

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BTL INDUSTRIES, INC.,
Petitioner

v.

INMODE LTD.,
Patent Owner

Case IPR2024-00703
U.S. Patent No. 8,961,511

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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PETITIONER’S UPDATED EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 8,961,511 to Parmer (“the ’511 patent”)
1002	File History of U.S. Patent No. 8,961,511 (“’511 File History”)
1003	Declaration of Dr. Joseph Berenholz in Support of Petition for <i>Inter Partes</i> Review (“Berenholz Decl.”)
1004	<i>Curriculum Vitae</i> of Dr. Joseph Berenholz
1005	U.S. Patent No. 6,463,331 to Edwards (“Edwards”)
1006	U.S. Patent Application Publication No. 2004/0193238 to Mosher et al. (“Mosher”)
1007	U.S. Patent No. 6,216,704 to Ingle et al. (“Ingle”)
1008	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) (“Ollivier”)
1009	<i>Thermigen, LLC v. Viveve, Inc.</i> , IPR2018-00088, Decision to Institute (PTAB May 8, 2018)
1010	<i>Thermigen, LLC v. Viveve, Inc.</i> , IPR2018-00088, Patent Owner’s Preliminary Response (PTAB February 14, 2018)
1011	<i>Thermigen, LLC v. Viveve, Inc.</i> , IPR2018-00089, Decision to Institute (PTAB May 8, 2018)
1012	<i>Thermigen, LLC v. Viveve, Inc.</i> , IPR2018-00089, Patent Owner’s Preliminary Response (PTAB February 14, 2018)
1013	U.S. Patent No. 6,350,276 to Knowlton
1014	U.S. Patent No. 6,283,987 to Laird et al.
1015	F.H. Netter, “Netter’s Atlas of Human Anatomy,” 4 th Ed., Saunders Elsevier, 2006 (“Netter”)
1016	D.J. Goldberg, “Nonablative Laser Technology: Radiofrequency,” <i>Aesthetic Surg J</i> 2004; 24:180–181 (“Goldberg”)
1017	C. Squier and K.A. Brogden, “Human Oral Mucosa: Development, Structure, and Function,” 1 st Ed., Wiley-Blackwell 2011 (“Squier”)

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1018	N. Sadick, “Tissue Tightening Technologies: Fact or Fiction,” <i>Aesthetic Surg J</i> 2008; 28:180–188 (“Sadick”)
1019	N.T. Wright and J.D. Humphrey, “Denaturation of Collagen Via Heating: An Irreversible Rate Process,” <i>Annu. Rev. Biomed. Eng.</i> 2002; 4:109–128 (“Wright”)
1020	M. Paul et al., “Three-Dimensional Radiofrequency Tissue Tightening: A Proposed Mechanism and Applications for Body Contouring,” <i>Aesth Plast Surg</i> 35:87-95 (2011) (“Paul”)
1021	J.A. Burns, “Thermage: Monopolar Radiofrequency,” <i>Aesthetic Surgery Journal</i> , 25:638–642 (“Burns”)
1022	Barry E. DiBernardo, “Clinically Relevant Lasers for the Plastic Surgeon,” <i>Aesthetic Surgery Journal</i> (2005)
1023	Salon.com, “Salon Traffic & Audience Profile” Webpage, accessed at https://web.archive.org/web/20010401003237/http://www.salon.com/adsales/index2.html
1024	<i>Viveve, Inc. v. ThermiGen, LLC</i> , 2-16-cv-01189, Claim Construction Order (E.D. Tex. November 13, 2017)
1025	Alinsod, R.M., “Temperature Controlled Radiofrequency for Vulvovaginal Laxity,” <i>Prime Journal</i> , pp. 16-21 (July/August 2015)
1026	ThermiVa, “Doctors are Weighing in on ThermiVa,” (IPR2018-00088, EX2007, accessed August 20, 2015)
1027	Kern, Louis J. “Venus Envy – Penis Envy: Aesthetic Autoplasty, Genital Reconstruction, and Erotic Embodiment,” pp. 43-57 in “The EmBodyment of American Culture,” <i>Lit Verlag Münster</i> (Tschachler, H., et al., eds., 2003)
1028	Wilson, Robert R., “The Hydra’s Tale: Imagining Disgust,” <i>The University of Alberta Press</i> (2002)
1029	Salon.com Search Webpage, accessed at https://web.archive.org/web/20010331124153/http://search.salon.com/

Exhibit No.	Description
1030	Salon.com Advanced Search Webpage, accessed at https://web.archive.org/web/20001117105100/http://search.salon.com/query.html?op0=+&fl0=&ty0=n&tx0=&op1=&fl1=url:&ty1=w&tx1=&op2=-&fl2=&ty2=w&tx2=&nh=25&rf=0&lk=1&qp=&qt=&qs=&qc=&ws=0&qm=0&st=1&oq=&rq=0&ql=a
1031	Affidavit of Nathaniel E. Frank-White (April 2, 2024)
1032	Deposition Transcript of Dr. Denise Poulos (April 8, 2025) (including deposition Exhibits 1-3)
1033	Definition of Erythema, National Cancer Institute, accessible at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/erythema (last accessed April 29, 2025)
1034	Definition of Erythema, Taber's Online Dictionary, accessible at https://www.tabers.com/tabersonline/view/Tabers-Dictionary/740539/all/erythema (last accessed April 29, 2025)
1035	Definition of Substantial, Merriam-Webster, accessible at https://www.merriam-webster.com/dictionary/substantially (last accessed April 29, 2025)

I. INTRODUCTION

The Board should find claims 1-53 of the '511 patent obvious because both asserted prior-art combinations present a classic case of obviousness. The claims recite nothing more than applying a known treatment technique—applying RF energy to heat and remodel tissue via collagen denaturation—to particular treatment areas in the female genitalia. The record evidence shows it was known before the priority date of the patent to treat the claimed treatment areas to improve both appearance and sexual function.

