

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3
4

5 BTL INDUSTRIES, INC.,

6 Petitioner,

IPR2024-00703

7 vs.

U.S. Patent

8,961,511 B2

8 INMODE LTD.,

9 Patent Owner.

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11 -- CONFIDENTIAL PROTECTIVE ORDER MATERIAL --
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14 DEPOSITION OF JOSEPH BERENHOLZ, M.D.

15 Remote Zoom Proceedings

16 Washington, D.C.

17 Thursday, January 9, 2025
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23 REPORTED BY:

24 LESLIE ROCKWOOD ROSAS, RPR, CSR 3462

25 Pages 1 - 178

Job No. 7095421

Page 1

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13 Deposition of JOSEPH BERENHOLZ, M.D., taken on
14 behalf of the Patent Owner, Remote Zoom Proceedings from
15 Washington, D.C., beginning at 9:37 a.m. Eastern Standard
16 Time and ending at 5:30 p.m. Eastern Standard Time, on
17 Thursday, January 9, 2025, before Leslie Rockwood Rosas,
18 RPR, Certified Shorthand Reporter No. 3462.
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I N D E X

Thursday, January 9, 2025

WITNESS

EXAMINATION

JOSEPH BERENHOLZ, M.D.

BY MR. HECTOR

7

QUESTIONS WITNESS INSTRUCTED NOT TO ANSWER:
(None)

DEPOSITION EXHIBITS

JOSEPH BERENHOLZ, M.D.

NUMBER	DESCRIPTION	IDENTIFIED
Exhibit 1	Joseph Berenholz, M.D., CV	14
Exhibit 2	Declaration of Joseph Berenholz, M.D.	48
Exhibit 3	Neurourology and Urodynamics, Volume 41, Issue 6, 2022	59
Exhibit 4	Atlas of Human Anatomy, 4th Edition, Frank H. Netter, M.D.	73
Exhibit 5	United States Patent Number 8,961,511 B2, 02/24/15	103
Exhibit 6	United States Patent Number 6,463,331 B1, 10/8/02	122
Exhibit 7	United States Patent Application 2004/0193238 A1, 9/30/04	122
Exhibit 8	United States Patent Number 6,216,704 B1, 4/17/01	122
Exhibit 9	Designer Vaginas by Debra Ollivier	157
Exhibit 10	Administrative Complaint against Joseph Berenholz, M.D.	166
Exhibit 11	Consent Order and Stipulation against Joseph Berenholz, M.D.	166

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Washington, D.C.; Thursday, January 9, 2025

9:37 a.m. Eastern Standard Time

PROCEEDINGS

--oOo--

JOSEPH BERENHOLZ, M.D.,

having been first duly sworn, was examined
and testified as follows:

THE WITNESS: I do.

09:37:20

THE REPORTER: Thank you, sir.

This is Leslie Rosas, CSR Number 3462. We're on
the record.

Counsel, please introduce yourselves.

MR. HECTOR: This is Bill Hector of the law firm
Venable. And with me today is also Parker Zimmerman from
the law firm Venable, and we're here on behalf of the
Patent Owner.

09:37:38

MR. BEMBEN: And this is Richard Bemben from
Sterne Kessler. And with me today is Jennifer Chagnon
from Sterne Kessler, Dallin Glenn from BTL, and of
course, the witness, Dr. Berenholz.

09:37:54

And just for the record, I wanted to mention
that we have hard copies of Dr. Berenholz's declaration,
the exhibits cited in his declaration, as well as the

09:38:10

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1 Institution decision. They are unmarked, clean copies
2 that we printed off and provided to Dr. Berenholz.

3 MR. HECTOR: Great. Thank you.

4

5 EXAMINATION

09:38:25

6 BY MR. HECTOR:

7 Q. Good morning, Dr. Berenholz.

8 A. Good morning.

9 Q. As I said, my name is Bill Hector, and I'm an
10 attorney representing InMode, the Patent Owner in this
11 case. 09:38:30

12 A. Good morning. Good morning.

13 Q. Have you been deposed -- good morning. Can you
14 hear me okay?

15 A. Yes, I can. 09:38:39

16 Q. There's a little bit of an echo. I don't know
17 if there's a way to -- we'll roll with it.

18 Have you been deposed before, Dr. Berenholz?

19 A. Yes.

20 Q. And how many times? 09:38:56

21 A. Approximately six.

22 Q. Okay. So you're familiar with kind of the
23 initial questions of a deposition. I'll try and keep
24 that short.

25 Is that -- does that work for you? 09:39:14

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1 A. Yes. I've never been involved in a patent
2 deposition.

3 Q. Okay. You said you've never been involved in a
4 patent deposition. So what -- what -- what type of cases
5 have you been involved with? 09:39:30

6 A. Well, I'm a medical doctor so my depositions
7 involve medical malpractice.

8 Q. Okay. And would those be medical malpractice
9 claims against you?

10 A. Some of them. 09:39:46

11 Q. And then does some of that cover medical
12 malpractice claims against others?

13 A. Yes, I was an expert for the -- for the
14 plaintiff.

15 Q. And how many cases have you been -- served as an 09:40:07
16 expert?

17 A. As an expert, twice, I believe.

18 Q. And both of those are medical malpractice cases?

19 A. Yes, that's correct.

20 Q. Okay. Just to handle a few formalities: As 09:40:25
21 you're aware, this is, you know, formal proceeding, and
22 this is just like testifying in -- in what you've
23 testified in court before, but before the Board of the US
24 Patent Office -- Patent Trademark and Appeal Board.

25 Do you understand that you're testifying here as 09:40:50

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1 if you were testifying in front of the Board?

2 A. I do.

3 Q. Okay. And you understand that you're under the
4 same obligations to tell the truth as if you were
5 testifying in court?

09:41:08

6 A. I do.

7 MR. HECTOR: I'm sorry, I'm getting a really bad
8 echo. Can we go off the record for a second to clear
9 that up? It's a bit distracting.

10 THE REPORTER: Off the record, Counsel.

09:41:25

11 (Discussion off the record.)

12 (Recess.)

