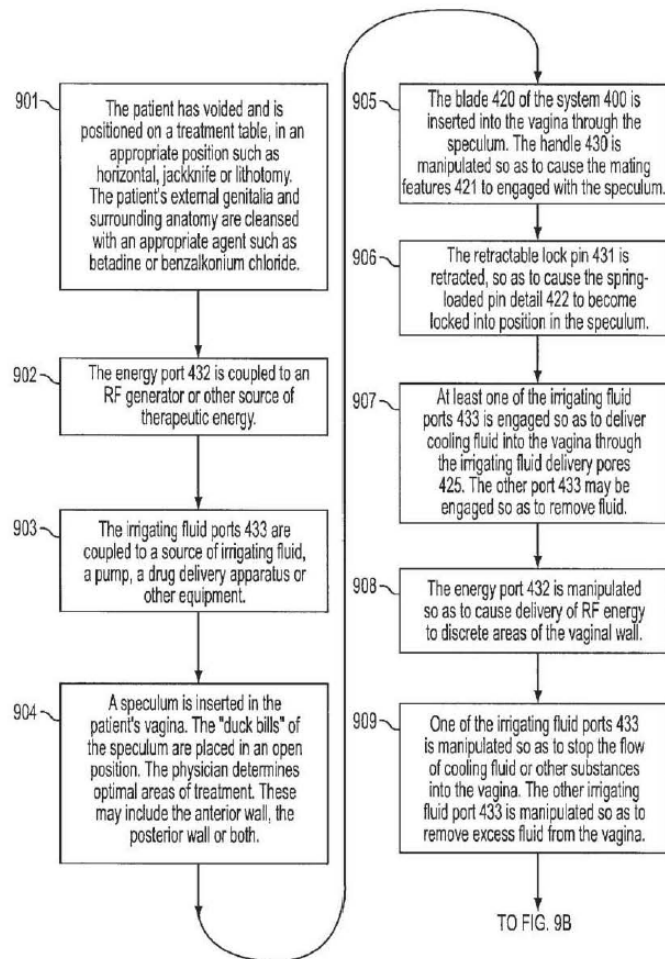


Figure 9A illustrates the method of Edward's fourth embodiment for vaginal remodeling. *Id.* at 3:38–39. As explained in detail at column 13, line 12 through column 14, line 4: “[A] speculum is inserted in the patient's vagina.

The blades of the speculum are placed in an open position. The physician determines optimal areas of treatment. These may include the anterior wall, the posterior wall, or both.” *Id.* at 13:38–42. The treatment element of system 400 is inserted into the vagina through the speculum. *Id.* at 13:43–46. Cooling fluid is delivered into the vagina through irrigating fluid delivery pores 425, and RF energy is delivered “to discrete areas of the vaginal wall.” *Id.* at 13:54–56.

According to Edwards, the method “create[s] a series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both. . . . Remodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting [in] physical and psychological improvement in the area of sexual function.” *Id.* at 13:14–22.

2. Overview of Ingle (Ex. 1010)

Ingle discloses devices and methods “for selectively heating and shrinking tissues, particularly for the noninvasive treatment of urinary incontinence and hernias, for cosmetic surgery, and the like.” Ex. 1010, 1:18–23. Ingle’s methods can “induc[e] controlled shrinkage or contraction of a support tissue of the body, typically being a collagenated tissue such as fascia, ligament, or the like” (*id.* at 11:8–11). “Tissue contraction results from controlled heating of the tissue by affecting the collagen molecules of the tissue.” *Id.* at 11:25–26.

According to Ingle, tissue is heated by applying RF or ultrasound energy. *See, e.g., id.* at 5:10–13, 30–32, 8:53–65. This energy “heats fascia and other collagenated support tissues, causing them to contract without substantial necrosis of adjacent tissues.” *Id.* at 2:58–61. The energy is “preferably . . . applied through a large, cooled electrode having a

substantially flat electrode surface. Such a cooled plate electrode is capable of directing electrical energy through an intermediate tissue and into fascia, while the cooled electrode surface prevents injury to the intermediate tissue.” *Id.* at 2:61–67; *see id.* at 5:40–58. “Preferably the target tissue will be raised to a temperature of about 60 nC¹⁵ or more, while the intermediate tissue remains at or below a maximum safe temperature of about 45 nC.” *Id.* at 8:41–44; *see also, id.* at 11:33–37 (“The temperature of the target tissue structure will . . . often be[] in the range from about 60 nC to 80 nC. . .”).