InMode attempts to distinguish the prior art by improperly narrowing the claims and ignoring key teachings of the prior-art references. InMode's arguments are premised on alleged requirements regarding the device used to implement the methods and particular conditions to be treated. But the claims do not include these elements. Further, InMode and its expert (Dr. Poulos) focus solely on the prior art's teachings regarding stress urinary incontinence (SUI) while ignoring other express teachings in the references regarding treatment for cosmetic purposes and enhanced sexual function.

InMode also attacks the credibility of BTL's expert, Dr. Berenholz. But Dr. Berenholz has extensive experience performing vaginal rejuvenation using RF-based remodeling techniques, whereas Dr. Poulos testified that she does not even offer this treatment. Moreover, Dr. Poulos's testimony on cross-examination

demonstrates that she did not understand the proper scope of the claims or of the prior art. The Board should credit Dr. Berenholz over Dr. Poulos, and find the claims unpatentable.

II. THE '511 PATENT MERELY CLAIMS APPLYING KNOWN TREATMENT TECHNIQUES TO ANATOMICAL REGIONS KNOWN TO AFFECT THE DESIRED RESULT.

It was well-known before the priority date of the '511 patent that vaginal tissue stretches during childbirth, which could lead to medical and sexual issues. EX1001, 1:62-2:16; EX1032, 102:1-103:14. One known issue was “decreased sexual pleasure for women” caused by “excessive loosening of the vagina and its opening, the introitus.” EX1001, 2:1-9. POSAs would have known that a loose vagina and introitus may lead to decreased sexual pleasure, as Dr. Poulos admits. EX1032, 103:15-19. Loose tissue of the labia was also known to cause other issues, including “pain with certain activities” or a patient may “simply be ... uncomfortable with the appearance of the labia.” EX1032, 23:17-24:7.

It also was known that treating loose vaginal tissue (including its opening) may alleviate the negative effects thereof, including decreased sexual pleasure. EX1001, 1:62-2:16; EX1032, 102:1-103:25 (“Q· Is it fair to say that the person of skill in the art would have understood that tightening a vagina introitus may lead to enhanced sexual pleasure? ... ·A· Yes.”). InMode admits as much: “Prior to the '511 patent, some doctors used invasive techniques, such as surgery” “to restore

genital tissue, which can be altered over time (and during childbirth) resulting in decreased sexual pleasure.” POR, 7. Indeed, Dr. Poulos has performed labiaplasties, i.e., a “surgical procedure to change the shape and/or size of the labia,” “[s]ince [her] residency, which ended in 1992.” EX1032, 23:17-24:10.

There also was patient demand for procedures to improve both the external appearance of the vagina and sexual function. EX1003, ¶¶49, 82, 142, 272; EX1032, 23:17-24:10, 90:1-12; EX1008. Dr. Berenholz testified, and Dr. Poulos agreed, that by February 2006 it was known to “perform[] Laser Vaginal Rejuvenation (‘LVR’) to *tighten vaginal support tissue and the outer third of the vagina, including the introitus, vulva, and the perineal body, both for cosmetic purposes and to improve sexual function.*” EX1003, ¶49¹; EX1032, 90:1-12, 139:1-6, 23:17-24:10. That Salon.com—a “news and opinion website,” POR, 61 (quoting EX2015)—ran a feature article on this topic confirms that vaginal-rejuvenation procedures were known even outside of medical circles. *See* EX1008.

The ’511 patent’s background discussion confirms using collagen denaturation to cause tissue “tightening” was a known technique, useful for medical and cosmetic purposes. EX1001, 1:35-61. Dr. Poulos agreed. EX1032, 102:1-103:14. Dr. Berenholz describes several prior-art treatments for tightening

¹ Emphasis added throughout unless noted.

collagen-rich tissue. EX1003, ¶¶44-49; *see also* EX1032, 88:3-91:6 (generally agreeing with Dr. Berenholz, with limited exceptions based on lack of personal knowledge of certain devices).

The '511 patent does *not* purport to have invented methods of restoring genital tissue to increase sexual pleasure. Rather, the alleged improvement of the '511 patent was merely using admittedly known techniques (i.e., RF tightening of collagen-rich tissue) to tighten the vagina, introitus, and vulva non-invasively. EX1001, 2:17-21. This is the classic case of applying a known technique to a known method ready for improvement to yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); Pet., 23-24; EX1003, ¶¶88-89. Nothing about the '511 patent's claimed methods was new.

III. INMODE'S ATTEMPT TO IMPERMISSIBLY NARROW THE CLAIM SCOPE SHOULD BE REJECTED.

The '511 patent broadly claims methods of remodeling target tissue underlying an epithelium of female genital tissue comprising at least one of vulva, introitus, and vagina tissue. But InMode improperly attempts to narrow the claims and to read in limitations from the specification, including: (i) requiring a particular device to perform the method, (ii) requiring treatment of a particular medical condition, (iii) prohibiting heating or treating tissue *in addition* to the recited "target tissue," and (iv) requiring "remodeling" or "heating" without substantially affecting the epithelium overlying the target tissue. The record does

not support InMode’s narrow reading. Regardless, even under InMode’s constructions, BTL demonstrated that the claims were obvious.

