

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

Record of Oral Hearing
Held: July 8, 2025

Before MEREDITH C. PETRAVICK, BENJAMIN D. M. WOOD, and
HYUN J. JUNG, *Administrative Patent Judges*.

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P R O C E E D I N G S

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JUDGE PETRAVICK: Good morning. This is Judge Petravick. I just want to make sure everybody can hear me. If you could, give me a thumbs up. Great, thank you. We're here today for oral arguments in IPR2024-00703 in the matter of BTL Industries, Inc. v. InMode LTD. With me on the panel today is Judge Jung and Judge Wood. If we could know who's here from the Petitioner.

MR. BEMBEN: This is Richard Bemben of Sterne, Kessler on behalf of the Petitioner, BTL Industries. And with me today is Jennifer Chagnon, as well as Stephanie Nguyen from BTL.

JUDGE PETRAVICK: Thank you. And who is here from the Patent Owner?

MR. HECTOR: This is Bill Hector of the Venable Law Firm here on behalf of the Patent Owner, InMode. And also in the audience is Michael Sandonato, also of the Venable Law Firm.

JUDGE PETRAVICK: Great, thank you. Today, we have the Judges in the hearing rooms and the parties on video conference, so that we ask that you mute yourselves when you are not speaking. That would be very helpful. The Judges do have your papers and the entire record on the screens in front of them, and we will also be able to see any demonstratives that you share on the screens in front of us. I believe, from your view, you can also see the clock in the hearing room.

MR. BEMBEN: Correct.

JUDGE PETRAVICK: Is that correct?

MR. HECTOR: Correct.

1 JUDGE PETRAVICK: All right. Each party has been given
2 60 minutes of oral argument time. I will set the clock at 60 minutes when
3 you begin to speak. Whenever you've finished your argument in chief, what
4 remains will be for your rebuttal. With that, I believe we can begin.
5 Petitioner, you may begin when you're ready.

6 MR. BEMBEN: Just one -- thank you, Your Honor. One
7 question for you. Would you prefer that I share --

8 JUDGE PETRAVICK: Sure.

9 MR. BEMBEN: -- demonstratives on the screen or just speak
10 to the demonstrative number while you have demonstratives on your screen?

11 JUDGE PETRAVICK: Sure. You can share the
12 demonstratives on the screen. If that, for some reason, fails or doesn't show
13 up, we also have copies and if you could refer to these slides by number, that
14 would be great.

15 MR. BEMBEN: Okay. Let me get that set up. Can you see
16 my screen? Or can you see the slides here?

17 JUDGE PETRAVICK: Yes. Yes, we can. We can see your
18 screen.

19 MR. BEMBEN: Okay, thank you very much. I'm ready to
20 begin.

21 JUDGE PETRAVICK: Thank you.

22 MR. BEMBEN: And I'd like to reserve 15 minutes for rebuttal.
23 So, good morning, Your Honors, and may it please the Board. The evidence
24 in this case demonstrates that the claims of the '511 patent would have been
25 obvious. The claims are directed to methods for remodeling certain regions
26 of the vagina by applying heat to tissue underlying the epithelium.

1 By February 2006, persons of skill in the art knew three key
2 things. First, they knew of the sexual and aesthetic problems caused by
3 loose vaginal tissue. Second, they knew that applying heat to collagen-rich
4 tissue produces a tightening effect. And third, they knew that training loose
5 vaginal tissue, including the vaginal canal, introitus, and vulva, that that
6 would improve sexual function and enhance appearance.

7 So the specific problem addressed by the '511 patent was
8 known. The treatment method in physiological response were known and
9 the anatomical locations to treat in order to address the problem was known.
10 This is also a case in which the level of skill is high. Now, there is some
11 disagreement about the exact credentials, but the parties agree that a person
12 of ordinary skill in the art would've had a medical degree, as well as clinical
13 experience with non-surgical treatment with female vaginal tissue.

14 This person of high skill armed with the knowledge, as well as
15 the expressed teachings and suggestions of the prior art reference, would
16 have found the claims obvious. Faced with the strength of this invalidity
17 case, InMode resorts to some pretty familiar tactics. They tend to limit the
18 scope of the claims by reading in limitations that are not required. They tend
19 to limit the scope of the prior art, arguing that the prior art only addresses
20 incontinence, which is untrue.

21 And they also simply ignore arguments or evidence that are
22 unfavorable, such as with respect to Ground 2, the Ollivier reference. They
23 continue to argue that that is not publicly accessible, but we have provided
24 research aids, which they have simply failed to address, and research aids in
25 the form of Exhibits 1027 and 1028, which show that this reference was
26 publicly accessible and was being cited by other publications.

1 InMode's tactics fail. This is a quintessential KSR type
2 obviousness case. With that, I'm going to move to the agenda. And to that, I
3 plan to talk about the -- I'm going to skip over the instituted grounds, the
4 independent claims. Those are just there for reference, but I'd like to discuss
5 the level of ordinary skill and the state of the art, which I just mentioned, and
6 talk about the scope of the claims and the prior art before jumping into
7 Grounds 1 and 2. And if there's time and there's interest, talk about
8 secondary considerations.

9 Before I go through any of those sections, I wanted to open it
10 up to the panel and welcome you to direct me to what you think are the most
11 critical issues. If you'd like me to continue with my presentation, I'd be
12 happy to do so, but if there's a critical issue, please direct me there and we
13 can talk about it now.

14 JUDGE PETRAVICK: I would like to talk about claim scope.

15 MR. BEMBEN: Sure. Okay.

16 JUDGE PETRAVICK: Focusing on exactly what the
17 independent claims require. We could start with Claim 1, the wherein
18 clause. I believe the parties are reading that cause differently. Would you
19 please tell us how you read --

20 MR. BEMBEN: Yes.

21 JUDGE PETRAVICK: -- the wherein clause in Claim 1 and
22 where you find support in the spec or in the other claims, or how you're
23 reading that?

24 MR. BEMBEN: Sure. So I have Slide 5 up. This is showing
25 independent Claim 1 and the wherein clause that you're referring to is shown
26 in red text. And that states, wherein the heating includes a portion -- heating

1 a portion of the vagina, extending from the introitus inwardly, to the location
2 from 1 cm to 3.5 cm in from the introitus.

3 Now, with respect to -- the first thing I want to say about claim
4 construction, it is our position and has been our position throughout this
5 proceeding that the claim terms should be given the plain and ordinary
6 meaning, and that regardless of the construction that you adopt -- there's
7 been a lot of prior constructions, a lot of arguments from Patent Owner in
8 prior proceedings -- but regardless of the construction that you adopt, that
9 the prior art teaches and renders obvious these claim limitations. So I just
10 wanted to say that right off the bat.

11 With respect to limitation 1.3, I believe you're referring to the
12 parties are taking a slightly different views than how this claim term should
13 be construed. Petitioner, BTL, our position is that the area -- the portion that
14 is being treated is within the range of 1 cm to 3.5 cm inward from the
15 introitus. The reason -- the way that we're reading the claim is that the
16 language that the portion extends from the introitus inwardly, that is
17 describing the direction and the location of this being treated is between 1
18 cm and 5 cm in that direction from the introitus.

19 Now, we understand that InMode has taken a different position.
20 Their reading is that the treatment location begins at the introitus and
21 extends or ends at some location between 1 cm and 3.5 cm in. That is the
22 dispute. And like I said, we covered both of them in our papers in our
23 petition, but that is the basic dispute between the parties. And so we believe
24 that the plain language of the claim dictates that a treatment location is
25 between 1 cm and 3.5 cm, and that's, as I mentioned, just the fact that the
26 language extending from the introitus inwardly as describing the direction --

1 orienting you as far as direction, but the actual portion that's being treated is
2 the location from 1 to 3.5 cm.

3 JUDGE PETRAVICK: And what's that based upon?

4 MR. BEMBEN: The plain language of the claim specification.

5 JUDGE PETRAVICK: So let me ask you a question. Looking at
6 the spec -- I believe it's in Column 11 -- it talks about -- gives sort of the
7 same range, but it goes to 0.4 cm. And it says at column 11, line 48 , it says,
8 thus, according to embodiments of the invention, the portion of the vagina to
9 be treated is a region between the introitus and a position located no further
10 than about 3 cm to about 4 cm inward from the introitus. Is that a quote that
11 corresponds to that limitation?

12 And based on the specification, it seems like what the claim is
13 trying to capture is the lower portion of the vagina, and since people have
14 different lengths of vaginas, they're trying to capture a range of the lower
15 portions from the introitus to the position located no further than about 3 cm.
16 Can you tell me whether you agree or not that this portion of the
17 specification sort of supports Patent Owner's reading or doesn't support
18 Patent Owner's reading of that limitation and why or why not?

19 MR. BEMBEN: Sure. So I think that the portion of Column 11
20 that you just read, it supports both, quite frankly. I think that it's vague. It
21 doesn't describe the specific area or range that's treated. It says that this --
22 the invention is seeking to, as you just mentioned, treat the lower portion of
23 the vagina, but then when we get to the claim limitations, they specifically
24 describe specific locations or specific treatment areas.

25 And so I don't think that this is dispositive of one or the other
26 interpretation of this limitation, limitation 1.3, because the range under our

1 interpretation, 1 cm to 3.5 cm would be -- if the treatment area had to be
2 within that location, is also the lower portion of the vagina. Patent Owner's
3 construction is the lower portion of the vagina, would start at the introitus
4 and move within the range that's described in Column 11, as well.

5 And so I don't think it's dispositive as to either of those
6 constructions, but maybe more to the point, I think that the -- regardless of
7 the construction that is adopted by the panel, it is taught by prior art
8 references and if you'd like me to move to that discussion, I can move to that
9 discussion now.

10 JUDGE PETRAVICK: Not quite yet. You know --

11 MR. BEMBEN: Okay.

12 JUDGE PETRAVICK: -- the first step of the analysis is figuring
13 out what the claim actually requires. So in the papers, you point to Claim
14 26 --

15 MR. BEMBEN: Yes.

16 JUDGE PETRAVICK: -- as showing that that can't include the --
17 Claim 1 doesn't include the introitus. But Claim 1 is directed to the
18 remodeling instead of the heating portion, so it doesn't quite correspond to
19 that — heating includes the introitus or not in treating the introitus. Can you
20 explain to me how your argument about Claim 26 affects that limitation?