According to Ingle, the selective shrinkage of fascia may be used to treat a wide variety of conditions, “and may even be used in cosmetic procedures . . . to remove wrinkles by shrinking the collagenated skin tissues, or to lift sagging breasts by shrinking their support ligaments.” *Id.* at 17:65–18:7. Exemplary target tissues, however, “include the urethral wall, the bladder neck, the bladder, the urethra, bladder suspension ligaments, the sphincter, pelvic ligaments, pelvic floor muscles, fascia, and the like.” *Id.* at 11:14–17. In one embodiment, energy is applied “to fascia . . . within the vagina” via an energy transmitting element on the distal end of a probe introduced into the vagina. *Id.* at 3:36–43. In this embodiment,

[t]he transmitting element is capable of transmitting sufficient heating energy through the vaginal wall to heat and contract the fascia. A cooling system is disposed adjacent to the transmitting element. The cooling system is capable of maintaining the vaginal wall adjacent the probe below a maximum safe

¹⁵ “nC” appears to be pervasive formatting error in the published patent. Absent evidence to the contrary, we understand “nC” in Ingle to mean “°C”. *See id.* at 15:31 (referring to body temperature as “approximately 37 nC”), 15:5–39 and Figures 3A–E (illustrating exemplary temperature ranges, in °C).

temperature when the fascia is heated by the transmitting element.

Id. at 3:43–50. “[I]ntermediate tissue is cooled with the probe to avoid injuring the intermediate tissue when the target tissue is heated by the probe.” *Id.* at 3:51–58; *see id.* at 4:4–10, 15:65–16:4.

3. Overview of Mosher (Ex. 1009)

Mosher is generally directed to the treatment of urinary incontinence by selectively heating and remodeling a portion of the pelvic support tissue. *See, e.g.*, Ex. 1009, Abstract, ¶¶ 9, 45. Mosher discloses techniques for “directing energy from a probe into collagenous tissues of the pelvic support system” to cause contraction of the collagenous tissue and/or structural stiffening related to scarring or healing. *Id.* ¶ 45. According to Mosher, the treatment may be directed to a variety of tissue structures, including “structures of the vagina” such as the lamina propria, a “dense connective tissue layer just under the epithelium.” *Id.* ¶ 48; *see also id.* ¶ 9 (disclosing “heating provided through . . . the vaginal wall”).

Mosher discloses figures 6 and 6a as “illustrative non-invasive vaginal probes and a method for non-invasively treating endopelvic fascia using cooled [RF] electrodes.” *Id.* ¶¶ 27, 58. In one embodiment, “[a] non-invasive cooled electrode probe similar to that shown in FIGS.6 and 6A heats tissue until the temperature sensing needle at 4.5 mm depth reaches a set point of 75 °C. at 185 seconds.” *Id.* ¶ 85. In one embodiment

a laterally elongate treatment region of the endopelvic fascia will preferably be significantly wider (along the medial-lateral orientation) than its urethral length, ideally having a width of about 25 mm and a length of about 15 mm. Treatment depths will preferably be at least about 2 mm, optionally being as much as 6 mm.

Id. ¶ 74.

4. Analysis of Ground 1

a) Claim 43

(1) Elements a-c

Relying on the testimony of Drs. Dmochowski and Tucker, Petitioner argues that Edwards, Ingle, and Mosher, independently, teach all elements preceding the wherein clause of claim 43—designated by Petitioner as elements a through c.¹⁶ See Pet. 28–34 (citing Ex. 1003 ¶¶ 36, 48–54, 56–59, 79, 81–86; Ex. 1004 ¶¶ 18–19). We find Petitioner’s arguments and evidence to be reasonable in light of, e.g., Edward’s teaching to treat female uro-genital disorders by delivering RF energy “to the anterior and posterior regions of the vaginal wall” in conjunction with the delivery of “cooling liquids, so as to minimize thermal damage,” in order to effect “circumferential tightening of the vaginal wall”; Ingle’s teaching to treat female urinary incontinence through selective shrinkage of fascia by directing energy “through an intermediate tissue and into fascia, while the cooled electrode surface prevents injury to the intermediate tissue”; and Mosher’s teaching to treat female urinary incontinence by selectively heating and remodeling a portion of the pelvic support tissue using non-invasive vaginal probes comprising cooled RF electrodes. See sections II(C)(1)–(3), above.

