

Filed on behalf of: InMode Ltd.

Date Filed: June 11, 2025

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
Patent No. 8,961,511

PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY

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<i>Voter Verified, Inc. v. Premier Election Sols., Inc.</i> , 698 F.3d 1374 (Fed. Cir. 2012)	25
<i>WBIP, LLC v. Kohler Co.</i> , 829 F.3d 1317 (Fed. Cir. 2016)	26

TABLE OF EXHIBITS

Exhibit	Description
2001	Declaration of Denise M. Poulos, M.D.
2002	Curriculum Vitae of Denise M. Poulos, M.D.
2003	Stedman's Medical Dictionary (28 th Edition), Lippincott Williams & Wilkins (2006)
2004	Stedman's Medical Dictionary (25 th Edition), Williams & Wilkins (1990)
2005	Transcript of Deposition of Dr. Berenholz, dated January 9, 2025
2006	<i>Viveve, Inc. v. ThermiGen, LLC</i> , 2-16-cv-01189, Summary Judgment Order (E.D. Tex. May 26, 2018)
2007	Merriam-Webster's Collegiate Dictionary (Tenth Edition), Merriam-Webster (2000)
2008	Taber's Cyclopedic Medical Dictionary, F.A. Davis Company (2005)
2009	Neurology and Urodynamics (Cover image), Vol. 41, Issue 6 (2022)
2010	Speculum, Cleveland Clinic, available at https://my.clevelandclinic.org/health/drugs/24238-speculum
2011	About Debra Ollivier, available at https://www.debraollivier.com/about
2012	<RESERVED>
2013	Red Alinsod, "What are the Differences Between ThermiVa Radiofrequency and FemiLift/MonaLisa/IntimaLase lasers for use in Aesthetic Vulvovaginal Therapies?" (2015)
2014	M. Bajka, "Detailed Anatomy of the Abdomen and Pelvis of the Visible Human Female," Clinical Anatomy (2004)
2015	Salon.com, Wikipedia, available at http://en.wikipedia.org/wiki/Salon.com
2016	Thermi Announces Settlement of Patent Infringement Litigation with Viveve, available at https://www.prnewswire.com/news-releases/thermi-announces-settlement-of-patent-infringement-litigation-with-viveve-300659000.html
2017	Y. Sekiguchi, "Laxity of the Vaginal Introitus After Childbirth: Nonsurgical Outpatient Procedure for Vaginal Tissue Restoration and Improved Sexual Satisfaction Using Low-Energy Radiofrequency Thermal Therapy," Journal of Women's Health (2013)

Exhibit	Description
2018	L. Millheiser, “Radiofrequency Treatment of Vaginal Laxity after Vaginal Delivery: Nonsurgical Vaginal Tightening,” Journal of Sexual Medicine (2010)

I. INTRODUCTION

Petitioner BTL's Reply improperly re-writes its Petition to present new arguments that misapprehend the alleged prior art and are unsupported by evidence. Indeed, Petitioner chose not to submit a reply declaration from its expert.

As the POR demonstrated, no reference teaches treatment of the anatomical areas required by the claims. Recognizing this, Petitioner attempts to pivot by citing new passages of the references and advancing new claim construction arguments. For claim 1, Petitioner's Reply cites to new passages of Edwards regarding the *result* of remodeling on the bladder outlet as purportedly disclosing the claimed internal treatment area. For claim 35, the Petition argued that a POSA would be motivated to treat the vagina circumferentially based on Edwards' statement that "[r]emodeling both the anterior wall and posterior wall provide[s] circumferential vaginal wall tightening," (effectively conceding Edwards does not explicitly disclose circumferential tightening). Pet., 37-38¹. Petitioner now mischaracterizes this statement to allege that Edwards expressly discloses the "heating circumferentially" limitation of claim 35. Petitioner also introduces new critiques of the Board's prior constructions (from the *ThermiGen* IPR), in manners

¹ Citations and quotations omitted throughout.

inconsistent with the claim construction section of the Petition. For both claims, Petitioner's new theories are nothing but attorney argument because Petitioner (tellingly) chose to not submit a reply declaration.

A fundamental premise of Petitioner's revised positions concerning all claims—independent claims 43 and 51 in particular—is the proposition that surgical and laser treatments of the vagina were known. But Petitioner's only purported evidence in support of this position is the gossip-website article Ollivier, which vaguely reports that laser surgical techniques were being performed by a lone doctor, who indisputably kept his technique (whatever it was) confidential and whose work was questioned by the medical community in that same article. No evidence supports Petitioner's assertion that this secret technique meets the limitations of claims 43 or 51, would have motivated a POSA to apply other techniques to the treatment areas, or demonstrated any ubiquity of surgical treatments for vaginal tightening.