InMode cites Dr. Poulos’s declaration to support its narrow reading of the claims. POR, 13-22. But her opinions on claim scope should be given no weight because she admitted on cross-examination that she simply used constructions provided by counsel:

Q: ... All of the claim constructions that you have in Section 6 of your declaration, starting on page 24.

A: Yes.

Q: They were provided to you by counsel?

A: Yes.

EX1032, 56:13-57:14. Further, despite claiming to rely on “the constructions from the ThermiGen IPR,” EX2001, ¶54, Dr. Poulos appeared to be unfamiliar with those constructions and how they were determined. EX1032, 54:11-17 (“Q: ... are you talking about the board’s constructions in the Decision to Institute in Exhibit 1009 [IPR2018-00088]? A: I believe so.”), 55:10-56:5 (unfamiliar with BRI and that the prior constructions were under BRI); *see generally* EX1032, 53:5-57:13.

InMode accuses BTL of “vacillat[ing] between constructions.” POR, 13. Not true. BTL applies the plain and ordinary meaning. Pet., 7. But recognizing that InMode had previously presented narrower constructions, BTL demonstrates unpatentability of the claims under both the plain and ordinary meaning and under

InMode's artificially narrow constructions. *See* Pet., 7-12.

A. The claimed methods are agnostic regarding the particular device used.

InMode's attempts to distinguish the claims from the prior art often focus on the specific devices discussed in the prior art. For example, InMode argues "the Edwards device would not provide for treatment of the area from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus," because "the speculum dilates the introitus and moves it out of the way so that deeper structures of the vagina can be treated." POR, 36.

InMode's arguments are not commensurate with the claims' scope. The claims are directed to "*method[s]* for remodeling a therapeutic zone within a target tissue." The claims do not recite any particular device. EX1032, 127:18-129:3 (testifying the independent claims do not recite what device performs the method). Dr. Poulos's deposition testimony confirms, however, that she improperly reads the '511 patent's disclosed *device* into the claims:

Q· Claim 1 is just describing the method, correct?

A· I read it to be the method that would be *using the device described by the patent*.

EX1032, 128:17-20.

This is improper. *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("[A] particular embodiment appearing in the written

description may not be read into a claim when the claim language is broader than the embodiment.”). The claims here simply do not require any particular device. “[A] method claim which is not tied to a particular device ... must be interpreted to cover any process that performs the method steps.” *Schumer v. Lab’y Comput. Sys., Inc.*, 308 F.3d 1304, 1312 (Fed. Cir. 2002).

B. The claimed methods do not require treatment of a particular medical condition.

InMode also attempts to distinguish the prior art based on the references’ alleged focus on treating SUI. POR., 1. These arguments ignore the claims’ broad scope. Dr. Poulos admitted the claims do not require treatment of any particular medical condition. EX1032, 126:22-127:12. Regardless, the prior-art teachings are not limited to treatment of SUI, but also include, e.g., treatment for sexual function and cosmetic purposes. Pet., 13-24; *see infra*.

C. The claimed methods do not prohibit heating or remodeling other tissues *in addition to* the recited “target tissue.”

InMode contends “target tissue” should be construed to mean “tissue immediately beneath the mucosal epithelium of genital tissues exclusive of deeper tissue, such as endopelvic fascia.” POR, 14-17. BTL agrees that the claimed target tissue does not include endopelvic fascia. But it is also true that the claims do not *prohibit* heating or treating other areas in addition to the target tissue, including endopelvic fascia. *See* Pet., 8-9; DI, 12. Dr. Poulos confirmed the ’511 patent does

not say that “it’s prohibited or forbidden to treat other regions” beyond the intended treatment depth. EX1032, 111:6-15; *see also id.*, 131:2-132:4 (incorrectly assuming that other tissue could not be heated because the claim is silent).

D. The claimed methods do not require “remodeling” or “heating” *without substantially affecting the epithelium overlying the target tissue.*

InMode contends “the ‘remodeling’ term should be construed to recite ‘without substantially affecting the epithelium overlying the target tissue.’” POR, 17-19. Again, InMode improperly narrows the claims.

Cooling is the *only* method disclosed in the specification for attempting to protect the epithelium, but cooling is not required by the independent claims. EX1032, 124:16-125:13 (confirming independent claims do not mention cooling). The recitation of cooling in several dependent claims, including claims 9-16, 39, 47, and 55, confirms it is *not* required by the independent claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (“[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.”). Even the dependent claims reciting cooling are silent as to what effect, if any, the heating has on the epithelium. Regardless, the prior art teaches the claimed “remodeling” even under InMode’s improperly narrow construction. Pet., 25-34; *see infra*.

IV. GROUND 1: EDWARDS-MOSHER-INGLE

By February 2006, POSAs knew (i) of the sexual and aesthetic problems caused by loose vaginal tissue, (ii) that applying heat, via RF or another mechanism, to collagen-rich tissue produces a tightening effect, and (iii) treating loose vaginal tissue, including the vaginal canal, introitus, and vulva, would improve sexual function and enhance appearance. The Edwards-Mosher-Ingle combination renders obvious all claims.

A. The Edwards-Mosher-Ingle combination teaches “heating the target tissue.”

Edwards teaches delivering RF energy to the vaginal wall to effect tightening, while Mosher identifies “target tissue” for RF treatment, including lamina propria, and Ingle teaches treating “collagenated support tissues.” Pet., 26-28.