21 MR. BEMBEN: Sure. And so let me start by just addressing one
22 of the things you just said about heating and remodeling. In the patent
23 itself -- I'm going to turn to Slide 34 -- the remodeling is the result of the
24 heating, and so in order to remodel a location, it really needs to be heated.
25 And we have here on Slide 34 a quote -- or a portion of the '511 patent that
26 just says, a zone of tissue that is heated within the target tissues to a

1 threshold level, i.e. to a therapeutic temperature that causes remodeling is
2 termed a therapeutic zone.

3 And so my point here is just that although Claim 26 refers to
4 remodeling or maybe other claims refer to remodeling, in order to remodel
5 that area, it needs to be heated. And so the way we read Claim 26,
6 dependent Claim 26, is that it requires the introitus in order to remodel the
7 introitus. And from a claim differentiation standpoint with limitation 1.3
8 that we're discussing -- I'll go back up to Claim 1 on Slide 5 -- we believe
9 that that demonstrates that the introitus is already covered by Claim 26,
10 heating the introitus, and so limitation 1.3 should mean something different.
11 Again, our position is that the prior art teaches under either of the
12 constructions, whether it's Patent Owner's construction or Petitioner's
13 construction, but that is our claim differentiation position with respect to
14 Claim 26.

15 JUDGE PETRAVICK: And one more question. I know that in the
16 prosecution history, the limitations were added after a rejection. The claims
17 were amended to specify the locations. Was this limitation amended again
18 after it was added or was that the end of the prosecution history?

19 MR. BEMBEN: So I'd have to go back and doublecheck. My
20 recollection of the prosecution history, Your Honor, is that it was not
21 amended again. There were several limitations that I believe were in
22 dependent claims that the Examiner identified as allowable. Those
23 dependent claims were rewritten in independent form, which led to the
24 allowance without further discussion of the specific locations or -- yeah, the
25 specific locations that were required by the wherein clauses in the
26 independent claims.

1 JUDGE PETRAVICK: Thank you. Could we talk about Claim 35
2 now and the wherein clause in that claim?

3 MR. BEMBEN: Yes, Your Honor.

4 JUDGE PETRAVICK: I believe there's --

5 MR. BEMBEN: So --

6 JUDGE PETRAVICK: -- a dispute about how much of this
7 portion has to be heated or treated, and if I am -- and maybe you could
8 confirm for me that your position is that only one point within this arc that is
9 described has to be heated.

10 MR. BEMBEN: So, yes, Your Honor. So I'm turning to Slide 6
11 and this shows the operative language in red. Our position is -- so there was
12 some discussion about what is a point versus which is a contact site and
13 we -- okay, so I don't think that our position is just that it's one point needs
14 to be treated, but that a contact site within this range from 1:00 o'clock to
15 11:00 o'clock needs to be treated.

16 And when a contact site is described in the patent, a 30 degree arc.
17 This is in the patent, Column 14, line 41 through 45 -- it describes that the
18 region from -- the region of the vagina from 1:00 o'clock to 11:00 o'clock,
19 where the urethra is at 12:00, that that's about a 300 degree arc and that a
20 contact point or a contact site that they describe being treated within that, is
21 about 30 degrees. And so it's our position that it doesn't -- the claim
22 limitation 35.3 does not require heating the entire arc. It requires heating a
23 portion of that arc and a contact site is sufficient.

24 And I also mentioned that it appears that Patent Owner's
25 construction, which is heating multiple contiguous contact sites into 300-
26 degree arc is similar. Heating multiple means two or more contiguous

1 contact sites, so that would be about 60 degrees within that arc of 300
2 degrees. This is on the POR on page 22 of their construction.

3 And so just to kind of summarize, our position is not that the entire
4 arc from 1:00 o'clock to 11:00 o'clock needs to be treated. It's a portion of
5 that and the portion could be about 30 degrees and -- but I'll say just like I
6 said in the prior discussion of Claim 1, though, is that we have covered all
7 the interpretations in our papers recognizing that there are prior
8 constructions and prior arguments, whether it's heating a portion or heating
9 the entire arc between 1:00 o'clock and 11:00 o'clock. We have shown that
10 that is obvious, but we do believe that the correct instruction is that it's a
11 portion within that arc, not the entire arc.

12 JUDGE PETRAVICK: And what supports your position in the
13 specification?

14 MR. BEMBEN: Yeah. So I think that one of the portions is what
15 I just mentioned, Column 14, lines 41 through 45, and the discussion around
16 Column 14, line -- Column 14, kind of starting at around line 18 through 45
17 describes the contact site and specifically, with respect to lines 37 through
18 45 of Column 14, describes a contact site and contacting different portions
19 within that arc. And then we also believe that the plain language of Claim
20 35, element .3, which says, a portion is heated of that arc supports the
21 construction that we're presenting.

22 JUDGE PETRAVICK: So in the specification when it describes
23 this device, it really is just sort of the contact portion of the device does not
24 match the whole width of the vagina or the portion of the vagina that's going
25 to be heated. It always contacts points within there. It depends on how --
26 depending on how many points you put in there is how much you cover of

1 the vagina; is that correct?

2 MR. BEMBEN: I believe I understood your question, Your
3 Honor, and I believe that is correct, that the device that's described in the
4 '511 patent, which is not part of the claims, but the only device it had -- it is
5 a device that provides contact points. It's not something that would treat --
6 that has, for example, like contact points all the way around that would treat
7 all at once, if that's what you're asking. So in order to treat
8 circumferentially, you would need to treat multiple contact points, as
9 described in the '511 patent.

10 JUDGE PETRAVICK: Thank you. That's the questions I have
11 about the claim construction, so if you want to move on to the prior art, that
12 would be fine with us, or if you want to tell us something else, that would be
13 fine, too.

14 MR. BEMBEN: Thank you, Your Honor. And just to clarify,
15 when I say contact points with respect to the '511 patent, the '511 patent is
16 talking about a contact point that is 30 degrees, for example, and that contact
17 point would satisfy, based on our construction, Claim 35.3, but it is just a
18 contact point or a contact site, I should say.

19 Okay. With that, so as I mentioned, I want to -- I jumped to Slide
20 10 because we do believe that this is a case -- maybe one of the rarer cases
21 or unique case in which the level of skill in the art is very instructive. And
22 so on Slide 10, we have kind of juxtaposed Dr. Berenholz's testimony about
23 who he believes a person of skill in the art should be, versus Dr. Poulos'
24 definition. Kind of the bottom line is that regardless of the definition that
25 you adopt, the parties do seem to agree that this person of skill in the art has
26 a medical degree, has experience with non-surgical cosmetic treatment.

1 And I want to draw your attention to Dr. Poulos' testimony, the
2 very last sentence that's highlighted. According to them, the person of skill
3 in the art has clinical experience in the application of radiant energy to
4 female genital tissue. So this person is very highly skilled, and we have a
5 situation in which -- I'm going to move to Slide 11 -- the problem was
6 known, as I mentioned, you have loose vaginal tissue causes certain medical
7 and sexual problems. Slide 11 talks about -- it shows the background of the
8 patent, it acknowledges this problem.

9 On Slide 12, we have admission from Dr. Poulos that a loose
10 vagina and the introitus, specifically, may lead to decreased sexual pleasure.
11 She was asked that question. She said that is correct. As I mentioned in my
12 opening, moving to Slide 13, the physiological response was known, this is
13 collagen denaturation, applying heat would denature the collagen and cause
14 a tightening effect.

15 I'm going to skip to Slide 16. This is important also that the
16 experts are agreeing here on Slide 16 that it was known to use radiant energy
17 to heat and tighten collagen tissue, so the physiological effect was known,
18 the delivery mechanism was known. And on Slide 17, what we have is
19 again, the experts agreeing that the devices that we're employing RF energy
20 were in use by the critical date in 2006. So again, the mechanism for
21 delivering the effect, the tightening effect, was known.

22 And then finally, it was also known the specific areas to treat. So
23 it was known to treat the introitus. This is on Slide 18. This is an admission
24 from Dr. Poulos, that tightening the vaginal introitus may lead to sexual
25 pleasure. It was known to treat also the vulva, which is the external portion
26 of the vagina, including the labia minora. This is on Slide 19. Of course, so

1 we have testimony with respect to both Dr. Berenholz and Dr. Poulos
2 agreeing that 2006 clinicians were using laser vaginal rejuvenation to treat
3 certain areas, introitus, vulva, in particular. And what this demonstrates is
4 just that those locations were known. We're not relying on vaginal laser
5 rejuvenation in our papers or in our combinations.

6 This is particularly important for Ground 2, which introduced the
7 Ollivier reference. Just to kind of level set, we are not relying on laser
8 techniques. We are relying on delivery of radiant energy in the form of RF
9 or ultrasound, or other forms that are described in the references. However,
10 the point of this is just that these areas to treat were known, and that includes
11 the labia minora, which is Slide 20.

12 So that's the backdrop that we come at the claims in the prior art,
13 and so with that, I want to talk a little bit more about the scope of the claims
14 and the prior art.

15 The first thing that I want to mention -- and this is on Slide 22 -- is
16 that during the cross-examination, Dr. Poulos, she acknowledged that her
17 claim constructions were simply provided by InMode's Counsel. So this is
18 essentially her adopting attorney argument. The claims -- this is important --
19 the claims do not require treatment with a particular device.

20 I'm on Slide 23 now, and Dr. Poulos, she was improperly reading
21 the device into the claims. We asked her specifically, Claim 1 is just
22 describing a method, correct? And she testified, I read it to be a method that
23 would be using the device described in the patent. We submit that that's the
24 incorrect way to be viewing these method claims. The specific devices
25 described in the patent is not part of the claims.

26 Also, very importantly here, I'm moving to Slide 24. The claims

1 don't require treatment of a particular medical condition. There's quite a bit
2 of argument from Patent Owner that the references only are directed to stress
3 urinary incontinence, SUI. First of all, that simply isn't the case. The prior
4 art references expressly acknowledge that they can be used outside of that
5 field. Some describe using them to treat other types of medical problems,
6 but it's also just that there's nothing in the claims that limit the scope of the
7 claims to specifically treating sexual functionality or problems with sexual
8 functionality.

9 Another point that has been disputed, but it seems that the parties
10 agree right now -- at least we can ask InMode's Counsel -- but is that there's
11 a discussion about treating the target tissue. What is the target tissue? And
12 it's always been our position that the target tissue is the tissue underlying the
13 epithelium, but that the claims are not limited or do not prevent heating other
14 tissues, such as endopelvic fascia.

