

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BTL INDUSTRIES, INC.,
Petitioner,

v.

INMODE LTD.,
Patent Owner.

IPR2024-00703
Patent 8,961,511 B2

Before MEREDITH C. PETRAVICK, HYUN J. JUNG, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

BTL Industries, Inc. (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–58 of U.S. Patent No. 8,961,511 B2 (“the ’511 patent,” Ex. 1001). Paper 2 (“Pet.”). InMode Ltd. (“Patent Owner”) did not file a Preliminary Response.

We review the Petition and accompanying evidence under 35 U.S.C. § 314. An *inter partes* review may not be instituted unless “the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Further, a decision to institute may not do so on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); 37 C.F.R. § 42.108(a).

After considering the evidence and arguments presented in the Petition, we determine that Petitioner demonstrates a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the ’511 patent is unpatentable. Accordingly, we institute an *inter partes* review as to all the challenged claims of the ’511 patent on all the grounds of unpatentability set forth in the Petition.

A. Real Parties-in-Interest

Petitioner identifies itself, BTL Industries, Inc., as the real party-in-interest. Pet. 73. Patent Owner identifies only itself, InMode Ltd., as the real party-in-interest. Paper 4, 1. Patent Owner avers that it is the owner of the ’511 patent, as evidenced by the assignment accorded with the Office at Reel No. 064258, Frame No. 0525. *Id.*; *see also* Ex. 3001 (assignment history abstract).

B. Background and Related Proceedings

The '511 patent was previously challenged by ThermiGen, LLC and Thermiaesthetics, LLC in IPR2018-00088 and IPR2018-00089 (jointly, “the ThermiGen IPRs”). These cases were terminated shortly after institution at the request of Petitioner ThermiGen, and then-Patent Owner, Viveve, Inc. *See* IPR2018-00088, Papers 10 (Ex. 1009), 12; IPR2018-00089, Papers 11 (Ex. 1010), 12. Coincident with the ThermiGen IPRs, the '511 patent was then at issue in *Viveve, Inc. v. ThermiGen, LLC et al.*, Civil Action No. 2:16-cv-1189-JRG (E.D. Tex.) (“*Viveve*”), which also settled. *See, e.g.*, Ex. 1009, 2.

According to the parties here, the '511 patent is now at issue in *InMode Ltd. v. BTL Industries, Inc.*, Case No. 2:23-cv-08583 (C.D. Cal.), filed October 11, 2023. *See* Pet. 74, Paper 4, 1.

C. The '511 Specification

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. The patent pertains to the use of radiant energy to “treat[] a loose vagina and introitus”^[1] via “corrective or restorative remodeling of the mucosal surfaces of the vagina, introitus, and vulva.” Ex. 1001, Abstract, 1:13–15, 2:17–21. According to the Specification:

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

¹ The Specification defines “introitus” as “the opening of the vagina” (Ex. 1001, 2:3–4, 3:51).

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.

Id. at 3:41–48.

The Specification describes “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, such 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.

D. Prosecution History of the ’511 patent

During prosecution, the Examiner repeatedly rejected claims as anticipated and/or obvious in view of Knowlton,² which is cited as background in the ’511 patent and incorporated therein by reference. Ex. 1001, 1:47–49, 5:65–26:6 (referencing Knowlton); Ex. 1002, 0079–0094, 0135–0151, 0198–0214, 0260–0266 (Office Actions); *see also id.* at 0115–0126, 0165–0174, 0234–0244, 0295–0306 (Applicant responses and amendments);

² US 6,350,276 B1, issued Feb. 26, 2002. Ex. 1013.

Knowlton discloses a 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. 1013, Abstract, 13:9–13; 15:25–28. In one embodiment, Knowlton discloses treating pre-term cervical dilation by applying RF energy to tighten the dilated cervix. *See, e.g., id.* at 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.”).

The Examiner asserted, for example, that,

Knowlton discloses a method for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying a mucosal epithelium of female genital tissue (as in the embodiment of figures 13–14 describing the treatment of cervix, see col. 13; 35–37), the method comprising heating the target tissue and remodeling the therapeutic zone of target tissue.

Ex. 1002, 82.

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 0165–0174. 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.³ *Id.* at 235.

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, 317 (Notice of Allowance).

E. Illustrative Claims

Petitioner challenges claims 1–58 in this proceeding, of which claims 1, 35, 43 and 51 (reproduced below) are independent. The independent claims differ only with respect to the “wherein” clauses, shown below in italics.⁴

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*

³ In addition to the amendments of claim 1, Applicant re-drafted certain dependent claims in independent format, which subsequently issued as claims 35, 43, and 51. *See id.* at 238.