13 THE REPORTER: Back on the 10:18 a.m. Thank
14 you.

15 Q. BY MR. HECTOR: Great. Thank you,
16 Dr. Berenholz.

10:18:18

17 Before we took a break, I think I'd asked you
18 whether it was clear that you are under the same
19 obligations to tell the truth as if you are testifying in
20 court.

10:18:33

21 You understand that to be true?

22 A. I do.

23 Q. Okay. I've got to go over some quick ground
24 rules I mentioned before so I'll go through quickly.

25 You know, during this deposition, I'm going to

10:18:46

Page 9

1 ask you questions, and you'll give answers.

2 Do you understand that?

3 A. Yes, I do.

4 Q. And I'll try not to speak over you and ask that

5 you do the same so that the court reporter can have a 10:18:57

6 clear record.

7 A. I understand.

8 Q. Do you agree to that?

9 Yeah. So just please wait until I finish my

10 answer. 10:19:09

11 And I'm just going to remind you also to give

12 audible answers out loud as opposed to shaking your head

13 or nodding.

14 Do you understand that?

15 A. I do. 10:19:22

16 Q. And if you ever don't understand one of my

17 questions, please let me know, and I'll try to rephrase

18 it.

19 Does that make sense?

20 A. It does. Thank you. 10:19:35

21 Q. But if you do answer the question, I'll assume

22 that you understood it; is that fair?

23 A. Yes.

24 Q. As you're aware, your counsel may object to some

25 of my questions during the deposition, but you are still 10:19:51

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1 obligated to respond unless your counsel instructs you
2 not to answer.

3 Do you understand that?

4 A. I do.

5 Q. And if you need a break at any time today, you 10:20:03
6 know, please let me know, and we'll take a break.

7 Is there any reason why you cannot provide
8 truthful answers to my questions today?

9 A. No.

10 Q. Are you on any -- taking any medications in the 10:20:24
11 near term that would affect your ability to provide
12 truthful answers --

13 A. No, I'm not.

14 Q. -- to the questions? Or to participate in this
15 deposition? 10:20:37

16 A. No.

17 Q. And I think you stated before, you're located in
18 Washington, D.C.; is that correct?

19 A. I live in Milford, Michigan. I'm located right
20 now in Washington, D.C., yes. 10:20:53

21 Q. Okay. And I think you said before that you've
22 testified under oath about six times; is that correct?

23 A. Yes.

24 Q. And is that six depositions or does that include
25 also trial testimony? 10:21:16

1 A. No. Depositions.

2 Q. Have you ever testified at trial?

3 A. I have not.

4 Q. Okay. When was the last deposition before this

5 one that you testified in?

10:21:34

6 A. About two years ago.

7 Q. And what was that case?

8 A. It was a medical malpractice case.

9 Q. And were you testifying as an expert in that

10 case?

10:21:51

11 A. No, I was not.

12 Q. You were testifying on -- as a lay witness?

13 A. No. I was the defendant.

14 MR. BEMBEN: I'll just caution the witness not

15 to divulge any confidential information about that case.

10:22:10

16 You can answer it, but do not divulge any confidential

17 information.

18 Q. BY MR. HECTOR: And so your counsel has

19 instructed you not to divulge confidential information

20 about that case.

10:22:29

21 Why are you not permitted to divulge

22 confidential information about that case?

23 A. It was a patient who filed a claim regarding an

24 outcome against me.

25 Q. And what was the outcome?

10:22:50

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1 A. It was a surgical outcome.

2 Q. What was the type of surgery?

3 A. It was a urinary sling.

4 Q. You said urinary sling. Was that the --

5 A. Yes. S-L-I-N-G. It was a major urethral sling 10:23:13
6 case.

7 Q. And what was were the plaintiff's allegations in
8 that?

9 MR. BEMBEN: Objection to scope, and I'm going
10 to instruct the witness not to divulge any confidential 10:23:34
11 information about that case.

12 Q. BY MR. HECTOR: So you're refusing to answer
13 that question?

14 A. Could you repeat -- did you ask -- what was your
15 question again? 10:23:52

16 Q. I asked: What were the plaintiff's allegations
17 in that case?

18 A. She had urinary retention after surgery.

19 Q. What do you mean by "urinary retention after
20 surgery"? 10:24:16

21 MR. BEMBEN: Objection to scope. And again, I
22 caution you that if the allegations or anything was under
23 seal and is confidential that you should not answer the
24 questions. You do not need to divulge that information.

25 THE WITNESS: I have to abide by counsel. 10:24:34

1 Q. BY MR. HECTOR: So the entire contents of that
2 case are under seal?

3 A. Yes.

4 Q. How about other malpractice cases? I think if
5 my math is correct, I think you said you've testified as 10:24:59
6 an expert in one case. You've -- so you had testified on
7 your own behalf in five other cases. Are the allegations
8 in those other cases also confidential?

9 MR. BEMBEN: Just objection to scope, and also I
10 think it mischaracterizes testimony. 10:25:21

11 THE WITNESS: I was an expert in two cases,
12 Mr. Hector.

13 Q. BY MR. HECTOR: Okay. What were those two
14 cases?

15 A. They were malpractice cases. I was representing 10:25:32
16 the defendants -- or the plaintiffs. I'm sorry.

17 MR. HECTOR: Okay. I'm going to introduce your
18 CV, which is Exhibit 1004. So your counsel can hand you
19 a copy of that.

20 (Exhibit 1, Joseph Berenholz, M.D., CV, was 10:25:59
21 marked for identification by counsel
22 electronically.)

23 MR. HECTOR: Just for the record, that should
24 also be available on Exhibit Share. I don't know if you
25 have access to that, but... 10:26:51

1 THE CONCIERGE: What exhibit do you want that
2 marked as?

3 MR. HECTOR: I think it's marked as Exhibit 1.

4 THE CONCIERGE: Okay. It was previously marked
5 Exhibit 1004; is that right? 10:27:10

6 MR. HECTOR: Yes, correct.

7 THE CONCIERGE: Okay. I just wanted to confirm.

8 Q. BY MR. HECTOR: Sir, so you have in front of you
9 what I've marked as Exhibit 1, which is I believe to be
10 Exhibit 1004 from this proceeding. 10:27:23

11 Do you recognize this document?

12 A. I do.

13 Q. And does this document -- this document is your
14 CV; correct?

15 A. Yes, it is. 10:27:38

16 Q. And is this your entire -- does this CV include
17 your entire professional résumé credential, credentials?

18 MR. BEMBEN: Objection. Form.

19 THE WITNESS: Yes, it is.

20 Q. BY MR. HECTOR: And does this document, your CV, 10:28:04
21 does it the list prior cases in which you've testified,
22 the six other cases?