Contrary to Petitioner’s arguments and the testimony of Petitioner’s experts, Patent Owner contends that “Edwards does not disclose heating without damaging the mucosal epithelial surface,” as required by claim 43.

¹⁶ This language is the same as the corresponding portion of independent claim 51 and, accordingly, the same arguments and analysis apply.

Prelim. Resp. 30–33 (citing Ex. 2001 ¶¶ 21–23); *see also*, Ex. 2001 ¶ 24 (Dr. Bass’s testimony that “A POSITA would understand that all embodiments in Edwards create a healing response based on this top down injury, such that the mucosal epithelium is thermally damaged.”).

Because the conflicting testimony of the parties’ experts creates a genuine issue of material fact, “such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review.” 37 C.F.R. § 42.108(c). Accordingly, on the present record, we determine that Petitioner has demonstrated a reasonable likelihood that Edwards discloses elements a–c of claim 43.

Patent Owner also attempts to distinguish Mosher and Ingle as “directed to heating the ‘endopelvic fascia,’ which is not a target tissue in connection with the ’511 patent.” Prelim. Resp. 32–35. Although we agree with Patent Owner that target tissue as used in the claims of the ’511 patent refers to tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissues, such as the endopelvic fascia (*see* section II(B)(1), above), we are not persuaded on the present record that either Mosher or Ingle is limited to the treatment of such deeper tissues. Mosher, for example, teaches the treatment of a variety of tissues including vaginal lamina propria, a “dense connective tissue layer just under the epithelium” (*see* section II(C)(3), above) which, Patent Owner admits, comprises target tissue within the meaning of the ’511 patent (*see* Prelim. Resp. 9). Moreover, whether Mosher and/or Ingle are limited to the remodeling of endopelvic fascia, is a disputed factual issue best resolved on the full record.

See id. Prelim. Resp. 34 (noting that Dr. Bass disputes Dr. Dmochowski’s testimony that Mosher describes remodeling the muscularis).

(2) Element d

With respect to the wherein clause of claim 43 (element d), “wherein the heating includes heating a portion [of the target tissue] radiating outward from the introitus to Hart’s line,” Petitioner argues that “[i]n light of the variety of procedures and target tissues structures disclosed in Edwards, Mosher, and Ingle, and the knowledge of the POSITA, it would have been obvious to apply energy to heat target tissue located radiating outward from the introitus to Hart’s line.” Pet. 36 (citing Ex. 1003 ¶¶ 70, 89; Ex. 1004 ¶ 76). According to Petitioner,

Because it was well-known in the art that the nature of the mucosal epithelium of the vaginal wall is the same type of simple squamous epithelial tissue which makes up not only the epithelia of other, non-vaginal female genital tissue, but also the epithelial surface of *extragenital* tissue— i.e., “normal” skin surface tissue all over the body – the vaginal tissue remodeling teachings of Edwards were obviously applicable to remodel any other bodily tissue where the dermal surface is likewise simple squamous epithelial tissue. (EX. 1003, ¶¶69-70.) As, e.g., Ingle teaches, this is the case in the facial, abdominal, and breast tissue. (EX. 1003, ¶¶54, 69, 91.) This was also well-known to be the case with the “external” female genital tissue which extends beyond the introitus – i.e. the vulva – including the labia, and specifically the labia minora. (EX. 1003, ¶¶54, 69, 91.)

Id. at 55.

