UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

BTL INDUSTRIES, INC., Petitioner,	Case No. IPR2024-00703
vs.	
INMODE LTD., Patent Owner.	Patent No. 8,961,511

Deposition of DR. DENISE POULOS, taken in the above-captioned cause, at 227 West Monroe Street, Suite 1900, before Rachel F. Gard, CSR, CCR, RPR, CRR, Notary Public, commencing at the hour of 9:30 a.m. Central on Tuesday, April 8, 2025.

BTL EX1032
IPR2024-00703
U.S. Patent No. 8,961,511

Dr. Denise Poulos
April 08, 2025

APPEARANCES:

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	(Exhibit Nos. 1, 2, and 3 attached. All others retained by counsel.)	

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(Witness sworn.)

WHEREUPON:

DR. DENISE POULOS,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

CROSS-EXAMINATION

BY MR. BEMBEN:

Q Please state your name for the record.

A Denise Poulos.

Q Do you understand that you're under oath today?

A Yes.

Q Are you on any medication that would impair your ability to give truthful testimony?

A No.

Q Is there any reason today that you cannot give truthful testimony?

A No.

Q Are you represented by counsel today?

A I don't know how to answer that.

Q Okay. Let's go over some ground rules for the deposition today. I ask that you provide verbal answers so that the reporter can transcribe our conversation, so let's try not to speak over each other.

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Is that okay?

A Yes.

Q You understand that I'm here today to ask the questions and you're here to answer them, correct?

A Yes.

Q If you don't understand a question that I've asked, please let me know and I'll try to clarify it. Okay?

A Okay.

Q But if you answer a question, I'll assume that you understood the question.

Is that fair?

A Yes.

Q We can try to take a break every hour or so. If you need a break, just let me know. The only thing that I ask is that, you know, we wrap up a line of questioning or the question that we're on.

Is that okay?

A Yes.

(Exhibit Number 2001 previously marked for identification.)

Q So I'll introduce your declaration now so you can consult it any time you need to during

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today's deposition.

If I'm asking questions during the deposition and you feel the need to consult another document that's in the record, just ask. I'm not here to, you know, fool you or surprise you. If there's something you need to reference, let me know and I'll introduce it.

Okay?

A Okay.

Q With that -- I guess before we start, since it's remote today, can you just generally describe where you are, who you're with, et cetera?

A I'm at Venable law offices in Chicago, and we're in a conference room.

Q And who's with you?

A I'm with Bill Hector, Parker Zimmerman, and Raquel?

THE COURT REPORTER: Rachel.

A Rachel, our court reporter.

Q Okay. And did you bring any materials to the deposition with you?

A No.

Q You don't have any notes or anything along those lines?

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A No.

Q Okay. So, Mr. Hector, Bill informed me before the deposition that you have paper copies of the exhibits that we'll be discussing today.

MR. BEMBEN: Bill, can you provide the Exhibit 2001, which is Dr. Poulos' declaration.

Q Did I pronounce your name right, Poulos?

A Poulos, yeah.

MR. HECTOR: Sure, yeah. Just for the record, Bill Hector of the Venable law firm, along with me, Parker Zimmerman, also of the Venable law firm on behalf of the witness and plaintiff -- or I guess defendant in this action.

A Can you repeat? Did you ask for me to open the declaration?

Q Just can you confirm that the document that you were just provided is a copy of your declaration in this matter?

A Yes, it is.

Q Can you turn to the last page of your declaration?

A Yes.

Q Do you see your signature on that last page?

A I do.

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Q Okay. And you signed the declaration?

A Yes.

Q Okay. So another important document we'll talk about today is the '511 patent, which is Exhibit 1001.

MR. BEMBEN: Can you guys provide a copy of 1001, please?

(Exhibit Number 1001 previously marked for identification.)

A I have it in front of me.

Q Have you seen this document before, Dr. Poulos?

A Yes, I have.

Q Okay. And is it okay if I refer to this document as the '511 patent?

A Yes.

Q Did you read the '511 patent in preparing your declaration?

A Yes.

Q Did you read it from cover to cover?

A Yes, I did.

Q Did you understand the '511 patent?

A I believe I understood a great deal of it.

Q Is there anything that you didn't understand?

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A Nothing specific that I could point out at this time.

Q Okay. Did you read all the claims of the '511 patent?

A Yes, I did.

Q Do you understand what I mean when I say "claim"?

A I believe so.

Q Tell me what your understanding is.

A May I turn to my declaration?

Q Yes.

A Are you asking for what a claim is or specific claims?

Q No. I'm just asking, you understand that the claims of the patent are at the end of the patent? In this case, they're labeled 1 through 58. You understand that, correct?

A Yes.

Q Do you understand that the claims define the scope of the invention?

A Yes.

Q So when you prepared your declaration, did you read all the claims?

A I did read all the claims.

Q Did you understand them?

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A I believe I did.

Q Is there anything that you did not understand?

A Nothing specifically.

Q Okay. Can you turn to the front page of the patent, the '511 patent?

A Yes.

Q Do you see that the '511 patent was filed on February 7, 2007? It's on the left-hand side.

A Yes.

Q Do you see that the '511 patent claims priority to what's called a provisional application that was filed on February 7th, 2006? Left-hand side below the filing date.

A Yes.

Q In preparing your declaration, did you review the provisional patent application, which is No. 60/743247?

A I don't recall.

Q Do you understand that the earliest possible priority date of the '511 patent is February 7th, 2006, which is the date of that provisional application?

MR. HECTOR: Objection. Legal conclusion.

A I don't understand that.

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Q So I guess in your analysis in this proceeding, did you consider February 7, 2006, to be the date of the invention?

A Yes.

Q Okay. And so if I refer to "date of the invention" or "date of the '511 patent," will you understand I'm referring to February 7, 2006?

A Okay.

Q Okay? Is that a yes?

A Yes.

Q Okay. And do you understand that you're here today to be deposed in an Inter Partes Review proceeding of the '511 patent that's before the United States Patent Trial and Appeal Board?

A I understand that I'm here to provide the expertise that a POSA at the time this was filed would have understood. And what the deposition is called, I would not understand that.

Q Okay. So can you go to the first page of your declaration, just the cover page.

A Okay.

Q Do you see it says: United States Patent and Trademark Office, Before the Patent Trial and Appeal Board.

Do you see that?

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A Yes.

Q Okay. And then it says: BTL Industries, Incorporated, versus InMode, Limited.

Do you see that?

A Yes.

Q Okay. And it says InMode, Limited is the owner of the '511 patent.

Do you see that?

A Yes.

Q Okay. And you're here to testify today on behalf of InMode, correct?

A Correct.

Q Okay. Before you became involved in this proceeding, were you aware of InMode?

A Yes.

Q And can you explain to me what your relationship was with InMode before this proceeding?

A I had no relationship. I would say ads or perhaps articles or a booth at a conference.

Q Okay. When did you first become aware of InMode, do you recall?

A I don't recall.

Q Do you have any -- before this proceeding, had you had any contractual relationships with

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InMode?

A No.

Q Did you use any of InMode's devices in your practice?

A No.

Q Have you ever met with any InMode reps?

MR. HECTOR: Objection. Vague.

A I may have.

Q Do you recall when?

A No.

Q But you don't use any of InMode's devices in your practice, correct?

A I do not.

Q What about BTL? Prior to this proceeding, were you aware of the company BTL?

A Yes.

Q And how were you aware of BTL?

A Excuse me. In a similar way, that I may have seen ads or read articles or seen a booth at a conference.

Q Do you recall when you first became aware of BTL?

A No.

Q Do you use any of BTL's devices in your practice?

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A No.

Q Have you ever tried one of BTL's devices?

A I don't recall.

Q Same question for InMode. Have you ever tried using one of InMode's devices in your practice?

A I don't recall.

Q How did you come to be involved in this proceeding?

MR. HECTOR: Objection. Vague. Also, objection. Privileged. Just remind you not to reveal anything, discussions you've had with counsel.

A I was contacted a few months ago.

Q Who contacted you?

A It was Bill Hector.

Q Do you know why they selected you to participate in this proceeding?

MR. HECTOR: Again, same objection on privileged. Be mindful not to reveal the substance of communications you've had with your attorneys.

A I do not.

Q Did you prepare for today's deposition?

A I did.

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Q What did you do?

MR. HECTOR: Again, same objection. Privileged.

A I should still answer; is that correct?

Q You can answer.

A I read over my declaration and some of the materials that were in my possession, and I met with the attorneys.

Q Okay. Which attorneys did you meet with?

A Bill Hector and Parker Zimmerman.

Q Did you meet with anyone else?

A Justin was on the phone as well for a short while yesterday.

Q Did you meet with anyone else?

A I believe there was another attorney -- I'm sorry that I don't recall his name -- on a previous phone call.

Q I'm sorry. So there were, you said, Bill, Parker, Justin, and perhaps one other attorney; is that correct?

A Well, Parker Zimmerman and perhaps one other attorney.

Q Okay. What materials did you review?

MR. HECTOR: Again, objection on privilege. Instruct you not to reveal any

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specific documents that were shown to you by counsel.

A I read over my declaration and some of the exhibits that were provided to me.

Q The exhibits that were provided to you, were those materials that you reviewed when you prepared your declaration?

MR. HECTOR: Same instruction. Objection. Privilege.

A Yes.

Q Okay. Let's talk about your declaration. Do you have that in front of you?

A I do.

Q Did you prepare the declaration?

A I prepared it in combination with the attorneys.

Q Okay. Can you describe the process for preparing the deposition with the attorneys?

MR. HECTOR: Objection on privilege, not to reveal any communications with counsel. But you can answer to the extent you can do so without revealing privilege.

A A draft was provided, which I then edited, and we went back and forth with edits for a few different times.

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Q Did you actually write your declaration, or was all the writing done by the attorneys?

MR. HECTOR: Objection. Misleading.

A A draft was provided to me, and I made substantial edits to it.

Q So you actually typed those edits into the document yourself?

A I did.

Q How long did you spend preparing the declaration?

A I don't recall.

Q Can you give me a ballpark?

A It was some hours. I don't remember how many.

Q Was it more than 5 hours?

A It was more than 5 hours.

Q Was it more than 10 hours?

A Yes.

Q Was it more than 15 hours?

A Yes.

Q More than 20 hours?

A I don't think so.

Q Okay. So between 15 and 20 hours about?

A Yes.

Q Okay. Why don't you open up your

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declaration and turn to page 4, Section 2, which describes your professional background.

A I am there.

Q Okay. And in paragraphs 11 and 12, look at those, you describe your experience performing incontinence surgeries and pelvic organ prolapse surgeries for women; is that correct?

MR. HECTOR: Objection. Misstates the regard.

A I do describe my surgical repairs for incontinence and prolapse.

Q Is that specifically for women?

A Yes.

Q Do you treat men?

A Yes, I do.

Q Do you know whether incontinence can also affect men?

A Incontinence can affect men, yes.

Q Do you have any experience with vaginal rejuvination?

MR. HECTOR: Objection. Vague.

A Can you be more specific, please?

Q Have you heard of the term "vaginal rejuvination"?

A Yes, I have.

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Q What does that mean to you?

A Vaginal rejuvination is a vague term that can describe surgical or nonsurgical approaches to a vagina that's lax.

Q Okay. So let's start with nonsurgical. Do you have experience with nonsurgical vaginal rejuvination?

A Yes, I do.

Q Can you explain?

A Part of our nonsurgical rejuvination would include medication, physical therapy, injections, and can include energy-based rejuvination.

Q What do you mean by "energy-based rejuvination"?

A Such as a radio frequency treatment or CO2.

Q So in your practice, you perform radio frequency treatment for vaginal rejuvination?

MR. HECTOR: Objection.

A I do not perform them. Currently I have tried a device in my office at one point. It's not a treatment I'm currently offering.

Q I'm sorry. Can you repeat your answer? I believe you mentioned a device in your office, but I don't see that in the transcript. Can you just repeat what you said?

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A Yes. I have tried a device in the office, but I am not currently performing that.

Q What device do you -- what device did you try in your office?

A It was a number of years ago, and I do not remember which one I used.

Q Okay. Was it an InMode device?

A I don't recall which company it was.

Q Do you recall how many years ago it was?

A No.

Q Do you recall -- let me rephrase that.

Why do you not provide treatment for -- strike that.

Why do you not provide RF vaginal rejuvination treatment in your office?

A My practice has been more focused on incontinence, prolapse, and hemorrhoids, and I did not find that the patients in my office were interested in this treatment enough for me to invest in a device.

Q Do you recall when you made that decision not to invest in this device and provide that treatment?

A No.

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Q Was it 5 years ago?

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MR. HECTOR: Objection. Calls for speculation.

A I don't recall.

Q You don't recall if it was more than 5 years ago?

A Oh, I thought you asked if it was 5 years ago.

Q I'm sorry. Let me -- yeah, sorry. Fair.

Do you know if it was more than 5 years ago?

A I would be speculating, but I think it was.

Q Do you know if it was more than 10 years ago?

A I don't know.

Q So it could have been between 5 and 10 years ago you made that decision?

MR. HECTOR: Objection. Speculation.

A It could have been.

Q But sitting here today, you can't recall when you decided not to provide RF vaginal rejuvination in your office?

A That's correct.

Q What types of treatments do you provide in your practice?

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A For all types of medical conditions?

Q Yes.

A I see women for incontinence and provide options, including medication, physical therapy, pelvic -- excuse me, yeah, pelvic floor physical therapy, posttibial nerve stimulation, as well as injections of bulking agents. We also -- I also perform slings, but that's not done in the office.

For women with prolapse, I will provide pessaries, offer pelvic floor physical therapy, or perform surgery in the hospital or surgicenter.

And I also treat women who have pelvic pain, and that may be with medication, physical therapy, or injections.

And I treat men and women for hemorrhoids, as well as constipation and other pelvic-related bowel disorders.

Q Okay. In your answer you mention you perform slings. Can you explain what a sling is?

A A sling is a surgery to correct incontinence, and there are different types of slings.

Q You also mentioned you offer pelvic physical therapy. What condition are you treating for when you offer pelvic physical therapy?

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A Pelvic floor physical therapy is prescribed for a number of disorders, including stress incontinence, overactive bladder, prolapse, and pelvic pain.

Q What is prolapse?

A Prolapse occurs when there's a defect in the fascia ligaments of the pelvis, as well as the pelvic muscles, and the organs protrude through into the vaginal canal or through the vaginal opening.

Q Okay. And so in your answers that you just provided, you mentioned that you treat incontinence, prolapse, and hemorrhoids. Are there any other conditions that you, let's say, you focus on in your practice?

A I also talked about constipation, pelvic pain, dyspareunia. And I do see women for surgical labioplasty.

Q And can you tell me what a labioplasty is?

A It is surgical procedure to change the shape and/or size of the labia.

Q And what condition does a labioplasty treat?

MR. HECTOR: Objection. Vague.

A It treats a number of conditions from pain

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with certain activities, appearance. I've seen a number of women that are involved in professions where they need to wear very tight clothing, such as gymnasts and ballerinas. And it also could simply be a patient is uncomfortable with the appearance of the labia. They may cause pain during sex if they become enlarged.

Q And how long have you been performing labioplasties?

A Since my residency, which ended in 1992.

Q Are there any other treatments you provide in your practice, other than the ones we just discussed?

A There may be. I brought up the majority of the common treatments.

Q Okay. Can you turn to paragraph 12 of your declaration?

A I'm there.

Q So just the third line, I just don't know what this acronym is. What is a TVT?

A It stands for tension-free vaginal tape.

Q And can you explain what that is, please?

A Well, the retropubic TVT -- TVT is the abbreviation for tension-free vaginal tape -- is a sling that was placed in the under the urethra

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and through the retropubic area with two small incisions just above the pubic bone on the abdomen, and that was placed to treat stress incontinence.

Q Is the TVT used to treat incontinence in women?

A Yes.

Q Is it used to treat incontinence in men?

A No.

Q Can you look at paragraph 13, you mentioned the SURx transvaginal system.

A Yes.

Q What types of procedures are performed using the SURx transvaginal system?

A Stress incontinence.

Q You see in paragraph 15 you mention your standard hourly rate?

A Yes.

Q What is your standard hourly rate?

A For review of cases and meetings, it is 750 per hour. And for depositions, 850.

Q You know what a vaginal speculum is, right?

A Yes.

Q So if I say "speculum" during today's

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deposition, will you understand that I mean a vaginal speculum as opposed to other types of speculums?

A Could I clarify that we'll be talking about a bivalve speculum?

Q Explain to me what a bivalve speculum is.

A It is a speculum that has two blades which is inserted into the vagina and then spread to allow visualization of the deeper vagina.

Q Are there other types of speculums besides bivalve speculums?

A Yes.

Q What other types?

A There can be a single-bladed speculum and a weighted speculum.

Q Can you generally describe a single-bladed speculum?

MR. HECTOR: Objection. Calls for narrative.

A When we look at the bivalve speculum, if we took the top part off and used the lower blade, this is used to examine for prolapse so that the speculum isn't holding the top wall of the vagina up.

Q The top wall of the vagina, is that also

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known as the anterior wall of the vagina?

A Yes.

Q Can you describe a weighted speculum?

A A weighted speculum has a single blade with a weight that hangs on the outside of the vagina to put extra pressure.

Q And what is a weighted speculum used for?

A It may be used for surgery on the anterior vaginal wall or the cervix.

Q Which portion of the anterior vaginal wall?