⁴ The Petition applies a short-hand designation identifying elements of the independent claims. With respect to claim 1, for example, [1.P] refers to the preamble, [1.1] refers to the step of “heating the target tissue,” [1.2] refers to “remodeling the therapeutic zone of target tissue,” and [1.3] applies to the claim-specific “wherein” clause. *See* Pet. 25, 28, 32, 35.

extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus.

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

heating the target tissue, and

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

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

heating the target tissue, and

remodeling the therapeutic zone of target tissue, wherein the heating includes *heating a portion radiating outward from the introitus to Hart's line.*^[5]

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.*

⁵ The Specification defines “Hart’s line” as the portion of the vulva “where mucosal epithelium gives way to skin on the outer surface of the labia minora,” i.e., “the boundary where mucosal epithelium and labial skin meet” (*id.* at 3:49–54, 11:59–62).

F. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 12):

Ground	Claims	Basis	Reference(s)
1	1–58	§ 103	Edwards, ⁶ Mosher, ⁷ Ingle ⁸
2	43–58	§ 103	Edwards, Mosher, Ingle, Ollivier ⁹

In support of its patentability challenges, Petitioner relies on the Declaration of Dr. Joseph Berenholz, M.D. (Ex. 1003).

II. ANALYSIS

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

⁶ US 6,463,331 B1, issued Oct. 8, 2002. Ex. 1005.

⁷ US 2004/0193238 A1, published Sept. 30, 2004. Ex. 1006.

⁸ US 6,216,704 B1, issued Apr. 17, 2001. Ex. 1007.

⁹ Ollivier, D., “Designer Vaginas,” Salon.com, accessed at <https://web.archive.org/web/20010124063400/http://www.salon.com/sex/feature/2000/11/14/vagina/print.html> (Nov. 14, 2000). Ex. 1008.

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). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of non-obviousness, if present. *KSR*, 550 U.S. at 406.

“[W]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But in analyzing the obviousness of a combination of prior art elements, it can also 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.” *Id.* at 418.

“[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). Moreover, a precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *KSR*, 550 U.S. at 418. Rather, “any 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) (quotations and citations omitted).

A. Person of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

In the ThermiGen IPRs, the panel preliminarily determined that one of ordinary skill in the art in the field of the ’511 patent would have had “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.” Ex. 1009, 8–9; Ex. 1010, 8. Petitioner here proposes a similar definition, specifically, “a medical doctor . . . [with] at least three years of experience in the non-surgical treatment of uro-gynecological conditions and/or the non-surgical cosmetic treatment of female genital tissues.” Pet. 6.

Absent evidence or argument to the contrary, we apply Petitioner’s proposed definition, as it appears consistent with the prior art and is supported by the presently unopposed testimony of Dr. Berenholz. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355, (Fed. Cir. 2001) (the level of ordinary skill in the art may be reflected in the prior art itself); Ex. 1003 ¶¶ 28–31, 58–60.

B. Claim Construction

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe claims in a civil action in federal district court. *See* 37 C.F.R. § 42.100(b)). In construing claims, district courts give claims their 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.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

With respect to the challenged claims, Petitioner asserts that “no claim term requires construction—all terms should receive their ordinary and customary meaning in view of the patent specification.” Pet. 7 (citing Ex. 1003 ¶ 61). Accordingly, Petitioner contends that formal constructions are unnecessary. *Id.* (citing *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. 2017) (explaining that only those terms need be construed “that are in controversy, and only to the extent necessary to resolve the controversy.”)).

Petitioner, nevertheless, succinctly reviews the preliminary construction of certain terms of the ’511 patent claims in the ThermiGen IPRs, and the construction by the District Court in *Viveve*. *See* Pet. 8–11. We note first that, whereas these two sets of prior constructions may differ in

focus or scope, we do not view them as in conflict. And although the preliminary constructions in the ThermiGen IPRs were conducted under the then-applicable broadest-reasonable-interpretation (BRI) standard, we are not presently aware of any reason that those definitions would differ under the *Phillips* standard, and we provisionally apply them here for clarity. And while we recognize that the *Viveve* constructions are not binding on this proceeding, the district court’s definitions are instructive and generally complementary to ThermiGen IPR constructions. Accordingly, we also provisionally apply them here for clarity. Although none of these terms are presently in dispute, we find it useful to clarify the meanings we apply at this stage of the proceeding. The parties are, of course, welcome to address the construction of any claim term at trial.

