

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 IPR2018-00088
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 1–42 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 6 (“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 1–42.

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. 3, Paper 3, 2.

In addition to the present proceeding, Petitioner concurrently challenges claims 43–58 of the ’511 patent in IPR2018-00089.

¹ Petitioner further identifies Almirall, S.A. of Barcelona, Spain, as a real party-in-interest. Pet. 3.

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 noted by both parties, the Examiner rejected then-pending claims over Knowlton.^{3,4} *See* Pet. 7–10; Prelim. Resp. 4–5. Knowlton discloses

² Petitioner argues, and Patent Owner does not presently contest, that at least independent claims 1 and 35 are not entitled to the filing date of the provisional application. *See* Pet. 5–6.

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 arguing 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 1–42 in this proceeding,⁶ of which claims 1 and 35 are independent (*italicized to highlight differences*).

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

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 43–58, of which claims 43 and 51 are independent, in co-pending IPR2018-00089.

extending from the introitus^[7] inwardly to a location from 1 cm to 3.5 cm in from the introitus.

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

heating the target tissue, and

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

E. Asserted Grounds of Unpatentability

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

Ground	Claims	Basis	Reference(s)
1	1–10, 13–14, 17, 23 and 25–33 ⁸	§ 102	Edwards ⁹
2	1–42	§ 103	Edwards, Ingle, ¹⁰ and Mosher ¹¹

⁷ The Specification defines “introitus” as “the opening of the vagina” (Ex. 1001, 2:3–4, 3:51).

⁸ Petitioner lists claim 24 in its statement of ground 1, but discusses the merits of claim 26, rather than claim 24 in the Petition. See Pet. 13, 35–36; see also PO Resp. 31–32 (noting that Petitioner fails to address claim 24 under ground 1 but responding to arguments relating to claim 26).

Accordingly, we consider Petitioner’s substitution of claim 24 for claim 26 in its statement of ground 1 a typographical error.

⁹ US 6,463,331 B1, issued Oct. 8, 2002. Ex. 1008.

¹⁰ US 6,216,704 B1, issued Apr. 17, 2001. Ex. 1010.

¹¹ US 2004/0193238 A1, published Sept. 30, 2004. Ex. 1009.

In support of its patentability challenges, Petitioner relies on the Declarations of Dr. Roger Dmochowski, M.D. (Ex. 1003) and Dr. Robert Tucker, Ph.D., M.D. (Ex. 1004). Patent Owner relies on the Declaration of Dr. Lawrence S. Bass, M.D. (Ex. 2001).

II. ANALYSIS

To anticipate a claim under 35 U.S.C. § 102, “a single prior art reference must expressly or inherently disclose each claim limitation.” *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). That “single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002).

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. 20. 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. 21–22 (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.¹² *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

¹² 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.

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 80 degrees C. The inventive method, therefore includes heating target tissue to as high as 80 degrees C.” *Id.* at 11:25–29; *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. 12–13. 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 (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. 27 (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.

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.

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

Petitioner contends that the term “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock,” as recited in claim 35, should be interpreted as “[h]eating at least one point of the vaginal wall between 1 o’clock to 11 o’clock positions in a circumferential view with the urethra at 12 o’clock.” Pet. 22–23. In contrast, Patent Owner argues that a dictionary definition of the preposition “over” means “from one point to another across an intervening space or barrier,” such that the claim language requires heating substantially the entire 300 degree arc of vaginal wall from 1 o’clock to 11 o’clock, as shown in the embodiment illustrated in figures 9A and 9B of the Specification, illustrated below. See Prelim. Resp. 14–16.

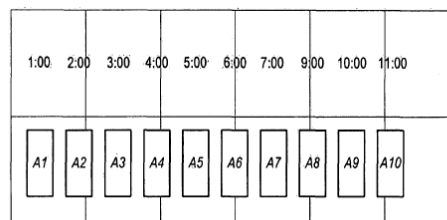
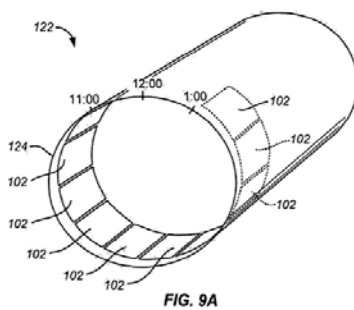