InMode counters that Mosher teaches only “heating and remodeling the endopelvic fascia to treat bladder outlet hypermobility.” See POR, 54-57. That is wrong and ignores Mosher’s express teaching: “[a]s the techniques of the present invention will be effective for controllably and repeatably enhancing the structural support of a *wide variety of fascia and other collagenous tissues* throughout the body, they will find applications in a *wide variety of therapies*.” EX1006, ¶46; Pet., 16. And, while Mosher’s Figure 6 embodiment discusses endopelvic fascia,

Mosher makes clear that other tissues, e.g., lamina propria, can also be treated.²

See EX1006, ¶48; Pet., 27; EX1003, ¶95. InMode attempts to cast doubt on Mosher’s teachings at paragraph 48 because the list of potential treatment targets includes male anatomy. POR, 27-28. But Dr. Poulos testified that men also suffer from and can be treated for incontinence, EX1032, 18:14-18, confirming Mosher’s inclusion of male anatomy is sound. And both experts agree that heating collagen to contract tissue was known. EX1003, ¶¶39-40; EX1032, 86:8-14.

InMode’s arguments regarding Ingle similarly ignore express teachings. InMode argues Ingle is “directed to heating the endopelvic fascia to treat bladder outlet hypermobility.” POR, 57-58. But Ingle describes using “energy [to] heat[] fascia *and other collagenated support tissues*, causing them to contract.” EX1007, 2:59-63; *see also id.*, 15:8-11 (target zone can “comprise fascia *or some other collagenated tissue*”); Pet., 18-19; EX1003, ¶76. Thus, Ingle’s Figure 3 temperature profile applies to “other collagenated support tissues.” Pet., 18-21; EX1003, ¶¶79-81.

² The claims do not prohibit heating tissue other than the “target tissue,” including endopelvic fascia. Section III.C.

B. The Edwards-Mosher-Ingle combination teaches “remodeling” target tissue, even under InMode’s impermissibly narrow construction.

The independent claims recite “remodeling the therapeutic zone of target tissue” but do not require doing so without substantially affecting the epithelium overlying the target tissue, as InMode argues. However, even if that limitation is improperly imported from the specification, the combination teaches this element.

Edwards discloses applying RF energy to the vaginal wall, resulting in tightening. Mosher and Ingle confirm such tightening is caused by heat-induced changes to collagenous tissues. All three describe cooling to protect the tissue. Pet., 28-34; *cf.* EX1001, 12:17-26 (cooling used to protect epithelium); EX1032, 114:18-115:5 (in the absence of cooling, the surface could be damaged), 124:16-125:17 (confirming that independent claims do not mention cooling).

InMode contends Edwards causes *ablative* lesions and therefore does not teach remodeling “without substantially affecting the epithelium overlying the target tissue.” POR, 51-54. InMode mischaracterizes Edwards’s fourth embodiment, upon which BTL relies, which teaches simply “lesions”—not the “ablative lesions” of the first, second, and third embodiments. *See* EX1005, 13:14-16 (“A method 900 is performed to create a *series of lesions* in either the anterior vaginal wall, the posterior vaginal wall or both.”); *compare* EX1005, FIGs. 6A (step 608), 7B (step 710), 8B (step 811) (describing three embodiments with

“ablative lesions”), *with* EX1005, FIG. 9A (describing fourth embodiment with *no* mention of “ablative lesions”); EX1032, 152:22-155:21 (Dr. Poulos acknowledging this distinction); EX1005, 2:37-39 (describing application of energy to “ablate, tighten, shrink *or* reshape the tissue ...”).

A POSA would have understood that any lesions created by Edwards’s method would not substantially affect the epithelium. Dr. Berenholz testified, “a lesion would be a disruption of tissue caused by thermal energy,” and “disruption” means, an “area that’s been treated and becomes, let’s say, erythematous due to heat.” EX2005, 102:10-15. Such minor effects to the epithelium, i.e., skin redness,³ fall within InMode’s construction, which includes “without *substantially* affecting the epithelium.” POR, 20. This is consistent with the specification, which describes that the “remodeling ... does not substantially affect the epithelium itself,” and that cooling is used to avoid the accumulation of excess heat, so “the epithelium itself is not damaged or substantially modified by the method.” EX1001, 12:17-19, 13:16-23; EX1035 (*substantial* definition: “5: being largely but not wholly that which is specified”); *see also* EX1032, 104:1-105:25.

³ Erythema means “[r]edness of the skin.” EX1033; *see also* EX1034 (similar definition).

C. The Edwards-Mosher-Ingle combination teaches each of the claimed treatment areas.

The Edwards-Mosher-Ingle combination further demonstrates the claimed treatment areas were obvious.

1. The combination discloses or renders obvious each of the claimed treatment areas.

The independent claims differ only in the specific area of “female genital tissue” being heated (i.e., the treatment area). EX1032, 120:25-123:17. Edwards teaches applying RF energy to the vaginal wall. Pet., 13-16, 22-25. InMode does not dispute this, but argues Edwards teaches treating the *wrong portion* of the vagina. POR, 23-25. InMode improperly focuses on Edward’s treatment of incontinence at the bladder neck, while ignoring other teachings, such as incontinence treatment at the mid-urethral region and treatment for sexual function via circumferential vaginal wall tightening.