Further in support of its position that it would have been obvious to apply the techniques of Edwards, Mosher, and Ingle to “vulva-specific claims 43 (requiring heating genital tissue radiation outward from the

introitus to the Hart's line), and 51 (heating the labia)," Petitioner points to Olivier's¹⁷ discussion of Laser Vaginal Rejuvenation (LVR) and Designer Laser vaginoplasty (DLV) for vaginal tightening, and aesthetic modification of vulva and labia. Pet. 56, 36–38. Relying on the testimony of Dr. Dmochowski, Petitioner argues that the techniques highlighted in Olivier demonstrate that one of ordinary skill would have recognized that well-known treatments similar to those claimed were used to treat not only vaginal wall tissue, but labial tissue and tissue radiating outward from the introitus to Hart's line. See Pet. 36–38 (citing Ex. 1003 ¶¶ 92–102).

Dr. Dmochowski explains that well-known LVR techniques discussed in Olivier, (electrosurgical vaginoplasty and labiaplasty) involve "heating the to-be-excised genital tissue to at least 100°C so as to ablate the tissue." Ex. 1003 ¶¶ 94–98. According to Dr. Dmochowski, in electrosurgical labiaplasty, sub-epithelial "dermal tissue . . . adjacent to the line of vaporization is heated to some temperature between 60° C and 100° C," which one of ordinary skill in the art would have understood to result in collagen denaturation and subsequent "remodeling of at least a portion of the therapeutic zone of the target tissue by way of denaturation of collagen and induction of new collagen." *Id.* ¶¶ 99-100; see Pet. 37. Dr. Dmochowski further testifies that similar heating and remodeling occurs in the context of electrosurgical vaginoplasty. *Id.* ¶¶ 101–102; see *id.* ¶ 102 (noting that "[t]he mucosal epithelium surface of the vaginal wall to which the laser is directly applied is completely vaporized.").

¹⁷ D. Olivier, "Designer Vaginas," SALON (Nov. 14, 2000), http://www.salon.com/2000/11/14/vagina_3/. Ex. 1011.

(3) Reason to Combine

Petitioner argues that it would have been obvious to combine Edwards, Mosher, and Ingle because they “all disclose non-invasive treatment probes that can be used to provide RF energy to and through the vaginal wall to denature the underlying collagen containing tissue to tighten it”; “all describe methods of cooling the intermediate tissue while heating the underlying tissue”; and “[a]ll . . . relate to the same field as they all disclose non-invasive treatments that can be used to treat urinary incontinence as well as other uro-genital disorders. Pet. 38–39. In sum, all three references relate to the use of RF and other energy sources to heat, and thereby remodel, female genito-urinary target tissue, while cooling non-target tissue. *See generally*, Pet. 44–46. Because the three references disclose similar, non-invasive treatments to treat female urinary incontinence and other uro-genital disorders, we find it reasonable on the current record that one of ordinary skill would have looked to their combined teachings to improve upon such treatments. *See id.*

Petitioner also points to the overlapping functionality of the energy delivery devices disclosed in Edwards, Ingle, and Mosher. *See id.* at 40–42, 45–46. According to Petitioner, one of ordinary skill in the art would have been motivated “to combine the more robust cooling mechanisms described in . . . Ingle and Mosher with the non-invasive urogenital treatment probe in Edwards” to better minimize thermal damage to the mucosal epithelium. *Id.* at 40, 45–46; *see* Ex. 1003 ¶ 132 (indicating that one of ordinary skill in the art would have understood Edwards to contemplate ultrasound energy as disclosed in Ingle). According to Petitioner, the combined teachings “would

lead to a safer treatment for the patients and easier treatments to administer by physicians.” *Id.* at 42.

Arguing that Petitioner presents insufficient motivation to combine the cited references, Patent Owner states, for example, that Petitioner does not sufficiently articulate how the Edward’s apparatus could have been combined with that of Mosher or “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.” Prelim. Resp. 26. We note, however, that Edwards teaches the application of RF energy “so as to ablate, *tighten, shrink or reshape*” female uro-genital tissue. Ex. 1008, 2:33–38 (*italics added*). Moreover, although Edwards refers to “ablative lesions” in connection with embodiments 1–3 (*see, e.g., id.* at Figs. 6A, 7B, 8B), we do not discern where Edwards defines “lesions” as “ablative” in the context of the fourth embodiment (*see id.* at 13:14–16). Accordingly, we do not find Patent Owner’s argument persuasive. We, nevertheless, invite the parties to discuss the meaning and implication of Edward’s use of this term in Patent Owner’s Response and Petitioner’s Reply.