23 A. No, it doesn't.

24 Q. Why does it not include the prior cases you've
25 testified in? 10:28:26

1 A. It's just not normally part of a CV for a
2 physician.

3 Q. Have you -- have you provided a list of those
4 cases in this proceeding, that you're aware of?

5 A. Sorry, could you repeat that, Mr. Hector? 10:28:44

6 Q. Have you provided the list of those cases in
7 this Inter Partes Review proceeding?

8 A. No, I haven't.

9 Q. So focusing on the cases where you've been a
10 testifying expert before, are those cases confidential? 10:29:08

11 A. I believe they are.

12 Q. So there is no public record where I could find
13 those cases?

14 A. I can't speak to that directly.

15 Q. Okay. I think before I introduced the CV I had 10:29:34
16 asked you about -- to give me an overview of those two
17 cases and your role as an expert in those cases.

18 Could you please do so starting with the first
19 case.

20 MR. BEMBEN: Again, I'm just going to object to 10:29:51
21 scope and remind you not to divulge anything that's
22 confidential from those cases.

23 THE WITNESS: The first case was a damaged
24 newborn, severely damaged newborn, which the plaintiff
25 attorney asked me to be deposed as an expert. 10:30:13

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1 Q. BY MR. HECTOR: And what was the general
2 substance of your expert opinion in that case?

3 MR. BEMBEN: Again, caution the witness not to
4 divulge anything confidential. And objection to scope
5 here.

10:30:35

6 THE WITNESS: It was a case involving a woman in
7 labor who displayed fetal distress and whose subsequent
8 delivery resulted in an injured baby.

9 Q. BY MR. HECTOR: And what was the general outcome
10 of that case?

10:31:00

11 MR. BEMBEN: Again, Counsel, I'm going to object
12 to scope here and counsel the witness that anything
13 that's confidential, including settlements or outcomes
14 that's confidential, you know, do not divulge that
15 information.

10:31:15

16 It's a medical malpractice case, Counsel. It
17 nothing to do with the case we're here today to discuss.

18 MR. HECTOR: I disagree. It goes to the
19 witness' credentials.

20 Q. Please answer.

10:31:28

21 MR. BEMBEN: I caution you to answer to the
22 extent that it's not confidential. And objection to
23 scope.

24 THE WITNESS: I honestly don't know the outcome
25 of the case. After the deposition, I don't know how it

10:31:36

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1 was resolved between the two parties.

2 Q. BY MR. HECTOR: And approximately when did this
3 case occur?

4 A. Mr. Hector, it was many, many years ago. So
5 forgive me. I don't know an exact date. 10:31:58

6 Q. Over ten years ago?

7 A. I believe so, yes.

8 Q. Would it have been before 2006?

9 A. I believe so.

10 Q. Okay. And then I think you had indicated you'd 10:32:17
11 also testified as an expert in a second case. I'd like
12 to ask the same question with regard to that case.
13 Generally, what was that second case about?

14 MR. BEMBEN: And again, I'll object to scope and
15 caution the witness not to divulge any confidential 10:32:36
16 information about that case.

17 THE WITNESS: It was an injury to a woman's
18 labia.

19 Q. BY MR. HECTOR: And how did that injury occur?

20 MR. BEMBEN: Objection to scope. 10:32:59

21 And again, if that's confidential, if there's
22 anything that he's asking you that's confidential, do not
23 divulge that information.

24 THE WITNESS: Excuse me. How was the injury?
25 How did it happen? Was that your question, Mr. Hector? 10:33:18

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1 MR. HECTOR: Sure.

2 THE WITNESS: That was your question?

3 MR. HECTOR: Yes.

4 MR. BEMBEN: Same objections.

5 THE WITNESS: It was a labial injury secondary 10:33:34
6 to a waxing at a salon.

7 Q. BY MR. HECTOR: Okay. And your -- were -- in
8 those two cases, did you submit expert declarations or
9 expert reports?

10 MR. BEMBEN: Objection. Scope. 10:34:00

11 And again, if that's confidential, you do not
12 need to answer that question.

13 THE WITNESS: I offered expert opinion.

14 Q. BY MR. HECTOR: And were those expert opinions
15 challenged in -- before the Court in a motion that's 10:34:15
16 sometimes called a Daubert motion?

17 A. No. This was a simple deposition between the
18 insurance company and the plaintiff.

19 Q. Have you ever had any of your opinions struck by
20 a Court? 10:34:42

21 A. Never.

22 Q. Have you ever had any of your opinions excluded
23 by a Court?

24 A. Never.

25 Q. Okay. So turning to your background, I 10:34:53

1 understand that you have an undergraduate degree from the
2 University of Michigan. What is that degree in?

3 A. That was a Bachelor's degree in general studies.

4 Q. And did you complete all of the premedical
5 school requirements while at Michigan? 10:35:37

6 A. I did.

7 Q. And then where did you go to medical school?

8 A. The Autonomous University of Guadalajara,
9 Mexico.

10 Q. What does "autonomous" mean in relation to that 10:35:56
11 school?

12 A. That's the name of the school. I really never
13 delved into its meaning. Autonomous means -- strictly
14 their title.

15 Q. Did you live in Guadalajara, Mexico, when you 10:36:18
16 went to school there?

17 A. I did.

18 Q. Okay. And did you study urogynecology at the
19 Autonomous University of Guadalajara?

20 A. Yes. 10:36:38

21 Q. Did you apply to other medical schools?

22 A. No.

23 Q. You just applied to one school?

24 A. Yes.

25 Q. Why? Why just one school? 10:36:52

1 A. I had a cousin-in-law who was attending the
2 school, and he had recommended me to come join him. So I
3 applied to the school.