We summarize those constructions below.

1. “*target tissue*”

Each independent claim before us recites “method[s] for remodeling a therapeutic zone within a target tissue, the target tissue comprising tissue underlying an epithelium of female genital tissue.” Addressing this language, the Board in the ThermiGen IPRs preliminarily construed “target tissue” as “tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissues, such as the endopelvic fascia,” but indicated that the “comprising” language of the preambles were permissive of heating or treating *non*-target tissue such as the endopelvic fascia. Ex. 1009, 10–12; Ex. 1011, 10–11. The *Viveve* court similarly found that “The preamble [of the independent claims] limits the claims by requiring the target tissue to include tissue underlying an epithelium of female genital

tissue that includes at least one of vulva, introitus and vagina tissue.”

Ex. 1024, 21–28.

While we do not disagree with the definition articulated by the *Viveve* court, we find it sufficient to preliminarily adopt the definition set forth in the ThermiGen IPRs. *See* Ex. 1009, 12.

2. “heating”

All independent claims of the ’511 patent recite the step “heating the target tissue.” The Board in the ThermiGen IPRs preliminarily construed “heating” in this phrase as “raising the temperature of target tissue to no more than about 80 degrees C,” and expressly rejected the prior Patent Owner’s argument that the heating step requires “heating without damaging the mucosal epithelial surface.” Ex. 1009, 9–14; Ex. 1011, 11–14. The *Viveve* court provided an arguably broader construction of the “heating” step as meaning, “heating the tissue underlying the epithelium to a temperature that is higher than the temperature of the epithelium.” Ex. 1024, 7–14.

Again, while we do not disagree with the definition articulated by the *Viveve* court, we preliminarily adopt the definition set forth in the ThermiGen IPRs which, in accord with the Specification, expressly defines an upper limit “of about 80 degrees C.” *See* Ex. 1009, 14 (citing Ex. 1001, 4:34–40, 11:21–23, 11:25–29).

3. “remodeling the therapeutic zone of target tissue”

Each independent claim recites the step of “remodeling the therapeutic zone of target tissue.” The Board in the ThermiGen IPRs preliminarily construed this “remodeling” as “the result of raising the temperature of target tissue to no more than about 80 degrees C without substantially affecting the epithelium overlying the target tissue, wherein

that result includes a tightening or contraction of the target tissue.” Ex. 1009, 14–16; Ex. 1011, 14–15. The *Viveve* court similarly, if more succinctly, construed this term as “causing a zone of tissue within the target tissue to tighten or contract by heating the zone of tissue to a therapeutic temperature.” Ex. 1024, 14–21.

Although we find both constructions reasonable, for simplicity, we provisionally adopt the *Viveve* court’s construction of this term.

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

The unique “wherein” clause of independent claim 35 specifies that “heating includes heating a portion of the vagina circumferentially around its wall from 1 o’clock to 11 o’clock.” The Board in the ThermiGen IPRs preliminarily construed “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.” Ex. 1009, 18. The *Viveve* court did not reach this term. *See generally* Ex. 1024. For the purpose of institution, we provisionally adopt the Board’s construction in the ThermiGen IPRs.

C. Overview of Asserted References

1. Overview of Edwards (Ex. 1005)

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. 1005, 2:33–38. In targeting this energy, Edwards teaches that “[t]he physician determines optimal areas of treatment,” and “create[s] a

series of lesions in either the anterior vaginal wall, the posterior vaginal wall or both.” *Id.* at 13:14–16, 13:38–42. According to Edwards, “[r]emodeling of the anterior wall treats incontinence,” whereas “[r]emodeling both the anterior wall and posterior wall provide circumferential vaginal wall tightening, resulting [in] physical and psychological improvement in the area of sexual function.” Ex. 1005, 3:5–11, 13:14–23.

Edwards discloses system 400, reproduced below in Figure 4, for use in vaginal remodeling. *See id.* at 3:25–27, 7:14–8:5, 13:12–14:4.