15 It seems -- and I'm on Slide 25 on the right-hand side -- that there's
16 an agreement now. This -- I'm looking at the surreply at 5 -- InMode's
17 surreply where they say, InMode's position is not about prohibiting anything
18 and it's further about what needs to be heated. Seems that we're agreeing on
19 this point, just simply that the claims don't prohibit heating deeper tissues,
20 such as endopelvic fascia. With that --

21 JUDGE PETRAVICK: Counsel, and there's not a dispute between
22 the parties that the prior art shows heating targeted tissue. The dispute rests
23 upon where that tissue is located?

24 MR. BEMBEN: That's correct, Your Honor. I don't think that
25 there's a dispute that its target tissue. There is -- I believe that there is some
26 dispute. I'll allow InMode to answer this question, but there is some dispute

1 that the target tissue is the type of tissue that is described in the '511 patent
2 and I can get to -- let's see -- I believe that they are arguing that Mosher --
3 sorry -- that Edwards, Mosher, and Ingle, they don't teach treating the lamina
4 propria which is specifically described in Mosher.

5 I'm on Slide 33. Mosher does teach specifically treating the lamina
6 propria. Mosher talks about treating the endopelvic fascia, but in this
7 paragraph 48 on the right-hand side, if you -- it's a very long paragraph.
8 We're only able to capture part of it, but it explains that there's some
9 situations after childbirth in which the endopelvic fascia is no longer present,
10 and so it's necessary to treat other areas and other structures in that area.
11 And one of those structures of the vagina that would be treated includes the
12 lamina propria, which Mosher says is the dense connective tissue layer
13 underneath the epithelium.

14 So we submit that there is no dispute or there should be no dispute
15 that the target tissue is the same tissue that's being treated in the '511 patent.
16 I believe that InMode has a different position on that, but that is our position.

17 JUDGE PETRAVICK: Thank you.

18 MR. BEMBEN: So just with respect to heating, I'll just go jump
19 back up to Slide 32. So as I mentioned, we do believe that the heating step
20 that's recited in all of the independent claim is captured or is taught by the
21 prior art. We also believe that the remodeling step -- I'm going to move to
22 Slide 35 -- is also taught. And so remodeling -- the limitation that's recited
23 in independent claim elements 1.2, 35.2, 43.2, and 51.2 is remodeling the
24 therapeutic zone of the target tissue, and we have expressed teachings in
25 Edwards with respect to remodeling. Mosher talks about remodeling, as
26 well, and Ingle has similar teachings. And so we don't think there's any

1 dispute that there is remodeling that takes place.

2 The dispute around heating and remodeling seems to be whether
3 heating needs to be -- whether either of the steps, heating or remodeling has
4 to be done without substantially affecting the epithelium. InMode is
5 attempting to read that limitation into one of the two steps, heating or
6 remodeling.

7 And so we addressed that claim construction, which we think is
8 incorrect, under the remodeling step. I'm moving to Slide 36. We believe
9 that even if you adopt the construction, which we think is incorrect, that the
10 remodeling has to be conducted without substantially affecting the
11 epithelium, that that is clearly and squarely taught by the prior art references.
12 Edwards, Ingle, and Mosher all teach that you would use cooling in order to
13 avoid thermal damage to the surface. Mosher -- I'm looking at Slide 36 --
14 Mosher, paragraph 58. It teaches specifically that you could use pre-cooling
15 to inhibit heating of intervening tissue to a temperature causing surface
16 lesions within the vagina.

17 One of the disputes that InMode raises is that Edward's
18 embodiment 4, the embodiment that we are relying on, talks about causing
19 lesions -- not ablative lesions -- but lesions to the surface. In combination
20 with Mosher, Mosher teaches a pre-cooling step, which would have avoided
21 even those lesions by using cooling. So we believe that this -- the
22 remodeling even under InMode's narrow construction is taught by the prior
23 art references.

24 Kind of just on this point of claim construction now, with respect
25 to what does -- whether heating or remodeling requires the limitation that the
26 heating or remodeling is done without substantially affecting the

1 epithelium -- we think that you should adopt the construction that you
2 provided in the preliminary construction and the decision on institution, and
3 also the construction of the Viveve court, which was conducted after a
4 Markman.

5 First, the fact that InMode can't decide whether this requirement
6 should be part of heating or remodeling kind of demonstrates that it should
7 be part of either of them. And second, we believe that the only discussion of
8 protecting the epithelium in the patent -- if we look at the intrinsic record --
9 is methods and mechanisms for cooling.

10 Now, there are dependent claims that are directed to cooling. And
11 so it's -- cooling is not a part of the independent claims. And we'll note that
12 even those dependent claims talk about cooling do not have a requirement
13 that the epithelium is not substantially affected. And so we don't think that
14 this limitation that the epithelium isn't substantially affected should be part
15 of the heating or remodeling steps. It simply something that they're trying to
16 read in. But in the event, it is pretty clearly taught by the prior art
17 references. If there are no questions on that point, I think I'll move to the
18 treatment locations. Okay.

19 If we could, let's move to Slide 40 and just kind of level set, again.
20 This is Dr. Berenholz's testimony about that a person of ordinary skill in the
21 art would've exercised their judgment -- their professional judgment -- to
22 determine optimal treatment area based on the desired outcome. Again, a
23 person of skill in the art is a physician or a person with a medical degree, as
24 well as clinical experience with the specific types of treatment.

25 What Dr. Berenholz says in paragraph 91 of his declaration is that
26 the vagina region is not a large area, and a person of ordinary skill in the art

1 would have recognized that there's limited areas to treat, to choose from, and
2 depending on what you're treating, if you're treating incontinence, if you're
3 treating sexual functionality, a person of skill in the art would've known
4 where to treat. It would also be treated based on the anatomy of the patient.

5 So a person skilled in the art, these locations were well within what
6 they would have known to do and where they would have known to treat.

7 Let me move to Slide 41. And this is specifically of a limitation, Judge
8 Petravick, that we were talking about, limitation 1.3, and we believe that this
9 is taught by the prior art references, as well as supporting testimony from Dr.
10 Berenholz.

11 To start with, on Slide 41, we have discussion in Edwards that
12 talks about remodeling the anterior and posterior wall of the vagina to
13 provide circumferential tightening. Dr. Berenholz, in paragraph 122 of his
14 declaration, explains that a person of ordinary skill in the art would've
15 understood, based on this teaching, that in order to achieve improvements in
16 sexual function, the treatment must be near or include the opening of the
17 vagina, which is the introitus and that first portion, the lower portion of the
18 vagina.

19 Now, Mosher provides additional support, explaining that -- in this
20 paragraph 74 of Mosher -- again, it's a long paragraph and so we didn't have
21 the whole thing, but it's talking about protecting the nerves around the
22 bladder neck of the urethra. Again, Mosher is treating through the vaginal
23 canal, but it's treating certain portions along the urethra, which I'll show in a
24 second.

25 But what Mosher says is that you'd want to be treating away from
26 the bladder neck in order to avoid damaging nerves in that area, and talks

1 about a treatment length of 15 millimeters, which is 1.5 cm. What Dr.
2 Berenholz explained is that a person of skill in the art reading this discussion
3 of Mosher would have been motivated and understood that heating a portion
4 of the vagina, extending from the introitus, inwardly to a location of about
5 1.5 cm, would have been known.

6 And so this is what I was talking about before where that range,
7 from the introitus to 1.5 cm, that covers BTL's construction of limitation 1.3,
8 where the treatment location has to be between 1 cm and 3.5 cm. It also
9 covers InMode's construction where the treatment location has to be between
10 the introitus and 1 cm into the lower portion of the vaginal canal.

11 JUDGE PETRAVICK: Mr. Bemben?

12 MR. BEMBEN: Yes, Your Honor.

13 JUDGE PETRAVICK: Patent Owner is arguing that Edwards
14 can't treat the introitus because there's a speculum in the way.

15 MR. BEMBEN: That is -- yes, ma'am.

16 JUDGE PETRAVICK: If one of ordinary skill in the art was going
17 to modify Edwards or use Edwards device to treat other areas, why would
18 the speculum still be there? It seems to me that in Edwards, the speculum is
19 there because they're treating deeper areas, and that if you were going to
20 modify it in a 103 and use it to treat other areas that were known to need
21 treatment, would this speculum stay if it was no longer needed?

22 MR. BEMBEN: So the answer to that question is no, Your Honor.
23 I'm going to move to Slide 50. So that's exactly correct. That's what Dr.
24 Berenholz testified, that we have, on Slide 50, paragraph 69 of Dr.
25 Berenholz's declaration, he explains that a person of ordinary skill in the art
26 would have also understood that treating areas closer to the introitus, that the

1 physician would be able to complete this treatment without using the
2 speculum. This is, again, something that is well within the judgment of a
3 physician based on the anatomy and the location that's being treated, and
4 whether to use a speculum.

5 JUDGE PETRAVICK: So if we were to agree that it would be
6 obvious or would it have been obvious to use the device on other areas that
7 need to be -- that are known to -- need this treatment, then would we need to
8 reach the issue of what Mosher teaches as to centimeters or not centimeters?

9 MR. BEMBEN: I don't believe you would, Your Honor. I believe
10 that -- I mean, I think Mosher piles on the teachings and Mosher provides
11 motivation for moving away from the bladder neck and moving to different
12 locations. It gives you -- tells you why a physician would be thinking
13 through those things and would be doing that. For example, to be avoiding
14 damaging nerves in that area. But I think that you're absolutely right that if
15 you agree that a person of skill in the art, this physician, would know when
16 and when not to use a speculum and could use Edwards' device to treat
17 locations, you don't need to reach Mosher's teachings.

18 I'll also mention that in Slide 49, Dr. Poulos, she agreed that
19 whether or not a physician that uses a speculum, particularly with respect to
20 treating the introitus, that's something that they would know how to do.
21 What we asked her is, if a person of ordinary skill in the art wanted to treat
22 the opening of the vagina, which I believe is called the introitus, would they
23 use a speculum. She said, again, it depends on the patient's anatomy, but
24 usually no. So she's confirming that persons of skill in the art knew when
25 and when not to use a speculum, depending on the anatomy of the location
26 that's being treated.

1 Okay. We talked a little bit about the circumferential limitation
2 and I'm just going to move to Slide 44 to discuss that a little bit. This is --
3 what we have here is a pretty straightforward teaching from Edwards that
4 talks about remodeling both the anterior wall and the posterior wall, and
5 again, our position is that if you treat, for example, the posterior wall, that
6 that would be various contact sites along the posterior wall in order to
7 perform and provide the circumferential tightening that's described in
8 Edwards. A person of skill in the art would have known. This is testimony
9 from Dr. Berenholz and would have been motivated to treat the vagina
10 circumferentially to achieve this tightening.