4 Q. Was it always your goal to become a doctor
5 during undergrad at the University of Michigan? 10:37:18

6 A. Yes, it was.

7 Q. It says on your résumé that you're a diplomate
8 of the American Board of Obstetrics, 1992. What does
9 that mean?

10 A. It just means I'm a member of the Board of the 10:37:52
11 American -- of the American Board of Obstetrics and
12 Gynecology.

13 Q. Are you still are you still a member of the --

14 A. Yes, I am.

15 Q. -- of the American Board? 10:38:13

16 A. Yes.

17 Q. You have been continuously --

18 A. I'm Board-certified.

19 Q. And you have been continuously since 1992?

20 A. Every year we have to renew our Board. 10:38:26

21 Q. But under "Professional Experience," it provides
22 a series of roles. Maybe you can provide kind of an
23 overview narrative of your career as a medical doctor.

24 A. Could you give me specific questions with regard
25 to the subject? 10:38:56

1 Q. Oh, okay. So after you graduated residency, did
2 you immediately start your own practice? I'm just trying
3 to get a feel for -- for your career as a doctor and how
4 it progressed.

5 A. I was invited to join a private practice after 10:39:16
6 residency.

7 Q. And where was that?

8 A. That was in Southfield, Michigan.

9 Q. And is that listed on your résumé?

10 A. No. I was invited by Dr. Ken Trader. I was 10:39:36
11 there for about one year.

12 Q. How about after that?

13 A. Sorry?

14 Q. Where did you -- where did your practice take
15 you after that one year? 10:39:54

16 A. I opened my own office in Southfield, Michigan.

17 Q. And is that listed on your résumé, your CV?

18 A. Yes. Northwestern -- well, my own practice was
19 on 12 Mile Road and Northwestern Highway.

20 Q. And how long did you have your own practice for? 10:40:25

21 A. I've had my own practice ever since I left my
22 first practice with Dr. Trader.

23 Q. So what is -- what is the times -- or sorry --
24 dates of -- when did that start?

25 A. Oh, wow. I believe 1985 until present. 10:40:51

1 Q. And that practice is called -- what is that
2 practice currently called?

3 A. It's currently called The Michigan Center for
4 Women's Health.

5 Q. But it's operated under different names since 10:41:20
6 1985?

7 A. I'm sole proprietor. Joseph Berenholz M.D.,
8 sole proprietorship.

9 Q. But I thought you mentioned there was a practice
10 called Northwestern. Was the -- so your practice was 10:41:41
11 originally called Northwestern? It wasn't called the
12 Michigan Center for Women's Health?

13 A. We -- we had a practice called Michigan
14 Institute of Obstetrics and Gynecology, and we also had a
15 practice concomitantly, but had been there before, called 10:42:02
16 Brilliance Medical Spa.

17 Q. Okay. So those are all under the under the
18 umbrella of the Michigan Center for Women's Health?

19 A. Right.

20 Q. What about Better Women's Care; is that also 10:42:26
21 under the same company?

22 A. The same street, but it was a different
23 practice. It preceded that --

24 Q. What is that --

25 A. It preceded the ones we talked about. That was 10:42:40

1 a sole practice.

2 Q. Okay. And so what type of medicine do you
3 practice under these various entities?

4 A. Do you mean currently, Mr. Hector?

5 Q. We'll start with currently, yes. 10:43:03

6 A. Currently, I do cosmetic gynecology, which I've
7 been doing for approximately 30 years. General
8 gynecology, urogynecology, and menopausal medicine,
9 including hormone replacement therapy, as well as
10 laparoscopic surgery. 10:43:34

11 Q. And you said you're currently doing cosmetic
12 gynecology. You've been doing that for 30 years. How
13 about general gynecology; how long have you been doing
14 that?

15 A. My whole career, 40-some years. 10:43:53

16 Q. Okay. And is that the same for urogynecology?

17 A. Yes.

18 Q. And the same for menopausal gynecology?

19 A. The same as what again?

20 Q. Menopausal -- I think you've listed -- 10:44:08

21 A. Yes, yes.

22 Q. -- menopausal gynecology?

23 A. Yes.

24 Q. Okay. So when did you first start doing
25 cosmetic gynecology? You said 30 years ago. Do you know 10:44:39

1 roughly when that was?

2 A. About, I would say 29 or 30 years ago is when I
3 began.

4 Q. Okay. So 1995?

5 A. Let's see. We're in '24. So that would be 10:44:58
6 around 1995.

7 Q. What did you do before that in your medical
8 practice?

9 A. I was doing obstetrics and gynecology.

10 Q. And what is obstetrics and gynecology? 10:45:23

11 A. I was delivering babies as well as seeing
12 gynecologic patients.

13 Q. And do you still do obstetrics?

14 A. No.

15 Q. When did you stop doing obstetrics? 10:45:42

16 A. Oh, about I think 15 years ago.

17 Q. And why did you stop?

18 A. I wanted to sleep at night.

19 Q. And not be called to the hospital at three in
20 the morning to deliver babies? 10:46:15

21 A. Yes.

22 Q. That makes sense.

23 When did you start using radiant energy devices?

24 A. I would say 1995, 1994.

25 Q. And what devices were you using in '95, '94? 10:46:44

1 A. We were doing uterine ablations.

2 Q. Using what devices? What devices were you using
3 to do those uterine ablations?

4 A. It was a device that was used hysteroscopically
5 to pass into the woman's uterus through the vagina 10:47:15
6 through the cervix to destroy and contract the
7 endometrial cavity, which is the cavity inside the
8 uterus, for excessive bleeding.

9 Q. So you're that treating excessive bleeding of
10 the uterus? 10:47:40

11 A. That is correct.

12 Q. And you said "hysteroscopically." What does
13 that mean?

14 A. A hysteroscope is an fiberoptic scope that lets
15 you look inside the uterus while you're doing the 10:47:51
16 procedure, at the same time cooling the endometrial
17 cavity with a continuous flow of sterile saline.

18 Q. Does the sterile saline serve any other function
19 other than cooling?

20 A. No. 10:48:18

21 Q. Why would you use -- why would you use saline as
22 opposed to other fluids?

23 MR. BEMBEN: Objection to form.

24 THE WITNESS: It has to do with osmotic
25 pressures, and saline is the normal fluid in the human 10:48:37

1 anatomy. So you shouldn't be using water.