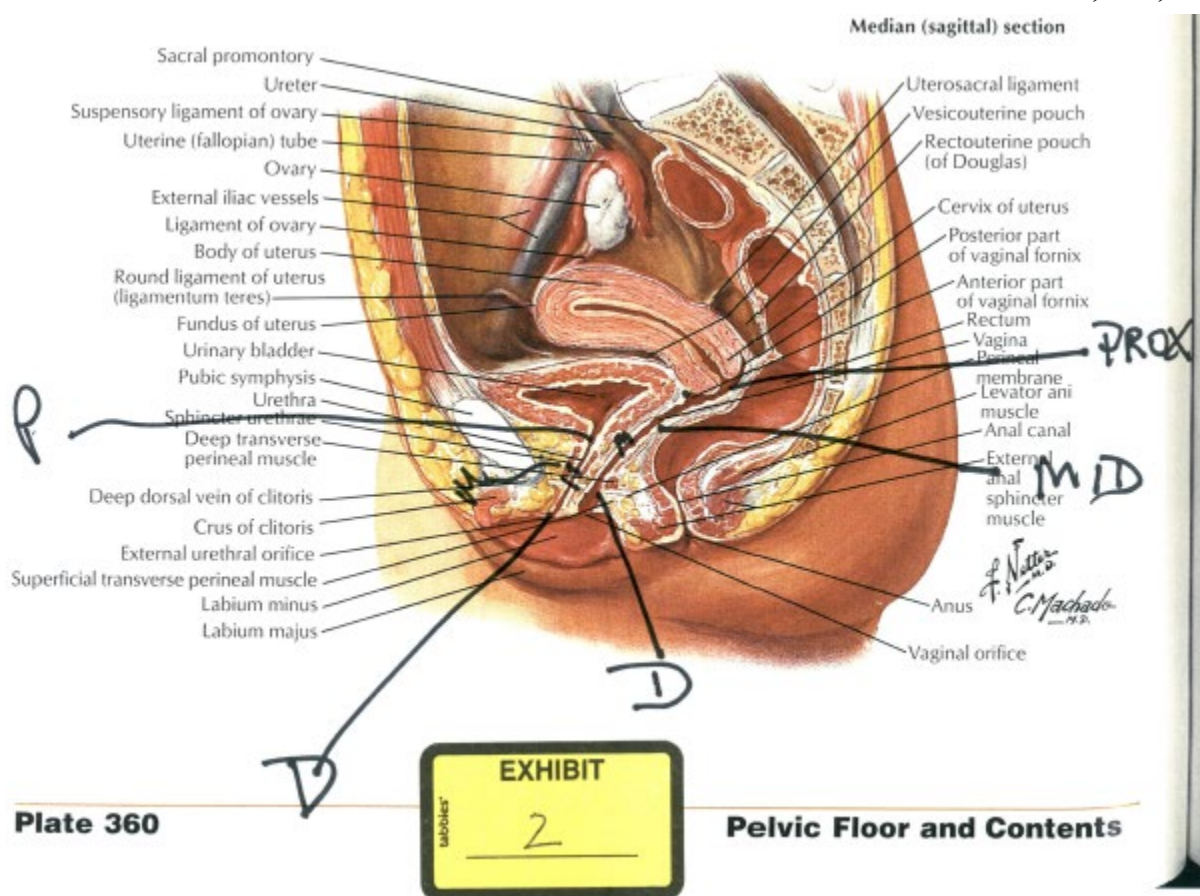
Further, InMode agrees that POSAs were highly trained physicians. POR, 11-12; EX1003, ¶¶58-60; EX2001, ¶¶35-39. Here, both the problem (i.e., sexual and aesthetic problems caused by loose vaginal tissue) and solution (i.e., treating loose vaginal tissue to improve sexual function and enhance appearance) were known. *See* Section II. Determining the specific treatment area, depending on the condition/needs of a particular patient and the desired result, was a simple exercise of professional judgment. EX1003, ¶91; EX1005, 13:40-41 (“The physician

determines optimal areas of treatment.”); EX1032, 29:5-30:19 (physician uses professional judgment). The Edwards-Mosher-Ingle combination teaches each of the claimed treatment areas.

Claim 1 recites “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.”

InMode focuses on the SUI teachings of Edwards, but Edwards teaches SUI can be treated by remodeling the anterior vaginal wall at areas “increasing support for the bladder outlet, *as well as the proximal and mid-urethra.*” EX1005, 13:14-23; *see also* EX1006, ¶¶46, 54 (Mosher preferably treating “*along a length of the urethra* between the bladder neck and the external meatus ...”).

Treating the vaginal wall adjacent to the mid-urethra is within the claimed region of “from 1 cm to 3.5 cm in from the introitus.” Dr. Poulos’s annotations below show the location of the mid-urethral region, as well as the distal and proximal ends of the vaginal canal and urethra, and the mid-vaginal canal. EX1032, 65:11-77:7.



EX1032, Exhibit 2.

The distance between the proximal and distal ends of the vaginal canal is about 9 cm. EX1032, 68:12-15; EX1003, ¶33; EX1001, 11:36-44. The distance between the proximal and distal ends of the urethra is about 4 cm. EX1032, 71:9-12. Dr. Poulos testified the mid-urethral region is approximately 2.5 cm from the introitus (relative to the vaginal canal), confirming Edwards's treatment of the vaginal wall adjacent the mid-urethra is within the claimed area of the vaginal

canal.⁴ EX1032, 76:20-24.

InMode argues treatment for SUI is at the bladder neck, which is 4 cm from the introitus and therefore is not within the claimed treatment area. POR, 31-34. However, as noted above, Edwards's teachings are *not* limited to treating near the bladder neck or even to treating SUI.