11 I'm going to move to -- now I'm at 43.3. And so just to kind of
12 level set, this is about where the treatment area is. What the claim requires
13 is heating a portion radiating outward from the introitus to Hart's line. This
14 is -- the location is described in the patent and it seems like there's an
15 agreement between Dr. Berenholz and Poulos where this is. This is a
16 portion of the vulvar vestibule. This is part of the external genital that would
17 be treated, but it has the same type of mucosal epithelium with rich collagen
18 tissue underneath.

19 Similarly, with respect to limitation 51.3 -- I'm now on Slide 46 --
20 this is just explaining where the labia minora is. Again, this is external
21 portion of the vagina, but part of that has a mucosal surface that has the
22 collagen-rich tissue, as well. And so what we have explained in our papers
23 is that based on the teachings in the prior art -- sorry, I'm at Slide 48 --
24 teachings in the prior art about extending and providing treatment of other
25 areas. Ingle talks about treatment for cosmetic surgery, providing
26 techniques for selectively heating and shrinking tissues. Edwards talks

1 about tightening, shrinking, reshaping tissue to correct unwanted conditions.
2 This is all about extending the teachings from -- that are directed to inside
3 the vaginal canal to treatment outside tissues that have similar make up and
4 similar physiology.

5 If there are no questions with respect to those limitations, I'll
6 mention that I'm going to move to Slide 53. This is the Ollivier reference.
7 And so just in case there's any doubt in the Board's mind about whether
8 these areas -- the external portion that's described in 43.3 or the labia
9 minora, the portion of the labia minora that's described in 51.3 -- these
10 would have been well known to treat. The Ollivier reference, we're not
11 relying on it, again, for any teachings other than the fact that it was known
12 that the external vagina and labia minora were portions that physicians were
13 treating, that there was demand for treatment in those areas to correct both
14 sexual functionality, as well as cosmetic reasons.

15 As I mentioned, Ollivier is printed publication. I'm moving to
16 Slide 54. There was search functionality. Slide 55, as I mentioned before,
17 there were research aids that provided citations to this reference, showing
18 that it was publicly available and that other people had access to this
19 website, Salon.com.

20 Absent any questions there, I'll move to secondary considerations.
21 InMode is arguing that there are secondary considerations with respect to
22 Claims 1, 26 and 35, specifically. Those are the claims that they argued.
23 They didn't argue any other claims. What they argued is that there is a
24 presumption of nexus, which requires both that the product embodies the
25 invention and is co-extensive with it; however, on Slide 58, InMode has
26 failed to establish this co-extensivity feature. The device is not co-extensive

1 because it doesn't have -- Claims 1, 26 and 35 don't have the critical cooling
2 feature that is described in the article.

3 And what I'll say about secondary considerations is even if you
4 assume that there is a nexus to this article, the analysis for obviousness is a
5 weighing of all the (INDISCERNIBLE) factors and you have to consider
6 them all together and weight them. Even if you find this article probative to
7 some extent of non-obviousness, it certainly does not outweigh -- it certainly
8 should not outweigh the very strong showing that these claims would have
9 been obvious under the other (INDISCERNIBLE) factors. And so with that,
10 unless there are any questions, Your Honor, I'll reserve the remaining
11 portion of my time for rebuttal.

12 JUDGE PETRAVICK: I have no more questions.

13 JUDGE WOOD: No, thank you.

14 JUDGE PETRAVICK: No, no more questions from the panel.
15 We have about 17 minutes and 45 seconds left for you.

16 MR. BEMBEN: Thank you, Your Honor.

17 MR. HECTOR: All right. I'm going to attempt to share my slides
18 here.

19 JUDGE PETRAVICK: Thank you.

20 MR. HECTOR: I just want to confirm that the Court can just see
21 the slides shared.

22 JUDGE PETRAVICK: Yes, we can see the slides.

23 MR. HECTOR: Okay, great. May it please the Board. Bill
24 Hector on behalf of the Patent Owner. And like Petitioner had also asked for
25 rebuttal time of about 10 minutes, just to kind of lay things out. I'd like to
26 start by turning the Board's attention to Slide 2.

1 So the invention of the '511 patent are treatments for specific
2 regions of female genital tissue, to improve the condition called vaginal
3 laxity. The '511 patent treatments are inventive because they are non-
4 invasive. That is they're not ablative and do not damage or substantially
5 affect the surface layer of the mucosal epithelium. And the '511 patent
6 treatments are also inventive because they apply to very specific regions
7 within the female genital anatomy to improve this condition of vaginal
8 laxity.

9 And as the Board is aware, Petitioner relies on references directed
10 to an entirely different condition, stress urinary incontinence, which is a
11 condition affecting the urinary system and particularly, the bladder outlet.
12 To make this distinction a little bit more clear, I'd like to just briefly provide
13 an overview of the anatomy to orient.

14 There are two main systems that are at issue here with regard to --
15 I'm referring to Slide 3 and this is an excerpt from EX 1015 at plate 360.
16 Broadly, you have the reproductive system, which includes the vulva, the
17 external vagina structures, and the vagina. And then you also have the
18 urinary system, which includes the bladder. At the bottom of the bladder is
19 a feature called a bladder neck, which is connected to the urethra, which
20 carries urine out of the body.

21 And as I mentioned, the '511 patents are treated -- are focused on
22 treating at the distal end of the vaginal canal. The prior art deals with the
23 opposite end of the vaginal canal -- the proximal end -- located at the
24 bladder neck, to address this issue of stress urinary incontinence. As the
25 Board knows, these claims have dimensional requirements, each one of
26 them, as to where the treatments are applied. And a critical aspect of this

1 case is that Petitioner's references are outside of those claimed areas.

2 I'd like to turn next to claim construction, and specifically, to Slide
3 13. And this was the first claim construction term that was addressed in
4 Petitioner's argument and this is with regard to Claim 1 and the treatment
5 area of heating a portion of the vagina extending from the introitus inwardly
6 to a location 1 cm to 3.5 cm in from the introitus.

7 Now, from our perspective, this claim is pretty clear. It's a simple
8 claim that is requiring heating a portion of the vagina from point A, the
9 introitus, to a location, point B, a location 1 cm to 3.5 cm in from the
10 introitus. Petitioner's interpretation, on the other hand, is that we should
11 start at potentially point B and go to point C, but this ignores the from
12 language, from the introitus inwardly to a location 1 cm to 3.5 cm in from
13 the introitus.

14 JUDGE PETRAVICK: Counsel?

15 MR. HECTOR: Particularly -- sure. Yes.

16 JUDGE PETRAVICK: I have a question about how you're
17 reading this claim limitation. The way you read the claim limitation, doesn't
18 it make the fact that there's a 1 cm in there sort of unnecessary? Wouldn't
19 what you're arguing is encompassed by, it would be the same as going from
20 the introitus to 3.5 cm instead of --

21 MR. HECTOR: With --

22 JUDGE PETRAVICK: Why do we have the 1 cm in there if that's
23 what's being read?

24 MR. HECTOR: We actually view this a little bit differently, that
25 the critical point is actually the region from point A to point B to 1 cm. So
26 in order to meet this claim, you must at least treat from the introitus to 1 cm,

1 and then --

2 JUDGE PETRAVICK: So then why does it include the language
3 about the 3.5 cm if that's not what's necessary?

4 MR. HECTOR: I would assume it includes that language to
5 account for varying sizes of anatomy across various patients, but I think our
6 interpretation -- and I think as you pointed out during Petitioner's
7 argument -- aligns with multiple portions of the intrinsic record. I think you
8 pointed to, for example, the '511 patent at Column 11, 48, and this idea of
9 treating the portion of -- it's focused on treating the lower aspect of the
10 vagina -- the lower aspect of vagina being the introitus to 1 cm at least. You
11 know, we're really focused on the introitus here, the lower aspect of the
12 vagina.

13 And the language I think you pointed to -- pointed Petitioner to
14 was treating from the introitus to a position no further than about 3 cm to 4
15 cm inward. There's also language in Column 3, for example, 30 to 34, as
16 well as Column 3, 54 to 59. Also, for example, at Column 3, 54 to 59
17 discusses treating a portion extending from the introitus to a location 2 cm to
18 4 cm in. So I think that the 1 cm to 3.5 cm is to account for the varying sizes
19 of the female anatomy, but the critical aspect from our perspective to meet
20 this claim is that you have to treat from point A, the introitus, to 1 cm in.

21 JUDGE PETRAVICK: So if I treat between 1 cm and 3.5 cm, that
22 does not read on the claim?

23 MR. HECTOR: No. From our perspective, you would need to
24 treat, yeah, at least introitus to 1 cm. I guess if you were treating at 1 cm --
25 maybe you're treating in the introitus to 1 cm.

26 JUDGE PETRAVICK: So it must treat between the introitus and 1

1 cm, and the reason that the 3.5 is in there is no further than 3.5 is how you
2 would read that?

3 MR. HECTOR: That's correct, yeah. And I think you raised the
4 issue of Claim 26 and the additional limitation remodeling comprises
5 tightening the introitus, and I think you key onto the distinction there that the
6 dispute -- the portion we're discussing in Claim 1 regards -- is related to
7 where the heating is applied, and Claim 26 merely provides that you must
8 heat that region in such a way that you would cause tightening of the
9 introitus. So we think that there's no claim differentiation overlap there.

10 I'd like to turn next to Slide 15 and discuss the circumferentially
11 around the vaginal wall element from 1:00 o'clock to 11:00 o'clock that's in
12 Claim 35. And our construction is that you should have to heat multiple
13 contiguous contact sites in the 300-degree arc, extending from 1:00 o'clock
14 to 11:00 o'clock. And just to be clear, the contact sites that we're referring to
15 here are contact sites on the vaginal wall. This is not a contact site on the
16 treatment device itself. You could have a very large electrode that treats in
17 the 300 degree arc and meet this by meeting multiple contiguous contact
18 sites.

19 We'll turn next to Slide 16. Our proposed construction finds ample
20 support in the '511 patent specification, and I believe in a section that
21 Petitioner pointed to discusses the treating of 10 contact sites allows
22 completion of a 300 degree arc of the circumference to get this
23 circumferential treatment. So, you know -- and I think the prior ThermiGen
24 panel additionally discussed that the heating of the vaginal wall should be
25 over a defined arc. And most optimally, over the multiple contiguous
26 contact sites in the 300-degree arc.