A The part that you couldn't see without pressing down on it with a speculum to reach it. Typically it's for something that involves the proximal vagina, the cervix, such as a procedure on the cervix or a hysterectomy.

Q And you mentioned that the weighted speculum has a single blade; is that correct?

A Yes.

Q Where is that blade when inserted in the vagina?

MR. HECTOR: Objection. Vague.

A I'm sorry. I didn't hear. You cut out a little. I didn't hear the whole thing.

Q No problem.

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Where is that blade when the speculum is inserted into the vagina?

A It's the part that is inserted into the vagina against the posterior wall.

Q Okay. So we mentioned bivalve speculums, single-bladed speculums, and weighted speculums. Are there any other types of speculums that you're familiar with?

MR. HECTOR: Objection. Foundation.

A No.

Q Okay. Let me just go back to my original question.

If I say "speculum," will you understand I'm referring to a vaginal speculum?

A Yes.

Q And were speculums known to persons of skill in the art before February 2006?

A Yes.

Q And why do persons of skill in the art use speculums?

A They use speculums to help us see or reach the upper vagina and/or cervix.

Q When you say "upper vagina," what are you referring to?

A The proximal vagina.

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Q The proximal vagina is the portion that is furthest from the entrance; is that correct?

MR. HECTOR: Objection. Vague.

A Yes.

Q Do persons of skill in the art exercise their judgment on whether and how to use a speculum?

MR. HECTOR: Objection. Vague.

A It depends on the situation.

Q Explain to me a situation in which you would use a speculum?

A When performing a Pap smear.

Q Okay. Explain to me a situation when you would not be using a speculum while treating the vagina?

A When treating the vagina in general?

Q Yes.

A That's quite vague. Can you be more specific?

Q Do you ever treat the vagina without using a speculum?

MR. HECTOR: Objection. Vague.

A Yes.

Q Can you explain to me a situation in which you do that?

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A If I'm placing a pessary for prolapse, I would not use a speculum to place the pessary.

Q What's a pessary?

A It's a device that women wear in the vagina to hold their prolapse up in a nonsurgical manner.

Q Okay. Do you ever inspect or treat a vagina without using a tool such as a speculum?

MR. HECTOR: Objection. Vague.

A Yes. If I'm assessing pelvic muscle tone or strength or feeling the size of the uterus, such as a bimanual exam, then I'm not using a speculum during that portion of the exam.

Q So depending on what you're doing, you're exercising your judgment as to whether you use a speculum or not; is that correct?

MR. HECTOR: Objection. Calls for speculation.

A In that situation, yes.

Q And you use speculums in your practice, right?

A Yes, I do.

Q Can you explain how a speculum is used in your practice?

MR. HECTOR: Objection. Scope.

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A I don't understand exactly what you're asking, how do I insert the speculum?

Q Just generally, yes, how is it inserted and used?

MR. HECTOR: Same objection. Scope.

A A speculum is inserted usually with some gel on the posterior blade, and then it's closed. Both blades are touching. It's inserted into the vagina. And then there's a valve that lets you put pressure to open the blades that are deeper in the vagina to let you spread the anterior from posterior wall and visualize the upper vagina and/or cervix.

Q You mentioned "blade" several times during this discussion. Is that the portion that's inserted into the vagina?

MR. HECTOR: Objection. Vague.

A Yes, we insert the blades of the speculum.

Q And the portion of the speculum that is not inserted in the vagina, what is that part called?

A The handle. The handle.

Q And the handle is the portion that the physician would manipulate to open the speculum; is that correct?

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A Yes.

Q Are there different size speculums?

A Yes, there are.

Q And was that true before February of 2006?

A Yes.

Q Why are there different size speculums?

A There are different sizes so if a young lady is coming into the office who needs, say, a Pap smear and she's not had intercourse and/or not delivered a child, she may need a narrow speculum.

There are times when children need to be examined for a GYN exam and may need a pediatric speculum, which is very small.

And women who have prolapse and the organs are falling into the vagina may need the larger speculum to be able to visualize the upper vagina.

Q So you mentioned a pediatric speculum. Is that only used on children?

MR. HECTOR: Objection. Misstates testimony.

A No, rarely would we use it on an adult.

Q But just answer my question.

It's not -- a pediatric speculum is not only used on children, correct?

MR. HECTOR: Objection. Misstates

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testimony.

A Yes.

Q And are the blades of a pediatric speculum shorter than other types of speculums?

MR. HECTOR: Objection. Misstates testimony.

A Yes.

Q How long are the blades of a pediatric speculum in general?

A I don't know the measurement.

Q Do the different size speculums allow physicians to view different portions of the patient's vaginal canal?

MR. HECTOR: Objection. Vague.

A Can you rephrase that, please?

Q There are different size speculums, correct?

A Yes.

Q And do those different size speculums allow a physician to view different parts of the vaginal canal?

A Not really.

Q What do you mean by "not really"?

A I -- when evaluating a patient, we use a standard speculum unless there is some reason that

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I decided she needed a more narrow speculum. It's not that I bring multiple speculums to examine the same patient to look at different parts of the vagina.

Q If you wanted to view a portion of a patient's vagina that was on the proximal end, would you use a larger speculum?

MR. HECTOR: Objection. Vague.

A Can you clarify what you're referring to as "proximal end"?

Q I believe we mentioned that earlier. It's the end that's opposite of the entrance.

MR. HECTOR: Objection. Vague.

A Can you repeat the question, please?

Q If you wanted to view the proximal end of a patient's vagina, what type of speculum would you use?

A A standard speculum.

Q What is a standard speculum?

A The regular bivalve speculum.

Q How long are the blades on a standard speculum?

A I haven't measured them in a long time. But since the vagina is on average 9 centimeters, I believe they're around 9 centimeters.

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Q When you use a speculum, do you insert the entire blade into the vaginal canal?

A Until I hit the patient's top of the vagina or cervix.

Q I'm sorry. Can you clarify your answer? Is that yes, you do insert the entire blade into the vaginal canal?

A We insert the blades into the end of the vaginal canal.

Q Okay. So you just testified that a standard speculum, the blade is around 9 centimeters, correct?

A I said I didn't recall the measurement, but the average vagina is 9 centimeters. So it would be around there. Maybe a little shorter. Maybe a little longer.

Q Okay. And so would you insert all 9 centimeters of the blade of the speculum into the vaginal canal?

MR. HECTOR: Objection. Vague.

A I would insert it until I reached the top of that lady's vagina.

Q And what do you mean by "the top of that lady's vagina"?

A To either the vaginal cuff or the

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posterior -- the posterior cul-de-sac, the sulcus.

Q Is your answer because you treat incontinence?

MR. HECTOR: Objection. Vague. Misstates the record.

A No. Typically I'm not inserting a speculum in the office for patients with incontinence.

Q Okay. So going back to your answer that you would insert the blades until you reached the top of that lady's vagina, why are you inserting the blades to that location within the vagina?

A So that I can open the blades to visualize the cervix or the top of the vagina.

Q Okay. And if you wanted to view a portion of the vagina that was closer to the entrance, would you insert the blades of the speculum to a shallower portion?

MR. HECTOR: Objection. Vague.

A It really depends what the patient's anatomy is.

Q But you could do that?

MR. HECTOR: Objection. Calls for speculation.

A I could do that.

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Q And do physicians view different portions of the female vagina using a speculum at different locations?

MR. HECTOR: Objection. Speculation.

A I can't speak to all physicians. But as a gynecologist, I could inspect -- insert the speculum partway in the vagina to look at a different portion of the vagina, depending on the patient's anatomy.

Q What is the smallest speculum that you're familiar with?

MR. HECTOR: Objection. Vague.

A A pediatric speculum.

Q If a person skilled in the art wanted to treat the opening of the vagina, which I believe is called the introitus, would they use a speculum?

MR. HECTOR: Objection. Vague.

A Again, it depends on the patient's anatomy, but usually no.

Q If a person of skill in the art wanted to treat the first inch of the vaginal canal, starting at the introitus, would they typically use a speculum?

MR. HECTOR: Objection. Vague.

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A It depends what the treatment is.

Q Can you elaborate on that answer?

MR. HECTOR: Objection. Same objection.

A I don't know what you want me to elaborate.

Q Well, you said it depends on what the treatment is. So under what treatments would you not use a speculum to treat the first inch of the vagina starting at the introitus?

MR. HECTOR: Same objection. Vague.

A I'm going to repeat it to make sure I understood you. So in what condition would I not use a speculum to treat the first inch of the vagina?

Q Yes.

MR. HECTOR: Same objection.

A And we're talking about the proximal end, to be clear, closest of the opening? Am I correct?

Q So my understanding is the proximal end was furthest from the opening.

A Okay. So you would want to know when I would not use a speculum to treat the proximal end of the vagina?

Q No. I want to know -- so the opposite end

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of the proximal end is the distal end, correct?

A Yes.

Q Okay. And the distal end is where the introitus is, correct?

A Yes.

Q Okay. And so I want to know when you would not use a speculum to treat the introitus?

MR. HECTOR: Objection. Vague.

A Since many of the women in my office have had children and have a lax vaginal opening and have some prolapse, I may be able to see it or reach it without needing a blade, the blades of a speculum to visualize that.

Q And I'm assuming this is true, but I'd ask a question. Is a speculum a tool a person of skill in the art would typically own and use in their practice?

A They would use it in their practice. I don't know if they would own it.

Q Do you own speculums?

A I own speculums, yes.

Q Are speculums a common tool in your practice?

A Yes.

Q Are you aware of any common vaginal

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treatment devices that are shipped with a speculum?

MR. HECTOR: Objection. Vague.

A I don't -- I can't think of any right now.

Q Okay. Since we were just talking about the distal and proximal end of the vaginal canal, can you turn to paragraph 41 of your declaration? You can take a minute to review that, if you'd like.

MR. HECTOR: You said 41?

MR. BEMBEN: 41.

MR. HECTOR: Four one.

A Page or paragraph?

Q Paragraph 41, page 17.

A Yes.

Q Okay. So you see about halfway into that paragraph, you state: The introitus is the entrance to the vagina, open paren, or the distal-most portion of the vagina, close end -- I'm sorry, close paren.

Do you see that?

A Yes.

Q And then in two sentences later you say: In other words, the introitus is around 9 centimeters on average from the distal end of

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the vaginal canal.

Do you see that?

A And that should say "proximal end."

Q Okay. So that's a mistake. It should say "proximal end."

Did you write that sentence? In other words, the introitus is around 9 centimeters on average from the distal end of the vaginal canal?

A I don't remember if I was the first one to write that or not.

Q Okay. Can you go to paragraph 5 of your declaration, on page 4?

A Yes.

Q Okay. You see in paragraph 5, the second sentence, it says: My understanding of the relevant law as discussed below is based on my discussions with counsel for Signify.

A Yes.

Q Who is Signify?

A I have not met with anyone from Signify.

Q Do you know who Signify is?

A I did look it up, but I don't want to answer from memory. I need to look it up again.

Q When did you look up who Signify is?

A When I was first looking at this

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declaration.

Q Have you had discussions with counsel for a company called Signify?

A I have been working directly with physicians -- excuse me, attorneys from Venable, and I don't recall the relationship to Signify at the moment.

Q Did you write this sentence that includes Signify?

A I did not write that sentence.

Q Do you think that that sentence is a mistake?

A No.

Q Okay. Can you turn to paragraph 51 of your declaration? And this spans pages 21 through 22.

A I'm there.

Q Okay. Go ahead and review it, if you'd like.

A Okay.

Q On page 22, kind of the second line, do you see where you say: Treatment of the using treatment temperatures below 80 degrees Celsius, and you go on. Is that missing a word?

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A It is missing a word.

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Q What should the word be?

A I believe it would be "vulvovaginal tissue."

Q Did you write that sentence that omitted the word "vulvovaginal tissue"?

A I don't recall.

Q Are you aware of any other mistakes in your declaration you'd like to correct?

A I know there was one place where there was an exclamation point instead of an L, I believe, but I don't know what page it's on.

Q Okay. Other than the exclamation point, were there any other mistakes you'd like to correct?

A I may point them out as we read them, but I don't know of any offhand right now.

Q Okay. So can we just go back to our discussion of speculums briefly? During our discussion, I believe you mentioned a narrow speculum. Am I recalling correctly?

MR. HECTOR: Objection. Misstates the record.

A We have a regular speculum and a -- it would be a narrow speculum or a pediatric.

Q So in your answer just now, you said

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narrow speculum or a pediatric. Is a narrow speculum the same as a pediatric speculum?

A No.

Q Okay. Can you explain to me what a narrow speculum is?

A It is a speculum where the blades are not as wide as the regular speculum.

Q Okay. So speculums -- let me rephrase that.

The blades of speculums can vary in both length and width; is that correct?

MR. HECTOR: Objection. Misstates the record.

A They can.

Q Let's turn back to your declaration. And if you go to page 2 in the table that you have there --

A Yes.

Q -- okay, this table lists the materials that you considered in forming the opinions of your declaration; is that correct?

A Yes.

Q All right. And I notice that the board's decision on institution is not included in this table. Do you know what I'm referring to when I

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say the decision on institution?

A Yes.

Q Did you review the board's decision on institution when you performed the analysis in your declaration?

A I've reviewed a portion of it.

Q Which portion did you review?

A Give me a moment.

Q Sorry. Let me just clarify.

When I say "the board's decision on institution," I mean the decision on institution in this proceeding.

A Oh, thank you for clarifying.

It is mentioned in the declaration, I believe, and I discussed it with the attorneys, but I did not review that document.

Q Okay. All right. And the first entry in the table on page 2 of your declaration is BTL's petition.

Do you see that?

A Yes.

Q Okay. Can you get out a copy of BTL's petition, please?

A I believe it says NA here. Let me look in my list. Okay. I have it.

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Q Can you turn to Roman numeral (iv), smaller numeral. This is the exhibit list in the petition.

Before I do that, can you just take a look at the petition and let me know that you have a copy of the petition that you reviewed when preparing your declaration?

A Yes, I have it.

Q And you reviewed this when you prepared your declaration, correct?

A I did.

Q So now can you turn to Roman (iv), small Roman. It's the exhibit list.

A I'm on that page.

Q Okay. And looking at that page which has the exhibits that were provided with the petition and looking at the table on page 2, starting at page 2 of your declaration, your list does not include Exhibits 1009 through 1013, 1023, 1027 through 1031?

Do you see that?

MR. HECTOR: Objection to the extent it misstates the record.

A I got lost in all those numbers. Would you repeat that for me?

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Q Okay. No problem.

Okay. If you look at your list on page 2, it says that you reviewed Exhibits 1001 through 1008.

Do you see that?

A Yes.

Q Then it goes to 1014, correct?

A Yes.

Q So in the petition, there were Exhibits 1009 through 1013 that were also provided, and that's in the exhibit list on Roman numeral (iv) of the petition.

Do you see that?

A Yes.

Q Okay. Is there a reason you didn't include Exhibits 1009 through 1013 in your materials considered?

A No.

Q Do you know whether you reviewed 1009 through 1013?

A I did not.

Q Okay. If we look at your list, go to page 3, so you see it goes 121, 122, and then skips to 124 -- I'm sorry, 1021, 1022, and skips to 1024.

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Do you see that in your list on your page 3?

A Yes.

Q So it skips Exhibit 1023?

A Yes.

Q Do you know if you reviewed Exhibit 1023?

A I did not.

Q And then on page 3 of yours, it ends 1026 and then skips over to 2001.

Do you see that?

A Yes.

Q Okay. But with the petition, there are also Exhibits 1027 through 1031.

Do you see those?

A Yes.

Q Did you review Exhibits 1027 through 1031?

A No.

Q Can you turn to page 12 of your declaration?

A I am here.

Q Okay. And Roman numeral (IV), you have a section of Person of Ordinary Skill in the Art.

Do you see that?

A Yes.

Q Okay. And then paragraph 33, you list the

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factors that should be considered when determining the level of skill in the art. Do you see those factors 1 through 6?

A Yes.

Q And then going down to paragraph 36 of your declaration, do you see that?

A Yes.

Q Review that. Let me know when you've finished.

A Okay.

Q To paraphrase, in paragraph 36, you're disagreeing with Dr. Berenholz's definition of a person of skill in the art because not many individuals would fit under his definition.

Do you see that?

MR. HECTOR: Objection. Foundation.

A I see that.

Q You say: Indeed, similar to Dr. Berenholz, I was only aware of a handful of doctors practicing in the field of cosmetic gynecology in 2006.

Do you see that?

A Yes.

Q And so my question is: Why does the number of people who are practicing in a certain

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field affect the level of ordinary skill in the art, in your opinion?

MR. HECTOR: Objection. Vague.

A Yeah, I don't know if I can answer that.

Q Well, did the number of physicians who were practicing in the field influence your opinion as to the level of skill in the art here?

A No.

Q Okay. So it doesn't matter the number of physicians practicing in the field for the purposes of the level of skill in the art; is that correct?

MR. HECTOR: Objection. Misstates.

A I think the experience of that physician and physicians at that time would affect the skill in the art.

Q But does the number of physicians practicing in a certain field affect the level of skill in the art?

A A person of ordinary skill in the art at the time was a gynecologist treating female genital tissues but not necessarily a cosmetic gynecologist who was specializing in that field.

Q Go back up to paragraph 33 of your declaration. Does the number of people practicing

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in the field, is that one of the factors that are considered when evaluating the level of skill in the art?

MR. HECTOR: Objection. Foundation.

A No.

Q All right. Can you turn to paragraph 54 of your declaration, which is on page 21?

A Okay.