2 Q. BY MR. HECTOR: So you said that this device
3 would -- it's a hysteroscope that would go up through the
4 vagina and then like destroy the endometrial lining; is
5 that what you said? 10:49:23

6 A. Yes.

7 MR. BEMBEN: Objection to form.

8 THE WITNESS: It would pass through the cervix,
9 through the vagina, through the cervix into the uterine
10 cavity. The saline would inflate the cavity, keep it 10:49:35
11 under a certain temperature while you destroyed the
12 lining.

13 Q. BY MR. HECTOR: How do you destroy the lining?

14 A. You would run the device over the surface of the
15 endometrial cavity, destroying it with high temperature, 10:49:56
16 thermal energy.

17 Q. And what type of thermal energy did that device
18 use?

19 A. I believe that was radio frequency energy.

20 Q. And it would destroy the surface? 10:50:16

21 A. Only.

22 Q. Only. Okay.

23 A. Yeah.

24 Q. Would that be ablating the surface?

25 A. Yes, it is. 10:50:27

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1 Q. Okay. You said the saline in that case was used
2 to expand the cervix?

3 A. The uterine cavity.

4 Q. The uterine cavity. Okay.

5 Would there be like bleeding or like 10:50:46
6 sloughed-off tissue during that procedure?

7 MR. BEMBEN: Objection to form.

8 THE WITNESS: I don't remember that happening,
9 no.

10 Q. BY MR. HECTOR: So no -- when you ablate the 10:51:03
11 uterine wall, there's no tissue that's sloughed off or
12 nothing comes off the wall?

13 A. Not at the time of the actual surgery. That's
14 correct.

15 Q. You said not at the time, but maybe after the 10:51:24
16 surgery?

17 A. I never received that complaint from patients.

18 Q. You said not at the time of the surgery. It is
19 possible there's bleeding after the surgery?

20 A. Bleeding afterwards? Is that what you asked? 10:51:45

21 Q. After the surgery, yes. Yes.

22 A. There would be spotting because of all of our
23 manipulation.

24 Q. And would there be scarring of the uterine wall?

25 A. Definitely. 10:52:02

1 Q. Now you said just the surface layer. Like
2 what -- just the mucosal surface would be ablated in
3 that --

4 MR. BEMBEN: Objection.

5 Sorry. Go ahead. Finish, Bill. 10:52:20

6 THE WITNESS: Hold on.

7 MR. BEMBEN: Sorry about that. I interrupted
8 you. Please go ahead.

9 Q. BY MR. HECTOR: Would just the mucosal surface
10 be ablated in that procedure? 10:52:38

11 A. Yes, the endometrial lining only.

12 Q. Okay. That was the -- that was the first
13 procedure that you did. What subsequent procedures have
14 you done using radiant energy devices?

15 A. About 29, 30 years ago, I began doing laser 10:53:06
16 vaginal rejuvenation surgery.

17 Q. And what is that?

18 A. That is we tightened vaginas and sculpted labium
19 minora as well as labium majora to reduce their size.

20 Q. And that what radiant energy device would you 10:53:43
21 use for that treatment?

22 A. That was a diode laser, like a YAG laser.

23 Q. And how does that work? How does a diode or YAG
24 laser work?

25 A. It works twofold. It cuts and contracts 10:54:01

1 simultaneously as well as actually ablating
2 simultaneously.

3 Q. You said cuts and contracts. How does it cut
4 and --

5 A. Well, the energy from the laser has a cutting 10:54:25
6 mechanism, and in response to the thermal energy, the
7 tissue shrinks. And at the same time, the heat
8 coagulates the blood vessels.

9 Q. And what do you mean by "coagulation" or
10 "coagulates" blood vessels? 10:54:55

11 A. Excuse me.

12 Q. I'm sorry?

13 A. Stops bleeding. Seals them. I'm sorry. Seals
14 the blood vessels.

15 Q. Okay. So when you use a laser, does it create 10:55:05
16 like a crater in the skin?

17 MR. BEMBEN: Objection to form.

18 THE WITNESS: I'm not sure what you mean by a
19 crater. And which skin are you referring to?

20 Q. BY MR. HECTOR: Yeah. So with -- with -- with 10:55:30
21 regard to the diode YAG laser and the treatment you were
22 describing, you know, if you directed this laser to
23 mucosal epithelium, it would basically burn a hole down
24 through that tissue; is that fair?

25 A. I think it was more of a thermal energy scalpel, 10:55:49

1 if you would think of it that way, that was sculpting.

2 Q. Can you describe a little more what a thermal
3 energy scalpel would be? I mean...

4 A. The laser is a fiber that transmits very high
5 thermal energy resulting in tissue both being cut, 10:56:21
6 shrunk, and ablating at the same time. It's a cutting
7 tool that does all three things.

8 Q. And are RF devices also used for the same
9 functionality: Cutting, ablating, and coagulating?

10 A. Which RF devices are there? I use several 10:56:59
11 currently.

12 Q. Well, you were describing treatments with a
13 diode YAG laser. Do you also use RF devices for laser
14 vagina rejuvenation?

15 A. Oh, yes, we do. 10:57:23

16 Q. And when you do that laser vaginal rejuvenation
17 with an RF device, are you cutting, coagulating, and
18 ablating like you would with a diode YAG laser?

19 A. No. Different modality. We're heating,
20 contracting, and essentially tightening the female 10:57:47
21 reproductive organs.

22 Q. Okay. So you're not -- you're not ablating or
23 cutting with RF?

24 A. No. The next generation of endometrial or
25 uterine ablation is RF, and those are the ones today 10:58:16

1 we're still using, but more sophisticated.