1 And just a final point on Claim 35, both experts agree that you'd
2 want to have as many close to contiguous contact sites as possible. Dr.
3 Berenholz, BTL's expert, testified to that, and Dr. Poulos agreed on that
4 point.

5 I'd like to turn briefly back to Slide 10 and just quickly discuss the
6 target tissue element. I think we're in agreement there. Through the
7 briefing, I think we've found agreement on that, that in order to either heat or
8 remodel the target tissue, you must treat the tissue immediately beneath the
9 mucosal epithelium. That is you must treat the lamina propria and
10 muscularis, but it's permissive to treat the endopelvic fascia, but the critical
11 distinction there from our perspective is that you cannot meet the claims
12 heating and remodeling the target tissue with just treating the endopelvic
13 fascia.

14 I'd like to speak briefly about the heating and remodeling
15 construction. Petitioner made the -- and turning specifically to Slide 11 --
16 Petitioner made the point that InMode can't decide whether this 'without
17 substantially affecting the epithelium element' should be in the heating or
18 remodeling. That's not the case. We're simply dealing with the prior context
19 where in the Viveve court, this notion of not substantially affecting the
20 epithelium was embodied in the heating construction, whereas in the prior
21 ThermiGen construction, it was embodied in the -- or included in is probably
22 a better word -- in the remodeling construction, and we think that the
23 intrinsic record supports that it should be included in the remodeling
24 construction, as following the ThermiGen IPR.

25 Turning to Slide 12, we've provided in our briefing substantial
26 citations to the specification, repeatedly talking about protecting the mucosal

1 epithelium providing non-uniform heating that avoids risk of damage to the
2 epithelium. Column 12, 17 to 21, the treatment should be non-invasive.
3 And we've also provided testimony from our expert, as well as identifying
4 the ThermiGen IPR's finding of clear teaching and the Viveve court's finding
5 that this is a critical aspect. And in the reply, as we noted several points,
6 Petitioner did not -- elected not to put forward a reply declaration to rebut
7 any of those points.

8 With that, I'd like to turn to the specific grounds and direct the
9 Court's attention to Slide 21, which is directed to Claim 1 under Ground 1 of
10 Petitioner's petition. And from our perspective, we feel that the proposed
11 combination of Edwards, Mosher, and Ingle fails to teach the required
12 treatment area of introitus inward to 1 cm to 3.5 cm for several reasons.

13 For one, Edwards is focused on treating at the bladder outlet. You
14 see this quote at Column 620, also in the fourth embodiment description, it
15 discusses that 16 to 19 treating bladder outlet hypermobility. And as I think
16 you eluded to during Petitioner's presentation, the Edwards device also
17 inhibits treatment at the introitus, which is required by Claim 1.

18 JUDGE PETRAVICK: Counsel, your argument is very focused on
19 Edwards' reference individually, as opposed to looking at the combination as
20 a whole. And it's a 103 with a proposed sort of combination. Why wouldn't
21 one of ordinary skill in the art, if they wanted to use this device on other
22 locations to treat other similar tissues, use the speculum? Like why wouldn't
23 that be an obvious modification? I mean, one of ordinary skill in the art is
24 not an automaton.

25 MR. HECTOR: I think that idea which Petitioner raises that for
26 the first time in its reply, that the blade can be used separate from the

1 speculum failed for several reasons. First of all, it's nowhere in their
2 petition. It's based on attorney arguing and not supported by any sort of
3 evidence. But moreover, there's no teaching or suggestion of any of the
4 references to remove the blade from the speculum. The Edwards patent is
5 clearly teaching a treatment further into the vaginal canal that requires a
6 speculum and what is treated is not the claimed area. And what BTL is
7 propose is something entirely different from Edwards, and this is classic
8 hindsight bias, kind of deconstructing and redesigning --

9 JUDGE PETRAVICK: Well --

10 MR. HECTOR: -- Edwards.

11 JUDGE PETRAVICK: -- Counsel -- Counsel --

12 MR. HECTOR: Sure.

13 JUDGE PETRAVICK: -- I mean, you keep focusing on the stress
14 incontinence, but as Petitioner points out clearly, Edwards talks about that it
15 could also be used for cosmetic and sexual functions, too. I mean, that is
16 suggested flat out in Edwards. So why, if somebody of one of ordinary skill
17 in the art, having that suggestion from Edwards itself, there seems to be
18 evidence that treating these particular areas was known to be treated with
19 other types of treatments in order to have this desired result of remodeling
20 the vagina in those certain locations.

21 Why wouldn't somebody -- why wouldn't a POSITA have found it
22 obvious to use the same device, which apparently is better because it doesn't
23 cause harm, those harms -- to do something that's very similar to very
24 similar tissue, but in other locations. Specifically, since we know that it is
25 being used on tissue in the vagina. I mean --

26 MR. HECTOR: Sure. So --

1 JUDGE PETRAVICK: -- I don't think somebody would look -- a
2 POSITA would look at the speculum and say, oh now I can't -- that would
3 prevent me from finding this obvious.

4 MR. HECTOR: Well, I guess first of all, there's no description of
5 not using the speculum, and in addition, the fourth embodiment of Edwards
6 makes passing reference to improvements of sexual function, but it's really
7 focused on also this issue of treating hypermobility at the bladder outlet. So
8 from our perspective, it would be a leap for -- and basically a reengineering
9 of Edwards to remove it from -- remove the blade from the speculum.
10 There's no notion in Edwards that one would want to do that. Edwards is
11 providing these treatments for bladder outlet, hypermobility, which are
12 located at the bladder outlet on the --

13 JUDGE PETRAVICK: I mean --

14 MR. HECTOR: -- posterior and anterior wall.

15 JUDGE PETRAVICK: Counsel, it does seem to be that there's
16 plenty of evidence in this record to show that treatment for incontinence by
17 tightening the vagina is also the same type of treatment used for this
18 cosmetic thing and the sexual function. So I have to say that I would look
19 for something more if I was going to find for you that it wouldn't be obvious.
20 What I'm asking you for is there something else, other than what you're
21 telling me is that the speculum would be in the way, which sort of suggests
22 further that one of ordinary skill in the art would have removed it, given that
23 they are a medical doctor.

24 MR. HECTOR: Yeah. Well, I think he raises the issue that
25 Edwards does not provide an invasive treatment. As we'll get to at a point
26 later, Edwards, from our perspective, and it is clearly supported by the

1 record, is an ablative treatment. So it's describing an ablative treatment that
2 is in line with what the background of the '511 patent describes as the prior
3 art surgical methods, which came with risk of scarring and downtime. So
4 from our perspective, there would be necessarily the motivation to modify
5 Edwards in the manner you're setting forth. And maybe it would be helpful
6 to kind of go through some of those -- the kind of background facts that --

7 JUDGE PETRAVICK: Well --

8 MR. HECTOR: -- Petitioner has started with. Yeah.

9 JUDGE PETRAVICK: I mean, is there any criticality to these
10 certain locations? It seems that the modification is taking what Edwards
11 already does. We're not modifying the treatment, but we're using them in
12 other areas. So the fact that there is some sort of -- Edwards for embodiment
13 6 says lesion -- doesn't seem to stop it from being used where it is used.
14 Why wouldn't somebody also use it in other places? I mean, the motivation
15 seems to be sort of a known treatment to be used in one location to do
16 tightening. There are other locations that are known to need tightening.
17 Why, under KSR, would that not be obvious?

18 MR. HECTOR: Because I think you get to a slippery slope type
19 argument there and I think that's kind of the punchline of the Petitioner's
20 position on this. They point to all these conditions that were purportedly
21 known or acknowledged in the background section of the '511 patent as
22 being purportedly known, vaginal laxity, doing surgical treatments to
23 decrease (sic) pleasure, but the innovation and the point of novelty of the
24 '511 patent over the prior art during prosecution was the recitation of these
25 particular areas, and with respect to Claim 1, it's the introitus to 1 cm, and
26 you don't have Edwards treating at that location.

1 And the prosecution -- during original prosecution, you -- the
2 primary reference was Knowlton, which was treating at the uterus, which is
3 also in the vaginal canal. And the prosecution there found it not to be
4 obvious. So I think by presenting these various facts that were purportedly
5 known kind of creates a false backdrop to this. But importantly, what Dr.
6 Poulos in the '511 patent itself acknowledges were not known -- that it was
7 not known to treat vaginal laxity or treat the introitus with a non-invasive
8 procedure. That's at Column 2, lines 17 to 18, and it's further -- Dr. Poulos
9 said -- testified that it wasn't known that RF could be used to improve sexual
10 function. So that's the -- you would have to make that leap in order to -- a
11 person of ordinary skill in the art would have to make that leap to come up
12 with the particular treatment areas, which is the point of novelty of the '511
13 patent and we think that --

14 JUDGE PETRAVICK: So my question is, is that we're talking
15 about obviousness, not novelty here.

16 MR. HECTOR: Yeah.

17 JUDGE PETRAVICK: Right? And I mean, the facts are very
18 important in that, and the fact that we know from other references that it was
19 known to tighten those areas seems to be the missing fact in the leap.

20 MR. HECTOR: But I think the --

21 JUDGE PETRAVICK: I mean --

22 MR. HECTOR: -- key there --

23 JUDGE PETRAVICK: -- you have to agree -- I mean, you do
24 agree that it was known to tighten these areas in order to remodel the vagina
25 to treat cosmetics and sexual function. It might have been used with a
26 different treatment type, but it was known that those areas needed to be

1 tightened.

2 MR. HECTOR: But that's the -- so the things that were known that
3 were surgical treatments that came with risks of downtime there, required
4 anesthesia in a very sensitive area. This is not a procedure that you would
5 likely want to go like subject yourself to is what the '511 patent background
6 acknowledges. But what the '511 patent background also makes clear is this,
7 the idea of the non-ablative, non-substantially -- treatments that don't
8 substantially effective the mucosal epithelium to treat the introitus and
9 vaginal laxity were not known. So that's the leap there you need to make.

10 And I guess in regards to your point on novelty, I'm not sure
11 during the prosecution history, it may have been a combination of Knowlton
12 and other references, so I may have spoken out of turn there, whether that
13 was obviousness or novelty, but I'd have to take a look at that.

14 JUDGE PETRAVICK: But Knowlton is not at issue here. It's not
15 a basis of the grounds.

16 MR. HECTOR: No, but I was just using that as a comparison to
17 the analysis that happened during original prosecution. Okay. So I'd like
18 to -- unless you had further questions on that?