Q Do you see the second-to-last sentence in that paragraph says: A POSA would understand that the constructions from the ThermiGen IPR are proper constructions?

A Yes.

Q Which constructions from the ThermiGen IPR are you referring to?

A I would need to take a look at that.

Q Okay. Well, did you mean the board's constructions from ThermiGen IPR? I'm just trying to clarify what you meant there. I'm not trying to trick you.

A Oh, I would have to -- I would have to take a look at that, this report or document, to confirm that's what I was referring to.

Q Okay. Why don't we do that.

MR. HECTOR: Are you okay? We've been

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going an hour. Are you good to keep going, Dr. Poulos?

THE WITNESS: Yeah, I'm okay.

MR. BEMBEN: We can wrap up -- we can take a break after this line of question.

Bill, can you introduce Exhibit 1009?

MR. HECTOR: Introduce or just make sure she has it in front of her.

MR. BEMBEN: I'm sorry. Can you give her a copy of Exhibit 1009.

MR. HECTOR: We may have to go in your box for that. It will just be a second. Is it okay to open your box up?

MR. BEMBEN: Yes.

(Exhibit Number 1009 previously marked for identification.)

A It's wrapped up really well.

Q Dr. Poulos, would you like to take a break while we get that exhibit out?

A That's probably perfect. Thank you.

Q Okay. Would you like to take a 15-minute break?

A Sure. I think 10 would be fine, unless you want 15.

MR. BEMBEN: 10 is fine.

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MR. HECTOR: Take us off the record.

MR. BEMBEN: Off the record.

(A short break was taken.)

Q Okay. Welcome back.

So I believe Mr. Hector was providing you a copy of Exhibit 1009. Do you have a copy of that, Dr. Poulos?

A Yes, I do.

Q Okay. And so this is the Decision to Institute in ThermiGen v. Viveve case, IPR2018-00088.

Do you see that on the front cover?

A I was looking for the word "Decision to Institute," so I found it, and then I didn't pay attention to the numbers you read.

Q That's okay.

Do you see above Decision to Institute, a few lines, it says Case IPR2018-00088.

A Yes.

Q Okay. At the very top right corner, it says Paper 7?

A Yes.

Q Can you take a look at this document and let me know if this is the document -- or if this is a document that you reviewed when preparing

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your declaration?

A Yes, it looks familiar.

Q Going back to your declaration in paragraph 54 that we were discussing --

A Yes.

Q -- do you recall that you stated: A POSA would understand that the constructions from the ThermiGen IPR are proper constructions.

Do you see that?

A Yes.

Q Okay. When you say "ThermiGen IPR" -- I'm sorry. Let me rephrase that.

When you say "the constructions of the ThermiGen IPR," are you talking about the board's constructions in the Decision to Institute in Exhibit 1009?

A I believe so.

Q Okay. You can take a look at Exhibit 1009 starting on page 10. That's where the board outlines construction of certain terms.

A Okay.

Q Okay. And so just to confirm, in paragraph 54, when you refer to the constructions from the ThermiGen IPR, you are referring to the board's claim constructions in Exhibit 1009,

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correct?

MR. HECTOR: Objection. Asked and answered.

A Yes, I believe so.

Q If you look at page 9 of the board's decision in Exhibit 1009, under the subsection (B), Claim Construction, let me know when you're there.

A Yes.

Q Okay. Do you see that: In an Inter Partes Review, claim terms in an unexpired patent are in accordance with the broadest reasonable construction in light of the specification of the patent in which they appear?

Do you see that?

A Yes.

Q Do you understand that in the ThermiGen IPR, the board analyzed the claims under the broadest reasonable claim construction standard?

A I don't think I can answer that.

Q Do you know what the broadest reasonable construction, claim construction standard is?

A No.

Q Did you apply the broadest reasonable construction standard when reviewing the claims in

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this proceeding?

A I can't answer that.

Q Why can't you answer that?

A It's not a term that I know what the definition is.

Q Okay. Let's go to page 24 of your declaration. Do you see that you provided constructions on page 24 of target tissue? Go to page 26, remodeling; page 29, heating.

Do you see those claim constructions that you provided?

A Yes.

Q What claim construction standard did you apply when you analyzed the claim terms of the '511 patent?

A I was following the terms as they were defined.

THE COURT REPORTER: I'm sorry, Doctor. I couldn't hear you.

A I was following -- I was using the terms as they were defined.

Q That they were defined where?

A In this document that we're looking at.

Q When you say "this document that we're looking at," are you referring to your

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declaration?

A Yes.

Q Okay. So were you provided the claim constructions that are in your declaration?

MR. HECTOR: Objection. Vague.

A These claim constructions that you just mentioned?

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

A Yes.

Q They were provided to you by counsel?

A Yes.

Q Okay.

MR. BEMBEN: Bill, did you receive the email of the document?

MR. HECTOR: Yeah.

MR. BEMBEN: Okay. Do you guys want to take a minute to print it out?

MR. HECTOR: We've got it.

MR. BEMBEN: Okay. Can you provide a copy to Dr. Poulos?

MR. HECTOR: Should be 4 pages, right? Oh, 2, 2 pages.

MR. BEMBEN: Yeah, it should just be

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2 pages.

MR. HECTOR: She has it.

MR. BEMBEN: Okay.

MR. HECTOR: Take your time to read it, of course.

Q I'm going to introduce a document that the top of the document says Anatomical Terminology. It's the very top of the document. I'll represent to you this is a document that I printed off personally from a government website on the 6th of April.

Do you have a copy of that document in front of you?

A Yes.

Q Okay. And so this is probably something that I should have done at the beginning of the deposition, so forgive me. But this document has anatomical terminology in it.

Do you see that?

A Yes.

Q Can you take a minute to review the document? It's only 2 pages. And all I want to do is just establish that when you and I talk about anatomical terminology, direction, things of that nature, that we're on the same page, and that

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I'm not a physician, that I'm understanding the terminology that you're using. Okay?

A Yes.

Q So go ahead and take a minute to review that. Make sure it's accurate. It's from the National Cancer Institute.

A While I start reviewing that --

MR. HECTOR: Objection. Foundation.

A -- can I say that the exclamation point that should be L is right there at the top of page 24.

Q Sure.

A I think you'll see what I mean.

MR. HECTOR: Just a general objection to this document as outside the scope. And foundation.

A Okay.

MR. BEMBEN: And for the court reporter, can we mark this as Deposition Exhibit 1, please?

(Deposition Exhibit Number 1 marked for identification.)

Q Okay. And so, Dr. Poulos, upon reviewing this document, are there any terms or claims of the body that you disagree with as they're stated in this document?

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A Well, I think we already talked about what proximal and distal vagina would be, so I may not exactly agree with this document the way it's worded. But it's the way, as gynecologists, we use those terms.

Q Okay. Well, let me start by just in general, outside of gynecological use of the terms, if we look at directional terms, the term "superior," does that mean toward the head end of the body?

A Yes.

Q Okay. And "inferior" means away from the head?

A Yes.

Q "Anterior" means front?

A Yes.

Q "Posterior" means back?

A Yes.

Q "Medial" means toward the midline of the body?

A Yes.

Q "Lateral" means away from the midline of the body?

A Yes.

Q "Proximal" means toward or nearest the

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trunk of a point of origin?

A Yes.

Q Okay. And "distal" means away from or furthest from the trunk?

A Yes.

Q And so the distal end, for example, would be the opposite end of the proximal end; is that correct?

MR. HECTOR: Objection. Vague.

A Yes.

Q Okay. And so just to clarify what you said earlier about use of this proximal and distal in the terms of gynecological, can you explain what you meant by that?

A Because some people, especially if they're not medical, would think of the vaginal opening as the start of the vagina. We already discussed that we're calling the introitus the distal vagina and the upper vagina at the apex or near the cervix as proximal.

Q Okay. And is that the accurate way to describe those locations from a gynecological perspective?

A Yes.

Q And that's how a person of ordinary skill

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in the art would have understood those terms, correct?

A Yes.

Q Okay. So just wanted to establish a level set with respect to the terms.

Now I'd like to --

MR. BEMBEN: Bill, can you provide Exhibit 115? I'd like to introduce exhibit what was previously marked as Exhibit 115.

(Exhibit Number 1015 previously marked for identification.)

A 1015?

Q Yes, correct. I'm sorry. 1015, correct.

A Okay.

Q And I'm going to ask you to make some markings on some of the figures on this document.

MR. BEMBEN: Bill, I believe we provided some Sharpies in the box. Can you grab one of the Sharpies for Dr. Poulos?

MR. HECTOR: Objection to the form of the question.

Q Okay. While we're getting that out, I'd like to introduce Exhibit 1015. It's Atlas of Human Anatomy, 4th Edition, by Frank H. Netter, Medical Doctor.

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Have you seen this document before?

A Yes.

Q Are you familiar with Netter's textbooks?

A Anatomy books, yes.

Q Yes, anatomy books, sorry.

Prior to this proceeding, were you familiar with Netter's anatomy books?

A Yes, I was.

Q Are they considered authoritative books?

A They're an excellent resource. I've never considered it authoritative.

Q Okay.

MR. HECTOR: Just a blanket objection to having the witness make markings on the document, introducing things that aren't in the record.

Q Can you explain why you don't consider the Netter textbooks authoritative?

A The Netter textbooks, I think the copy I have is from my high school friend's father who was a physician, and I don't remember what year it was published, but it was well before I was born.

Q I see.

A So some things have changed the way we describe anatomy since then.

Q The exhibit that I provided to you, turn

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to page 6, the copyright page

A I don't have page numbers.

Q If you go to the copyright page, it's the sixth page of the PDF you have.

A Okay.

Q Do you see it's copyright 2006?

A Yes.

Q And I think we established before, the time of the invention or the time of the '511 patent was February 2006, correct?

A Yes.

Q So would a person of skill in the art have understood that Netter, Netter's anatomy book from 2006, would be authoritative at that time?

A No.

Q And why not?

A As I said, it's a good reference for anatomy. I don't know that it's authoritative, and I don't know if these are the original drawings or if they changed in any way since he first drew them.

Q Do you have any reason to believe that these drawings changed since he first drew them?

A No, I don't.

Q Okay. Can you turn to page 360, please?

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A Three six zero?

Q Three six zero, yes.

A Okay.

Q Okay. And in the bottom figure, it's labeled Median Sagittal Section.

Do you see that?

A Yes.

Q Okay. So here's where I want you to provide some labels.

MR. HECTOR: Instruct you not to --

Q For the vagina on the vaginal canal, can you label the proximal end with a P?

MR. HECTOR: Instruct the witness not to annotate the drawings.

MR. BEMBEN: On what basis?

MR. HECTOR: As introducing testimony into the record based on privilege.

MR. BEMBEN: How is this based on privilege?

MR. HECTOR: I mean, the document speaks for itself.

MR. BEMBEN: No, there is absolutely no basis for you to say that there's privilege here when all I'm asking her to do is annotate a document that she's reviewed.

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MR. HECTOR: Yeah, I misspoke on privilege. The document speaks for itself.

MR. BEMBEN: That's fine. That's an objection, but you cannot instruct her not to annotate the drawings.

Q So please annotate the proximal end of the vaginal canal with a P.

THE WITNESS: I have to go ahead?

MR. HECTOR: Whether you follow my instructions or not is up to you.

A I think I have to follow Mr. Hector's instructions.

MR. BEMBEN: Okay. Mr. Hector, what basis are you saying that she cannot annotate the drawings?

MR. HECTOR: That the document speaks for itself.

MR. BEMBEN: That's not a basis. That's a basis for objection. That's not a basis for instructing the witness not to answer.

MR. HECTOR: We disagree on that point.

MR. BEMBEN: Okay. Well, then I think we need to shut this down and go to the board and get a ruling on this. Is that what you want to do?

MR. HECTOR: Could we go off the record

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for a moment?

MR. BEMBEN: Yes.

(A short break was taken.)

MR. HECTOR: Okay. Yeah, so withdraw the objection to the witness writing on the document. But I just want to say to the extent that she's writing things that you tell her to write, I just want to make clear that that's counsel's statements and not necessarily hers. But go ahead and proceed.

Q Okay. So we were looking at plate 360.

A Yes.

Q Okay. And what I had asked you to do is with that Sharpie that I gave you, if you could mark the proximal end of the vaginal canal.

A (Complied).

Q Let me know when you've done that.

A Okay.

Q And just before we move on any further, did you discuss the content of the deposition with counsel during our break?

A Not at all. I went to the bathroom.

Q Okay. Can you label the distal end of the vaginal canal with a D?

A (Complied.)

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Q Are you finished?

A Yes.

Q Can you label the midvaginal canal?

MR. HECTOR: Objection. Vague.

A (Complied).

Q I believe we discussed this before, but can you just confirm that the distal end of the vaginal canal is also known as the introitus?

A Yes.

Q And the distal end -- let me rephrase that.

The distance between the proximal end and the distal end of the vaginal canal is about 9 centimeters; is that correct?

A Yes.

Q Okay. And you see in plate 360, the one that we're referring to, the one on the bottom, there is a label: Posterior part of vaginal fornix.

Do you see that?

A Yes.

Q Okay. And there right below that, there is a label: Anterior part of the vaginal fornix.

Do you see that?

A Yes.

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Q And do you see where that's pointing to in the vaginal canal?

A Yes.

Q Okay. Can you confirm that the distance between the distal end of the vaginal canal and the anterior part of the vaginal fornix is about 7 and a half centimeters?

MR. HECTOR: Objection. Foundation.

A The average vaginal length is 9 centimeters. The anterior wall is a bit shorter when the woman has a uterus.

Q Okay. And so what is the distance between the distal end of the vaginal canal and the anterior part of the vaginal fornix?

A Will you say it again?

Q Sure. What is the distance between the distal end of the vaginal canal and the anterior part of the vaginal fornix?

MR. HECTOR: Objection. Vague.

A It depends on the length of the cervix.

Q So you said it depends on the length of the cervix; is that correct?

A Yes.

Q And so does that mean that the distance from the distal end of the vaginal canal to the

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anterior part of the vaginal fornix is a range?

MR. HECTOR: Objection. Vague.

A Yes.

Q And what is that range?

A The cervix is typically going to be 1 to 2 centimeters, so from 7 to 8 on average.

Q And so just to confirm, you said the distance between the distal end of the vaginal canal and the anterior part of the vaginal fornix is from 7 to 8 centimeters on average, correct?

A Yes.

MR. HECTOR: Objection. Foundation.

A Sorry. Yes.

Q In plate 360, can you label the midpoint between the distal end of the vaginal canal and the anterior part of the vaginal fornix?

MR. HECTOR: Objection. Vague.

A (Complied.)

Q When you're finished, can you hold those annotations up so I can see them on the camera?

A (Complied.)

MR. HECTOR: I just want to make the objection that these are counsel's instructions to draw and not necessarily the witness' testimony.

Q Okay. Thank you. You can put it down.

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Now, do you see the urethra in plate 360?

A Yes.

Q Okay. Can you label the proximal end of the urethra with a P?

A (Complied.)

Q Can you label the distal end of the urethra with a D?

A (Complied.) Okay.

Q The distance between the proximal end of the urethra and the distal end of the urethra is about 4 centimeters, correct?

A Yes.

Q Have you heard of the term "midurethra"?

A Yes.

Q What does that term mean?

A In what context?

Q Well, what context have you heard that term used?

A In a few different contexts. That's why I'm asking.

Q Okay. Well, let's start with the first context you've heard it. What does it mean in the first context?

MR. HECTOR: Objection. Vague.

A It could be the middle of the urethra when

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we're measuring pressures and measuring the functional length of the urethra strictly dealing with incontinence, or -- oh, you said start with the first one.

Q Okay. Since you said "or," what other context?

A Or if describing where a lesion is when we're performing urethroscopy and evaluating the urethra visually with a telescope.

Q Is midurethra typically used to describe a region of the urethra?

MR. HECTOR: Objection. Vague.

A Yes.

Q Can you label the midurethra region on plate 360?

MR. HECTOR: Further objection on these instructions to the witness. Your -- these are not questions. These are instructions to the witness, so the witness can choose whether she wants to follow your instructions or not.

MR. BEMBEN: No, that's not accurate.

Q So you have to answer the question. I'm asking you to just label the midurethra region on the plate 360.

MR. HECTOR: Again, that's not a question.

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That's instruction to the witness which she can follow or not follow.

MR. BEMBEN: That is not correct. The only one you cannot answer one of my questions is if you assert privilege or very certain reasons. This is not one of those reasons. You're objecting, Bill.

Q You still need to answer my question.

MR. HECTOR: Again, they're not questions. They're instructions. And the witness can choose whether she wants to follow your instructions or not.

Q Can you label -- can you show me where the midurethra region is on plate 360 by labeling it?

A I need to know which context we're specifically talking about. Is the middle of the midurethra when I'm looking internally to describe a lesion to a colleague? Is it to place a sling? Is it for some other reason? Because I need to know what context I'm using.

Q Does the midurethra region change depending on the context in which you're using that term?

MR. HECTOR: Objection. Vague.

A Can you be more specific?

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Q Does the midurethra region change depending on the context in which you use the term "midurethra"?

A Yes.

Q Does the location of the midurethra change depending on the context in which you're using that term?

MR. HECTOR: Objection. Vague.

A The description changes. I don't think the urethra is changing, so I'm not sure how to answer you.

Q Right. So the midurethra, I believe we just agreed, that it is a region of the urethra, correct?

A Correct.

Q Okay. Can you label that on plate 360?