Figure 9A depicts a treatment area of a mucosal epithelium comprising multiple contact sites; figure 9B is a representation of the treatment area as a mapping grid. Ex. 1001, 5:55–57. More particularly:

FIG.9A is a schematic representation of a vagina 122, with the introitus 124 forming the entrance to the vagina. In a typical procedure, the treatment tip would contact various contact sites

in the lower vagina, just inside the introitus. As shown in FIG.9A, an accumulated set of contact sites 102 that have been treated by the treatment tip, and they collectively comprise a treatment area on the vaginal epithelium.

Id. at 14:46–53. As illustrated in Figure 9B,

the contact sites may be recorded on a grid 115, the completed grid thus being a mapped representation of the treatment area, which can be referred to during evaluation of the remodeling at some time point following the treatment. As shown, the treatment grid may contain reference points with respect to the circumferential location on the vagina, as provided, for example, by the clock dial scheme.

Id. at 14:62–15:3. The Specification further explains:

The circumference of the lower portion of an unfolded vagina, gently stretched as it is during the practice of this method, is approximately 12 cm. Accordingly, with a treatment tip of about 1 cm in width, a series of about 10 contact sites allows completion of an [sic] 300 degree arc of the circumference, between the 1 o'clock and 11 o'clock positions. These dimensional considerations underlie the rationale for an embodiment of the treatment wherein the surface of the energy delivery element has a curvature of about 30 degrees, each contact site accounting for about 10% of the 300 degree arc.

Id. at 14:35–45.

As an initial matter, the plain language of claim 35, “heating a portion of the vagina *circumferentially* around its wall,” requires the heating of a vaginal wall over a defined arc, and thus excludes the “at least one point” language of Petitioner’s proposed instruction. As illustrated above in Figure 9A, for example, a “contact site” along the vaginal wall extends some distance around the curvature of the vaginal wall. *See, e.g., id.* (“each contact site accounting for about 10% of the 300 degree arc”).

Whether “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock” requires heating substantially *all* of the wall 1 o’clock to 11 o’clock, however, is a close question. According to Petitioner, claim 35 should not be interpreted to require a series of contact sites as described in the above embodiment as this would improperly import limitations from the Specification. Pet. 23. Petitioner further argues that construing claim 35 to require a series of contact sites as shown in Figures 9A and 9B would ignore the principle of claim differentiation because claim 40, depending from claim 35, recites “contacting the epithelium with a treatment tip at one or more contact sites during a procedure.” *Id.*

On the record presently before us, we find Petitioner’s arguments more persuasive. Accordingly, we construe “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock,” as heating at least one contact site in the 300 degree arc extending from 1 o’clock to 11 o’clock along the vaginal wall.

C. Ground 1: Anticipation by Edwards

Petitioner challenges claims 1–10, 13–14, 17, 23, and 25–33 as anticipated by Edwards. Pet. 24–38. Patent Owner opposes. Prelim. Resp. 20–33. We begin with an overview of Edwards.

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.

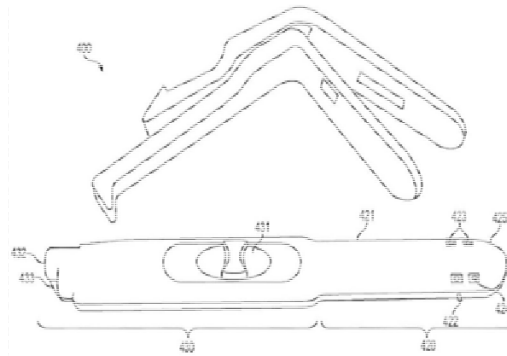


FIG. 4

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.