Ultimately, none of the applied references teach the '511 patent's use of radiofrequency on the specific, claimed regions of the vagina and vulva—a non-obvious treatment that was the subject of industry praise.

II. PETITIONER’S OVERBROAD CLAIM CONSTRUCTIONS THAT CONTRADICT PRIOR DISTRICT COURT AND PTAB CONSTRUCTIONS SHOULD BE REJECTED

A. Petitioner’s attempts to reconstrue the “heating” or “remodeling” terms (all claims) as permitting damage to the epithelium should be denied

Advancing new constructions in its Reply, Petitioner now contends that InMode improperly narrows the “heating” and “remodeling” elements by adopting the *ThermiGen* IPR construction of remodeling “without substantially affecting the epithelium overlying the target tissue.” EX1009, 16; EX1011, 15. This is a pivot from the Petition that explicitly adopted the *ThermiGen* IPR construction for “heating” and otherwise asserted that “no claim term requires construction,” without criticizing any prior construction of the “heating” or “remodeling” terms. Pet., 7, 9-11. After InMode adopted the *ThermiGen* IPR’s constructions (POR, 17-20), Petitioner now presents its untimely criticisms of these prior constructions (*compare* Pet., 9-10 *with* Reply, 8). Regardless, InMode’s constructions accord with the intrinsic record and *Viveve* constructions. POR, 17-19.

Arguing against the “without substantially affecting the epithelium” limitation, which should be an element of either the “remodeling” or “heating” construction, Petitioner claims that cooling is the only method for protecting the epithelium. But this ignores Dr. Poulos’s un rebutted testimony regarding the

various techniques to “prevent mucosal damage, such as heat dissipating gel, adjusting the energies used, adjusting the interval of exposure, turning the exposure on and off (for example, pulsing), insulating the energy applicator,” or cooling the tissue in contact with the applicator. EX2001, ¶141; POR, 53.

Petitioner’s claim differentiation arguments based on the recitation of cooling in dependent claims 9-16, 39, 47, and 55 are also unavailing. Reply, 8. These same arguments were previously rejected in *Viveve*. EX1024, 13 (claim construction order finding “Even if there is overlap [between heating step and cooling dependent claims], the claim differentiation argument is overcome by the intrinsic evidence.”). And this argument again ignores the other techniques of protecting the epithelium that are within the scope of the independent claims—use of gel, adjusting energies used, moving the applicator, and pulsing the RF. EX2001, ¶141.

B. Petitioner’s criticisms of InMode’s claim constructions are without merit

1. InMode does not limit the claims to a particular device

Petitioner contends that InMode interprets all of the claims to require a “particular device.” Reply, 6-7. Not so. Rather, the POR demonstrates that the particular device of Edwards *would not allow* for treatment in the vagina “extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from

the introitus,” in the vagina “circumferentially around its wall from 1 o’clock to 11 o’clock,” or any external vulval structures. *See, e.g.*, POR, 36. That is not an argument requiring a “particular device,” but an argument that the reference neither discloses nor enables treatment of the claimed areas. Petitioner’s reliance on *Schumer* is inapt because Edwards does not disclose “any process that performs the method steps” of the ’511 patent. Reply, 7 (citing *Schumer v. Lab. Comput. Sys., Inc.*, 308 F.3d 1304, 1312 (Fed. Cir. 2002)).

Further, InMode’s expert did not read any specific device into the claims. Reply, 6. Dr. Poulos testified that “claim 1 ... does not state specifically” which device performs the method, but not just “any device that delivers RF energy can be used” to perform the claims. EX1032, 128:4-16.

2. Petitioner is mistaken that InMode attempts to narrow the claim scope by construing “target tissue” (all claims) to prohibit treating other tissues in addition to the recited “target tissue”

There is no dispute that “target tissue” does not include deeper tissue, such as endopelvic fascia. Reply, 7; POR, 14-17. However, Petitioner misleadingly suggests InMode’s position is that the “target tissue” term “prohibit[s] heating or treating ... the endopelvic fascia.” Reply, 7. InMode’s position is not about prohibiting anything and is rather about what needs to be heated. Specifically, the intrinsic evidence establishes that the “heat[ed] target tissue” of the claims “lies

immediately beneath the mucosal epithelium of genital tissues,” such as the lamina propria and muscularis, and “does not include deeper tissue, such as endopelvic fascia.” EX1001, 3:43-48; POR, 51-52. Thus, treating the endopelvic fascia alone, as in Mosher and Ingle, does not qualify. EX2001, ¶¶57-60 (*citing* EX1001, 3:43-48, 12:2-16); *see infra* Section III.C. Further, Dr. Berenholz acknowledged that he is “not aware of any reason to treat endopelvic fascia for sexual function.” EX2005, 147:12-25.