MR. HECTOR: Again, same objection. She can answer your questions. To the extent you're providing her instructions to do something, the witness can choose to follow or not follow those instructions.

A Then I will choose not to.

Q Okay. You cannot choose not to follow. I'm not providing you instructions. I'm asking you to answer my question.

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Can you show me on plate 360 where the midurethra region is by labeling it?

MR. HECTOR: Same objection.

A My attorney is recommending that I don't label that portion of the urethra.

MR. BEMBEN: Bill, okay, we're going to go to the board on this. Off the record again.

MR. HECTOR: I mean, she can answer your question but --

MR. BEMBEN: Bill, this -- no, she has labeled this point in her declaration --

THE COURT REPORTER: Hang on. Do you guys want to stay on the record or off the record?

MR. BEMBEN: Let's go off the record.

THE COURT REPORTER: Do you agree?

MR. HECTOR: Sure.

THE COURT REPORTER: Okay.

MR. BEMBEN: You don't have to agree to go off the record.

THE COURT REPORTER: Yes, I need both in agreement to go off because if one person wants to be on, I have to, by my license in Illinois, stay on.

MR. BEMBEN: I believe we agree to go off.

(A short break was taken.)

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Q So before we took a break, we were annotating plate 360, and I had asked you to annotate or to show me where the midurethral region is by labeling it on plate 360.

Can you please do that for me?

MR. HECTOR: Objection. Vague.

A (Complied). I would like to say, the drawing is not to scale so neither is my Sharpie on here.

Q Can you show me the annotation?

A (Complied).

Q Thank you. And relative to the vaginal canal, about how many centimeters from the introitus is the midurethral region that you just labeled?

MR. HECTOR: Objection. Vague. Misstates the record.

A I was listening to Bill. Could you repeat the question?

Q Relative to the vaginal canal, about how many centimeters from the introitus is the midurethral region that you just labeled?

A From the introitus, it's around the 2 and a half region, 2 and a half centimeters.

MR. BEMBEN: Can we please mark plate 360

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that you annotated as Deposition Exhibit No. 2?

THE WITNESS: Should I hand it off to somebody?

MR. BEMBEN: To her, just to annotate for now.

(Deposition Exhibit Number 2 marked for identification.)

Q Do you have the exhibit back, Dr. Poulos?

A I do.

Q Okay. Can you please go to plate 357, and I'm looking at the top inferior view.

A Okay. I'm there.

Q Do you see the vagina?

MR. HECTOR: Objection. Vague.

A I see the vagina.

Q Can you show me where the anterior wall of the vagina is by labeling it with an A?

MR. HECTOR: Objection. Instructing.

A (Complied.)

Q Can you show me where the posterior wall of the vagina is by labeling it with a P?

MR. HECTOR: Objection. Instructing.

A I'm not able to do that on this picture.

Q Are you not able to show the posterior wall in this picture?

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A Correct.

MR. HECTOR: Objection. Vague.

Q Are you looking at the anterior -- sorry, let me rephrase that.

Are you looking at plate 357?

A Yes.

Q The inferior view?

A Yes.

Q Okay. And you do not see -- in the vagina, you do not see the posterior wall of the vagina?

A It's a cut section, and so I see a wall of the anterior wall of the vagina. I see the cut portion of the posterior. So I was not understanding what you were asking for, so can you be more specific for me?

Q Okay. Can you show me what you labeled for the anterior wall?

MR. HECTOR: Objection. Instructing the witness.

MR. BEMBEN: Bill, I'm not there in person so I can't see what she labeled.

A (Complied.)

Q Okay. And just ... thank you, Dr. Poulos. And just to -- sorry. Let me rephrase that.

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So what you labeled on the vagina as the anterior wall is the top portion of the vagina in this picture; is that correct?

MR. HECTOR: Objection. Vague.

A It is.

Q Okay. And is the bottom portion of the vagina in this picture a portion of the posterior wall?

MR. HECTOR: Objection. Vague.

A It's a cut edge. I could label it edge of the posterior of the vagina, but I don't see the wall there.

Q Okay. Let me rephrase that question.

Can you label the posterior of the vagina in plate 357?

A Yes.

MR. HECTOR: Objection. Instruction.

Q Can you label the lateral portions of the vagina in plate 357 using an L?

MR. HECTOR: Objection. Instructing.

A (Complied.)

Q Can I see your annotations?

A (Complied.)

MR. HECTOR: Objection. Instructing.

Q Okay. Thank you, Dr. Poulos.

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MR. BEMBEN: Can we mark that as Deposition Exhibit 3, please?

(Deposition Exhibit Number 3 marked for identification.)

Q So, Dr. Poulos, the vagina is oval shaped, correct?

MR. HECTOR: Objection. Vague.

A It can be.

Q Okay. As shown in plate 357 of Netter, what shape would you describe the vagina?

A In this picture, it looks more rectangular.

Q Okay. And in this picture, the anterior and posterior walls are longer than the lateral walls, correct?

MR. HECTOR: Objection. Vague.

A In this picture, they are.

Q In your experience, are the anterior and posterior walls of the vagina longer than the lateral walls?

MR. HECTOR: Objection. Vague.

A It really depends.

Q What does it depend on?

A The condition of the patient.

Q Okay. So under what conditions of the

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patient would the anterior and posterior walls be longer than the lateral walls?

MR. HECTOR: Objection. Vague.

A In a patient who has not delivered a child and does not have vaginal laxity and prolapse.

Q Okay. And in the -- well, strike that.

(Exhibit Number 2009 previously marked for identification.)

Q All right. Can we pull out Exhibit 2009, please.

A I'm on 2009.

Q Okay. I'd like to introduce Exhibit 2009, which is titled Neurourology and Urodynamics.

Have you seen this document before, Dr. Poulos?

A Yes, I have.

Q Did you review this document when you prepared your declaration?

A Yes.

Q Before this IPR, were you familiar with Neurology and Urodynamics?

A Neurourology and Urodynamics, yes.

Q Sorry, just to clarify your answer, you were familiar with this periodical?

A Yes.

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Q Is the image of the vagina that's shown here in Exhibit 2009 anatomically accurate?

MR. HECTOR: Objection. Vague.

A I would say yes, it's relatively accurate.

Q You say "relatively accurate." What parts are not accurate?

A This is an average vagina without prolapse.

Q So is it your opinion that this image on the front of Exhibit 2009 is accurate for an average vagina without prolapse?

A Yeah, obviously there are ranges. But yes, it's a good demonstration of a vaginal anatomy.

Q Okay. You can put that away.

(Exhibit Number 1003 previously marked for identification.)

Q And now I would like to -- can you get a copy of Dr. Berenholz's declaration, which is Exhibit 1003? Actually, we've been going for about an hour and 15 minutes, Dr. Poulos, and it's about noon.

Would you like to take a break and have lunch now?

A If you want to break now, we're thinking

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lunch at 1:00 o'clock, I believe.

Q That's fine. Yeah, just let me know. Would you like to take a short break now, though, since we've been going for about an hour, hour and 15 minutes?

A I was able to leave the room while you guys were having a discussion, so I'm okay.

Q You're okay?

A But if you want a break, we can take a break.

Q No, I'm fine as well. I just wanted to check with you.

So let me know when you have a copy of Exhibit 1005 -- sorry, 1003.

A I have it.

Q All right. So on the front page, this document is titled Declaration of Joseph Berenholz, M.D.

Do you see that?

A Yes.

Q It's been previously marked as Exhibit 1003 in this proceeding.

Are you familiar with this document, Dr. Poulos?

A Yes.

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Q Did you review this document in preparing your declaration in this proceeding?

A Yes, I did.

Q Can you turn to Section 4 of the declaration, Dr. Berenholz's declaration, which begins on page 13? And can you review Section 4, which is titled Basic Concepts and Technologies? Feel free to take your time.

A I want to clarify. I think you said 4, and I'm seeing a 6.

Q I'm sorry, yes. Let me rephrase the question.

Can you please turn to Section 6 of Dr. Berenholz's declaration and review that section.

A How far did you want me to review it?

Q The entire section, which ends on page 23.

A Okay.

Okay. I've read it.

Q Okay. Can you go back up to paragraph 32 of Dr. Berenholz's declaration, which is the subsection Anatomy of Female Urogenital System.

Do you see that?

A I see that.

Q Do you agree with Dr. Berenholz's

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testimony in paragraph 32?

A Yes.

Q Do you agree with Dr. Berenholz's testimony in paragraph 33?

MR. HECTOR: Objection. Foundation.

A Yes.

Q Do you agree with Dr. Berenholz's testimony in paragraph 34 of his declaration?

A Yes.

Q Do you agree with Dr. Berenholz in paragraph 35 of his declaration?

A Yes.

Q Do you agree with Dr. Berenholz in paragraph 36 of his declaration?

A Yes.

Q Do you agree with Dr. Berenholz in paragraph 37 of his declaration?

A Yes.

MR. HECTOR: Objection. Foundation.

Q I'm sorry. Can you repeat your answer, Doctor?

A Yes.

MR. HECTOR: Same objection.

THE WITNESS: Sorry.

Q Sorry. Your answer was yes, Dr. Poulos?

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A Yes, it was yes.

Q Do you agree with Dr. Berenholz in paragraph 38 of his declaration?

A Yes.

Q Do you see paragraph 39 starts a new subsection called Collagen Remodeling?

A I see it.

Q Okay. Do you agree -- do you agree with Dr. Berenholz in paragraph 39 of his declaration?

MR. HECTOR: Objection. Foundation.

A Yes.

Q Do you agree with Dr. Berenholz in paragraph 40 of his declaration?

A Yes.

MR. HECTOR: Objection. Foundation.

THE WITNESS: I was trying to wait for you. I'm sorry.

Q Dr. Poulos, your answer was yes?

A My answer was yes.

Q Do you agree with Dr. Berenholz in paragraph 41 of his declaration?

MR. HECTOR: Objection. Foundation.

A No.

Q What do you disagree with in paragraph 41 of Dr. Berenholz's deposition?

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A I'm not sure if it triggers a normal healing response. It triggers a response.

Q I see. Other than Dr. Berenholz's use of the word "normal" in the first paragraph -- I'm going to ask that again.

Other than Dr. Berenholz's use of the word "normal" in the first sentence of paragraph 41, do you agree with Dr. Berenholz in paragraph 41 of his declaration?

MR. HECTOR: Objection. Vague.

A I also would question if it results in long-term tightening, and I don't know that it does.

Q Is there anything else in paragraph 41 of Dr. Berenholz's declaration that you disagree with?

MR. HECTOR: Objection. Vague. Calls for narrative.

A No.

Q Do you agree with Dr. Berenholz in paragraph 42 of his declaration?

MR. HECTOR: Objection. Foundation.

A Yes.

Q Do you agree with Dr. Berenholz in paragraph 43 of his declaration?

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MR. HECTOR: Objection. Foundation.

A Yes.

Q Okay. Do you see paragraph 44 of Dr. Berenholz's declaration begins a new subsection titled: Prior Art Treatments of Female Urogenital Tissue Using Radiant Energy?

A Yes.

Q Do you agree with Dr. Berenholz in paragraph 44 of his declaration?

MR. HECTOR: Objection. Foundation.

A Yes.

Q Do you agree with Dr. Berenholz in paragraph 45 of his declaration?

MR. HECTOR: Objection. Foundation.

A Yes.

Q Do you agree with Dr. Berenholz in paragraph 46 of his declaration?

MR. HECTOR: Objection. Foundation.

A I can't agree. I'm not familiar with the Titan.

THE COURT REPORTER: Familiar with the what?

A Titan, T I T A N.

Q Do you agree with Dr. Berenholz in paragraph 47 of his declaration?

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MR. HECTOR: Objection. Foundation.

A Yes.

Q Do you agree with Dr. Berenholz in paragraph 48 of his declaration?

MR. HECTOR: Objection. Foundation.

A I can't agree with this one.

Q Why not?

A I don't know what parts of the body Thermicol was used to treat.

Q Are you familiar with Thermicol?

A No. I've heard of it, but I'm not familiar with it.

Q Do you agree with Dr. Berenholz in paragraph 49 of his declaration?

MR. HECTOR: Objection. Foundation.

A I would want explanation of what the use of these technologies is.

Q Other than an explanation of use of these technologies in the first sentence of paragraph 49, do you agree with Dr. Berenholz in paragraph 49 of his declaration?

MR. HECTOR: Objection. Foundation.

A I cannot agree that these technologies were well known in the field of urogynecology without knowing which technologies.

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Q Do you agree that by February 2006, based on the modification of a decades-old traditional gynecological surgery for stress urinary incontinence, clinicians also performed laser vaginal rejuvination to tighten vaginal support tissue in the outer third of the vagina, including the introitus, vulva, and the perineal body, both for cosmetic purposes and to improve sexual function?

MR. HECTOR: Objection. Foundation. The document speaks for itself.

A Yes.

Q Do you agree with the second-to-last sentence that begins: And even as early as November 2000?

MR. HECTOR: Objection. Foundation.

A No.

Q What do you disagree with in the second-to-last sentence of paragraph 49 of Dr. Berenholz's declaration?

A I don't know which laser was being used in a laser vaginal rejuvination or do I know what more sophisticated tools were being compared because I don't know what it's being compared to.

Q Okay. Do you agree with the last sentence

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in paragraph 49 of Dr. Berenholz's declaration?

MR. HECTOR: Objection. Foundation. Vague.

A I could agree that other sources, including RF-based technologies were being considered at that time.

Q Can you turn to paragraph 138 of Dr. Berenholz's declaration?

A One three eight?

Q Yes, one three eight. It's on page 63.

A Thank you. Okay.

Q Go ahead and read that paragraph.

Do you agree with the second sentence that reads: Like the tissue of the vaginal wall, the epithelium that covers the vulva vestibule is a non-keratinized mucosal type?

MR. HECTOR: Objection. Foundation.

A No.

Q Okay. Can you explain why you disagree?

A It's a transition zone from one to the other, so it has some of each element, keratinized and non-keratinized.

Q I see. Do you agree with the third sentence in paragraph of 138 of Dr. Berenholz's declaration that begins "Is beneath"?

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MR. HECTOR: Objection. Foundation.

A Yes.

Q Can you please turn to paragraph 145 of Dr. Berenholz's declaration? And it's on page 66.

A Okay. I'm there.

Q Do you agree with Dr. Berenholz in paragraph 145 of his declaration? Please take a minute to review it, if you need to.

MR. HECTOR: Objection. Foundation.

A I've read it.

Q Do you agree with Dr. Berenholz in paragraph 145 of his declaration?

MR. HECTOR: Objection. Foundation.

A I need to look at what element 51.3 is referring to.

Q Okay. Element 51.3 is referring to the '511 patent itself, claim 51. Go ahead and read that and paragraph 144, the preceding paragraph of Dr. Berenholz's declaration.

A Okay.

Q Okay. And so Dr. Berenholz is comparing claim 1 to claim 51.

Do you understand that?

MR. HECTOR: Objection. Vague.

A I did not understand that. Let me read it

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again.

Q Okay.

A I've read it.

Q Okay. Do you understand that in paragraphs 144 and 145, Dr. Berenholz is comparing claim 1 and claim 51?

A Yes.

MR. HECTOR: Objection. Vague.

Q Let me rephrase that.

Do you understand that paragraphs 144 and 145 of Dr. Berenholz's declaration is comparing claims 1 and 51 of the '511 patent?

A Yes.

Q Did you hear my question?

A I think I answered it. Maybe you didn't hear me. Can we repeat it?

Q Sure. Do you understand that paragraphs 144 and 145 of Dr. Berenholz's declaration is comparing claims 1 and 51 of the '511 patent?

A Yes.

Q And in the first sentence of paragraph 145 of Dr. Berenholz's declaration, he is explaining that the only difference between claims 1 and 51 is this element 51.3.

Do you see that?

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MR. HECTOR: Objection. Vague.

A I see it.

Q Okay. And so with that understanding, do you agree with Dr. Berenholz in paragraph 145 of his declaration?

MR. HECTOR: Objection. Foundation.

A I'd like a moment to look at claim 1 for a second.

Q Take your time.

A Bear with me. If someone wants to point me to a page, it might make this go smoother.

Q So you're looking for claim 1 of the '511 patent?

A Yes.

Q So if you go to the back of the '511 patent, the second-to-last page should have claim 1.

A It's Section 1001, okay. And what page was that?

Q So claim 1 of the '511 patent is on the second-to-last page of the patent.

A Okay. I'm there reading claim 1. And I lost my page in Dr. Berenholz's document. Can you refresh that? We're at 145, I think, paragraph?

Q Paragraph 145, page 66.

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A Okay. Claim 1 and -- did you say page 66?

Q Of Dr. Berenholz's declaration, yes.

MR. HECTOR: You may be in a different --

A Yeah, wrong document. Berenholz 66, almost there.

I've read them both. Could you repeat your question for me?

Q Sure. So do you agree with Dr. Berenholz in paragraph 145 of his declaration?

MR. HECTOR: Objection. Foundation.

A No.

Q What don't you agree with?

MR. HECTOR: Same objection.

A The claim 1 talks about heating a portion of the vagina extending from the introitus inwardly to a location from 1 centimeter to 3.5 centimeters in from the introitus.

Q Correct. And paragraph 145 is saying that the difference between 51 and 1 is that 51 recites the heating includes heating a mucosal surface of the labia minora, correct?

A Yes.

Q Okay. And so then do you agree with Dr. Berenholz in paragraph 145 of his declaration?

MR. HECTOR: Objection. Vague. Misstates

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the record.

A No.

Q What do you disagree with?