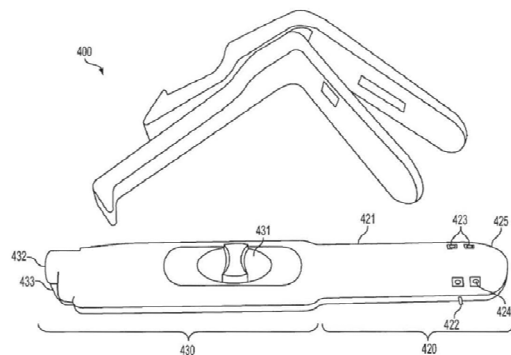


FIG. 4

Figure 4 shows system 400, including treatment element 410 (bottom portion, not labeled). Treatment element 410 includes blade 420 and handle 430. Ex. 1005, 7:18–28. The blade includes a plurality of electrodes 423, a plurality of irrigating fluid delivery pores 425 “disposed to deliver cooling liquids so as to minimize thermal damage,” and at least one thermocouple 424 to monitor temperature. *Id.* at 7:18–28, 7:51–55, 7:66–8:5, 13:43–53.

Figure 9A of Edwards, reproduced below, describes a method employing the device shown in Figure 4.

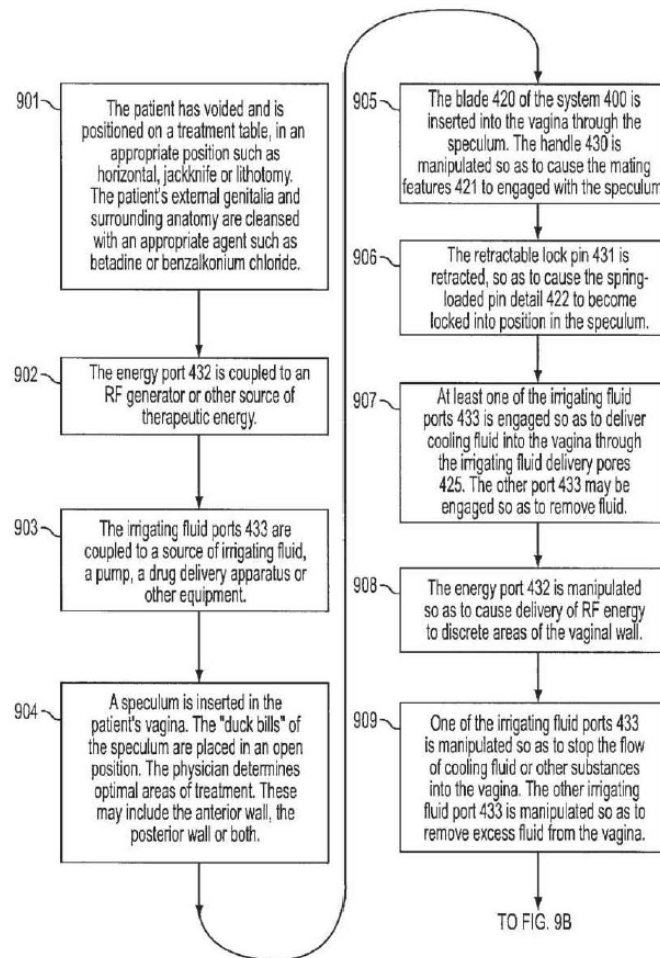


Figure 9A illustrates a method for vaginal remodeling. *Id.* at 3:38–39. According to Edwards, “[A] speculum is inserted in the patient’s vagina. The blades of the speculum are placed in an open position. The treatment element of system 400 is inserted into the vagina through the speculum.” *Id.* at 13:43–46; *see generally, id.* at 13:12–14:4. 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. “In a preferred embodiment, the blade 420 may be disengaged and relocked in

another position in the speculum, so as to deliv[er] energy to another area of the vagina.” *Id.* at 13:60–62.

2. Overview of Mosher (Ex. 1006)

Mosher discloses treatment of urinary incontinence by selectively heating and remodeling “collagenous tissues of the pelvic support tissue.” *See, e.g.*, Ex. 1006, Abstract, ¶¶ 9, 45. In this respect, Mosher discloses the introduction of a probe having “tissue-penetrating electrodes” into the vagina for “heating provided through . . . the vaginal wall.” *Id.* at ¶¶ 9, 24–25, 54, Figs. 4B, C.

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.

According to Mosher, “directing energy from a probe into collagenous tissues of the pelvic support system” may cause contraction of the collagenous tissue and/or structural stiffening related to scarring or healing. *Id.* ¶ 45. In addition to the treatment of urinary incontinence, Mosher teaches that such methods “will find applications in a wide variety of therapies,” and “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.* ¶¶ 46, 48.