C. Petitioner’s construction of “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” (claims 1-34) should be rejected

Petitioner continues to advance its misconceived construction that treatment area of claim 1 is “a portion of the vagina starting 1 cm from the opening and extending a further 2.5 cm back towards the cervix (i.e., 3.5 cm from the introitus).”² Reply, 16; Pet., 35. This is contrary to the plain meaning of the claim language “*from* the introitus *to a location* from 1 cm to 3.5 cm in from the

² While the Petition does not address this in its claim construction section (Pet., 7-12), Petitioner’s arguments implicitly construe this language.

introitus,”³ which requires that the claimed treatment area must begin at the introitus and extend at least the first centimeter into the vagina and up to 3.5 cm in from the introitus. *See* POR, 30-31. Petitioner’s construction also contradicts the written description, which repeatedly explains that the internal embodiments of the ’511 patent include treating the “lower aspect of the vagina,” the distal-most portion of the vagina near the introitus. EX1001, 3:28-40, 3:54-59.

In a misguided attempt at claim differentiation, Petitioner argues that InMode’s construction would render claim 26’s element of “remodeling comprises tightening the introitus” superfluous. Reply, 16. Whether claim 1’s treatment area includes the introitus or instead begins immediately proximal to the introitus in the lower aspect of the vagina, claim 1 still requires treating at least the first centimeter into the vagina.

D. Petitioner’s criticisms of Dr. Poulos’s analysis miss the mark

Petitioner argues that InMode’s expert “simply used constructions provided by counsel” and appeared unfamiliar with how the constructions were determined. Reply, 5. However, Dr. Poulos stated that she reviewed the constructions from the

³ Emphasis added throughout.

Viveve litigation and the *ThermiGen* IPR and concluded that the “constructions from the *ThermiGen* IPR should be adopted” with modifications. EX2001, ¶54. That Dr. Poulos was not conversant in legal standards is irrelevant where she understood the constructions and applied the correct standard. EX2001, ¶19; 37 C.F.R § 42.100(b) (2020).

III. GROUND 1: EDWARDS, MOSHER, AND INGLE FAIL TO TEACH THE CLAIMED METHODS

A. The Edwards-Mosher-Ingle combination fails to teach the treatment areas of claims 1, 26, 35, 43 and 51

The Petition fails to identify any disclosure in Edwards, Mosher, or Ingle teaching the specific treatment areas of the independent claims. Petitioner now attempts to fill the gaps through unsupported (and incorrect) attorney argument. Reply, 13.

1. The Combination fails to teach Claim 1’s treatment area of “a portion of the vagina extending from the introitus inwardly to a location from 1 cm to 3.5 cm in from the introitus”

Petitioner misquotes Edwards and Mosher to suggest that the references teach heating the vaginal wall from the introitus inward to 1 to 3.5 cm from the introitus. First, for Edwards, Petitioner for the first time relies on the statement that “remodeling of the anterior wall treats incontinence ... by increasing support for the bladder outlet, as well as the proximal and mid-urethra.” Reply, 14; EX1005,

13:14-19. However, this passage of Edwards describes the **result** of the remodeling the bladder neck area, which has the effect of increasing support for the bladder neck, proximal urethra, and mid-urethra. It in no way describes the treatment area, as Dr. Poulos confirmed. EX1032, 141:13-23 (“describes treating at the bladder neck, which ***may provide support at different parts of the vagina***”). Petitioner’s expert offered no response to Dr. Poulos on this point, and Petitioner opted not to question her on it.

Second, Petitioner mischaracterizes the requirement of claim 1 in arguing that the prior art teaches a treatment that falls “within the claimed area of the vaginal canal.” Reply, 15-16, 16 n.4. As explained above, claim 1 does not recite a range that covers merely the treatment of any portion of the vaginal canal between the introitus to 3.5 cm in from the introitus. Claim 1 requires treating ***from*** the introitus ***to a location*** 1 to 3.5 cm, such that at least the first centimeter of the vagina and up to 3.5 cm is treated. Petitioner makes no showing that the prior art treats this initial part of the vagina. Instead, Petitioner argues (incorrectly) that, e.g., Edwards’s and Mosher’s bladder neck treatments may reach to a point within 3.5 cm of the introitus. Reply, 15-16.

Third, the Reply for the first time argues that Mosher discloses treatment of the endopelvic fascia distal from the bladder neck toward the “external meatus.”

Reply, 14 (citing EX1006, ¶¶46, 54). But this contradicts Petitioner’s expert testimony that the endopelvic fascia is located at and supports the bladder neck. EX2005, 79:24-81:7. Again, Petitioner declined to have its expert opine further on this issue or to question Dr. Poulos on the matter. EX1032, 3, Index at 19 (neither listing Mosher).