19 JUDGE PETRAVICK: I do not.

20 MR. HECTOR: We can move -- okay, great. So in the reply, the
21 Petitioner puts forth this belated theory that, pointing to portions of Edwards
22 that describes the result of heating, but not the actual treatment itself, and
23 that the result of the heating may provide support at proximal and mid-
24 urethra, but Dr. Poulos' testimony was clear that this is -- that Edwards
25 describes treating at the bladder neck, but it may provide support for other
26 portions.

1 I'd like to turn to Slide 24 and specifically, the Mosher reference.
2 Mosher is clear repeatedly throughout that it is treating the endopelvic
3 fascia, which Dr. Berenholz testified is located at the bladder neck, as shown
4 in this quote here at EX 2005; 79. And in addition, Dr. Poulos testified at
5 paragraph 105 that the endopelvic fascia is also adjacent to the bladder. So
6 it's clear from the record that Mosher's treatments are at the bladder neck.

7 Turning to Slide 25, Petitioner cites and discussed during the
8 presentation this portion of a 25 x 15 mm, in paragraph 74 of Mosher. This
9 is just basically defining the shape of a square, where the treatment may
10 have occurred, but it doesn't provide any location within the vaginal canal
11 itself, let alone any location relative to the introitus, so it doesn't demonstrate
12 that Mosher was treating in the introitus region.

13 A couple things. So, Petitioner -- turning to 26 -- Petitioner does
14 not dispute that Edwards' speculum inhibits treating the introitus and in
15 addition Petitioner fails to specifically say how a POSA would modify
16 Edwards or that there was a motivation to do so.

17 I'd like to turn next to Slide 29, and specifically, Claim 35. And
18 for this element, Petitioner, again, relies on Edwards' fourth embodiment,
19 which describes providing RF energy to the anterior and/or posterior regions
20 of the vaginal wall. And this argument doesn't meet the claim elements for
21 several reasons. First of all, the anterior wall is outside of the claimed
22 treatment area. That's within the 11:00 o'clock to 1:00 o'clock region. And
23 second, the posterior wall provides treatments at discrete points due to the
24 fact that Edwards' treatment is applied through a speculum that is placed into
25 the vagina.

26 Turning to Slide 30, in the reply, Edwards -- or Petitioner, again,

1 points to the results of the Edwards disclosure, but not the actual treatment
2 in the statement with regard to embodiment 4 that remodeling both the
3 anterior and posterior wall may provide circumferential vaginal wall
4 tightening, but Edwards doesn't explicitly describe heating in a
5 circumferential manner. And in effect, with regard to the Edwards
6 description, it doesn't suggest that the blade is moved in any way. It's held
7 in place by the speculum and to the extent there are a series of lesions, those
8 would be extended longitudinally because the speculum is never moved
9 within the vaginal canal.

10 I'd like to turn briefly to the external treatments and direct the
11 Board's attention to Slide 33. The key point here, and I think Petitioner
12 acknowledges this, that none of the Edwards, Mosher, and Ingle references
13 discuss any sort of treatment in the external genital area, and I think
14 emblematic of that is the fact that the Petitioner's only recitation of the Hart's
15 line are quoting to the '511 patent itself. There's no disclosure in any of
16 Edwards, Mosher, Ingle, or Ollivier of the Hart's line -- of treating the Hart's
17 line. And Petitioner does not dispute that the references are treating at the
18 bladder neck..

19 Again, Petitioner improperly focuses on what a POSA would have
20 been able to do, rather than what they would've been motivated to do. And
21 there would be no motivation based on -- and I think Petitioner pointed to
22 there's passing references in Ingle to cosmetic surgery or Edwards'
23 references to treating unwanted conditions. These fall well short of any sort
24 of providing a motivation for a POSA to take the treatments of Edwards,
25 Ingle, and Mosher, which are well inside the vaginal canal and somehow
26 modify those to treat the external tissue structures.

1 JUDGE PETRAVICK: Counsel?

2 MR. HECTOR: Yes.

3 JUDGE PETRAVICK: Counsel, there's teachings in those
4 references that the device could be used on other tissues. They're not
5 specific, but it does suggest that you could use the device on other tissues.
6 In your -- the background section of your own Patent Owner's response, you
7 cite a reference, Exhibit 2013. Exhibit 2013 tells us that in 2005 it was
8 known that you would want to tighten vulvar structures to get tightening of
9 the labia and the internal vaginal skin. Why isn't it within one of ordinary
10 skill in the art to know that -- which structures would need tightening?

11 MR. HECTOR: Well, I think for one -- I'm not sure -- was that
12 argument raised in Petitioner's papers?

13 JUDGE PETRAVICK: You provided this evidence. It came from
14 you. I'm looking at the --

15 MR. HECTOR: Yeah.

16 JUDGE PETRAVICK: -- evidence you provided.

17 MR. HECTOR: Okay. Sorry, that was EX 2013?

18 JUDGE PETRAVICK: Yes. It's cited --

19 MR. HECTOR: Okay.

20 JUDGE PETRAVICK: -- in the background of your -- when you
21 were telling me about the background of the procedures in your --

22 MR. HECTOR: Okay, yeah. I --

23 JUDGE PETRAVICK: -- Patent Owner's response.

24 MR. HECTOR: Okay, great. Sorry, it just took me a second there
25 to orient.

26 JUDGE PETRAVICK: It's okay.

1 MR. HECTOR: So EX 2013 is an article from Dr. Alinsod
2 regarding the prior surgical approaches that were performed at the time, and
3 that article goes into grave detail about all of the blisters and burns and nasty
4 side effects that would be associated with surgical techniques applied to the
5 external structures. And the background of the '511 patent itself also
6 acknowledges that those prior surgical techniques came with this risk of
7 scarring and other nasty side effects.

8 JUDGE PETRAVICK: But it also tells us directly what one of
9 ordinary skill in the art would know, that certain areas of the vagina need
10 tightening, and it tells us that those areas include the vulva and the labia,
11 which would be the external portions, that those are in need of tightening.
12 So why wouldn't that be within the knowledge of one of ordinary skill in the
13 art it says in 2005 --

14 MR. HECTOR: The --

15 JUDGE PETRAVICK: -- that those are the portions that need
16 tightening -- that are tightened by other procedures?

17 MR. HECTOR: Yeah. I mean, Dr. Poulos testified herself that
18 labiaplasties were performed since the early '90s, but yet no one came
19 forward with -- and actually disclosed these particular treatments in the
20 manner described in the '511 patent, despite labiaplasties being performed
21 since at least the 90s and maybe earlier. So you have decades of time where
22 these surgical techniques were used and no one until the '511 patent came
23 along -- came to define these specific areas of treatment.

24 And then also, returning back to that EX 2013, the Alinsod article,
25 Dr. Alinsod is the same doctor who described treatments aligning directly
26 with the claims of the '511 patent that landmark years after the '511 patent

1 was filed. So, the notion that the surgical approaches were known, I think it
2 was also known that those surgical approaches came with this risk of
3 scarring that was counterproductive and --

4 JUDGE PETRAVICK: But Counsel, the issue is --

5 MR. HECTOR: Yes.

6 JUDGE PETRAVICK: The issue is not whether the previous
7 devices or lasers were -- created scarring. You told me in the prosecution
8 history the point of novelty that was added to these claims was the location
9 and where the device was used, but this article and sort of the testimony
10 you've pointed to tells us that tightening in these locations was known.

11 MR. HECTOR: But it was known --

12 JUDGE PETRAVICK: I mean, are you --

13 MR. HECTOR: Yeah.

14 JUDGE PETRAVICK: Do you agree with me that it was own
15 maybe with using other surgical procedures, that tightening was needed in
16 these locations? The vulva and the external -- the labia.

17 MR. HECTOR: I think if it says that in the Alinsod article. But
18 yeah, I think the key there is that those procedures were also known to have
19 these side effects. And in addition, there was no specificity known in the
20 public art as to how to perform these procedures and I think that's why the
21 Petitioner has come forward with Ollivier. There's no -- we do have
22 testimony from Dr. Poulos saying that she did perform labiaplasties, but the
23 only specific evidence they've come forward with -- the Petitioner has come
24 forward with is this vague article from Dr. Ollivier describing external
25 treatments with absolutely no specificity --

26 JUDGE PETRAVICK: Well, I'm looking at the evidence that you

1 provided to me about where these previous procedures were performed, and
2 that's in the vulva and the labia, and the internal vaginal skin. Those are the
3 areas that we are -- that's claimed.

4 MR. HECTOR: Yeah. I think just the distinction there is that
5 those treatments were performed in a highly invasive manner, whereas, the
6 improvement here in the '511 patent is performing these treatments in a non-
7 invasive manner in these specific locations and no one had done that until
8 the '511 patent. I mean, I think the background acknowledges that there
9 were surgical approaches that existed before.

10 JUDGE PETRAVICK: All right, thank you.

11 MR. HECTOR: And yeah, turning to Slide 34, I mean, Dr. Poulos,
12 some of her concessions regarding this were related to the Ollivier reference,
13 which we'll get to in a little bit further down the road. Just looking at the
14 time. I'd like to briefly address this issue of remodeling the target tissue.
15 Can you still see my slides hopefully?

16 JUDGE PETRAVICK: Oh, yes, we can. Thank you.

17 MR. HECTOR: Okay, great. And specifically, with regard to
18 Slide 37, as we set forth there's no dispute as to target tissue and we think
19 that the proper construction -- remodeling is that it must treat the tissue
20 without substantially affecting the epithelium. And from Patent Owner's
21 perspective, the Edwards, Mosher, and Ingle combination does not meet the
22 remodeling the target tissue element for several reasons.

23 For one, Edwards' ablates and creates lesions in the target tissue.
24 The tissue immediately below the mucosal epithelium, and then Mosher and
25 Ingle actually cool the target tissue and are focused on remodeling
26 endopelvic fascia. Turning to Slide 38, it's clear from Edwards itself that it's

1 creating ablative lesions in the --

2 JUDGE PETRAVICK: Counsel, it's not flipping the slides as
3 you're --

4 MR. HECTOR: Oh, it's not?

5 JUDGE PETRAVICK: -- talking. No.

6 MR. HECTOR: Oh, sorry. I'm turning now to Slide 38. Is that
7 what you see?

8 JUDGE PETRAVICK: Yes.

9 JUDGE WOOD: Yes.

10 JUDGE PETRAVICK: Thank you.

11 MR. HECTOR: Okay. Yes, in turning to Slide 38, the Edwards
12 description is clear that the lesions created in the vaginal wall are ablative
13 and this is -- finds support in Edwards, Column 3, 5 to 9, which describes
14 the only difference between the fourth embodiment, which involves treating
15 of the vaginal wall and the other embodiments, is that RF energy is delivered
16 to the anterior and posterior regions of the wall.