Patent Owner further argues that one of ordinary skill in the art would not have been motivated to treat the tissue radiating outward from the introitus to Hart’s line, as required by claim 43. *See* 35–38. As discussed above, Petitioner reasonably describes the combined disclosures of Edwards, Mosher, and Ingle as teaching the application of electromagnetic energy to heat, remodel, and tighten, target tissue underlying a mucosal epithelium of female genital tissue for the treatment of female uro-genital disorders and, as set forth in Edwards, to “provide physical and psychological improvement in

the area of sexual function.” See Ex. 1008, 3:11–13. Petitioner also reasonably argues that, as exemplified in Olivier, another form of electromagnetic energy, lasers, were used to tighten a patient’s vagina and aesthetically modify a patients labia. On the current record, we are persuaded that one of ordinary skill in the art would have applied the techniques of Edwards, Mosher, and Ingle to the target tissues identified in Olivier.

Further, relying on the testimony of Dr. Bass, Patent Owner asserts that one of ordinary skill in the art would not have had “a reasonable expectation of success in modifying the laser labia treatment [discussed in Olivier] by substituting UV energy with RF energy, given the significant differences between UV energy and RF energy.” *Id.* at 38–39 (citing Ex. 2001 ¶¶ 63–65). The cited testimony of Dr. Bass, however, does not discuss the laser energy used in the Olivier procedures but, instead, compares “the mechanisms of action between RF and the UVA1 light sources used to treat [lichen sclerosis]”—i.e., the light source used in Kreuter and Beattie. See Ex. 2001 ¶¶ 46, 56, 65; section II(D), below. Accordingly, while Patent Owner’s argument may ultimately prove persuasive, we will consider this issue on the fuller record developed at trial.

(4) Secondary Considerations

Finally, we acknowledge the evidence of secondary considerations and Patent Owner’s argument that such evidence establishes the non-obviousness of the challenged claims. Prelim. Resp. 28–30 (citing Ex. 2006, 2007). Evidence of secondary considerations, when present, must always be considered in determining obviousness. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983). Here, however, the secondary-

considerations evidence Patent Owner relies on is first presented together with the Preliminary Response, and Petitioner has not yet had an opportunity to respond to that evidence and arguments. Thus, in this case, a better course of action is to permit the parties to fully develop the record during trial before further weighing the alleged evidence of secondary considerations.

(5) Conclusion

Patent Owner presents similar arguments regarding why Petitioner has not shown that independent claim 51 is obvious in view of Edwards, Ingle, and Mosher. Prelim. Resp. 40–42 (arguing, *inter alia*, that “[t]he 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.”). As with claim 43, we find that the parties’ arguments are best evaluated on a more developed record. Because Petitioner has demonstrated a reasonable likelihood that at least one claim would have been rendered obvious by Edwards, Ingle, and Mosher, we institute *inter partes* review of all claims challenged under Ground 1.

D. Ground 2: Obviousness in view of Edwards, Kreuter, Smith, and Beattie

Petitioner challenges claims 43–58 as obvious in view of Edwards, in light of Kreuter, Smith, and Beattie. Pet. 55–66. Patent Owner opposes. Prelim. Resp. 42–61. As the teachings of Edwards are discussed above, we begin with an overview of Kreuter, Smith, and Beattie (collectively, “the LS references”).

1. Overview of Kreuter (Ex. 1012)

According to Kreuter, “[l]ichen sclerosis (LS) is a relatively rare, chronic inflammatory skin disease characterized by white porcelain-like polygonal plaques and atrophic and/or hypertrophic skin lesions,” which can affect genital and extra-genital tissues, particularly the anogenital area. Ex. 1012, 251.¹⁸ Both male and female patients were treated 4 times weekly for 10 weeks with about 15 minutes of UVA1 radiation at 20J/cm². *Id.* at 252. Of the eight female patients treated, three had extragenital LS and five had combined genital and extragenital involvement. *Id.* All patients responded with “obvious softening of sclerotic plaques . . . [and] repigmentation of former porcelain-like polygonal patches.” *Id.*

Kreuter discloses that “3 pathways are thought to be responsible for the development of scleroderma and LSA: increased collagen synthesis and deposition, vascular damage, and altered immunoregulation.” *Id.* at 254. Noting that previous studies have shown that UVA1 radiation results in “an increase of interstitial collagenase mRNA and protein expression,” and the induction of cytokines and soluble factors implicated in stimulation of collagenase, Kreuter “speculate[s] that UVA1 irradiation may suppress collagen synthesis and induce collagenase activity, resulting in clinically observed softening of former sclerotic plaques.” *Id.* at 255.