Finally, Petitioner misrepresents Dr. Poulos’s testimony to contend that it was known that treating in and around the introitus would improve sexual function. Reply, 17. But the testimony Petitioner cites pertains to laser vaginal rejuvenation (“LVR”) treatment of the introitus and vulva, not heating techniques. *Id.* (citing EX1032, 90:1-12). And Petitioner ignores Dr. Poulos testimony that she “cannot agree that these [LVR] technologies were well known in the field of urogynecology.” EX1032, 89:23-24. Indeed, both experts agree that LVR treatments were kept confidential, required execution of an NDA, and payment of thousands of dollars to learn about the treatment. POR, 61-64; EX2001, ¶¶163-164; EX2005, 162:3-6, 162:23-163:4, 165:23-166:1. Notably, Petitioner has not provided any reference detailing the LVR procedure. While these and Petitioner’s other cites to Dr. Poulos’s testimony on this point suggest that surgical techniques were performed on the vagina, the ’511 patent makes clear that “surgical

approaches are not highly popular because of the risks associated with an invasive procedure, in a sensitive area.” EX1001, 2:13-16.

2. The Combination fails to teach Claim 26’s treatment of “tightening the introitus”

Petitioner’s Reply admits that Edwards, Mosher, and Ingle do not explicitly disclose this limitation, and so tries to stretch Edwards and a POSA’s knowledge to get there. *See* Reply, 17 (exclusively relying on a POSA’s understanding for this claim); POR, 58-59. Those efforts fail because Edwards treatment of the bladder neck would not tighten the introitus. EX2001, ¶155. Further, Edwards’ speculum-based RF device inhibits treatment of the introitus. POR, 59; EX2001, ¶155. Petitioner never explains how a POSA would modify Edwards (either the device or the technique) to tighten the introitus. And Petitioner makes no arguments regarding Mosher or Ingle at all.

3. The Combination fails to teach Claim 35’s treatment of heating “circumferentially around its wall from 1 o’clock to 11 o’clock”

Petitioner does not rebut InMode’s evidence that Edwards’ speculum-treatment blade is not moved while inside the patient, thereby inhibiting circumferential treatment. *Compare* POR, 41-42 (citing EX2001, ¶114) *with* Reply, 17-18. Petitioner also does not dispute InMode’s evidence that the “series of lesions” in Edwards extend along the length of the device (as opposed to

extending circumferentially). *Compare* POR, 42-43 (citing EX2001, ¶116) *with* Reply, 17-18. Nor does Petitioner dispute that Mosher fails to remedy the deficiencies of Edwards. *Compare* POR, 43-45 *with* Reply, 17-18.

Instead, Petitioner now presents unsupported attorney argument that Edwards teaches heating multiple contiguous contact sites in the 300 degree arc from 1 o'clock to 11 o'clock. Reply, 18. Petitioner's argument is based on a misrepresentation of Edwards statement that "[r]emodeling **both** the anterior wall and posterior wall provide circumferential vaginal wall tightening." EX1005, 13:19-20 (emphasis added). Once again, Petitioner improperly focuses on the purported **result** of Edwards rather than the taught treatment. *Compare id.* ("**provide** circumferential vaginal wall tightening") *with* Claim 35 ("**heating** ... the vagina circumferentially"). The unrebutted expert evidence shows that a POSA would not understand this statement in Edwards to describe "heating a portion of the vagina circumferentially" as required by claim 35. *See* EX1034, 141:3-23. Again, Petitioner declined to have its expert opine on this issue or to further question Dr. Poulos on the matter after she clearly articulated that while Edwards uses the phrase "circumferential tightening," she disagrees that treating the anterior and posterior walls would "caus[e] circumferential vaginal wall tightening." *Id.* As Dr. Poulos testified, Edwards's effect would be akin to "mak[ing] the elastic

tighter on just ... two non-contiguous locations (e.g., sites) around the elastic waistline” of sweatpants, and “no circumferential tightening of the wa[ist] band would occur.” EX2001, ¶71.

4. The Combination fails to teach claim 43 and 51’s treatment areas of “heating a portion radiating outward from the introitus to Hart’s line” and “heating a mucosal surface of the labia minora”

The Combination does not suggest the vulva treatment areas required by claims 43 and 51. Petitioner points to InMode’s expert testimony to reiterate the ’511 patent specification’s concession that “surgical options” existed for treatment of vulvar structures. Reply, 19. But Petitioner ignores the specification’s guidance that surgical options were associated with “a risk of scarring.” EX1001, 2:11-16. These surgical options therefore fall outside the scope of the ’511 patent’s claims, which are directed to procedures that do not substantially affect the mucosal epithelium. *Id.*, 2:9-12; EX2001, ¶43; EX1009, 15. Petitioner also cites to Dr. Poulos’s testimony that LVR treatments were performed. Reply, 19. As discussed above, however, both experts agree the treatment was kept secret. POR, 62-63; *supra* Section III.A.1.