2 Q. Okay. So as of today, you're using RF for
3 endometrial ablation?

4 A. Very much so, yes.

5 Q. Okay. When you say "we," do you mean your 10:58:53
6 practice?

7 A. Sorry. It's an old habit. We always speak in
8 the collective in medicine, but it's me.

9 Q. Okay.

10 A. And my colleagues. 10:59:11

11 Q. Your CV lists three papers. Is that the entire
12 list of papers that you've published?

13 A. Yes, it is.

14 Q. What's the date on the second paper, "Safety and
15 Efficacy of Non-Invasive," dot, dot, dot? 10:59:55

16 A. I believe that's 2020.

17 Q. So you never published any papers before 2019?

18 A. No, I did not.

19 Q. Something you've gotten into later in your
20 career? 11:00:27

21 A. I'm getting older. I have more time to do
22 things like that.

23 Q. So it says under "Speaking Engagements" that
24 you're the lead speaker for Ultrafemme 360 North America
25 for the BTL Corporation. 11:00:56

1 What does that mean?

2 A. I lecture to physicians around the country
3 regarding RF therapy on behalf of the BTL Corporation.

4 Q. And what's the substance of those lectures?

5 A. Well, they entail both -- it's no longer called 11:01:33
6 Ultrafemme. It's now called EMFEMME 360. I lecture on
7 behalf of that as well as EMSELLA, E-M-S-E-L-L-A, Chair
8 which is the high-intensity electromagnetic therapy for
9 incontinence.

10 Q. How does the EMFEMME 360 device work? 11:01:58

11 A. How does it work?

12 Q. Yes.

13 A. It heats the vaginal mucosa to contract
14 secondary to treating the target tissue beneath the
15 mucosa, enhancing collagen production, stimulates 11:02:24
16 lubrication, and also enhances sensation. And it's used
17 to shrink the entryway into the vagina as well as shrink
18 the labia minora as well as shrink the labia majora.

19 Q. You said "target tissue." What do you mean by
20 "target tissue"? 11:03:08

21 A. The tissue that lies under the vaginal mucosa,
22 where there is excessive deposits of collagen.

23 Q. And what tissues are those?

24 A. The lamina propria.

25 Q. Any others? 11:03:33

1 A. Predominantly lamina propria. Could involve
2 muscularis as well.

3 Q. And I assume there's a -- if I understand the
4 way the EMFEMME 360 device works, there's kind of a bay
5 station that powers the whole operation, and then there 11:04:06
6 would be a hand piece.

7 Is it the same hand piece for all of those
8 treatment areas that you listed? I think is it entryway
9 to the vagina, the labia minora, the labia majora?

10 MR. HECTOR: Objection to form. 11:04:24

11 THE WITNESS: The vaginal probe is a probe, a
12 rounded lengthy probe, which has a transducer around the
13 tip that delivers energy in a 360-degree manner. The
14 device handle for the entrance to the vagina is a shorter
15 device that is used, hand held, again delivering RF 11:04:47
16 energy, and another short device to be used for labia
17 minora as well as labia majora.

18 Q. BY MR. HECTOR: So there are three different
19 hand pieces?

20 A. The short ones are very similar in appearance. 11:05:10

21 So yes.

22 Q. And are the RF settings the same for all -- used
23 for all three devices?

24 MR. BEMBEN: Objection to scope and form.

25	THE WITNESS: There are different temperature	11:05:40
----	--	----------

1 settings for the vaginal probe versus the external
2 structures as well as differences in time and use.

3 Q. BY MR. HECTOR: How do those different -- how do
4 those differ?

5 MR. BEMBEN: Objection to scope and form. 11:06:06

6 THE WITNESS: We spend shorter time on the
7 external structures versus the interior of the vagina.

8 Q. BY MR. HECTOR: And why is that?

9 MR. BEMBEN: Objection to scope and form.

10 THE WITNESS: Just tissue response is different 11:06:36
11 externally and in terms of tolerability versus vaginal
12 heating.

13 Q. BY MR. HECTOR: How do you know that the tissue
14 response is different externally?

15 A. When I meant tolerability. The patient has less 11:07:08
16 or almost no discomfort with internal, whereas external,
17 there seems to be more sensitivity to it.

18 Q. And by "internal," you mean in the vaginal
19 canal?

20 A. Yes. 11:07:28

21 Q. And by "external," you mean the labia minora and
22 labia majora?

23 A. As well as the entrance to the vagina.

24 Q. Okay. The external portion of the entrance to
25 the vagina? 11:07:47

1 A. Correct.

2 Q. Does that have a name medically?

3 A. Well, it's the introitus and vestibule of the
4 vagina.

5 Q. So the vestibule is the external mucosal 11:08:04
6 tissue --

7 A. Yes. You could --

8 Q. -- of the vagina?

9 A. -- call it that.

10 Q. Okay. And the external vestibule is more 11:08:15
11 sensitive to heating than the internal vaginal canal; is
12 that correct?

13 A. Seems to be, yes.

14 Q. And you said there are different temperature
15 settings -- 11:08:39

16 A. Yes.

17 Q. -- for the vaginal -- internal vaginal treatment
18 versus the external treatment.

19 MR. BEMBEN: Just objection to scope and form.

20 THE WITNESS: Yes, there is different 11:08:52
21 temperature settings.

22 Q. BY MR. HECTOR: And how do those differ?

23 MR. BEMBEN: Objection to scope.

24 THE WITNESS: Higher temp intravaginally,
25 slightly lower temp externally. 11:09:05

1 Q. BY MR. HECTOR: And how did you determine -- and
2 by "you," I mean you or BTL -- how did you determine that
3 the temperature should be different internally,
4 externally -- versus externally?

5 MR. BEMBEN: Objection to form and scope. 11:09:30

6 THE WITNESS: This was part of BTL's research,
7 and we follow their protocol.

8 Q. BY MR. HECTOR: And do you know who was involved
9 with that research?

10 A. I've never met them, no. 11:09:46

11 Q. Do you know their names?

12 A. No.

13 Q. Do you know how long that research took to
14 complete or what was involved?

15 A. I don't know. 11:10:03

16 Q. How did you learn about the difference in
17 temperature and time of treatment to be used in the
18 internal versus external use of the BTL device?

19 A. We followed prescribed protocol, and we are
20 currently in the -- we've been doing research on behalf 11:10:30
21 of BTL for another published paper regarding the therapy
22 of female anatomy with EMFEMME 360.