InMode also contends BTL misunderstands the claim language, and newly proposes the following construction: “treating of at least the introitus and the first 1 cm of the vagina (up to 3.5 cm in from the introitus).” POR, 30-31. The “extending from the introitus inwardly” language of claim 1 describes the location and direction from which the claimed range of 1 cm to 3.5 cm is measured, under BTL's correct construction. InMode's construction renders claim 26 superfluous, and thus should not be adopted.

Regardless, the Petition explained, a “POSA, based on Edwards's teachings of improvement of sexual function, would have understood Edwards's teachings to include *treatment near the opening of the vagina*,” i.e., at the introitus. Pet., 35;

⁴ Also, even under InMode's interpretation of Mosher, *see* POR, 33, 37, where the length of the treatment area is 15 mm and starts at the bladder neck, treatment would extend into the claimed region (i.e., treatment would occur between 2.5 cm and 4 cm from the introitus).

EX1003, ¶¶122, 250. As Drs. Berenholz and Poulos confirmed, it was well-known that treating in and around the introitus improved sexual function. EX1003, ¶49; EX1032, 90:1-12, 102:1-103:25, 139:1-6, 23:17-24:10; Section II. Thus, Edwards teaches or suggests claim 1’s treatment area under InMode’s construction, as well. POR, 30-31.

Claim 26 depends from claim 1 and recites “wherein remodeling comprises tightening the introitus.”

Again, it was well-known to treat the introitus to improve sexual function. EX1003, ¶49; EX1032, 90:1-12, 102:1-103:25, 139:1-6, 23:17-24:10. And Edwards teaches “circumferential tightening” for treating sexual function, which a POSA would have understood included treating the introitus. Pet., 35; EX1005, 3:11-13, 13:19-22; EX1003, ¶¶122, 249-250.⁵

Claim 35 recites “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.”

The Board’s preliminary construction of claim 35’s treatment area—
“heating at least one contact site in the 300 degree arc extending from 1 o’clock to

⁵ InMode’s arguments for claim 26 are directed to alleged deficiencies specific to Edwards’s device and motivation to modify, which are discussed below.

11 o'clock along the vaginal wall"—is correct, and Edwards discloses “circumferential tightening of the vaginal wall” including by applying RF energy “to the anterior and posterior regions of the vaginal wall.” Pet., 11, 37; EX1005, 3:5-13, 13:19-22; DI, 14. Even if the claim required more than one contact site (it does not), Edwards expressly describes “*circumferential* vaginal wall tightening,” which according to Dr. Poulos requires tightening more than one location. EX2001, ¶71.

Further, Edwards teaches this element under Dr. Poulos’s construction, which is “heating multiple contiguous contact sites in the 300 degree arc.” EX2001, ¶73. Dr. Poulos opined each “contact site” “covers 10% of the 300 degree arc” between 1 o'clock and 11 o'clock of the vagina, EX2001, ¶70, meaning that each 30 degree arc (e.g., between 1 o'clock and 2 o'clock) is a “contact site.” Dr. Poulos also opined the posterior vaginal wall is “from around 5 o'clock to 7 o'clock,” EX2001, ¶72, which (according to her logic) is at least two contact sites.⁶ Edwards’s teaching of treating the posterior wall would thus satisfy even Dr. Poulos’s construction, which the Board should not adopt.

⁶ BTL does not agree that the “posterior wall” of the vagina is so limited. See, e.g., EX1032, 77:10-80:24, Exhibit 3 (Dr. Poulos’s annotations showing the vagina is rectangular and anterior/posterior walls are longer).

Claim 43 recites “heating a portion radiating outward from the introitus to Hart’s line.” **Claim 51** recites “heating a mucosal surface of the labia minora.”

Both claims 43 and 51 recite treatment areas external of the introitus, i.e., the vulva. A POSA would have been motivated, both by Edwards’s teaching to use RF treatment to improve sexual function (by circumferential tightening within the vagina) and Ingle’s teaching to use RF for cosmetic purposes, to treat these external vulva areas as claimed. Pet., 40-43. Treating these external vulva areas, both to improve sexual function and for cosmetic purposes using other techniques was known. *See* Section II; *also* EX1003, ¶¶142, 146; EX1032, 23:16-24:10 (confirming treatment of the labia both to improve sexual function and for cosmetic reasons was known), 90:1-12.

InMode contends a “POSA would not have understood how to apply the treatments of SUI references to the external introitus to Hart’s line region” because different treatment times and temperatures may be required, and tissue response may differ internally versus externally. POR, 49. But the cited art provides no less guidance on these issues than the ’511 patent itself. *See In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (“[T]hat [an] appellant did not provide the type of detail in his specification that he now argues is necessary in prior art references supports” finding that “one skilled in the art would have known how to implement the features.”); *see also Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 902 (Fed.

Cir. 2018). For example, the '511 patent does not provide different implementation details of the claim 1 or 35 embodiments than it does for the claim 43 or 51 embodiments. Further, the treatment areas recited in claims 43 and 51 are mucosal tissue, just like internal vaginal mucosa. EX1003, ¶¶34, 38; EX1032, 85:7-86:4 (agreeing with Dr. Berenholz's testimony). A POSA would have understood the treatments of Edwards, Mosher, and Ingle to apply equally to the collagen-rich tissue in these areas. Pet., 41; EX1003, ¶142.