A Well, 51 talks specifically about mucosal surface of the labia minora but does not talk about the vagina inward from 1 to 3.5 centimeters.

Q Okay. I see. So in the second sentence of paragraph 145 of Dr. Berenholz's declaration, he states the '511 patent discloses that, and then has a block quote to the patent.

Do you see that?

A I see that.

Q Okay. And then he goes on to say: Based on the understanding of the female reproductive system, a POSA would have understood, quote, a mucosal surface of the labia minora, end quote, as claimed to refer only possibly to inner surfaces or a lining of the labia minora adjacent to the vulva vestibule in that it requires the treated surface to be mucosal epithelium.

Do you see that?

A I see that.

Q Do you agree with that statement?

MR. HECTOR: Objection. Vague.

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A No.

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Q What don't you agree with?

A That this was treating only -- that a POSA would understand it referred only possibly to inner surfaces of the labia minora.

Q Okay. What would you -- let me rephrase that.

In your opinion, how would a POSA have understood the term "a mucosal surface of the labia minora" in the '511 patent, claim 51?

A Heating the portion of the labia minora that appeared to be mucosal.

Q And when you say "mucosal," what does that mean?

A Mucosal is more like the lining of the vagina as it transitions to the external stratified squamous of the skin, and it's an imaginary line based on the coloration of the area.

Q Does the labia minora have non-mucosal surfaces?

A It has stratified squamous surface on part of it.

Q And is that not mucosal?

A Yes.

Q Do you see the sentence in paragraph 145

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of Dr. Berenholz's declaration that starts: The transition from non-characterized -- sorry, let me start that over.

In paragraph 145 of Dr. Berenholz's declaration, do you see the sentence that follows what we're discussing that begins: The transition from non-keratinized epithelium?

A Yes, I see it.

Q Do you agree with that sentence?

A Yes.

Q In the next sentence, do you agree with Dr. Berenholz that Hart's line is the demarcation between the labia minora and vulva vestibule, but this line is defined based on the transition between the smooth, non-keratinized epithelium of the vestibule and the keratinized skin of the labia minora?

MR. HECTOR: Objection. Foundation.

A Yes.

Q Then do you agree with the last sentence of Dr. Berenholz's testimony in paragraph 145 beginning: Thus, a POSA reading the '511 patent would have understood a mucosal surface of the labia minora to mean the outermost edge of the vulva vestibule and/or inner surfaces of the labia

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minora prior to this transition because the claim requires heating a mucosal surface?

MR. HECTOR: Objection. Misstates the document.

A No.

Q What do you disagree with in the last sentence of paragraph 145 of Dr. Berenholz's declaration?

A Mucosal surface of labia minora, being the outermost edge of the vulva or vestibule and/or inner surfaces of the labia minora because the claim requires heating a mucosal surface. The claim includes heating a mucosal surface. It does not require it.

Q Is there anything else that you disagree with in the last sentence of paragraph 145 of Dr. Berenholz's declaration?

MR. HECTOR: Objection. Vague.

A No.

Q Okay. You can put Dr. Berenholz's declaration aside, please, and take out the '511 patent, which is --

A I'm there.

Q If you open to the first page of text after the figures, there's a background section.

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Let me know when you're there.

A I'm there.

Q Do you understand that the background section of a patent describes what was known prior to the invention?

MR. HECTOR: Objection. Misstates the record. Foundation.

A I don't know exactly what it's made up of.

Q What is your understanding of the background section of a patent?

A It is a description of some technologies that were known but may not be all the technologies that were known. I don't know what's missing.

Q But it does describe some of what was known before the invention, correct?

A Yes.

Q Have you read the background section of the '511 patent?

A I have.

Q Do you agree with the statements in the background section of the '511 patent?

MR. HECTOR: Objection. Vague.

A I would need to read it again.

Q Okay. Please do.

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A All right. I've read it.

Q Okay. So do you agree with the statements in the background of the '511 patent?

MR. HECTOR: Objection. Vague.

A For the most part, although I have not read all of the patents and articles that are being referred to.

Q Let's take a look at the second paragraph that discusses collagen denaturation. Do you see that? Begins column 1, line 35.

A Yes.

Q Are you familiar with collagen denaturation?

A Yes.

Q Can you explain to me how collagen denaturation works?

A When collagen is heated to an adequate temperature, the collagen crosslinking bonds break, the collagen becomes more gel-like, and then new crosslinks are formed making a less loose tissue.

Q And at what temperature does collagen denaturation begin?

MR. HECTOR: Objection. Vague.

A I don't know when it begins.

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Q Can you take a look further down in column 1, starting around line 1 -- I'm sorry, starting around line 62 where it starts: The vaginal tissue.

Do you see that?

A I see that.

Q It states: The vaginal tissue of women is stretched during vaginal childbirth.

Do you see that?

A Yes, I see that.

Q Okay. Do you agree with that statement?

A Yes.

Q Okay. If we go to column 2, it explains the first sentence at the end of the first line: Some consequences may include sexual aspects, as may following from loosening of the vagina and its opening, the introitus.

Do you see that?

A Yes.

Q Do you agree with that?

A Yes.

Q It goes on to state that: Such loosening typically occurs with the first vaginal delivery, and the loosening tends to increase with subsequent vaginal deliveries.

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Do you see that?

A Yes.

Q Do you agree with that?

A Yes.

Q It goes on to state: This effective of looseness in this region may include decreased pressure and friction during intercourse and, as a consequence, decreased sexual pleasure for women and their conjugal partners.

Do you see that?

A I see that.

Q Do you agree with that?

A I think the word should be "this effect," but otherwise I agree with it.

Q And so it was known to a person of skill in the art that a loose vagina introitus may lead to decreased sexual pleasure, correct?

MR. HECTOR: Objection. Foundation.

A Correct.

Q Is it fair to say that the person of skill in the art would have understood that tightening a vagina introitus may lead to enhanced sexual pleasure?

MR. HECTOR: Objection. Foundation.

A Yes.

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Q Let's turn to -- I'm sorry. Stay in column 2, and if you look at line 53, beginning at line 53, do you see the paragraph that begins: The energy delivery element? It's at the bottom right.

A Yes.

Q Can you review that paragraph that goes on to column 3 of the next page.

A I've read it.

Q Okay. So the portion that you just read which begins at column 2, line 53 of the '511 patent, it describes the energy delivery element of the '511 patent, correct?

A Yes.

Q Okay. And do you see in line 63 a sentence that begins: These adaptive configurations?

A Yes, I see it.

Q Okay. So it states: These adaptive configurations include a side-mounted configuration of the energy delivery element, the face of the energy delivery element being substantially parallel with respect to the linear axis of the treatment tip.

Did I read that correctly?

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A Yes.

Q So the '511 patent, the energy delivery element that is used must be parallel with respect to the linear axis of the treatment tip, correct?

MR. HECTOR: Objection. Foundation. Misstates the document.

A I don't know that it must be parallel.

Q Why do you say that?

MR. HECTOR: Same objection.

A Reading the summary of the invention, I don't know that this means it must be parallel.

Q Well, that sentence that I just read does say "parallel," correct?

A It does say "substantially parallel."

Q Okay. Is substantially parallel different than parallel?

A Yes.

Q Can you explain how so?

A I mean, I would -- if it had to be parallel, they'd say "actually parallel." This says "substantially," which means partially or mostly parallel.

Q I see. And so "substantially" means partly or mostly, correct?

A That's what it means.

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MR. HECTOR: Objection. Calls for a legal conclusion.

Q Okay. Can you please turn to column 3, beginning in line 41, and can you review that paragraph? It begins: Embodiments of the invention.

A I've read it.

Q Okay. Do you see the last sentence that states: The target zone of embodiments of the invention does not include deeper tissue, such as endopelvic fascia?

A I see that.

Q Does the '511 patent say whether deeper tissue, such as the endopelvic fascia, is heated during remodeling of the target tissue?

MR. HECTOR: Objection. Vague.

A This states that endopelvic fascia is not target tissue.

Q Correct. But does the patent state whether the endopelvic fascia is heated during remodeling of the target tissue?

MR. HECTOR: Objection. Vague.

A Not in this sentence.

Q Does the '511 patent state that endopelvic fascia is heated during remodeling of the target

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tissue anywhere in the '511 patent?

MR. HECTOR: Objection. Vague.

A I have not memorized the entire thing, so I would need to review it and look for that.

Q Okay. Well, does it -- let me rephrase that question before you do that.

Does the '511 patent say that the endopelvic fascia cannot be heated during treatment of the target tissue?

MR. HECTOR: Objection. Foundation.

A May I take a moment?

Q Go ahead. Please.

A I wanted to refer to my declaration for a second. Is that okay?

Q Absolutely. Refer to the documents that you have.

A Could I have you repeat the question?

Q Does the '511 patent say that the endopelvic fascia cannot be heated during remodeling of the target tissue?

MR. HECTOR: Objection. The document speaks for itself.

A And by "cannot," do you mean it's prohibited or by "cannot" meaning it can't deliver heat, it just doesn't technically deliver heat to

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that area?

Q I mean prohibited.

MR. HECTOR: Same objection.

A The endopelvic fascia is not the target tissue.

Are you ready for me to answer?

Q Yes.

A I believe by the monitoring of temperatures, we understand it does not heat other layers to a substantial -- to a degree to substantially change them, but I would need a few more minutes to find what I'm looking for.

Q Go ahead, please.

A Okay. If I could refer to column 13 in the last paragraph --

Q Yes.

A -- more specifically within the target tissue of the invention, a treatment zone may be defined where the heat is particularly focused where the heat reaches a threshold temperature sufficient to cause remodeling. Such a treatment zone may be centered at a particular depth below the endothelium. So to go on, it may, for example, be broadly distributed across the full range of the lamina propria and muscularis and may

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occupy -- or it may occupy a relatively flat zone.

So my understanding is that it's being targeted to the lamina propria and muscularis so that significant heat is not extending deeper than that.

Q But the '511 patent doesn't prohibit heat from reaching the endopelvic fascia, correct?

MR. HECTOR: Objection. Vague. Leading.

A It doesn't describe heating the endopelvic fascia, and it's not the target tissue.

Q That wasn't my question, though.

My question was: Does the '511 patent prohibit heating the endopelvic fascia?

MR. HECTOR: Objection. Asked and answered.

A It does not describe heating endopelvic fascia or treating that layer.

Q It still doesn't answer my question.

My question is: Does the '511 patent prohibit heating the endopelvic fascia?

MR. HECTOR: Objection. Asked and answered. Argumentative.

A I don't know how to answer any differently. I don't know if you're asking me like a legal definition. I'm unaware of with the

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word "prohibited." It's targeting the layers that it needs to treat through this focusing the depth of where it wants to remodel or intends to remodel.

Q Okay. So earlier when we started this line of questioning, you asked if I was asking whether it was prohibited when I was saying "cannot."

Do you remember that?

MR. HECTOR: Objection. Misstates the record.

A I roughly asked you if you meant it cannot like it's not possible or you cannot because it's prohibited.

Q Yes. So you brought up the word "prohibited." What do you understand prohibited to mean?

A That you would not want to use the device to treat that layer for concerns of poor outcome.

Q That's your understanding of the definition of prohibited?

MR. HECTOR: Objection. Argumentative.

A In relation to a medical device.

Q Let me ask again.

What is your understanding of the word

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"prohibited"?

MR. HECTOR: Objection. Asked and answered.

A Prohibited in general terms, in a general word, would mean not allowed.

Q Okay. So let me ask the question that way.

Does the '511 patent say that it's not allowed to treat or heat the endopelvic fascia?

MR. HECTOR: Objection. Foundation. Asked and answered.

A Again, it's intending to focus energy to treat the depth of lamina propria and muscularis, and I don't -- I did not see them saying it's prohibited or forbidden to treat other regions.

Q Okay. Let's stay in column 13 of the '511 patent, and please review lines 11 through 26.

A I've read it.

Q Do you see starting at line 16 of column 13, it states: A purpose of cooling the epithelial surface is to protect it from potentially damaging effects of excess heat that would accumulate in the absence of cooling.

A Yes, I see that.

Q So do you agree that a person skilled in

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the art would have understood that the '511 patent uses cooling to protect the epithelial surface from potentially damaging effects of excess heat?

MR. HECTOR: Objection. Foundation.

A Yes.

Q In the absence of cooling of the epithelial surface, at what temperature would damage to that surface begin?

MR. HECTOR: Objection. Vague.

A It would depend on the concentration of heat being applied and how long it's being held.

Q Can you explain what you mean by the concentration of heat being applied?

A If heat is being applied at a very small pinpoint surface versus a larger surface, the tissue is going to react differently.

Q Okay. And if it is applied at a very small pinpoint surface versus a large surface -- let me ask that question again.

So if it's applied at a very small pinpoint surface how would it react differently than at a large surface?

MR. HECTOR: Objection. Vague.

A How would what react? The tissue?

Q Yes, the tissue that we're referring to,

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the epithelial surface.

MR. HECTOR: Same objection.

A I was listening to the objections. Can you say the question again for me?

Q So if heat is being applied to the epithelial surface at a very small pinpoint, how is the surface going to react differently than if it was applied at a larger surface?

A The heat --

MR. HECTOR: Objection. Vague.

A The heat would have a more concentrated effect in that pinpoint area.

Q Even if the same temperature is applied?

MR. HECTOR: Objection. Vague.

A I believe so.

Before you ask the question ...

MR. HECTOR: Should we take a break?

A Yeah, I drink a lot of water. Or do you want to finish up this part of questioning? It's 1:00 o'clock now.

MR. BEMBEN: We can take a break now. That's fine. Can we go off the record?

THE COURT REPORTER: Sure.

MR. BEMBEN: Do we have agreement to go off the record?

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MR. HECTOR: Yeah.

(A lunch break was taken.)

MR. BEMBEN: Okay. Back on the record.

Q Welcome back.

So we were discussing the '511 patent, column 13, lines 11 through 26, if you could pull that back up, please.

A Okay.

Q Okay. And we were talking about cooling of the epithelial surface.

Do you recall that?

A Actually, I don't remember what we were talking about but, okay, we're there now.

Q Okay. So do you want to take a minute just to reread column 13, lines 11 through 26 of the '511 patent?

A Okay. I've read it.

Q Okay. And so just to back up, you see kind in the middle, starting on line 16, it states, the '511 patent states: A purpose of cooling the epithelial surface is to protect it from potentially damage effects of excess heat that would accumulate in the absence of cooling.

Do you see that statement?

A Yes.

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Q Is it fair to say a person of skill in the art would have understood in the absence of cooling, the surface could potentially be damaged?

MR. HECTOR: Objection. Speculation.

A Yes.

Q And I believe I had asked you in the absence of cooling, at what temperature would damage to the epithelial surface begin?

A I recall that.

Q What was your answer?

MR. HECTOR: Objection. Asked and answered.

A I don't have an answer. I can't answer that question.

Q And remind me, why can't you answer that question?

MR. HECTOR: Objection. Asked and answered.

A I'm not sure -- I don't remember what the temperature of what we were talking about.

Q I'm sorry. You don't remember know what temperature we're talking about?

A The temperature of what?

Q We're talking about the treatment.

MR. HECTOR: Objection. Vague.

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A The temperature of the tissue or the temperature of the device?

Q So paragraph 13, the first sentence talks about heating the tissue.

MR. HECTOR: Objection. Foundation.

A I see that. I want to clarify when you're asking me, is it the heat of the RF electrode or the heat of the tissue?

Q Okay. So let's start with the heat of the tissue. At what temperature -- in the absence of cooling, at what temperature would damage to the epithelial surface begin?

MR. HECTOR: Objection. Vague.

A Could you repeat that for me?

Q In the absence of cooling, at what temperature would damage to the epithelial surface begin?

MR. HECTOR: Objection. Vague.

A I'm still not clear if you're talking about the temperature of the device or the temperature of the tissue.

Q With respect to the temperature of the tissue.

A Okay.

Q In the absence of cooling, at what

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temperature would damage to the epithelial surface begin?

A Give me a second.

Q Sure.

A It would be at some point above 80 degrees.

Q With respect to the device, in the absence of cooling, at what temperature would damage to the epithelial surface begin?

MR. HECTOR: Objection. Vague.

A That would depend on the device.

Q So the temperature of the device and the temperature of the epithelial surface are not necessarily the same; is that correct?

A Yes.

Q Okay. Can you please turn to column 11, line 19 of the '511 patent?

A Do you want me to read that?

Q Yeah, I'm sorry, please read line 19 through 35 -- I'm sorry, 26, 19 through 26.

A I've read it.

Q I'm sorry. I misspoke. For column 11, I mean line 19 through 35. It's that paragraph that starts "The heating of target tissue."

A Then I will take another minute.

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I've read it.

Q Do you see at line 25, the sentence that states: The therapeutic temperature in some cases may be only as high as 45 degrees C or as high as 80 degrees C.

Do you see that?

A I see that.

Q Okay. And then do you see in the remainder of that paragraph, the '511 patent goes on to describe similar treatment ranges that are smaller than 45 to 80 degrees C?

MR. HECTOR: Objection. Vague.

A I see the target tissue temperature may be heated to a temperature between about 50 degrees C and about 75 degrees C.

Q And then column 11, around line 33, says: In still other embodiments, the target tissue is heated to a temperature between 55 degrees C and about 70 degrees C.

Do you see that?

A I see that.

Q Okay. And so a person of ordinary skill in the art would have understood that the embodiments of the '511 patent heat target tissue in a range of 45 to 80 degrees, correct?