Attempting to minimize the effect of different treatment times and temperatures required for internal (e.g., SUI) and external (e.g., LVR) treatments, Petitioner’s Reply also walks back its own expert’s testimony that “tissue response

is different externally and in terms of tolerability versus vaginal heating” such that there is “almost no discomfort with internal, whereas external, there seems to be more sensitivity.” EX2005, 35:8-22. But Petitioner does not dispute that a POSA could not use the same procedure and technique for internal and external treatments. *Compare* POR, 49 *with* Reply, 19-20. Petitioner’s legal citations in support of its attempt to minimize this difference in internal treatments and vulva treatments are inapposite. *In re Epstein* addressed whether a POSA “would have concluded that the reference disclosures would have been enabling.” 32 F.3d 1559, 1568 (Fed. Cir. 1994). And *Paice LLC v. Ford Motor Co.* found that disclosure of “road load torque, rather than engine output torque” was sufficient to anticipate a claim element requiring engine output torque. 881 F.3d 894, 901 (Fed. Cir. 2018). Here, the combination does not disclose vulva treatments at all, let alone an enabling disclosure, as in *Epstein*. Nor does the combination describe another form of vulva treatment that could be equated to external treatments described in claims 43 and 51, as in *Paice*.

Also, Petitioner does not dispute that the ’511 patent acknowledges multiple references describing cosmetic treatment or that Petitioner’s arguments for these claims are rooted in hindsight bias. *Compare* POR, 47-48 *with* Reply, 19-20. Ultimately, Petitioner seems to argue that any disclosure of RF treatments external

to the vagina, such as Ingle's "cosmetic procedures" and treatment of "sagging breasts" (EX1007, 18:1-7, 1:18-23), teaches treatment of any body part using RF in any way. Such a broad reading has no basis and contradicts Petitioner's expert's admission that Ingle does not disclose "heating tissue for sexual function." EX2005, 153:3-6.

B. Mosher's and Ingle's catch all phrases do not teach "heating the target tissue" (all claims)

None of Petitioner's references disclose heating the "tissue immediately beneath the mucosal epithelium" (the lamina propria and muscularis). Instead, Petitioner contends that Mosher's and Ingle's catch-all references to a "wide variety of fascia and other collagenous tissues" (EX1006, ¶46) and "other collagenated support tissues" (EX1007, 2:59-63, 15:8-11), respectively, meet the "heating the target tissue" element. Reply, 9-10. But the Federal Circuit has repeatedly found laundry list recitations insufficient. POR, 28 (collecting cases). Mosher and Ingle's disclosures do not even include the specific tissues required by the claims; rather they vaguely reference treatment of a "wide variety" and "other" collagenous tissues. EX1006, ¶46; EX1007, 2:59-63, 15:8-11. As Dr. Poulos testified, these vague references do "not provide any detail as to how its techniques would be adapted—if at all—to treat any of these other tissues." EX2001, ¶86. Petitioner has provided no contravening evidence.

Dr. Poulos’s confirmation that men are treated for stress urinary incontinence (SUI) (Reply, 10 (*citing* EX1032, 18:14-18)) gives no credence to Petitioner’s reliance on Mosher’s list of tissues. Male anatomy is entirely different from female anatomy, as evident by the average male urethra length of 20 cm and average female urethra length of four cm. EX2001, ¶94; EX2004, 1672. Petitioner’s reliance on male anatomical structures highlights the untenable nature of Petitioner’s argument that the mere mention of RF and a list of options should render obvious any RF treatment. Such a broad reading is not supported by the law or factual record. *See infra* Section III.D.1.

C. The Combination does not teach “remodeling” (all claims)

The *ThermiGen* IPR construction of “remodeling,” adopted in the POR, precludes ablation. POR, 17. Petitioner contends that Edwards, Mosher, and Ingle teach cooling, such that Edwards’s disclosure of ablative lesions can be discounted. Reply, 11. But Edwards’ disclosure of “deliver[ing] cooling fluid into the vagina through the irrigating fluid delivery pores” would protect ***non-treatment areas*** and still “require [] local or regional anesthesia,” which is consistent with tissue damage to the mucosal epithelium. POR, 53-54; EX1005, 2:22-27, 13:50-53. Further, as Dr. Poulos testified, size of the Edwards electrodes would “create more

concentrated heat” and “the description of [Edwards] indicate[s] that [the lesions] are ablative.” EX1032, 149:1-3, 149:25-150:3.