3. Overview of Ingle (Ex. 1007)

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. 1007, 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. Ingle posits that “[c]ontraction occurs as a result of heat-induced uncoiling and repositioning of the collagen B-pleated structure.” *Id.* at 11:25–28.

Ingle teaches heating target tissues by application of RF or ultrasound energy. *See, e.g., id.* at 3:51–56, 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. To avoid such tissue damage, 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.

Ingle provides guidance for times and temperatures suitable to achieve “significant tissue contraction . . . without substantial collateral tissue damage.” *Id.* at 11:25–31. In a preferred embodiment, “the target tissue will

be raised to a temperature of about 60 nC¹⁰ or more, while the intermediate tissue remains at or below a maximum safe temperature of about 45 nC.” *Id.* at 8:41–44. Ingle further teaches that “[t]he temperature of the target tissue structure will . . . often be[] in the range from about 60 nC to 80 nC.” *Id.* at 11:33–37.

According to Ingle, selective, temperature-mediated 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 some embodiments 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. Fig. 11. In this aspect,

The 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 temperature when the fascia is heated by the transmitting element.

¹⁰ “nC” appears to be pervasive formatting error in Ingle, as published. We understand “nC” in Ingle to mean “°C”. *See* Ex. 1007, 15:31 (referring to body temperature as “approximately 37 nC”), 15:5–39 and Figures 3A–E (illustrating exemplary temperature ranges, in °C); Ex. 1003 ¶ 80.

Id. at 3:43–50; *see also id.* at 3:51–58 (“[I]ntermediate tissue is cooled with the probe to avoid injuring the intermediate tissue when the target tissue is heated by the probe.”), 4:4–10, 11:25–31, 15:65–16:4, 20:14–19.

4. Overview of Ollivier

Ollivier describes techniques for the cosmetic treatment of the vagina, vulva, and labia. *See generally* Ex. 1008. Ollivier describes, for example, the use of “Laser Vaginal Rejuvenation (LVR) to tighten [a patient’s] vagina and ‘enhance sexual gratification’ and Designer Laser Vaginoplasty (DLV) to ‘aesthetically modify’ her labia.” *Id.* at 1. Ollivier explains, “[b]y reconstructing the ‘optimum structural architecture’ of the vagina—namely, by reconstructing the outer third of the vagina: the orgasmic platform, internal and external vaginal diameter (introitus) and the perineal body— ... women not only are relieved of incontinence, but they also enjoy increased levels of sexual gratification.” *Id.* With reference to advances in remodeling technology, Ollivier states that, surgery for vaginal and labial “deformities” has “been around for 30 years. Lasers have even fallen out in favor. We have more sophisticated tools that do the same thing these days.” *Id.* at 3.

D. Ground 1: Asserted Obviousness in view of Edwards, Ingle, and Mosher

For Ground 1, Petitioner challenges claims 1–58 as obvious in view of Edwards, Ingle, and Mosher. Pet. 28–67. As noted above, Patent Owner did not file a Preliminary Response. Accordingly, Petitioner’s assertions—and the testimony of its declarant—are presently unopposed. For the purpose of institution, we focus on claim 1.

As a general matter, Petitioner contends that one of ordinary skill in the art would have been motivated to combine the teachings of Edwards,

Mosher, and Ingle with a reasonable expectation of success of arriving at the claimed invention because 1) “loose vaginal or vulval tissue was a known problem facing women at the time,” 2) “Edwards, Mosher, and Ingle are all directed to methods for the non-invasive treatment of female uro-genital conditions, for therapeutic and/or cosmetic reasons,” and 3) each of the cited references teaches the application of radiant energy, including RF, to heat and denature collagen, thereby tightening and remodeling the affected tissues. *See generally*, Pet. 22–24; Ex. 1003 ¶¶ 84–91.

More specifically, Petitioner relies on Edwards as providing general teachings of a non-invasive treatment using RF energy, and looks to Mosher and Ingle for details regarding parameters, techniques, and the physiological mechanism underlying heat-mediated collagen remodeling of female genital tissue. *See* Pet. 23. According to Petitioner, the asserted “combination is merely applying known techniques (Mosher/Ingle’s treatment methods) to a known method ready for improvement (Edward’s treatment method) to yield the predictable result of tightening via collagen denaturation.” *Id.*

With respect to the details of Ground 1, Petitioner presents an element-by-element comparison of claim 1 to the combined teachings of the asserted references, which is supported by the testimony of Dr. Berenholz. Pet. 25–36 (citing Ex. 1003 ¶¶ 99–124). We note, in particular, Petitioner’s arguments and evidence regarding the “wherein” clause of claim 1, element [1.3], which requires 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.” *Id.* at 35–36.