17 It's clear that just like the other embodiments, the fourth
18 embodiment is ablative and that's also evidenced by the fact that the
19 advantage of Edwards that it requires only local or regional anesthesia,
20 which would be necessary if you're creating ablating lesions in that sensitive
21 area. So from our perspective, Edwards does not meet the remodeling the
22 target tissue because it's ablating the target tissue.

23 Turning to Slide 40, Petitioner points to passages describing
24 irrigating cooling fluid in Edwards, but it's clear from the description and the
25 testimony of Dr. Poulos that this is -- the cooling fluid is to protect against
26 collateral damage to associated structures, so what Edwards is really

1 describing is you're ablating the actual tissue that the electrodes are in
2 contact with and then running cooling fluid through to prevent collateral
3 thermal damage.

4 But regardless, turning to Slide 41, Petitioner's expert testified that
5 a lesion would be a thermal injury of some kind that Edwards is substantially
6 affecting the mucosal epithelium. Turning briefly to Mosher, Mosher
7 describes actually treating the endopelvic fascia and cooling the intermediate
8 tissues. In other words, cooling the tissues contemplated by the '511 patent,
9 the target tissues contemplated by the '511 patent, the lamina propria and
10 muscularis.

11 Petitioner points to various -- turning to Slide 43 -- of these
12 laundry list passages in Edwards that list a whole slew of anatomical
13 structures, including the lamina propria, but Mosher provides no specificity
14 as to how any of those structures would be heated. All of Edwards -- oh,
15 sorry -- of Mosher's description is related to treating the endopelvic fascia.
16 And Ingle also does not -- also cools the intermediate tissue, the tissue
17 immediately below the mucosal epithelium and fails to meet this element for
18 the same way as Mosher.

19 I'd like to turn now to Ground 2 and specifically, the Ollivier
20 reference. And with respect to Slide 49, the Ollivier reference failed for
21 several reasons. It's not (INDISCERNIBLE), it's not a valid printed
22 publication, and it does not teach or suggest the claimed treatment regions.

23 Ollivier, as the Board is likely aware, is a Salon.com article that
24 vaguely describes what one doctor was supposedly -- treatments that one
25 doctor was supposedly performing. But Ollivier is clear that those
26 treatments are not documented anywhere, in any journal, peer reviewed

1 study. It makes clear that the details of the treatment were not provided
2 within the article itself, and the Ollivier article itself actually has quotes from
3 other doctors talking about run, run away from this Dr. Matlock's treatment.

4 Turning briefly to Slide 50, both experts in this case were clear that
5 the alluded to technique in the Ollivier reference was kept confidential. You
6 were required to sign an NDA, pay a hefty fee to study with Dr. Matlock.
7 There's no showing that the treatments within Ollivier were described with
8 any specificity or that they were well known.

9 Just turning briefly to printed publication. It's telling here that
10 neither of the experts had ever heard of Salon.com until this case. In fact,
11 Dr. Berenholz learned about it during his deposition and Petitioner's
12 evidence from the way back Wayback machine is insufficient.

13 Turning to Slide 53, there's just no evidence that Ollivier was
14 indexed. There's no evidence that a person of ordinary skill, a doctor
15 practicing in these areas, would have been familiar with Salon.com, and
16 there's no evidence that Ollivier was sufficiently accessible to the public
17 interest in the art.

18 And in addition, I think Dr. Berenholz's testimony brings forth
19 kind of the distinction with Ollivier and makes it clear that Ollivier is
20 describing this laser that's being used to cut, shrink, and ablate tissue. These
21 are procedures that require surgery, lots of down time, which are in stark
22 contrast to the non-ablative -- substantially non-ablative to the mucosal
23 epithelium treatments provided by the RF device contemplated by the '511
24 patent.

25 I'd like to turn just briefly to secondary considerations, and just to
26 set the stage here a little bit. So the evidence that we have put forward are

1 two studies that were published well after the filing of the '511 patent called
2 the Sekiguchi and Millheiser studies, and Dr. Berenholz, BTL's expert,
3 described these studies as landmark studies. I think Petitioner challenged
4 the fact that we have maybe not shown that these studies were co-extensive.
5 I'd like to just speak to that briefly. We've gone well beyond showing that
6 the Sekiguchi and Millheiser studies are reasonably commensurate with the
7 scope of the claims.

8 For one, the treatments are non-ablative as repeatedly described in
9 the claims and specifications of the '511 patents. The treatments use cooling
10 and gel to protect the epithelium. The treatments are located at the introitus
11 to 1.6 cm directly within the Claim 1 treatment region. These studies also
12 discuss the effects of tightening the introitus, directly in line with Claim 26.
13 The studies also describe in great detail treating around the entire
14 circumference from 1:00 o'clock to 11:00 o'clock, as required by Claim 35.

15 And ultimately, InMode is not required to produce objective
16 evidence of non-obviousness of every potential embodiment of the claim.
17 That's the *Rambus v. Rea* decision, but Petitioner's one challenge is that the
18 studies discuss cooling, but cooling is only one of the ways to not
19 substantially effect the epithelium.

20 Dr. Poulos testified that you could also use gels, which the
21 Sekiguchi and Millheiser studies discuss. You could also use movement,
22 uniform heating, which is described as protecting against substantial damage
23 in Column 2, lines 52 to 63 of the patent. And I think more importantly,
24 neither of these studies states that cooling is a critical feature and again,
25 using the *Rambus* decision as a guide, you don't need to show objective
26 indicia aligns with every embodiment of the claims, but we've put forth a

1 strong showing that it's coextensive with Claims 1, 26, and 35.

2 So for those reasons, we believe that there's a strong showing of
3 secondary indicia of non-obviousness in the form of enabling. And in
4 addition, this study was published by Dr. Alinsod and ThermiGen, and
5 ThermiGen also took a license to the '511 patent well into litigation, which is
6 a further indicia of non-obviousness. Unless the Board has any further
7 questions, I'd like to reserve the rest of my time.

8 JUDGE PETRAVICK: I do not.

9 JUDGE WOOD: No, thank you.

10 JUDGE PETRAVICK: So you have about 10 minutes and 20
11 seconds left of your time.

12 MR. HECTOR: Thank you.

13 JUDGE PETRAVICK: So we'll hear from Petitioner, again, but
14 please give me a minute to reset the clock. I'm just going to round that up to
15 18 minutes and we'll also round up Petitioner's time. You can begin when
16 you're ready.

17 MR. BEMBEN: Sure. I'll start by addressing some of the points
18 that InMode's Counsel just made. So with respect to secondary
19 considerations, there argument for nexus was that they're entitled to a
20 presumption of nexus. That's on page 69 of the Patent Owner response.
21 This argument that they're entitled to nexus or that there's a nexus for other
22 reasons or under something less than the presumption is new in the Patent
23 Owner's surreply. Also, just to remind the Board that they argued the
24 presumption of nexus only for Claims 1, 26, and 35; there were no other
25 claims that were argued under the secondary considerations.

26 With respect to the arguments that Counsel just made regarding

1 public availability and enablement of Ollivier, enablement -- that argument
2 is simply a red herring. We're not relying on any of the treatment that's
3 described there. The only thing that we're relying on Ollivier for is the
4 locations, which would be treated and were known to be treated.

5 It does not matter that neither of the physicians, the experts in this
6 case, knew of Salon.com. That is not the test for whether a reference is
7 publicly available. That test is provided by the Blue Calypso case, which
8 explains that if persons of ordinary skill or they're interested in the art,
9 exercising reasonable diligence could've found it, that is the test for
10 determining whether something is publicly accessible. And I'll reiterate
11 what I said in my opening is that you heard a number of reasons from
12 opposing Counsel why they believe that the reference is not publicly
13 available. They did not address the research aids that we discussed with
14 respect to -- I'm going to move to Slide 55 of our presentation.

15 Again, Blue Calypso instructs that research aids demonstrate
16 public availability. Here we have two articles that predate the patent, 2003
17 on the left-hand side -- it's really hard to see, but it's 2002 on the right-hand
18 side. These publications we're citing to the Ollivier document. This
19 document was publicly available, and it teaches treatment locations.
20 Nothing else is needed.

21 Kind of taking a step back, and I think Your Honors alluded to it a
22 bit, is that InMode is arguing the referencing individually. We heard a lot
23 about Edwards doesn't teach this, Edwards doesn't teach that, which we
24 disagree with, but we just want to reiterate, the combination is based on
25 Edwards, Mosher, and Ingle. And so, for example, there was discussion
26 about limitation 1.3 and I'm going to go to Slide 43.

1 This is an exhibit from Dr. Poulos' deposition. It's also an exhibit
2 in Netter, which is an anatomy textbook, and just to discuss a little bit about
3 the references and what they teach. So as I mentioned before, Mosher in
4 paragraph 48 expressly teaches that there are situations in which the
5 endopelvic fascia is not present anymore because of childbirth and that
6 specifically teaches treating structures of the vagina, including the lamina
7 propria, which is the dense connective tissue just underneath the epithelium.

8 Now, in paragraph 54, Mosher also teaches preferably the location
9 of the treatment volume is disclosed along the length of the urethra between
10 the bladder neck and the external meatus. Again, that's through the vaginal
11 canal, but treating those regions. And what we have on Slide 43 is Dr.
12 Poulos, InMode's expert's own annotations of this figure.

13 On the right-hand side, annotation in red are the annotations of the
14 vaginal canal on the left-hand side are annotations of the urethra. Starting
15 kind of going clockwise, she labeled the proximal portion in red of the
16 vaginal canal, the mid-portion and the distal portion, which is also known as
17 the introitus. Continuing clockwise, we have in blue, the distal portion of
18 the urethra, the mid-urethra, as well as the proximal portion of the urethra,
19 which is close to the bladder neck.

20 Now, treating the area along the length of the urethra, from the
21 bladder neck to the external meatus, if you look at where that treatment
22 location would be with respect to the corresponding location in the vaginal
23 canal, that is from the introitus, up through about the mid portion of the
24 vaginal canal. That would certainly be within the first centimeter, introitus
25 to 1 cm, that is described in element 1.3.