2. InMode's other arguments fail.

The prior art is not limited to treatment of SUI, as InMode alleges. POR, 23, 37-38, 46-47. In particular, the fourth embodiment of Edwards, relied on in the Petition, teaches "vaginal remodeling" and that "circumferential tightening of the vaginal wall may provide physical and psychological improvement in the area of sexual function." EX1005, 3:5-13, 3:25-27. Likewise, Mosher teaches "applications in a *wide variety of therapies*," EX1006, ¶46, and Ingle teaches "techniques for selectively heating and shrinking tissues, particularly for the noninvasive treatment of urinary incontinence and hernias, *for cosmetic surgery, and the like*." EX1007, 1:20-24.

Edwards's speculum is irrelevant; the claims are agnostic regarding the treatment device. InMode argues Edwards's device is not suitable for treating near the introitus because a speculum is required. According to InMode, Edwards's

speculum: (1) would result in treatment too far into the vagina, POR, 34-37, 58-59; (2) would not be rotated or moved within the patient, POR, 41-43; and (3) is used to treat internally, POR, 49. However, the claims are agnostic regarding the device. *See* Section III.A.

POSAs “would have understood that in treating areas of the vaginal wall closer to the introitus, a physician would be able to complete the treatment without a speculum.” EX1003, ¶¶69, 159; *see also* EX1032, 37:14-20, 39:6-13. As Dr. Poulos acknowledged, Edwards does not say the treatment element cannot be used without a speculum. EX1032, 144:17-23. She also acknowledged there are different types and sizes of speculums, Edwards does not specify which is used, and physicians exercise professional judgment in determining whether treatment requires a speculum. EX1032, 25:22-30:19, 32:2-33:7, 36:15-37:9, 143:8-144:2; EX2010, 4-5 (describing speculums of different types and sizes).

A POSA would have been motivated to make the proposed combination.

InMode argues BTL “fails to articulate a credible reason” to make the proposed combination. POR, 38-39; *see also* POR, 45-46, 49-50, 59. But InMode focuses only on the Petition’s discussion regarding each individual area of treatment, *e.g.*, POR, 38 (quoting Pet., 35), and ignores the earlier motivation-to-combine discussion. Pet., 22-25. Mosher and Ingle provide details of treatment parameters and the physiological mechanism of action to supplement Edwards’s teaching of a

non-invasive vaginal treatment method that lacks such details. *Id.*; EX1003, ¶¶84-

85. Applying Mosher's and Ingle's treatment details to Edwards's treatment method is simply combining prior-art elements according to known methods to yield predictable results. EX1003, ¶¶86-90; *KSR*, 550 U.S. at 416-17. Further, POSAs would have recognized there are limited areas of treatment within the vaginal region, and it would have been within a POSA's skill to determine the optimal area of treatment for a particular patient based on the desired outcome. EX1003, ¶91; EX1005, 13:40-42.

V. GROUND II: EDWARDS-MOSHER-INGLE-OLLIVIER

The Edwards-Mosher-Ingle-Ollivier combination renders obvious claims 43-58. InMode argues Ollivier is not a prior-art printed publication and is not enabling. Both arguments fail.

A. Ollivier is a prior-art printed publication

InMode contends Ollivier is not a printed publication. POR, 61-62. The Petition provided evidence that Ollivier was publicly available, including via Salon.com's search functionality and additional research aids. Pet., 12-13. The search pages show Salon.com includes categories such as "Health" and "Sex," further indicating the relevance of the website to a POSA. EX1029.

InMode faults Dr. Berenholz for not being personally aware of this article prior to his work on this Petition. POR, 61. But that is not the standard. Rather, a

POSA is a legal fiction—“a hypothetical person who is presumed to have known the relevant art at the relevant time.” MPEP § 2141(II)(C). “If accessibility is proved, there is no requirement to show that particular members of the public actually received the information.” *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1356 (Fed. Cir. 2018).

Regardless, BTL relies on Ollivier simply as confirmation of a POSA’s knowledge—that there were well-known techniques used to treat the vulva/labia for improving sexual function and for cosmetic reasons. EX1003, ¶¶49, 82, 142, 272; EX1032, 23:17-24:10, 90:1-12, 139:1-6. That an example was discussed in an article on a layman’s website is further proof that such treatment techniques were known.

B. Ollivier is enabling for the teachings relied on in the Petition.

InMode also argues Ollivier is not enabling because it does not provide specifics of the LVR treatment. POR, 62-64. “[A] prior art reference asserted under § 103 does not necessarily have to enable its own disclosure, i.e., be ‘self-enabling,’ to be relevant to the obviousness inquiry.” *Raytheon Techs. Corp. v. Gen. Elec. Co.*, 993 F.3d 1374, 1380 (Fed. Cir. 2021). BTL relies on Ollivier not for the specifics of the LVR treatment, but to teach the existence of prior techniques for treating both the vagina and portions external of the introitus (both for improving sexual function and cosmetically). Pet., 67. Armed with this

knowledge, a POSA would have been motivated to use the Edwards-Mosher-Ingle treatment method also to treat the external vulvar vestibule and labia minora. Pet., 67-68.

VI. INMODE HAS NOT ESTABLISHED NEXUS WITH ITS OBJECTIVE-INDICIA EVIDENCE.

InMode has not made a sufficient showing of nexus to support its contention that objective indicia support non-obviousness of claims 1, 26, and 35. POR, 68-71. InMode relies on the presumption of nexus. POR, 69 (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016)). “A presumption of nexus requires *both* that the product embodies the invention and is coextensive with it.” *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1211-12 (Fed. Cir. 2023). InMode does not even allege, let alone show, that the Viveve device is coextensive with claims 1, 26, and 35. This is fatal to the objective-indicia arguments. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (“The patentee bears the burden of showing that a nexus exists.”).