According to Petitioner, one of ordinary skill in the art would have understood that the combination of Edwards and Mosher teaches heating the

anatomical region of element [1.3] because “Edwards teaches performing its method “to create 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.” Pet. 35 (citing Ex. 1005, 13:14–22). Relying on the testimony of Dr. Berenholz, Petitioner contends that one of ordinary skill in the art “would have understood Edwards’s teachings to include treatment near the opening of the vagina.” *Id.* (citing Ex. 1003 ¶ 122).

According to Petitioner, “Mosher further provides motivation to focus treatment nearer the opening of the vagina, in order to avoid damage to nerves in the bladder neck region and in the antero-lateral vaginal wall.” *Id.* (citing Ex. 1006, ¶¶ 58, 74, 75, Figs. 6, 6A; Ex. 1003 ¶ 123). Petitioner argues that

Mosher describes the preferred treatment region as “significantly wider (along the medial-lateral orientation) than its urethral length, ideally having a width of about 25 mm and a length of about 15mm.” EX1006, ¶74. Despite the reference to “urethral length” in this description, a POSA would have understood this treatment region to apply to non-invasive treatment within the vagina. *Id.*; EX1003, ¶¶123-124. Indeed, Mosher describes several electrode configurations for its vaginal probe 54 to provide this “enhanced treatment width.” EX1006, ¶75; EX1003, ¶¶123-124.

Id. at 35–36. Further relying on the testimony of Dr. Berenholz, Petitioner contends that one of ordinary skill in the art “would have understood Mosher’s treatment length of about 15 mm (1.5 cm) refers to the length of the treatment region extending into the vagina.” *Id.* at 36 (citing Ex. 1003 ¶ 124). Petitioner thus concludes that one of ordinary skill in the “would

have understood that Mosher teaches treating a portion of the vagina extending from the introitus to 1.5 cm inward, which falls within the claimed treatment area.” *Id.* (citing Ex. 1003 ¶ 124).

We find Petitioner’s arguments and Dr. Berenholz’s testimony reasonable in light of the present—and presently uncontested—record.

E. Ground 2: Asserted Obviousness in view of Edwards, Ingle, Mosher, and Ollivier

For Ground 2, Petitioner challenges claims 43–58 as obvious in view of Edwards, Ingle, and Mosher for the reasons set forth with respect to Ground 1, and further in view of Ollivier—“to the extent Patent Owner argues or the Board finds that [treatment of the vulval areas recited in the ‘whereas’ clauses of independent claims 43 and 51] was not within the general knowledge of a POSA.” Pet. 67–68. In particular, Petitioner argues that Ollivier describes techniques to not only tighten the vagina and introitus for the relief of incontinence and increased sexual satisfaction, but also to “esthetically modify” the labia. Pet. 67. Petitioner, thus, contends that one of ordinary skill in the art “would have been motivated to use the treatment method of the Edwards-Mosher-Ingle combination, which teaches treating at least the vagina and introitus, to also treat the vulvar vestibule and labia minora in order to achieve the desired aesthetic modification expressly described in Ollivier.” *Id.* at 67–68 (citing Ex. 1003 ¶ 274). Petitioner reasons that:

Ollivier teaches using earlier laser techniques to provide cosmetic treatment to these vulvar tissues, as recited in claims 43 and 51, and adds that lasers have “fallen out of favor” and there are “more sophisticated tools that do the same thing.” EX1008, 0003. And as discussed above for Ground 1, it was known to use RF treatments to tighten other tissue areas for both therapeutic

and cosmetic purposes. EX1007, 1:18-23, 18:1-7; EX1003, ¶¶44-51, 84-90. A POSA would have had a reasonable expectation of success in doing so because the vulval region comprises similar mucosal epithelium, with the same underlying collagen-rich layers as the vagina. EX1003, ¶275.

Id. at 68.

While we find Petitioner's arguments for Ground 1 sufficient for the purpose of institution, its further arguments with respect to Ollivier appear to underscore that one of ordinary skill in art would have applied the teachings of Edwards, Mosher and Ingle to the treatment of the labial tissues encompassed by the language of independent claims 43 and 51. We would, nevertheless, re-evaluate any question of unpatentability of the challenged claims on the fuller record adduced at trial.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition, 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 1–58 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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