Mosher and Ingle also do not teach “remodeling the ... target tissue” (i.e., the tissue immediately beneath the mucosal epithelium). Instead, Mosher describes treating deeper fascia while cooling the tissue immediately beneath the mucosal epithelium. POR, 56; EX1006 ¶[0058] (discussing “alternative cooled electrode vaginal probes for indirect treatment of tissue ... through an intervening or intermediate tissue, which *may comprise a spared zone ... where tissue necrosis is inhibited.*” and “cool[ing] the intervening or intermediate tissue between probe body 54 and the endopelvic fascia EF”). Similarly, Ingle also discloses cooling the tissue immediately beneath the mucosal epithelium. Pet., 32 (citing EX1007, 2:59-61, 3:21-25); EX1007, 2:63-67 (“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.”); 3:11-35 (“The cooling system allows the electrode surface to cool the engaged intermediate tissue”).

Petitioner’s attempts to disclaim Edwards’ disclosure of ablative lesions fail. For one, the notion that Edwards’s fourth embodiment is somehow directed “non-ablative” lesions is contradicted by Edwards, which states “difference between [the

fourth] embodiment and the other embodiments is that the RF energy is delivered to the anterior and posterior regions of the vaginal wall.” EX1005, 3:5-9. There is no mention in Edwards of ablative vs. non-ablative lesions such that the fourth embodiment should be understood to encompass non-ablative lesions. Regardless, Petitioner’s own expert testified that “a lesion in the vagina” will result in “thermal injury,” “cell walls may be disrupted,” and “cellular breakdown” occurs. EX2005, 103:7-12. Again, Petitioner declined to have its expert testify further on this point. Further, Petitioner’s reliance of the definition of erythema as a “nonspecific sign of skin irritation, injury, or inflammation” does not help. Reply, 12n.3; EX1034. Dr. Berenholz’s description of “erythematous” only addresses whether there is a “sign” of injury, not whether Edwards’ ablative lesions “substantially affect the epithelium.” Reply, 12; EX1034. Petitioner’s new attorney argument should be rejected.

D. Petitioner’s additional criticisms are unavailing

1. The claimed combination of treatment techniques and anatomical regions was not known

Petitioner asserts that surgical techniques for treating the vagina were known. Reply, 2. The specification acknowledges this point but is clear that the “surgical approaches” were associated with “a risk of scarring.” EX1001, 2:1-16. These surgical procedures were also associated with “downtime,” “blisters,” and

“burns.” EX2013, 9. Conversely, “treating a loose vagina and introitus with a non-invasive procedure,” and the associated treatment techniques, were not known.

EX1001, 2:17-18. As Dr. Poulos testified “it wasn’t known” that RF could be used to improve sexual function. EX1032, 138:5-8.

Also unavailing is Petitioner’s argument that the claimed methods were not new because they apply a “known technique to a known method ready for improvement to yield predictable results.” Reply, 4. Applying Petitioner’s logic, because RF was used in one part of the body (e.g., the bladder neck) to treat one condition (SUI), it should be obvious to use RF in any part of the body to treat any condition. This argument would essentially render unpatentable any advance using RF technology in new ways and is unsupported by the law. *Virtek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 886 (Fed. Cir. 2024) (legal error to find a claim obvious simply because claim elements were known, particularly where there is no showing that the claimed treatment is the product of “design need or market pressure to solve a problem” or there was a “finite number of identified, predictable solutions.”). Prior to the ’511 patent, non-invasive RF treatment of vaginal tissue for improving sexual function was not known, let alone known to be effective. None of Petitioner’s cited references disclose the claimed techniques in the specified areas. EX1001, claims 1, 35, 43, 51.

2. Edward, Mosher, and Ingle are directed to treating stress urinary incontinence

Edwards's "Field of Invention" is "treating menorrhagia, female urinary incontinence and other related uro-genital conditions." EX1005, 1:24-26. The only uro-genital disorders that Edwards meaningfully discusses are incontinence and menorrhagia. *See* EX1005, 1:28-32. Edwards's fourth embodiment is directed to heating the anterior and posterior walls resulting in bladder outlet support, and Edwards in passing states that this heating may result in improvement of sexual function. EX1005, 3:9-13. Mosher is titled "Non-surgical Incontinence Treatment ..." and its "present invention ... [is] particularly for the treatment of urinary incontinence." EX1006, Title, ¶[0003]. Similarly, Ingle's "invention ... [is] particularly for treating urinary incontinence." EX1007, Abstract. Also, Petitioner's expert agrees that neither Mosher nor Ingle "discuss improving sexual function." EX2005, 146:19-21, 152:25-153:5.