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MR. HECTOR: Objection. Foundation.

A Yeah, I don't understand how these relate to which embodiment we are looking at in the end; but yes, this says of the embodiments, it could range from 45 to 80 degrees.

Q Does the '511 patent describe heating target tissue to anything outside of the range of 45 to 80 degrees?

MR. HECTOR: Objection. Vague.

A It describes other ranges within the 45 to 80, not outside of it.

Q Okay. Can you turn to your declaration in paragraph 50, on page 21 of your declaration, Exhibit 2001.

A Five zero?

Q Yes.

A Okay.

Q Do you see in the first sentence, you use the term "ablated"?

A Page 50?

Q No, I'm sorry, paragraph 50.

A Paragraph 50, okay. I did not see the word "ablated." That explains it.

Sorry. Yes, I see it.

Q Okay. What does "ablated" mean?

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A One second.

I think -- I thought I had it spelled out here, so I want to make sure I'm saying it the same way.

Ablated means to cause damage to tissue through an incision, heat -- incision or heat. I'm not finding where I have the definition in here, but I'm pretty sure I have it. I can't find it right now, but ...

Q That's okay. Can you go back to the '511 patent?

A Yeah.

Q And let's go to the claims. So the bottom of the '511 patent, the end of the '511 patent.

A I'm there.

Q Okay. Do you understand what an independent claim is?

A I believe so.

Q And so, for example, claim 1 is an independent claim, correct?

A Yes.

Q Claim 2 would be a dependent claim because it depends on claim 1, correct?

A Yes.

Q And the '511 patent includes four

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independent claims: claims 1, 35, 43, and 51, correct?

A Yes.

Q And do you know what a claim preamble is?

A I've not heard that term used in regard to claims.

Q So a claim preamble, so if you look at claim 1, for example, if you look at claim 1 --

A I am.

Q -- okay, do you see the word "comprising" and then a colon?

A Yes.

Q Like I said, the preamble is everything before that. So a method for remodeling a therapeutic zone within a target tissue, target tissue comprising tissue underlying the epithelium of female genital tissue comprising at least one of vulva, introitus, and vaginal tissue.

Do you see that?

A Yes, I see that.

Q It says claim 1, preamble. Can you just confirm for me claim 1's preamble is the same as claim 35, 43, and 51?

A Yes, they're the same.

Q Okay. And then you see after the

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"comprising" in claim 1, the first limitation is heating the target tissue.

Do you see that?

A What word did you use, the first ...

Q The first limitation. The first step is heating the target tissue.

A Okay. All right. I also didn't know you would call it a limitation, so the --

Q No problem.

A -- first phrase there.

Q The first step is heating the target tissue.

Do you see that?

A I see that.

Q And can you confirm that's the same in claims 35, 43, and 51?

A Yes, it's the same.

Q Okay. Then the next step is remodeling the therapeutic zone of the target tissue, and there's a comma.

Do you see that?

A I see that.

Q Okay. And can you confirm that that's the same in claims 35, 43, and 51?

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A Yes, it's the same.

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Q Okay. And then in claim 1 after the remodeling step, there's a "wherein."

Do you see that "wherein"?

A I see the "wherein."

Q Okay. And the "wherein" in claim 1 explains where the heating is performed, paraphrased; is that fair?

A Yes.

Q Okay. And claims 35, 43, and 51, there's a wherein that describes heating a different area; is that fair?

A Yes.

Q And so is it fair to say that the difference between the independent claims is where the heat -- where the heating is performed, the location?

A Yes.

Q Okay. So let me ask you a few questions about claim 1 that aren't related to the location of where the heating is performed. It's related to the limitations that are the same between claim 1, 35, 43, and 51. Okay?

A Okay.

Q Okay. So is the epithelium part of the target tissue?

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A No.

Q Does claim 1 require cooling the epithelial?

MR. HECTOR: Objection. Vague.

A In this main part of claim 1?

Q In any part of claim 1.

A Yes.

Q Where do you see that claim 1 requires cooling the epithelium?

A In the sub -- I don't know how you refer to these, the claims. I don't call them subclaims, right, just claim 9?

Q Okay. So ...

A -- claim 10, claim 11, which is part of -- it relies on claim 1.

Q Okay. Just focusing on claim 1, independent claim 1, does claim 1 require cooling the epithelium?

A Claim 1 does not mention cooling the tissue.

Q Okay. Same question for claim 35?

A 35 does not mention cooling the tissue.

Q And when you say "the tissue," you mean the epithelium?

A The epithelium.

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Q And claim 44 does not require cooling the epithelium, correct?

A I think you mean 43.

Q I'm sorry, yes.

Claim 43 does not require cooling the epithelium, correct?

A Claim 43 does not mention cooling the epithelium.

Q And claim 51 does not require cooling the epithelium, correct?

MR. HECTOR: Objection. Form.

A Claim 51 does not mention cooling the epithelium.

Q You just answered my question that claim 51 does not mention cooling the epithelium. What do you mean by "mention"?

A It's not described in that, in 51.

Q Do you mean that it's not part of claim 51?

MR. HECTOR: Objection. Vague. Calls for legal conclusion.

A Yeah, I was reading these that claim 1 was also made up of its subparts, so I don't know if I'm misunderstanding what I'm reading. And I obviously don't know what the rule is.

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Q But just going back to claim 1 with respect to cooling the epithelium, your position is that claim 9 includes cooling the epithelium, correct?

MR. HECTOR: Objection.

A 9 and others.

Q 9 and others. 9 and other dependent claims, correct?

A Yes.

Q Okay. And if we can look back up at claim 1, does claim 1 indicate the purpose of the remodeling?

MR. HECTOR: Objection. Vague.

A To remodel the therapeutic zone of target tissue.

Q Does claim 1 indicate whether the purpose is clinical?

MR. HECTOR: Objection. Vague.

A I can't answer that. Can you ask it more clearly? I don't -- I'm not sure what you mean by that.

Q Does claim 1 identify the condition that's being treated?

MR. HECTOR: Option. Vague.

A Claim 1 does not mention a condition.

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Q Does claim 35 indicate which condition is being treated?

MR. HECTOR: Objection. Vague.

A Not specifically in this paragraph.

Q Does claim 43 indicate a condition that's being treated?

MR. HECTOR: Objection. Vague.

A 43 does not mention a specific condition.

Q Does claim 51 indicate a condition that's being treated?

MR. HECTOR: Objection. Vague.

A 51 does not mention a specific condition.

Q Let's go back to claim 1. Does claim 1 require that the method is performed by a specific device?

MR. HECTOR: Objection. Vague.

A Can you explain that further?

Q Sure. So claim 1 is a method claim, correct? It states, "A method for remodeling," and then goes on.

Do you see that?

A I see that.

Q Okay. And so does claim 1 indicate what device performs the method?

MR. HECTOR: Objection. Vague.

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A Can I read this for a second?

Q Yes.

A Please ask the question again.

Q Does claim 1 indicate what device performs the method?

MR. HECTOR: Same objection.

A It does not state specifically in No. 1.

Q So you'd agree that any device that delivers RF energy can be used to perform claim 1?

MR. HECTOR: Objection. Leading. Legal conclusion.

A I don't agree with that.

Q Why not?

A As I'm reading this petition, it's describing the technology used and the design and then talks about the method that would be used.

Q Claim 1 is just describing the method, correct?

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

Q Okay. Claim 35, does claim 35 indicate what device performs the method?

MR. HECTOR: Objection. Vague.

A I would have the same answer.

Q Is your answer the same for claims 43 and

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51?

MR. HECTOR: Same objection.

A Yes.

Q Do you see claim 1 says: Heating the target tissue?

A Yes.

Q Does claim 1 indicate that the target tissue is the only tissue that is heated?

MR. HECTOR: Objection. Foundation. Calls for legal conclusion.

A This claim describes heating the portion of the vagina extending from --

THE COURT REPORTER: I'm sorry, Doctor. You have to speak up.

A The heating includes heating a portion of the vagina extending from the introitus inwardly to location form 1 to 3.5 in from the introitus. It does not describe any other portion in No. 1.

Q Okay. That's the portion of the vagina that was treated in claim 1, correct?

A Yes.

Q Okay. And after comprising in claim 1, the first step that we discussed was heating the target tissue, correct?

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A Yes.

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Q My question is: Does Claim 1 indicate that the target tissue is the only tissue that's heated?

MR. HECTOR: Objection. Asked and answered.

A It doesn't indicate that any other tissue would be heated.

Q Okay. And, conversely, it doesn't indicate that any other tissue could not be heated, correct?

MR. HECTOR: Objection. Foundation. Calls for a legal conclusion.

A It does not indicate that any other tissue could be heated.

Q And so my question was, though: It doesn't indicate any other tissue could not be heated, correct?

MR. HECTOR: Objection. Asked and answered.

A Can you elaborate on that a little bit?

Q Sure. You just answered that claim 1 doesn't indicate that any other tissue could be heated, right?

MR. HECTOR: Objection. Misstates the record.

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A I answered that would be heated.

Q Does claim 1 indicate tissue other than the target tissue could not be heated?

MR. HECTOR: Objection. Asked and answered. Foundation.

A It specifically describes the tissue to be heated using this method.

Q That doesn't answer my question, though. I'm asking, does it indicate that other tissue would not be heated?

MR. HECTOR: Objection. Asked and answered. Foundation.

A It describes a method for a specific portion inward of the vagina, inward from the introitus, and not -- it does not describe to treat anywhere else in this claim.

Q I'm not talking about the location. I'm talking about the target tissue.

MR. HECTOR: Same objection.

A It describes heating the target tissue so ...

Q Correct. And my question is: Does claim 1 indicate that tissue other than the target tissue cannot be heated?

MR. HECTOR: Objection. Asked and

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answered.

A By omission because it doesn't state it could be heated, I read that as it could not be heated substantially.

Q What do you mean that it could not be heated substantially?

A In a method -- in a manner or temperature to make significant change in the tissue other than target tissue.

Q Does claim 1 indicate the temperature to which the target tissue is heated?

MR. HECTOR: Objection. Vague.

A It describes it in the subsequent dependent claims.

Q But claim 1 does not indicate the temperature to which the target tissue is heated, correct?

A Claim 1 --

MR. HECTOR: Objection. Vague.

A Claim 1 does not state the temperature. However, it is described in the subsequent subclaims.

Q By "subsequent subclaims," you're referring to the dependent claims, correct?

A Yes.

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Q So look at claim 2. It says: The method of claim 1 where heating the target tissue comprises heating it to a temperature between 45 degrees C and 80 degrees C.

Do you see that?

A Yes.

Q Would heating the target tissue to a temperature between 45 degrees C and 80 degrees C perform remodeling?

MR. HECTOR: Objection. Vague.

A Collagen modeling?

Q The remodeling that's required by the claims?

MR. HECTOR: Same objection.

A Yes.

Q Would a POSA understand that temperatures below 45 degrees C would remodel the therapeutic zone of the target tissue?

A No.

Q Let's look at claim 35. And if we go to the "wherein" we looked at before, do you see that?

A Yes.

Q So it says: Wherein heating a portion of a vagina circumferentially around its wall from

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1:00 o'clock to 11:00 o'clock, wherein the aspect closest to the urethra is at 12:00 o'clock.

A Yes, I see that.

Q Does claim 35 indicate a size of a portion, that term that's used?

MR. HECTOR: Objection. Vague.

A It mentions heating circumferentially.

Q But it mentions -- it says its own words. It says: Wherein the heating includes heating a portion of the vagina circumferentially around its wall from 1:00 o'clock to 11:00 o'clock. Correct?

A Correct.

Q So the portion is heated, correct?

A Yeah, the portion between 1:00 o'clock and 11:00 o'clock.

Q So you're interpreting -- you're saying that a person of ordinary skill in the art would understand a portion to mean the entire area from 1:00 o'clock to 11:00 o'clock?

A Yes.

Q And what are you basing that opinion on?

A By using the word "circumferentially."

Q Anything else?

A One minute.

Yes, the word "circumferentially."

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Q Okay. Can we go back up to claim 1?

A Sure.

Q Okay. So after the comprising in claim 1, I think we already discussed this, there's the heating step, heating the target tissue, and the remodeling step, correct?

A Yes.

Q Okay. Is it your opinion that only these two steps can be performed in claim 1?

MR. HECTOR: Objection. Vague. Calls for legal conclusion.

A I don't -- I don't know what you mean by "could be performed."

Q I guess in order to satisfy claim 1 -- let me strike that.

Is it your opinion that in claim 1, only the heating and remodeling steps can be performed?

MR. HECTOR: Objection. Calls for legal conclusion.

A And did you say "would be performed"?

Q Can be performed.

MR. HECTOR: Same objection.

A Yes.

(Exhibit Number 1005 previously marked for identification.)

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Q Let's turn to Edwards, which is Exhibit 1005. Can you pull out a copy of that?

A I have a copy of that.

Q Okay. So I'd like to introduce U.S. Patent 6,463,331, which is previously marked as Exhibit 1005 in this proceeding.

I'll refer to this as Edwards. Is that okay?

A Yes.

Q Are you familiar with Edwards?

A With this document, yes.

Q Did you read -- when I say "Edwards," I mean this document, Exhibit 1005.

A Yes.

Q Did you read Edwards in preparing your declaration in this proceedings?

A Yes.

Q Did you understand Edwards?

A I believe so.

Q Okay. If you look at the face of the Edwards patent, do you see that it was filed on March 30th, 2000? It's on the left-hand side.

A Yes.

Q Do you see that Edwards issued as a patent on October 8th, 2002?

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A Yes.

Q If we turn to paragraph 3 of Edwards, which is after the figures, starting on line 5, can you review lines 5 through 13?

A Sorry. Which? Where do you want me at, which column?

Q Line -- column 3, line 5.

A I've read it.

Q Okay. And do you see that Edwards describes applying RF energy to regions of the vaginal wall?

A Yes.

Q Do you see in the last sentence, Edwards states: Circumferential tightening of the vaginal wall may provide physical and physiological improvement in the area of sexual functioning?

A I see that.

Q So at least by October 8th, 2002, which was the issue date of Edwards, applying RF energy to regions of the vagina to improve sexual function was known, correct?

MR. HECTOR: Objection. Speculation.

A I was just going to say it was speculated.

Q What does that mean, it was speculated?

MR. HECTOR: Same objection.

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A Here it doesn't say it's known that this will improve sexual function. Tightening may provide physical and psychological improvement in the area of sexual function.

Q So by 2002, it was known that applying RF energy to regions of the vagina may improve sexual function, correct?

MR. HECTOR: Objection. Speculation.

A It was purported that it may improve. It wasn't known.

Q You understand that Edwards was published, this patent, in 2002, correct?

A Yes.

Q So it was a publication available to the public. Do you understand that?

A I never thought about whether these were public, honestly. But I assume since it's published, anyone could look it up.

Q And so do you disagree with Edwards that circumferential tightening of the vaginal wall may provide physical and physiological improvement in the area of sexual function?

MR. HECTOR: Objection. Vague.

A Did you say "may," or do I agree or disagree?

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Q Do you disagree with the last sentence: Moreover, circumferential tightening of the vaginal wall may provide physical and physiological improvement in the area of sexual functioning?

A I agree with that.

Q Okay. Can you turn to Edwards, column 7, line 14.

A I'm there.

Q Do you see a line starting at line 14, Edwards states: Figure 4 of the block diagram showing a fourth embodiment of a device that can be used for vaginal remodeling?

A Yes.

Q Okay. So the fourth embodiment of Edwards discloses a device for vaginal remodeling, correct?

MR. HECTOR: Objection. Vague.

A Fourth embodiment is a device, yeah, that can be used for vaginal remodeling, I agree with that.

Q Do you understand that Edwards teaches four embodiments?

A Yes.

Q Do you understand that the first three

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embodiments of Edwards are for treating conditions such as menorrhagia and different forms of incontinence?

A Yes.

Q Can you turn to column 13, line 12, please?

A I'm there.

Q Okay. Do you see that Edwards states: Figure 9 is a process flow diagram showing a method for using a fourth embodiment for vaginal remodeling.

Do you see that?

A Yes.

Q So a person skilled in the art would have understood Figure 9 shows a method of vaginal remodeling using the device in Figure 4; is that right?

MR. HECTOR: Objection. Speculation.

A Yeah, it describes using this device for vaginal remodeling. Then it goes on to say for treating -- treat stress incontinence -- or treats incontinence, I should say.

Q Where does it go on to say "treats incontinence"?

A The last --

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Q Specifically with respect to Figure 9.

A Line 16.

Q And then it also states: Remodeling both the anterior and posterior wall provide circumferential vaginal wall tightening resulting in physical and physiological improvement in the area of sexual function, correct?

MR. HECTOR: Objection. Foundation.

A It states that, but I disagree with it.

Q You disagree with the plain language of the Edwards patent?

A Yes.

Q On what basis do you disagree with the Edwards patent?

A Well, it's for modeling of the anterior wall, treats incontinence, targeting bladder outlet hypermobility, by providing increasing support for the bladder outlet. And it describes treating at the bladder neck, which may provide support at different parts of the vagina. And as it describes remodeling anterior, posterior walls, I don't believe it's causing circumferential vaginal wall tightening.

Q That's what Edwards states, correct. If you look at column 13, line 19, it states, quote:

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Remodeling both the anterior and posterior wall provides circumferential vaginal wall tightening resulting in physical and physiological improvement in the area sexual function, correct?

MR. HECTOR: Objection. The document speaks for itself.

A Yes, that's what it says.