26 With respect to element 35.3, InMode argued that treating the

1 posterior wall would not meet that limitation. This is the circumferential
2 limitation. Here, I'm going to go to the deposition transcript of Dr. Poulos.
3 This is another exhibit from Netter that was attached. This is Exhibit 1032
4 at page 197. And what this is showing is the inferior view of the vaginal
5 canal. This is -- the patient would be lying with their belly button pointing
6 upwards, you see the rectum below, the vagina, and then the urethra above,
7 and Dr. Poulos labeled the anterior wall, the lateral walls, and the posterior
8 wall -- A, L, and P of the vagina. As you see, the posterior wall is a large
9 portion of the bottom part of the vagina that would include multiple contact
10 sites if you're treating that location, as Edwards teaches.

11 Now, I want to reiterate our point above. There was some
12 discussion about claim construction and about different claim terms and
13 what they mean. Our position is that the prior art renders obvious the claims
14 under any of the proposed constructions, and this kind of dovetails with
15 InMode's argument that we didn't provide a reply declaration.

16 Just because we didn't provide a reply declaration does not mean
17 that InMode's evidence is unrebutted. No reply declaration was necessary
18 because Dr. Berenholz's original declaration covered the proposed
19 constructions and arguments that InMode made here. We knew this because
20 of the ThermiGen dispute -- the prior ThermiGen dispute at the Board, and
21 also the Viveve litigation. We knew what the proposed constructions would
22 be, we anticipated them. We also knew what some of their arguments would
23 be and anticipated them, and Dr. Berenholz's testimony does rebut those
24 arguments that they presented here.

25 Additionally, a reply declaration wasn't necessary because Dr.
26 Poulos made key admissions on cross-examination. We encourage you to

1 look at her deposition transcript. This is Exhibit 1032, starting at page 84,
2 line 20 through 91-6. We walked her through the background, all the
3 paragraphs in the background section of Dr. Berenholz's declaration,
4 describing the state of the art, and there was much agreement with respect to
5 what was known, treatment locations, types of treatments during that -- or in
6 her testimony.

7 There were a few minor disagreements where she talked about she
8 didn't know about a particular device that Dr. Berenholz was talking about,
9 but for the most part, she agreed with the state of the art, what was known.
10 She admitted that the problem was known. She admitted that it was known
11 to treat the introitus, the vulva, and the labia for cosmetic purposes, and she
12 acknowledged that doctors exercise judgment when determining whether to
13 use a speculum or not. For all those reasons, all those admissions, it was
14 unnecessary to provide a reply declaration, but those positions are rebutted.
15 InMode's positions are rebutted.

16 InMode also argued that we did not provide a motivation to
17 combine Edwards, Ingle, and Mosher. That is simply untrue. The petition at
18 23 through 24, it discusses motivation to combine and reasonable
19 expectation of success. It explains it very similar to the way that Judge
20 Petravick characterized it, talking about applying a known treatment to
21 known portions that were ready for improvement.

22 And what we have said in there is that it's the combination of
23 Edwards provides specific -- general teachings with respect to treating
24 collagenated tissue, doesn't provide specifics such as the time and
25 temperature, which are kind of important for some of the dependent claims,
26 but also some of the treatment locations and the specific tissues that would

1 be treated, as well as the physiological response, which is described in great
2 detail in some of the other prior art references. And so for that reason, it's
3 not a novelty rejection we're talking about. It's obviousness based on the
4 combination of those three references.

5 Moving to Slide 36 of our presentation, I just want to reiterate
6 something. This is with respect to InMode's argument about the lesions and
7 lesions in Edwards. As I mentioned, we're not relying solely on Edwards'
8 teachings. Mosher, as we have on the right-hand side, paragraph 58, talks
9 about pre-cooling and that pre-cooling can inhibit heating of the intervening
10 tissue to temperature causing surface lesions within the vagina. The
11 combination of the references would have taught -- to the extent that not
12 substantially affecting the epithelium is required, which we do not believe it
13 is, but to the extent that it is, the references clearly cover protecting the
14 epithelium, the intermediate tissue, as well as just taking a step back. A
15 person of ordinary skill in the art is a physician that has experience using
16 these types of treatments. That person would know to prevent damage to
17 other areas when you're performing cosmetic surgeries or treatments that are
18 intended to improve sexual functionality. You'd be trying to protect those
19 areas as all of the references discuss.

20 Unless there are any questions, just to wrap up, as I began the
21 presentation, what has come out here is that, again, by February 2006, which
22 is the earliest possible priority date, persons of skill in the art knew about the
23 problem, they knew about the treatment methods and the physiological
24 response, and they knew of the anatomical locations to treat in order to
25 address those problems. Dr. Berenholz testified that the vagina is a small
26 region. A person of skill -- a highly skilled person would know where to

1 treat, would exercise their judgment based on the patient's desired outcome,
2 as well as the patient's anatomy. This is a clear cut, quintessential KSR type
3 obviousness case. We ask that you find the claims obvious. I have nothing
4 further, Your Honors.

5 JUDGE PETRAVICK: Thank you. Are there any other questions
6 for Petitioner?

7 JUDGE WOOD: No, thank you.

8 JUDGE PETRAVICK: We have no more questions. Thank you.
9 So Patent Owner, you have -- I'm going to give you 11 minutes. Round up.

10 MR. HECTOR: Thank you very much. May it please the Board.
11 Just to respond to a few of those points in turn. I think one of the first
12 arguments that Petitioner made in the rebuttal was that Olivier somehow
13 defines the locations where the treatments occurred. Olivier does not
14 suggest treating in the introitus to Hart's line. It doesn't use that term, nor
15 does it discuss the mucosal surface of the labia minora. In fact, it's a
16 surgical technique that would be just removing entire swaths of tissue. So
17 we disagree that Olivier actually treats those locations.

18 Next, turning to this idea related to the heating and remodeling
19 portion that -- Petitioner made the point that Mosher somehow provides the
20 particular structures and tissue structures that should be heated. You know,
21 as I stated in my opening presentation, Mosher does address -- it does list a
22 slew of tissues, including the lamina propria, but Mosher only discusses -- it
23 just provides this list, but it doesn't provide any sort of guidance on how a
24 physician would necessarily apply heat to those structures.

25 The only tissue structure that Mosher discusses in detail is the
26 endopelvic fascia and I think Petitioner alluded to the fact that maybe a

1 doctor would know to prevent damage, but there's a lot more that goes into it
2 than just knowing to prevent damages, knowing particularly how to heat to
3 avoid affecting those particular structures, and Mosher provides no guidance
4 on how to heat and avoid potential damage to the lamina propria or any
5 other structures. In fact, Mosher describes cooling those structures along
6 with Ingle and Edwards itself ablates through those structures.

7 Regarding motivation to combine, Petitioner argues that we did not
8 respond to their motivation to combine. In fact, it's a bit of the opposite.
9 We provided specific points demonstrating why there would be no
10 motivation to combine Edwards, Ingle, and Mosher, for example, in our
11 Patent Owner response at 38, 39, 45, 46, 48 to 50, and 59, and the Petitioner
12 did not respond to any of those in its reply.

13 That gets to the point of the Petitioner's decision to not submit a
14 reply declaration, and I think this is critical for several reasons. For one, the
15 decision to decide not to submit a reply declaration is a decision the
16 Petitioner made, but it's critical here because in multiple places, Petitioner
17 puts forth new arguments in its reply that are not supported by its expert
18 declaration. Mainly, Petitioner made the argument with regard to Mosher
19 and specifically to Claim 1 of Mosher -- let me get there -- and this idea of
20 Claim 1 of Mosher treating the elements of -- or treating the treatment area
21 of the introitus inwardly from 1 cm to 3.5 cm.

22 In its reply and as represented on BTL Slide 42, the Petitioner put
23 forth this new argument that this passage described in the urethral meatus
24 somehow would denote treatment in the range denoted by Claim 1 introitus
25 to 1 cm to 3.5 cm. You know, this is a new argument in the reply, it's pure
26 attorney argument.

1 The Petitioner's expert in no way discussed this in his opening
2 declaration and it's still -- the argument is still defective on its face because
3 Dr. Berenholz testified that Mosher is treating at the endopelvic fascia and
4 the endopelvic fascia is located at the bladder neck, and that specific
5 paragraph of Mosher at 54, including the language regarding the urethral
6 meatus, discusses treatment of the endopelvic fascia and Dr. Poulos also
7 made that clear, that the endopelvic fascia is located at the bladder neck.

8 And in addition to that, this occurs in several places where the
9 Petitioner introduced new arguments in its reply that were not supported by
10 any sort of expert testimony because it elected not to submit a reply
11 declaration. So it's not -- I think there is a significant distinction there. And
12 in addition, another reason the Petitioner said they didn't submit a reply
13 declaration is they supposedly got key admissions from Dr. Poulos, citing to,
14 I believe, 84, line 20 to 91, line 6 of her deposition testimony. All of those
15 purported admissions were Dr. Poulos acknowledging things that were
16 described in the background section of the '511 patent or that LVR
17 treatments were practiced by at least one doctor. Those are not new
18 admissions that somehow changed the face of the case or made it
19 unnecessary to submit a reply declaration. That's just simply not the -- those
20 are not key admissions in any way. They're just acknowledging what was
21 already in the record.

22 And I think that gets to the fundamental point also that we were
23 discussing earlier here. You know, ultimately, the '511 patent and BTL
24 comes forth with this evidence of lots of things that they would say were
25 purportedly known before the '511 patent and we've discussed a lot of those
26 today, treating for vaginal laxity, tightening via collagen denaturation, that

1 one doctor was performing LVR, that surgical techniques were performed to
2 treat the various vaginal structures.

3 It's one thing to know that some of these certain areas may need
4 tightening, as performed by surgical approaches, but it's another thing -- and
5 this is the invention of the '511 patent -- is how to do that in a non-
6 destructive way, in a way that doesn't require downtime or the risks of
7 scarring associated with this prior art -- potential prior art techniques. And
8 the key distinction here, again, is that the '511 patent acknowledges that
9 treating vaginal laxity and then treating the introitus with a non-invasive
10 procedure was not known and it was not known that RF energy could be
11 used to improve sexual function by treating these specific areas defined in
12 Claims 1, 26, 35, 43, and 51.

13 So for those reasons, we think that both Grounds 1 and Grounds 2
14 fail to prove that those claims are obvious, and the patentability of all '511
15 patent claims should be withheld. Unless you have any further questions,
16 that concludes my presentation.

17 JUDGE PETRAVICK: We have no further questions. I want to
18 thank you for coming here today and providing us with this information.
19 We have a lot to consider. We are adjourned.

20 (Whereupon, the above-entitled matter went off the record at 10:59
21 a.m.)

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