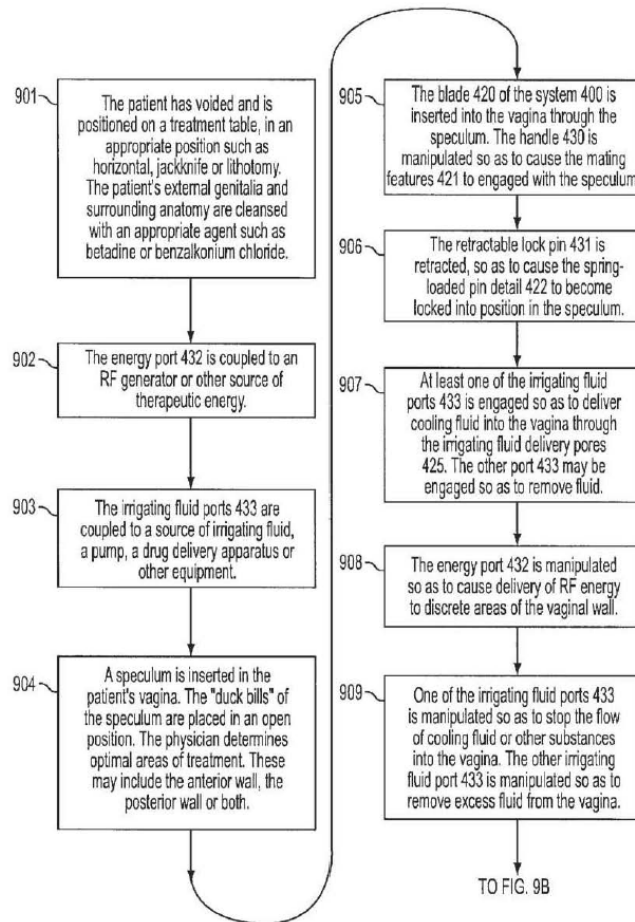


Figure 9A illustrates the method of Edward's fourth embodiment for vaginal remodeling. *Id.* at 3:38–39. As explained in detail at column 13, line 12 through column 14, line 4: “[A] speculum is inserted in the patient's vagina. The blades of the speculum are placed in an open position. The physician 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. Analysis of Ground 1

a) Claim 1

Petitioner relies on the testimony of Drs. Dmochowski and Tucker in asserting that Edwards discloses all elements of independent claim 1. Pet. 24–29 (citing Ex. 1003 ¶¶ 79, 81–88; Ex. 1004 ¶¶ 18–19. We find Petitioner’s arguments and evidence to be reasonable in light of Edward’s teaching to deliver 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.” See section II(C)(1), 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,” or “heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus,” as required by claim 1. Prelim. Resp. 20–31 (citing Ex. 2001 ¶¶ 19–23, 25–30); *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 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 at least claim 1 is anticipated by Edwards.

b) Claims 2–4

Depending from claim 1, claims 2–4 recite specific temperature ranges for the heating of target tissue. As Patent Owner points out at pages 30–31 of the Preliminary Response, Petitioner fails to show where Edwards expressly or inherently discloses those claimed ranges. See Pet. 29–30 (citing Ex. 1003 ¶¶ 90, 125; Ex. 1004 ¶¶ 57–62). Rather than apply the legal standards of anticipation, Petitioner, not unreasonably, argues that the claimed ranges are *obvious* in view of the understanding of one of ordinary skill in the art. See, e.g., Pet. 30 (quoting Examiner's statement that "[i]t would have been obvious to one of ordinary skill in the art . . . to heat the target tissue to the claimed temperature ranges").¹³ Although we will consider these arguments in the context of Ground 2, Petitioner has not demonstrated a reasonable likelihood that claims 2–4 are anticipated by Edwards.

¹³ Petitioner also appears to have inadvertently addressed claim 35 in the section discussing Ground 1. See Pet. 38.

c) Summary

Patent Owner presents additional arguments regarding why Petitioner has not shown that Edwards discloses elements of certain dependent claims. Prelim. Resp. 31–33. As with claim 1, 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 is anticipated by Edwards we institute *inter partes* review on Ground 1.

D. Ground 2: Obviousness in view of Edwards, Ingle, and Mosher
Petitioner challenges claims 1–42 as obvious in view of Edwards, Ingle, and Mosher. Pet. 39–67. Patent Owner opposes. Prelim. Resp. 33–59. As the teachings of Edwards are discussed above, we begin with an overview of Ingle and Mosher.

1. 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 nC¹⁴ 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

¹⁴ “nC” appears to be a 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.

2. 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.