Q Let's turn back to the description of Figure 4, which is on column 7, line 14.

A Okay.

Q And the description of Figure 4, if you go to column 7, line 14, and it continues to 8, line 5, do you see that?

A Yes.

Q Can you review that portion of Edwards, please?

A I've read it.

Q Just to confirm, you just read column 7, line 14 through column 8, line 5; is that correct?

A Yes.

Q With respect to Figure 4, Edwards describes a treatment element that he labels 110 that can be inserted into the vagina using a speculum, correct?

A I don't know where you're looking at 110.

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Q I'm sorry. Element 410. Let me restate that question.

With respect to Figure 4, Edwards describes a treatment element 410 that can be inserted into the vagina using a speculum, correct?

A Yes.

Q Does Edwards disclose the size of the speculum?

MR. HECTOR: Objection. The document speaks for itself.

A No, it states a speculum.

Q So Edwards doesn't disclose any dimensions of the speculum?

MR. HECTOR: Objection. The document speaks for itself.

A No. By not describing a size, I took this to be a regular speculum.

Q But Edwards doesn't say that the speculum is a regular speculum, correct?

MR. HECTOR: Same objection.

A I don't see it specifically written out.

Q And Edwards doesn't describe any dimensions of the speculum, correct?

MR. HECTOR: Objection. Asked and

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answered.

A Correct.

Q Does Edwards explain that the treatment element of Figure 4 cannot be used without a speculum?

MR. HECTOR: Objection. Foundation. The document speaks for itself.

A It only describes using it with the speculum and attaching it to the speculum.

Q That was my question. Does it explain the treatment element of Figure 4 cannot used without a speculum?

MR. HECTOR: Same objections. Asked and answered.

A It only describes using it with a speculum, not without.

Q That's not answering my question, though. I'm asking does Edwards explain that the treatment element cannot be used without a speculum?

MR. HECTOR: Objection. Asked and answered.

A It does not. It only explains using it with a speculum.

Q Would a person of ordinary skill in the art have understood the Edwards treatment element

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could be used without a speculum?

MR. HECTOR: Objection. Asked and answered.

A No. When using a device and having radio frequency and applying energy to a vagina, I would want to follow the description as described by the manufacturer and would use it the way it's indicated in the description of attaching the blade to the speculum.

Q Who is the manufacturer?

MR. HECTOR: Objection. Vague.

A That would -- sorry, that would be once it was commercially available. From reading this document in the patent, I would understand that it's intended to be used with a speculum as described.

Q Does Edwards explain that the treatment element of Figure 4 cannot deliver RF energy without first being positioned in the speculum?

MR. HECTOR: Objection. Vague.

A It only describes applying energy once the device is secured to the spectrum.

Q But Edwards does not explain that the treatment element of Figure 4 cannot deliver RF energy without first being positioned in the

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speculum, correct?

MR. HECTOR: Objection. Asked and answered. Leading.

A I could only conclude that it describes the way the device is meant to be used is with attachment to the speculum.

Q Well, can you show me where in Edwards it describes that the treatment element in Figure 4 cannot deliver RF energy without first being positioned in the speculum?

MR. HECTOR: Objection. Vague. Asked and answered.

A As a person of ordinary skill looking at a new device, I would not be analyzing this for what it could do that's not described. I would be reading the description and intending to use it as such.

Q Okay. But that doesn't answer my question.

Can you show me in Edwards where Edwards describes the treatment element in Figure 4 cannot be -- cannot deliver RF energy without first being positioned in the speculum?

MR. HECTOR: Objection. Asked and answered. Vague.

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A No, I can't answer that.

Q Why can't you answer that?

A Because --

MR. HECTOR: Same objection.

A I gave you my answer.

Q No, you didn't answer that question, so let me ask it again.

Can you show me where in Edwards, Edwards describes that the treatment element of Figure 4 cannot deliver RF energy without first being positioned in the speculum?

MR. HECTOR: Objection. Vague. Asked and answered.

A I cannot, but I would not -- I would not do such.

Q And you cannot because Edwards doesn't say that, correct?

MR. HECTOR: Objection. Asked and answered. Vague.

A Again, I would not use it other than the way it's described, as it's described here, and it does not describe using it in alternate methods.

Q Let's turn back to column 13, line 14 of Edwards.

A Line 14?

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Q Yes.

A Okay. I'm there.

Q Do you see, starting on line 14, Edwards states: A method 900 is performed to create a series of regions in either the anterior vaginal wall, the posterior vaginal wall, or both.

Do you see that?

A Yes.

Q I believe we discussed this before, but you disagree with that statement, correct?

MR. HECTOR: Objection. Misstates prior testimony.

A No, I didn't disagree that it creates a series of lesions.

Q Do you disagree that it treats both the anterior and posterior vaginal walls?

MR. HECTOR: Objection. Misstates testimony.

A I do not disagree that it treats anterior and posterior vaginal wall.

Q Okay. But Edwards does not say that the lesions are ablative; is that correct?

MR. HECTOR: Objection. Misstates the record.

Q I'm sorry. I didn't hear your answer.

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A No, the description indicates that they're ablative. I don't know if it describes it as being ablative.

Q I'm sorry. I don't understand your answer. You said, "No, the description indicates they're ablative. I don't know if it describes them being ablative."

A Oh, I don't know if it uses the word "ablative," but the description of these -- go back to 7. Plurality of relatively flat electrodes, and we can see the relative size of these electrodes numbered 423 in Figure 4. And those electrodes are positioned against the epithelium and so they would be ablative to the epithelium as the energy is being applied.

Q Where are you reading that?

A I'm looking at the picture.

Q You're looking at Figure 4?

A The Figure 4.

Q And so it's your position that just based on looking at Figure 4, that the lesions that are created would be ablative; is that correct?

MR. HECTOR: Objection. Mischaracterizes testimony.

A Well, by looking at Figure 4, and I

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believe, as we talked about earlier, the smaller electrodes are going to create more concentrated heat at that position.

Q How large are the electrodes in Figure 4?

A I don't have an exact measurement of those, but I'm looking at those relative to the blade.

Q Okay. How long is -- how large is the blade?

MR. HECTOR: Objection.

Q You said later, you're referring to 420?

A Yes.

Q Okay. So how long is the blade 420?

A I don't have an exact measurement.

Q Did Edwards provide a measurement for the blade 420?

MR. HECTOR: Objection. Foundation.

A I don't believe so.

Q And what are the electrodes in Figure 4? What are the labels?

A 423.

Q Does Edwards provide a measurement for the electrodes 423 in Figure 4?

MR. HECTOR: Objection. Foundation.

A No, I don't see an exact measurement. I'm

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looking at the relative scale on the size of the blade.

Q In your opinion, how -- what is the length of the blade?

A The speculum is going into the vagina to at least mid vagina and the blade is -- needs to go past -- do you see where the 431 is, the locking -- the spring to lock onto the blade, the electrode portion of 420 needs to be past that last blade, so I'm purporting at least 5 centimeters in from the introitus.

Q That's -- in your opinion, that's the length of the blade 420, 5 centimeters?

A That's the distance from the introitus where the electrodes are.

Q Is it your opinion that the blade 420 is 5 centimeters?

MR. HECTOR: Objection. Foundation.

A I'm saying that where the electrodes would be positioned has to be past the end of the speculum blade so that the position where the electrodes would sit would be approximately 5 centimeters into the vagina from the introitus.

Q Okay. So we're talking about the size of the RF elements 423. You said based on the size

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of the blade, you thought that they were a certain size, correct?

A Yes.

MR. HECTOR: Objection. Misstates testimony.

Q And so what is the size of the blade in your opinion, 420?

MR. HECTOR: Objection. Calls for speculation.

A It would be purely speculation. I think it needs to be at least 5 centimeters and have that portion of the electrodes sitting about 5 centimeters in from the introitus.

Q And so with that dimension that you just gave me, how large are the heating elements 423?

A I would estimate that they're in the realm of a couple millimeters.

Q Does Edwards say that the heating elements 423 are a couple millimeters?

MR. HECTOR: Objection. Foundation.

A Not that I know of.

Q Let's go back to column 13, line 14 of Edwards, please. Okay. And if we look again on 14, Edwards says: A method 900 is performed to create a series of lesions in either the anterior

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vaginal wall, the posterior vaginal wall, or both.

Do you see that?

A Yes.

Q In that sentence that I just read, Edwards does not describe the lesions as ablative, correct?

MR. HECTOR: Objection. Asked and answered.

A Not in that sentence.

Q As we discussed before, Edwards has four embodiments, correct?

A Yes.

Q Okay. If we go to column 9, line 2, do you see where it says: Figure 6 of the process flow diagram showing method for using a first embodiment for intrauterine ablation.

Do you see that?

A Yes.

Q If you go down to line 61 of column 9, this is with respect to step 608 of Figure 6.

Do you see that?

A Yes.

Q Edwards describes creating areas of ablative lesions.

Do you see that?

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A Yes.

Q Okay. So in the first embodiment, Edwards expressly states that the lesions are ablative, correct?

MR. HECTOR: Objection. The document speaks for itself.

A Yes.

Q Okay. If you look at column 10, line 15, do you see it says Figure 7 is a process flow diagram showing a method for using a second embodiment for urethral remodeling, correct?

A Yes.

Q If you go to column 11 --

A I'm there.

Q -- line 23, do you see that column, that section is referring to step 10 of Figure 7?

A Step 710?

Q 710 of Figure 7. Do you see that?

A I see that.

Q Line 23, Edwards specifically refers to ablative lesions, correct?

MR. HECTOR: Objection. Leading.

MR. BEMBEN: It's a cross-examination. Of course it's a leading question.

A Yes.

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Q In Figure -- if you go to Column 11, line 45, do you see Edwards says Figure 8 is a process flow diagram showing a method for using a third embodiment for remodeling of the bladder outlet?

A Yes.

Q In column 12, starting at line 38, Edwards describes step 11.

Do you see that?

A Which column? Which line? Sorry.

Q Column 12, line -- I'm sorry, column 12, line 38, describes step 811?

A Yes.

Q Okay. And if you skip down to line 43, Edwards specifically refers to ablative lesions.

Do you see that?

A Yes.

Q So in the third embodiment, Edwards specifically describes creating ablative lesions, correct?

A Correct.

Q All right. We've been going for -- this is a good place to take a break. Want to take a 10-minute break?

A I was hoping you'd say that. Thank you.

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MR. BEMBEN: 10 minutes. Thank you.

(A short break was taken.)

Q Dr. Poulos, did you talk to counsel about the substance of this deposition during the break?

A Nope.

Q Okay. Can you turn back to your declaration and paragraph 29 of your declaration, which is on page 11.

A Okay.

Q Do you see the term "nexus" in paragraph 29?

A Yes.

Q What is your understanding of nexus in the context of an objective indicia?

A My understanding is that would be the focus or the center.

Q The focus or the center; is that correct?

A Yes.

Q Okay. Can you turn to paragraph 177 of your declaration? Page 80.

A I'm there.

Q Okay. Do you see in paragraphs 177 and 178, 179, and 180, you provide some testimony about objective indicia?

A Yes.

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Q Do you provide any analysis of nexus in paragraphs 177 through 180 of your declaration?

A I am not sure if I can answer that using that as the center but being these objective indicia, which refer back to the invention claimed in the patent issued.

Q Is that your answer?

A It's my answer.

Q I don't understand what your answer is.

So you said you're not sure if you can answer that?

A By using nexus as meaning the center. But my understanding of that one word may not be -- I mean, I remember the legal definition. But my understanding is that we're talking about the objective indicia, for example, in these bullet points.

MR. BEMBEN: Okay. I have no further questions at this time. I'll pass the witness.

MR. HECTOR: I might just take a short break to look over my notes.

MR. BEMBEN: Sure. How long do you think you want?

MR. HECTOR: Like 5 minutes. Is that good for you?

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MR. BEMBEN: Yes, that works.

(A short break was taken.)

MR. HECTOR: No further questions from me.

MR. BEMBEN: Okay. Thank you very much, Dr. Poulos. Thank you, Bill, and your team for adjusting for remote deposition. Appreciate it. This concludes the deposition for today.

(Witness excused, 3:33 p.m. Central.)

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April 08, 2025

C E R T I F I C A T E

I, RACHEL F. GARD, CSR, CCR, RPR, CRR, within and for the States of Illinois, Michigan, and Nevada do hereby certify:

That DR. DENISE POULOS, the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 14th day of April, 2025.

Rachel F. Gard

RACHEL F. GARD, CSR, CCR, RPR, CRR
IL-CSR No. 084-003324
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NV-CCR No. 1010
Registered Professional Reporter
Certified Realtime Reporter
Indiana Notary Public
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Exhibits

EX 0001 Dr. Denise Poulos 040825
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EX 0003 Dr. Denise Poulos 040825
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Section Menu

Anatomical Terminology

Before we get into the following learning units, which will provide more detailed discussion of topics on different human body systems, it is necessary to learn some useful terms for describing body structure. Knowing these terms will make it much easier for us to understand the content of the following learning units. Three groups of terms are introduced here:

- Directional Terms
- Planes of the Body
- Body Cavities

Directional Terms

Directional terms describe the positions of structures relative to other structures or locations in the body.

Superior or **cranial** - toward the head end of the body; upper (example, the hand is part of the superior extremity).

Inferior or **caudal** - away from the head; lower (example, the foot is part of the inferior extremity).

Anterior or **ventral** - front (example, the kneecap is located on the anterior side of the leg).

Posterior or **dorsal** - back (example, the shoulder blades are located on the posterior side of the body).

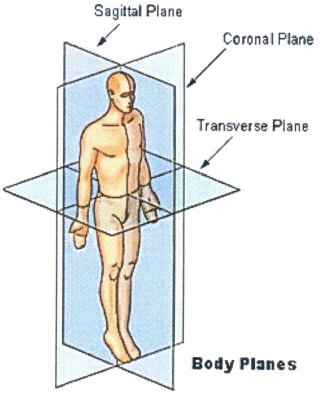
Medial - toward the midline of the body (example, the middle toe is located at the medial side of the foot).

Lateral - away from the midline of the body (example, the little toe is located at the lateral side of the foot).

Proximal - toward or nearest the trunk or the point of origin of a part (example, the proximal end of the femur joins with the pelvic bone).

Distal - away from or farthest from the trunk or the point or origin of a part (example, the hand is located at the distal end of the forearm).

Planes of the Body

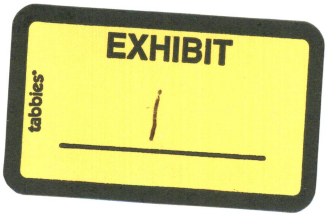


Coronal Plane (**Frontal Plane**) - A vertical plane running from side to side; divides the body or any of its parts into anterior and posterior portions.

Sagittal Plane (**Lateral Plane**) - A vertical plane running from front to back; divides the body or any of its parts into right and left sides.

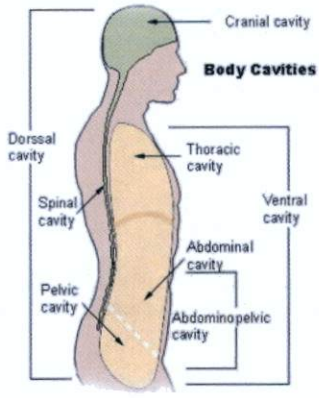
Axial Plane (**Transverse Plane**) - A horizontal plane; divides the body or any of its parts into upper and lower parts.

Median plane - Sagittal plane through the midline of the body; divides the body or any of its parts into right and left halves.



Body Cavities

The cavities, or spaces, of the body contain the internal organs, or viscera. The two main cavities are called the ventral and dorsal cavities. The ventral is the larger cavity and is subdivided into two parts (thoracic and abdominopelvic cavities) by the diaphragm, a dome-shaped respiratory muscle.



Thoracic cavity

The upper ventral, thoracic, or chest cavity contains the heart, lungs, trachea, esophagus, large blood vessels, and nerves. The thoracic cavity is bound laterally by the ribs (covered by costal pleura) and the diaphragm caudally (covered by diaphragmatic pleura).

Abdominal and pelvic cavity

The lower part of the ventral (abdominopelvic) cavity can be further divided into two portions: abdominal portion and pelvic portion. The abdominal cavity contains most of the gastrointestinal tract as well as the kidneys and adrenal glands. The abdominal cavity is bound cranially by the diaphragm, laterally by the body wall, and caudally by the pelvic cavity. The pelvic cavity contains most of the urogenital system as well as the rectum. The pelvic cavity is bounded cranially by the abdominal cavity, dorsally by the sacrum, and laterally by the pelvis.

Dorsal cavity

The smaller of the two main cavities is called the dorsal cavity. As its name implies, it contains organs lying more posterior in the body. The dorsal cavity, again, can be divided into two portions. The upper portion, or the cranial cavity, houses the brain, and the lower portion, or vertebral canal houses the spinal cord.