In contrast, the '511 patent claims are reasonably limited to the treatment of vaginal laxity. The specification is clear that the claims are directed to "remodeling tissue of the vagina and vulva" (EX1001, 1:13-15, 2:17-21) and "treating a loose vagina and introitus" (*id.*, 2:17-21).

Yet, Petitioner argues that a POSA would modify Edwards, Mosher, and Ingle to treat sexual dysfunction. But none of the references discloses the treatment areas recited in the independent claims.

3. Edwards' speculum prohibits treatment of the introitus and circumferentially around the vaginal wall

The relied upon embodiment of Edwards uses speculum-mounted electrodes to heat the vagina. EX1005, 7:16-33. Petitioner's Reply introduces a new, unsupported argument that a POSA would be able treat the introitus without a speculum. Reply, 21. Even if the Board were to entertain this new and unsupported argument, Petitioner would still have "needed to present evidence and argument that a person of ordinary skill would have been motivated to operate [Edwards] in a manner that satisfied the [claim 1, 26, and 35 treatment area] limitation[s]."

ParkerVision, Inc. v. Qualcomm Inc., 903 F.3d 1354, 1363 (Fed. Cir. 2018).

Petitioner has no evidence on this point. Instead, Petitioner misrepresents Dr. Poulos's repeated testimony that Edwards "only describes using [the treatment element] with the speculum." EX1032, 144:3-9, 144:10-16 (same), 144:17-23 (same); Reply, 21. Petitioner further posits that Edwards could be referring to a pediatric or other speculum. Reply, 21 (citing EX1032, 32:2-33:7 (Petitioner's counsel questioning Dr. Poulos whether a "pediatric speculum" is used on adults)). However, Dr. Poulos testified that the different size speculums do "not really"

“allow a physician to view different parts of the vaginal canal.” EX1032, 33:19-22.

In other words, use of a pediatric speculum would still prevent treating tissue near the introitus. Dr. Poulos’s testimony on this point is unrebutted.

4. Petitioner does not rebut InMode’s motivation to combine arguments

Petitioner’s Reply restates the Petition’s motivation to combine section. Reply, 21-22. But Petitioner fails to rebut any of InMode’s points demonstrating no motivation to combine the Edwards, Ingle, and Mosher references to arrive at the elements of the independent claims. POR, 38-39, 45-46, 48-50, 59.

IV. GROUND 2: PETITIONER’S COMBINATION OF EDWARDS, MOSHER, INGLE, AND OLLIVIER FAILS

Petitioner does not address InMode’s evidence that the combination of Edwards, Mosher, Ingle, and Ollivier does not teach the specific treatment areas of claim 43 and claim 51. POR, 64-66. Nor does Petitioner address InMode’s evidence that there would be no motivation to combine these references. POR, 66-68. Petitioner also (i) ignores the secrecy of the treatments alluded to in Ollivier, (ii) glosses over Ollivier’s complete lack of technical detail, and (iii) disregards printed publication accessibility jurisprudence pertaining to Ollivier.

1. Ollivier’s described treatments were not known to a POSA

Petitioner contends throughout its Reply that it was known to “perform[] [LVR] to tighten vaginal” tissue. *E.g.*, Reply, 3. Petitioner’s only support for this

proposition is the Ollivier reference. But Ollivier does nothing more than report on a technique that the author believed a lone doctor to be performing. It does not assert that the technique was publicly known, provides no details on that technique, and both experts agree that the treatments alluded to in Ollivier were kept secret subject to an NDA and a fee of \$10,000. POR, 62-63; EX2005, 162:17-22.

2. Ollivier does not enable the claim 43 and 51 treatment areas

Petitioner apparently only relies on Ollivier to suggest that treating external vaginal and vulval tissue existed. But that *something* may have existed and the scope of the knowledge of a POSA are distinct issues. The technique was maintained as a secret to all in the field but those who paid the high fee and signed an NDA. POR, 62-63. Petitioner makes no argument that a POSA would have had the guarded knowledge or that the treatment technique was in the public domain.

Because Ollivier fails to describe the secret treatment, it fails to enable a POSA to use the undisclosed details to modify any known treatment. *See Raytheon Techs. Corp. v. GE*, 993 F.3d 1374, 1380 (Fed. Cir. 2021) (explaining that while prior art “does not necessarily have to enable its own disclosure,” it still must “furnish the motivation to combine, and be combined with, another reference in which that limitation is enabled” or “supply claim elements enabled by other prior art or evidence of record”).