The Viveve device is *not* coextensive with claims 1, 26, or 35. “A patent claim is not coextensive with a product that includes a ‘critical’ unclaimed feature ... that materially impacts the product’s functionality.” *Id.* at 1375. In other words, where “there are one or more features not claimed ... that materially impact the functionality of the [product], ... nexus may not be presumed.” *Id.* at 1376.

Dr. Poulos admits the independent claims of the ’511 patent do not require

cooling the epithelium. EX1032, 124:2-126:9; *see also* EX1001, 16:9-28, 17:31-32 (dependent claims specifically reciting cooling). But the studies InMode cites indicate that a critical feature to the (alleged) success of the Viveve device is using cryogenic cooling to prevent tissue damage. EX2017, 776-777 (“The [Viveve] RF device ... provides a nonablative approach to creating heat within the submucosal layer of vaginal tissue *while keeping the surface cooled*. ... [T]he integrated *cryogen* is delivered to the inside of the treatment tip to cool and protect the surface tissue.”); EX2018, 6 (similar). Dr. Poulos confirmed a POSA would have understood “in the absence of cooling, the surface could potentially be damaged.” EX1032, 115:1-5. Because claims 1, 26, and 35 do not require cooling, they are not coextensive with the Viveve device and there can be no presumption of nexus.

VII. THE BOARD SHOULD CREDIT DR. BERENHOLZ OVER DR. POULOS.

The Board should credit Dr. Berenholz’s testimony over that of Dr. Poulos because his practice actually includes performing the types of remodeling contemplated by the ’511 patent whereas Dr. Poulos testified she chose *not* to offer those procedures in her practice (instead focusing on treating incontinence and other medical conditions). EX1003, ¶¶7-8, 60; EX1032, 19:16-21:23. InMode argues Dr. Berenholz’s testimony should be given little weight. POR, 71-72. But InMode mischaracterizes Dr. Berenholz’s testimony and holds him to a high standard of understanding legal concepts not required for a technical expert.

First, InMode argues Dr. Berenholz “did not prepare his declaration,” so it should be given little weight. POR, 71. However, InMode mischaracterizes Dr. Berenholz’s testimony. He testified that he provided “[his] expertise ... in thermal energy and non-invasive vaginal rejuvenation,” “summaries of reviewing references,” and “knowledge base about the technology.” EX2005, 164:24-168:14. He further confirmed that he provided this information via “discussions, meetings, Zoom meetings. And anatomy discussions, et cetera.” *Id.* There is no requirement that Dr. Berenholz personally type the words of his opinion into the declaration. *See Silicon Labs., Inc. v. Cresta Tech. Corp.*, IPR2015-00615, Paper 64 at 13 (P.T.A.B. Aug. 11, 2016) (noting PTAB has “no rule concerning how an expert report is drafted,” and analogizing Fed. Rule Civil Proc. 26(a)(2)(B)), *affirmed* 705 Fed. App’x 1000; *see also* EX1032, 16:17-17:5 (confirming attorneys provided first draft of Dr. Poulos’s declaration). His declaration contains his opinions, EX1003, ¶¶3-4, 9-11, 83, 282, and InMode does not allege otherwise.

InMode also argues Dr. Berenholz did not understand the legal concept of obviousness. POR, 71-72. But Dr. Berenholz testified that obviousness “[w]as explained to [him] by Petitioner’s counsel” and is summarized in his declaration. EX1003, ¶¶13, 18-27. To the extent InMode argues an expert should be able to expatiate on legal concepts in deposition, InMode’s own expert Dr. Poulos likewise stumbled in attempting to explain legal concepts during her deposition.

E.g., EX1032, 156:10-157:17. InMode does not allege any particular error in Dr.

Berenholz's application of the legal concepts.

Finally, InMode argues Dr. Berenholz does not testify from the viewpoint of a POSA because he "began performing cosmetic gynecological treatments in 1995-1996, giving him years of experience more than the POSA." POR, 72. InMode's argument implies that Dr. Berenholz's testimony should be discounted because he is not ordinary enough. This is not the law. *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997); *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1377 (Fed. Cir. 2022) ("[I]t would be improper to require an expert witness to possess ordinary skill in the art and *nothing more*." (emphasis original)). InMode's citation of one out-of-context quote from Dr. Berenholz's deposition does not negate that he properly considered the viewpoint of a POSA in formulating his opinions. EX1003, ¶¶3, 31. Dr. Berenholz is an expert who actually performs the treatment methods described in the '511 patent, and thus his testimony should be given substantial weight.

VIII. CONCLUSION

The Board should cancel the challenged claims as unpatentable.

Respectfully submitted,

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CERTIFICATE OF WORD COUNT (37 C.F.R. § 42.24(d))

1. This Petitioner's Reply complies with the type-volume limitation of 5,600 words, comprising 5,590 words, excluding the parts exempted by 37 C.F.R. § 42.24(c).

2. This Petitioner's Reply complies with the general format requirements of 37 C.F.R. § 42.6(a) and has been prepared using Microsoft® Word 2016 in 14-point Times New Roman font.

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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

I certify that the above-captioned **PETITIONER'S REPLY TO PATENT OWNER RESPONSE** and associated **Exhibits 1032-1035** were served in their entireties upon the Patent Owner on April 30, 2025, upon the following parties via email:

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