Figure 1 of Kreuter presents representative photomicrographs of skin before and after UVA1 phototherapy indicating “[n]ormalization of dermal architecture, [and] regularly sized collagen bundles” post-treatment. *Id.* at 253. Petitioner’s expert, Dr. Tucker, interprets Figure 1 of the reference as

¹⁸ Where possible, we refer to the native page numbers rather than those added by the parties.

showing an increase in the synthesis of new collagen following UVA1 phototherapy. See Ex. 1004 ¶ 80.

2. Overview of Smith (Ex. 1014)

Smith is a review article of the pathophysiology and treatment of vulval LS. Ex. 1014. According to Smith,

Lichen sclerosus is a chronic disorder of the skin and mucosal surfaces, and is most commonly seen on the female genital skin. It also occurs on other areas of the body. Any age group may be affected, although it is seen more often in elderly women. The exact cause of lichen sclerosus is unknown. There have been reports of family members with lichen sclerosus; thus it may have a genetic link. There is also the possibility of an autoimmune connection.

Id. at Abstract.

The location of the lichen sclerosus varies. The entire vulvar area (from the clitoris to the anus) may be involved. Often, swelling of the clitoral foreskin hides the clitoris. The labia minora may completely disappear. The most common areas where lichen sclerosus is found are on the labia majora and labia minora. Extragenital lesions (neck, shoulder, breast, etc.) occur less frequently. The frequency of lichen sclerosus varies depending on the location. A study by Lorenz et al. found lichen sclerosus to be located on the labia (100%), clitoris (70.4%), perineum (67.9%), buttocks (32.3%), perianal area (32.1%), crural area (8.6%), and urethra (3.7%).

Id. at 106 (internal endnotes omitted).

The area involved may vary from a small, single area to the entire vulva, extending out to the thighs. The most common description of lichen sclerosus is that of a thinned, whitened, crinkling, skin condition that often forms a figure-of-eight appearance. Initially the lesions are white, polygonal, and flat-topped papules or plaques which later form large atrophic patches. Fissuring and erosion may occur in the genital area. Fissuring is especially common between the clitoris and urethra, and on the perineum. Tears may also develop in the interlabial sulci. The skin may

appear bruised with small broken blood vessels. The vaginal opening may become smaller, interfering with intercourse (figure 2).

Id.

“Currently, ultra-potent topical corticosteroids are the medical treatment of choice. Other treatments that have been utilized for this condition include testosterone, progesterone, tacrolimus, surgery, and phototherapy.” *Id.* at Abstract. With respect to the latter, “[l]ow-dose UVA1 phototherapy has been used for extragenital lichen sclerosis.” *Id.* at 119 (noting that Kreuter “demonstrated a marked reduction or clearing of lichen sclerosis with low-dose UVA1 irradiation”).

3. Overview of Beattie (Ex. 1013)

Also citing Kreuter’s results in the treatment of extragenital LS, Beattie reports on the results of a study to determine the effectiveness of UVA1 on seven women with severe genital LS. Ex. 1013, Abstract, 344. “Patients received a variable number of total exposures (from 15 to 65) to whole body and perineum, given 3–5 times/week.” *Id.* For perineal irradiation, [i]rradiance at the skin surface, a distance of 300 mm from the lamp, was 65–74 mW/cm²” *Id.* Five patients showed minimal or moderate improvement. *Id.* at 345.

With respect to mechanism of action, Beattie states that, “a principal mechanism of action of UVA1 is immunomodulation via T-cell apoptosis and hence regulation of pro-inflammatory cytokines, including IL-1 α , -1 β and -6, which stimulate collagenase and cytokine receptors such as soluble IL-4R. UVA1 irradiation has also been shown to induce collagenase mRNA in a dose dependent manner.” *Id.* at 346 (internal footnotes omitted).