23 Q. And you're involved with the research for that
24 paper?

25 A. I am. 11:10:54

1 Q. And what's the kind of status of that paper; is
2 it being written, in peer review?

3 A. Right. It's currently being written.

4 Q. And is anyone else involved with that paper?

5 A. I believe there's another doctor doing 11:11:28
6 simultaneous research, but I don't recall her name. I
7 believe she lives in New Jersey.

8 Q. So you're not working -- you're working on your
9 own on the paper?

10 A. Yes, I am. 11:11:52

11 Q. And how long have you been affiliated with BTL?

12 A. About seven years.

13 Q. And does BTL compensate you for your services
14 outside of testifying here?

15 A. Not at all. 11:12:17

16 Q. You've received other than -- other than this
17 proceeding -- by "this proceeding," I mean the IPR
18 proceeding for which you're sitting for a deposition
19 today -- you've never received any compensation from BTL?

20 A. None at all. 11:12:33

21 Q. Have you received any stock in BTL?

22 A. I have not.

23 Q. Have you received any free medical devices from
24 BTL?

25 A. We only have one device, and the probes we use 11:12:48

1 are for research, strictly.

2 Q. Do you pay for those probes?

3 A. No.

4 Q. Do you use those probes as part of your

5 practice?

11:13:03

6 A. We do use the probes as part of the research and
7 the practice.

8 Q. I believe you're on the medical advisory board
9 of BTL; is that correct?

10 A. Correct.

11:13:24

11 Q. And what does that entail?

12 A. Well, we haven't had a meeting in several years
13 so -- and right now it doesn't entail anything.

14 Q. What about several years ago when you had a
15 meeting with them; what did that entail?

11:13:54

16 A. It was meetings about the EMSELLA Chair.

17 Q. Does the EMSELLA Chair use RF?

18 A. High-intensity electromagnetic therapy.

19 Q. And how does that device work, the EMSELLA
20 Chair?

11:14:17

21 MR. BEMBEN: So just objection to scope.

22 THE WITNESS: It stimulates contraction of the
23 pelvic floor.

24 Q. BY MR. HECTOR: How does it stimulate
25 contraction of the pelvic floor?

11:14:29

1 A. The electromagnetic waves are targeted to the
2 pelvic floor muscles and by contracting, strengthens
3 them.

4 Q. How does the patient use the EMSELLA device?

5 MR. BEMBEN: Objection to scope. 11:14:49

6 THE WITNESS: They sit on the chair fully
7 clothed.

8 Q. BY MR. HECTOR: In your résumé it lists that
9 you're a luminary speaker for ThermiGen Corporation?

10 A. Was. 11:15:14

11 Q. Was. That was from 2015 to 2018?

12 A. Yes.

13 Q. And what did that entail?

14 A. Meeting with physicians to discuss the
15 technology. 11:15:26

16 Q. Were you involved with the development of the
17 ThermiGen technology?

18 A. I was not.

19 Q. Was your role similar at ThermiGen to what it is
20 at BTL, you know, speaking on behalf of the company to 11:15:42
21 encourage other doctors to use it?

22 A. Similar, yes.

23 Q. What other doctors did you work with in your
24 time with ThermiGen? Yeah, what --

25 A. What other doctors did I work with at ThermiGen? 11:16:00

1 Q. Yeah, as part of your duties for ThermiGen.

2 A. I didn't work with any doctors.

3 Q. I thought you said -- you said earlier that

4 you -- you've met with physicians to discuss the

5 technology?

11:16:28

6 A. The technology, I spoke with private physicians

7 locally.

8 Q. And which -- which physicians?

9 A. There were numerous physicians that we had

10 dinner and I spoke to them about the technology we were

11:16:45

11 using in our office.

12 Q. Do any names come to mind?

13 A. Not really. Again, this is something that

14 transpired years ago.

15 Q. And were you aware of the litigation between

11:17:07

16 Vieve and ThermiGen?

17 A. I understand there was litigation.

18 Q. Were you involved in that litigation in any way?

19 A. Not at all.

20 Q. When did you learn of that litigation?

11:17:25

21 A. The past half year.

22 Q. The past half year?

23 Are you aware that Dr. Red Alinsod was a

24 defendant in that litigation?

25 A. Yes.

11:17:47

1 Q. Do you know Dr. Alinsod?

2 A. I do.

3 Q. How long have you known Dr. Alinsod?

4 A. Oh, I think I've known of Red Alinsod at least a

5 decade or so and had an opportunity to start working with 11:18:21

6 him about seven years ago.

7 Q. What was that opportunity, to with work with

8 the --

9 A. The EMSELLA Chair.

10 Q. The EMSELLA Chair? 11:18:44

11 A. Right.

12 Q. Did you work with Dr. Alinsod on the EMFEMME

13 360?

14 A. No.

15 Q. How about the Ultra Femme 360? 11:18:55

16 A. No.

17 Q. Any BTL products other than the EMSELLA Chair?

18 A. No.

19 Q. What do you think of Dr. Alinsod?

20 MR. BEMBEN: Objection to form and scope. 11:19:15

21 THE WITNESS: Could -- what do I think of him

22 professionally, personally? Could you clarify?

23 Q. BY MR. HECTOR: Yeah. What do you think of him

24 professionally?

25 MR. BEMBEN: So objection to scope and form. 11:19:30

1 THE WITNESS: He is a very good physician.

2 Q. BY MR. HECTOR: Do you trust his opinion?

3 MR. BEMBEN: Objection to scope and form.

4 MR. HECTOR: On medical? Yeah. I'll clean that

5 up. 11:19:55

6 Q. Do you trust his opinion on -- on medical

7 procedures?

8 A. Regarding --

9 MR. BEMBEN: Objection to scope and form.

10 THE WITNESS: I don't know what subject you mean 11:20:07

11 about trusting.

12 Q. BY MR. HECTOR: Well, you said he's a very good

13 physician. Do you trust Dr. Alinsod's expertise in use

14 of RF technologies?

15 MR. BEMBEN: Objection to scope and form. 11:20:34

16 THE WITNESS: I don't have an opinion about

17 that. He's a urogynecologist, trained urogynecologist,

18 in cosmetic gynecology.