3. Ollivier is not a qualifying printed publication

Petitioner's citation to the Wayback Machine's record of Ollivier existing on the Internet falls short. Reply, 22 (citing EX1029); Pet., 12-13. Petitioner provides no evidence that the Ollivier article was indexed to be searchable or that Salon.com would be a source with which a POSA would have been familiar. Nor does Petitioner provide "a satisfactory showing that [Ollivier] has been disseminated or otherwise made available to the extent that ... [a POSA] exercising reasonable diligence, c[ould] locate it." *SRI Int'l, Inc. v. Internet Sec. Sys.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008). It was Petitioner's burden to establish that Ollivier "was made 'sufficiently accessible to the public *interested in the art*' before the critical date." *Voter Verified, Inc. v. Premier Election Sols., Inc.*, 698 F.3d 1374, 1380 (Fed. Cir. 2012); *see also First Solar, Inc. v. Rovshan Sade*, IPR2023-00827, Paper 13 at 18 (P.T.A.B. Nov. 16, 2023) ("there was no evidence that the ordinarily skilled artisan would know of Wattsun or its web address."); *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363, 1369 (Fed. Cir. 2019) ("public accessibility requires more than technical accessibility"). Instead, Petitioner seems to believe that its mere existence is enough. The case law establishes it is not.

Petitioner's reliance on *Jazz Pharms., Inc. v. Amneal Pharms., LLC* is inapt because that case involved medical prior art references posted on an FDA website,

not a non-medical, political, gossip website as is the case here. 895 F.3d 1347, 1356 (Fed. Cir. 2018). Neither party's expert was even aware of Salon.com until this case. EX2005, 158:5-12; EX2001, ¶162. Thus, Petitioner has not met its burden.

V. OBJECTIVE INDICIA

Petitioner contends that InMode relies on an improper presumption of a nexus and did not show that the Viveve device described in the Millheiser and Sekeguchi studies is coextensive with claims 1, 26, and 35. Both arguments are unavailing.

To begin, Petitioner fails to address the permissible presumption set forth in *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016). Regardless, Petitioner's single challenge is that cooling is a "critical" feature of the Sekeguchi and Millheiser studies. Reply, 24-25. Neither reference indicates cooling is critical. Moreover, InMode's mapping accords with the *ThermiGen* IPR construction requiring "remodeling ... without substantially affecting the epithelium overlying the target tissue" and the *Viveve* construction requiring protection of the epithelium. EX1009, 14-16; EX1024, 10-11. As discussed above in Section II.A, heating and remodeling without substantially affecting the epithelium can be achieved by various techniques (e.g., cooling, the use of gel, adjusting energies

used, etc.). EX2001, ¶141; POR, 53. The Sekeguchi and Millheiser studies use multiple of these modalities including “coupling fluid” (i.e., gel) and cooling. EX2017, 777; EX2018, 3. This is sufficient. InMode is “not require[d] ... to produce objective evidence of nonobviousness for every potential embodiment of the claim.” *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013).

Moreover, cooling is explicitly recited in claims 9-16 and 39. *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir. 2022) (“if a dependent claim reads on a particular embodiment of the claimed invention, the corresponding independent claim must cover that embodiment as well.”)

For these reasons, InMode has demonstrated that the studies are “reasonably commensurate with the scope of the claims.” *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011).

VI. PETITIONER’S ATTEMPTS TO DISCOUNT DR. POULOS’S TESTIMONY ARE UNAVAILING

Petitioner’s attempts to downplay the credibility of Dr. Poulos’s testimony fall flat. Petitioner’s complaint that Dr. Poulos testified that she does not offer the procedures contemplated by the ’511 patent is irrelevant. Neither party has proposed a definition of a POSA that requires experience with these treatments. Pet., 6; POR, 11-12. Indeed, that would be impossible because these novel

treatments were invented by the '511 patent so were not in use before the priority date.

Regardless, Dr. Poulos's decision to not offer the '511 patent treatments does not impact her testimony regarding knowledge of a POSA at the priority date. To the contrary, Dr. Poulos's focus on SUI treatments (EX1032, 20:14-20) makes her very qualified to testify as to a POSA's understanding of the applied prior art, which as discussed above, pertains to SUI treatments rather than the claimed treatments (EX2001, ¶13).

VII. CONCLUSION

For the reasons above, the Petition fails.

June 11, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I hereby certify that the foregoing paper contains 5,545 words as measured by the word processing software used to prepare the document, excluding the cover page, signature block, and portions exempted under 37 C.F.R. § 42.24(d).

Respectfully submitted,

June 11, 2025

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CERTIFICATE OF SERVICE

I certify that a copy of Patent Owner's Sur-Reply to Petitioner's Reply was served to Petitioner by causing it to be sent by email to counsel for Petitioner at the following email address:

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