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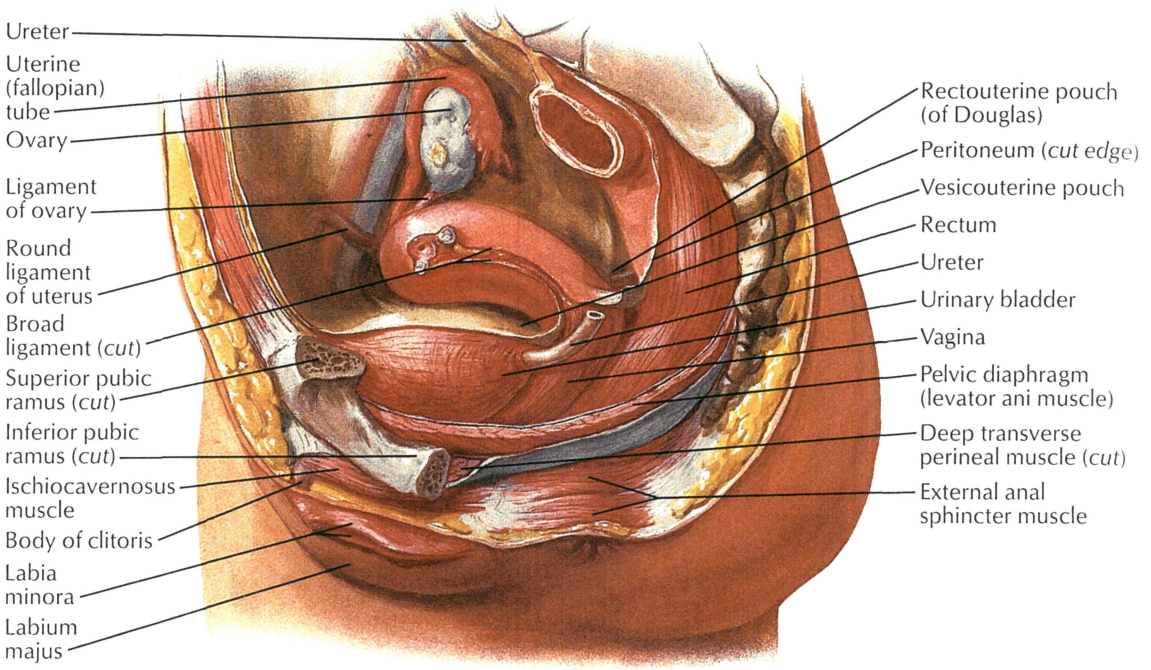
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Paramedian (sagittal) dissection



Median (sagittal) section

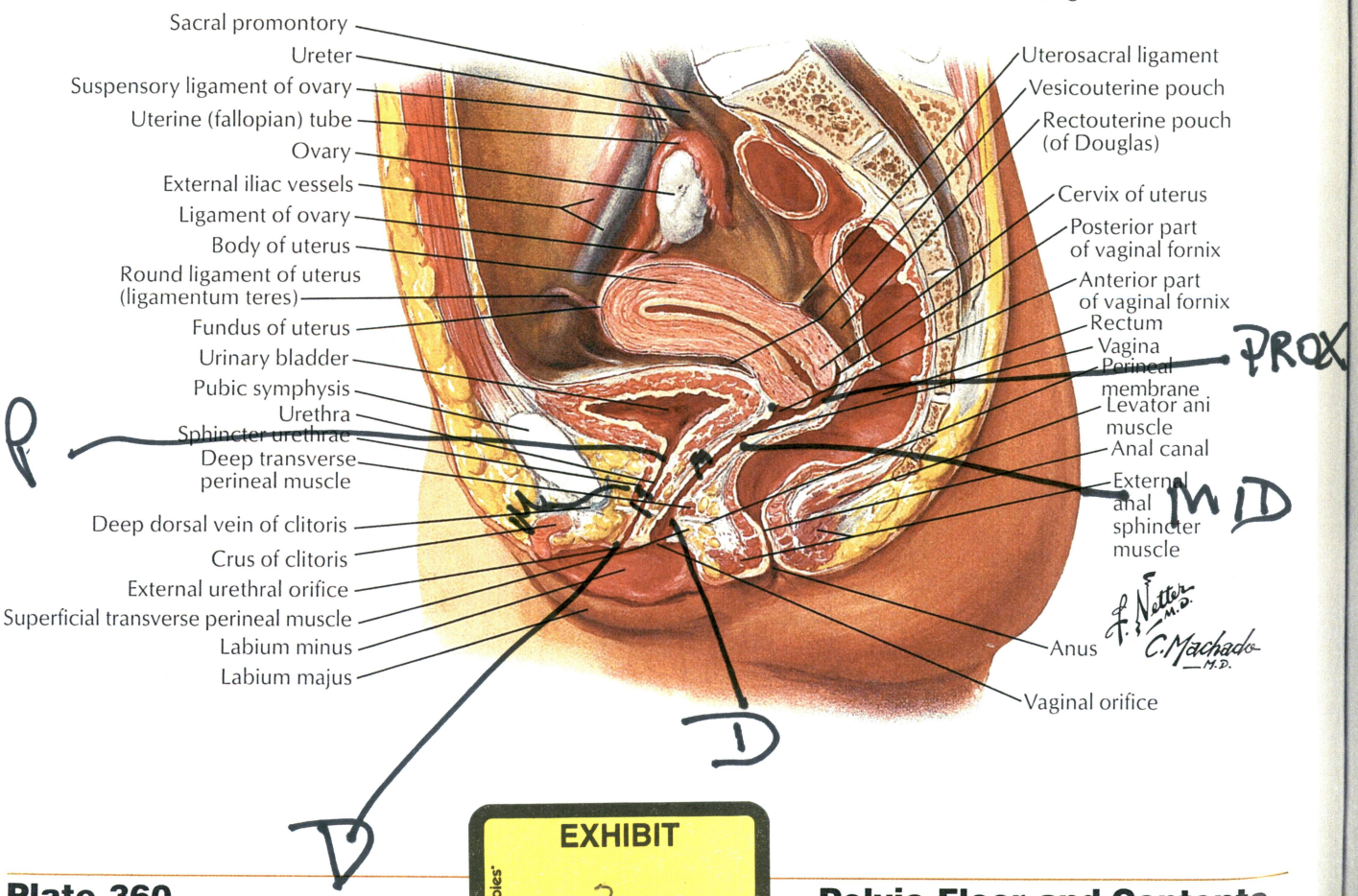
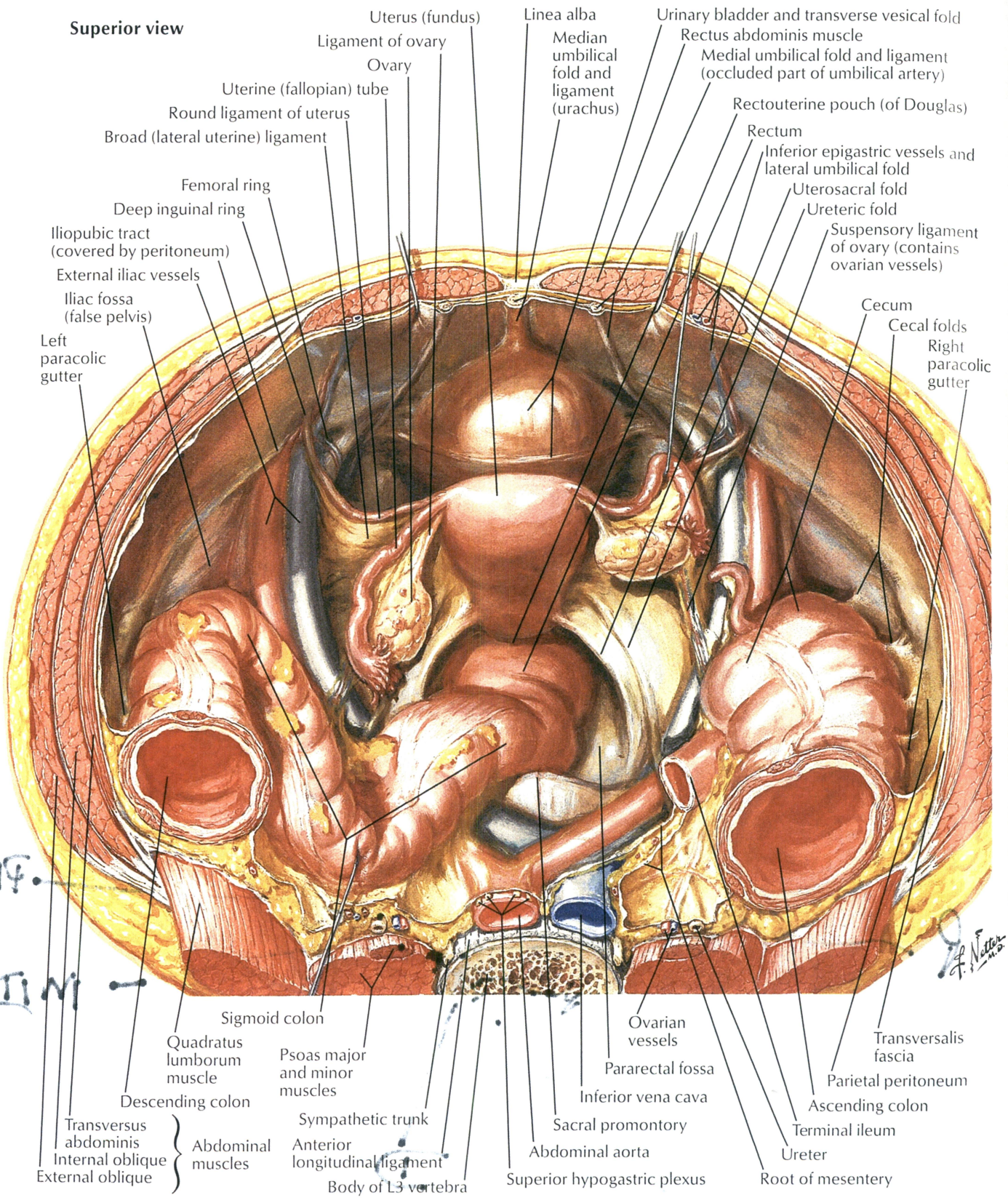
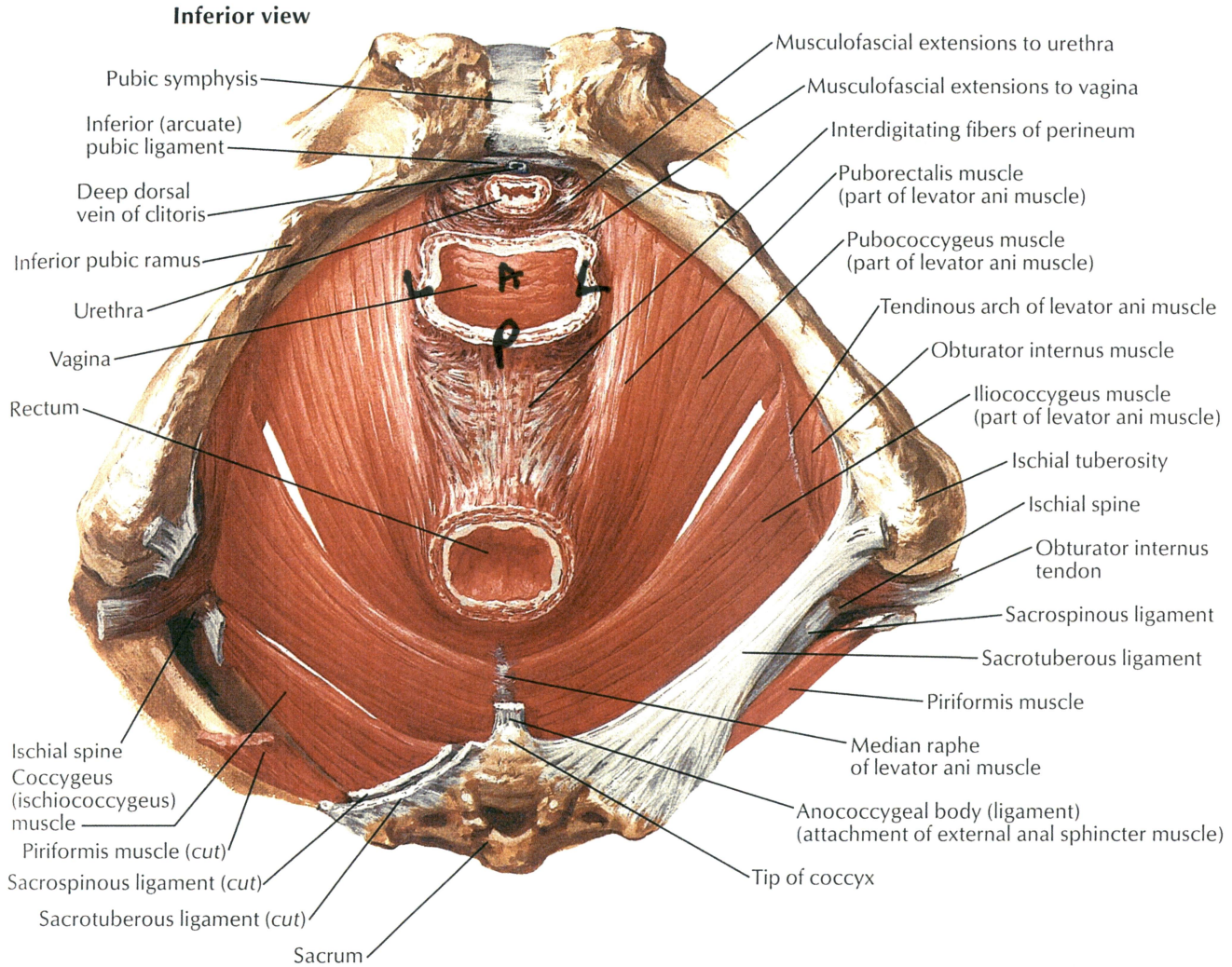


EXHIBIT
tabbies
2


Superior view
Uterus (fundus)
Ligament of ovary
Ovary
Uterine (fallopian) tube
Round ligament of uterus
Broad (lateral uterine) ligament
Femoral ring
Deep inguinal ring
Iliopubic tract (covered by peritoneum)
External iliac vessels
Iliac fossa (false pelvis)
Left paracolic gutter
Linea alba
Median umbilical fold and ligament (urachus)
Urinary bladder and transverse vesical fold
Rectus abdominis muscle
Medial umbilical fold and ligament (occluded part of umbilical artery)
Rectouterine pouch (of Douglas)
Rectum
Inferior epigastric vessels and lateral umbilical fold
Uterosacral fold
Ureteric fold
Suspensory ligament of ovary (contains ovarian vessels)
Cecum
Cecal folds
Right paracolic gutter
Sigmoid colon
Quadratus lumborum muscle
Psoas major and minor muscles
Descending colon
Sympathetic trunk
Transversus abdominis
Internal oblique
External oblique
Abdominal muscles
Anterior longitudinal ligament
Body of L3 vertebra
Ovarian vessels
Pararectal fossa
Inferior vena cava
Sacral promontory
Abdominal aorta
Superior hypogastric plexus
Transversalis fascia
Parietal peritoneum
Ascending colon
Terminal ileum
Ureter
Root of mesentery

For urogenital diaphragm see **Plate 379**



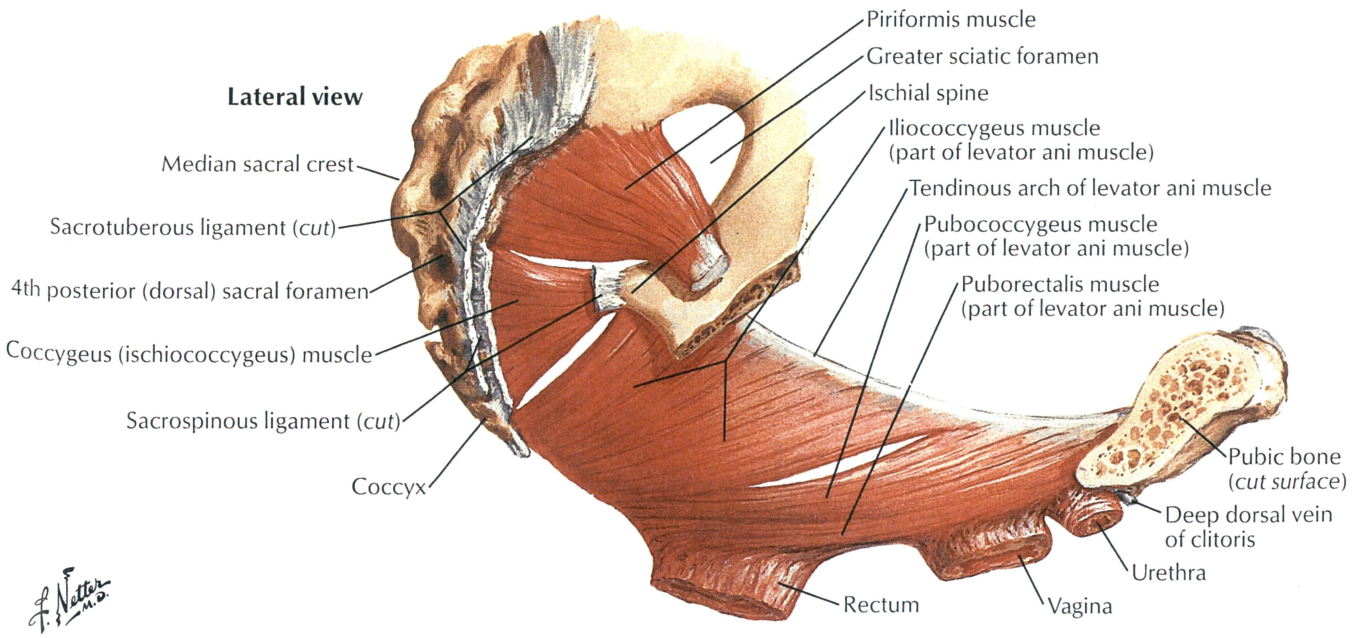


EXHIBIT
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3

5 Pelvic Diaphragm: Female

See also **Plates 263, 366, 370, 392**