4. Analysis of Ground 2

According to Petitioner, one of ordinary skill in the art “would have understood that the dose of UVA1 phototherapy described in Beattie would necessarily heat tissue underlying the treated epithelial surface.” Pet. 58; *see* Ex. 1003 ¶ 108 (“A POSITA would have understood that if the UV radiation treatment of Kreuter was applied to female genital tissue, the ‘target tissue’ would have been heated to a collagen denaturing temperature by the application of energy at 20 J/cm².”). Moreover, Petitioner argues, Kreuter’s Figure 1 shows fibroblasts synthesizing new collagen in response to the UVA1 treatment and, thus, “taught remodeling of target tissue underlying the extragenital epithelium where ultraviolet energy is delivered to and through that epithelial surface to heat the target tissue.” Pet. 58; *see also id.* at 59 (arguing that, like Kreuter, “Beattie teach[es] remodeling of [sic] by heating a therapeutic zone of female genital tissue underlying the vulva”).¹⁹

Petitioner reasons that the UVA1 treatments described in Kreuter, Smith, and Beattie, therefore, “reshape female genital tissue through the manipulation of collagen using a penetrating form of energy.” *Id.* at 61. And, accordingly, one of ordinary skill in the art “would have been

¹⁹ Whereas Petitioner’s expert, Dr. Tucker, states that the effects of UVA1 are “attributable to both the light and heat generated,” he does not definitively link these effects to the treatment of LS. *See* Ex. 1004 ¶ 77. Dr. Bass, in contrast, testifies that in treating LS, “UVA1 is not being used to heat the tissue but works in a non-thermal fashion. Instead, it is absorbed by chromophores in nucleotides in DNA, suppressing DNA synthesis which in turn has a number of immunomodulatory effects in the epidermis and superficial dermis such as reducing the number of T lymphocytes and mast cells and stimulating synthesis of prostaglandins and cytokines that are immune suppressive.” Ex. 2001 ¶ 65.

motivated to combine the teachings of Edwards with Kreuter, Beattie, and Smith because Edwards sought to remodel the vaginal wall by applying therapeutic heating energy to targeted tissue. . . . [and]. . . 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.” *Id.* at. 62.

We do not find Petitioner’s arguments persuasive. The LS references are directed to treating a dermatological disease of genital and non-genital tissue by applying UVA1 phototherapy “to down regulate inflammatory cells so the skin layers return to a normal state.” Ex. 2001 ¶ 60; *see* Ex. 1012, 255; Ex. 1013, 346. This is not the type of remodeling contemplated in Edwards, which discloses heating (via RF, microwave, laser, or other energies) to create lesions in the vaginal wall, which ultimately tighten the underlying tissue. *See* section II(C)(1), above; Ex. 2001 ¶ 52 (“Figure 1 [of Kreuter] does not indicate any tightening or contracting of the tissues.”). As stated by Patent Owner, “[a] nebulous directive to look to treatments ‘relating to the appearance of genital tissue as abnormal’ is hardly a rational basis to combine” these disparate teachings. Prelim. Resp. 54.

Rather, we agree with the thrust of Patent Owner’s arguments that the LS references are (1) non-analogous art (Prelim. Resp. 48–51 (arguing, *inter alia*, that Edwards is directed to urogynecologists, gynecologists, and plastic surgeons, whereas LS is a dermatological disease typically treated by dermatologists)); and (2) that the LS references are not properly combinable with Edwards (*id.* at 51–55; *see also id.* at 55 (arguing that heating is merely incidental to the UVA1 treatments of the LS references)).

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of success in proving that at least one challenged claim of the '511 patent is obvious over Edwards, in light of Kreuter, Smith, and Beattie.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one challenged claim of the '511 Patent is unpatentable. In particular, because Petitioner has demonstrated a reasonable likelihood that at least one claim is rendered obvious by the combination of Edwards, Ingle and Mosher, we institute *inter partes* review on Ground 1.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and completion of the record.

In keeping with our mission of resolving patentability disputes in a just, speedy, and inexpensive manner, we exercise our discretion to institute *inter partes* review as set forth in the following Order.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 43–58 of the '511 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '511 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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