3. Analysis of Ground 2

a) Claim 1

Petitioner reasonably contends that each of Edwards, Mosher, and Ingle “disclose the tightening or contracting the collagen tissue underlying the epithelium of female genital tissue and thus disclose remodeling of the therapeutic zone of target tissue.” Pet. 42. Relying on the testimony of Drs. Dmochowski and Tucker, Petitioner argues that, as with Edwards (*see* section II(C), above), Mosher and Ingle disclose “heating a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus,” as required by claim 1. *Id.* at 42–44 (citing Ex. 1003 ¶¶ 29–30, 59–62; Ex. 1004, ¶ 30).

We are unaware of any rule requiring Petitioner to rely on all cited references to show obviousness. *See In re Kronig*, 539 F.2d 1300, 1304 (CCPA 1976) (affirming obviousness rejection on subset of asserted references). Insofar as Petitioner has demonstrated a reasonable likelihood that at least claim 1 is anticipated by Edwards, it has also demonstrated a reasonable likelihood that it is obvious.¹⁵ *See Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (“a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for ‘anticipation is the epitome of obviousness’”) (citing *In re Fracalossi*, 681 F.2d 792 (CCPA

¹⁵ Although Patent Owner purports to rely on secondary consideration evidence (*see* Prelim. Resp. 19, 43–45), Petitioner has not had an opportunity to test this evidence at trial. We will consider the parties’ arguments and evidence on the fully developed record.

1982)). Accordingly, for reasons similar to those set forth in section II(C)(2), above, we institute *inter partes* review on Ground 2.

With respect to a reason to combine Edwards with Ingle and Mosher, we note that 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 treatments for 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 45–46. According to Petitioner, “[g]iven Edwards’ stated goal of minimizing thermal damage to the mucosal epithelium,” 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 treatment probe in Edwards” to better minimize thermal damage to the mucosal epithelium. *Id.* at 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).

Patent Owner argues that Petitioner presents insufficient motivation to combine the cited references, stating, 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. 40. 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). On the present record, we find Patent Owner’s argument unpersuasive, but invite the parties to discuss the meaning and implication of Edward’s use of the terms “tighten, shrink or reshape” and “lesions” in the Patent Owner Response and Petitioner’s Reply.

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. 45–49. 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(D)(2), above) which, Patent Owner admits, comprises target tissue within the meaning of the ’511 patent (*see* Prelim. Resp. 8-9). 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, e.g., id.* at 47–48 (indicating that the parties’ experts dispute whether Ingle discloses heating tissue immediately beneath the mucosal epithelium).

b) Claim 35

Claim 35, along with its dependent claims 36–42, recites “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock.” According to Petitioner,

Edwards describes treatment of both the anterior and posterior vaginal wall. (EX. 1008, 13:14-23.) The treatment of both the anterior and posterior wall in Edwards necessarily entails heating a portion of the vagina circumferentially around its wall within the range from 1 o’clock to 11 o’clock, as the dividing line between the anterior and posterior walls would be the 3 o’clock and 9 o’clock positions and Edwards is treating at least one position within the 3 o’clock and the 9 o’clock positions. (EX. 1003, ¶¶89, 119-120; EX. 1004, ¶¶70, 72.)

Pet. 38. Petitioner makes similar arguments with respect to Mosher and Ingle. *Id.* at 67.

As set forth in section II(B)(4), above, we construe “heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock” as heating at least one contact site in the 300 degree arc extending from 1 o’clock to 11 o’clock along the vaginal wall. Applying a similar construction, Petitioner presents uncontroverted argument and evidence that the cited references further disclose this limitation. Accordingly, we institute *inter partes* review for claim 35 and its dependent claims.¹⁶

¹⁶ We invite Patent Owner to consider the guidance regarding motions to amend set forth in the accompanying scheduling order. *See also, Sprint Spectrum L.P. v. General Access Solutions, Ltd.*, Case IPR2017-01885, Paper 7 (PTAB Mar. 9, 2018) for general guidance regarding motions to amend.

c) Summary

Because Petitioner has demonstrated a reasonable likelihood that at least one claim is rendered obvious by Edwards, and/or Edwards in light of Ingle and Mosher, we institute *inter partes* review on Ground 2 as to claims 1–42.

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.

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 1–42 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

IPR2018-00088
Patent 8,961,511 B2

the entry date of this Order, and notice is hereby given of the institution of a trial.

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