19 Q. BY MR. HECTOR: Do you trust his expertise in --

20 as a urogynecologist? 11:21:00

21 MR. BEMBEN: Objection to scope and form.

22 THE WITNESS: I believe he's a competent -- very

23 competent physician in that arena.

24 Q. BY MR. HECTOR: How about the arena of cosmetic

25 gynecology? 11:21:13

1 MR. BEMBEN: Objection to scope.

2 THE WITNESS: I believe he's a very competent
3 physician in that arena.

4 MR. BEMBEN: Counsel, we've been going for a
5 little over an hour. If you -- if this is a good place 11:21:30
6 to break, let us know, or if you want to finish this line
7 of questioning.

8 MR. HECTOR: Yeah, maybe just like a few more
9 minutes. Would that work?

10 MR. BEMBEN: Sure. 11:21:49

11 MR. HECTOR: Great.

12 Q. I think I've read somewhere that you've said
13 that Dr. -- or Dr. Alinsod is a mentor -- is your mentor
14 -- is a mentor of yours.

15 MR. BEMBEN: Objection to scope. Form. 11:21:59

16 Q. BY MR. HECTOR: Is that correct?

17 A. In the field of cosmetic gynecology, I respect
18 his opinions.

19 Q. Have you done any training with Dr. Alinsod?

20 A. I did. 11:22:19

21 Q. And what did those trainings regard?

22 MR. BEMBEN: Objection to scope and form.

23 THE WITNESS: It involved cosmetic gynecology,
24 surgical -- surgical cosmetic gynecology.

25 Q. BY MR. HECTOR: What do you mean by "surgical 11:22:40

1 cosmetic gynecology"?

2 MR. BEMBEN: Objection to scope.

3 THE WITNESS: Operating surgically on patients.

4 Q. BY MR. HECTOR: And by "operating," that means,

5 you know, the patient is anesthetized? 11:22:55

6 MR. BEMBEN: Objection to scope and form.

7 THE WITNESS: They are anesthetized, yes.

8 Q. BY MR. HECTOR: And what medical tools would you
9 use during those procedures?

10 MR. BEMBEN: Objection to scope and form. 11:23:09

11 THE WITNESS: We use a Surgitron as well as
12 standard surgical equipment.

13 Q. BY MR. HECTOR: What's a "Surgitron"?

14 A. It's a generator.

15 Q. A generator for what? 11:23:32

16 A. Power up thermal energy.

17 Q. And are those ablative RF treatments?

18 A. Cutting.

19 Q. Cutting?

20 A. Yes. 11:23:50

21 Q. So I asked you if they were ablative, and you
22 responded they were cutting. What's the difference
23 between cutting and ablating?

24 A. If you think of it as a scalpel as a radio
25 frequency scalpel that causes separation of tissue, 11:24:06

1 cutting, that's what we use it for.

2 Q. But when you cut, would you also be ablating
3 tissue?

4 A. It has a capability of doing that. I just don't
5 use it that way. 11:24:29

6 Q. So what's your definition of "ablating," then?

7 MR. BEMBEN: Objection to scope. Form.

8 THE WITNESS: Sealing blood vessels so they
9 don't bleed.

10 Q. BY MR. HECTOR: Isn't that coagulation? 11:24:47

11 A. Semantics. Mr. Hector, it's -- while there's
12 heating and it's cutting, it can sometimes coagulate
13 blood vessels.

14 Q. So you said that ablating is -- is the sealing
15 of blood vessels? 11:25:13

16 A. Ablating is destruction and sealing. So
17 ablation can mean destruction of tissue as well as
18 sealing blood vessels.

19 Q. And it would mean both of those together. It's
20 not -- 11:25:31

21 A. It can.

22 Q. -- destruction or. It's an "and"?

23 A. Yeah.

24 Q. Okay. Just a few more questions and we can take
25 a break. 11:25:36

1 Have you ever had any interactions with Vieve?

2 A. Their representative sales rep came to my office
3 a dozen times.

4 Q. Did you use any of their products?

5 A. Never. 11:26:02

6 Q. Are you aware of Dr. Jonathan Parmer?

7 MR. BEMBEN: Objection to scope.

8 THE WITNESS: I don't know him.

9 Q. BY MR. HECTOR: Do you know that he's the
10 inventor of the '511 patent? 11:26:21

11 A. Yes.

12 Q. The patent that's the subject of your
13 declaration?

14 A. Yes. I don't know him personally, no.

15 Q. You've never met him? 11:26:33

16 A. Never.

17 Q. What about Edward Knowlton?

18 MR. BEMBEN: Objection to scope.

19 THE WITNESS: I've never met him.

20 Q. BY MR. HECTOR: Then what are you -- what is
21 your compensation for involvement in this proceeding? 11:26:47

22 A. I'm being paid to offer my expert opinion on the
23 patent, '511.

24 Q. And what's your hourly rate?

25 A. It ranges anywhere from 300 to \$500 an hour. 11:27:12

1 Q. And what is it on -- what's your rate on this,
2 for this proceeding?

3 A. \$500 an hour.

4 Q. And are you receiving any other compensation
5 from BTL --

11:27:34

6 A. None.

7 Q. -- for your services?

8 A. None.

9 Q. Is your compensation in any way contingent on
10 the outcome?

11:27:46

11 A. No.

12 Q. Do you own any stock in BTL?

13 A. No.

14 Q. Have you signed agreements with BTL regarding --

15 A. I haven't signed any agreements.

11:28:02

16 MR. HECTOR: Okay. I think we can take a break
17 there.

18 THE WITNESS: Okay.

19 BY MR. HECTOR: How long do you want?

20 THE REPORTER: Off the record, Counsel.

11:28:20

21 (Recess.)

22 THE REPORTER: Back on the record 11:45 a.m.

23 (Exhibit 2, Declaration of Joseph Berenholz,

24 M.D., was marked for identification by counsel

25 electronically.)

11:45:54

1 Q. BY MR. HECTOR: So I just introduced into the
2 Marked Exhibits Exhibit 1003 from the IPR proceeding,
3 which is your declaration, Dr. Berenholz.

4 I believe you have a paper copy of it there?

5 A. Yes. 11:46:22

6 Q. I assume you have familiarity with this
7 document. I'll get to it in a second?

8 A. I'll -- all right.

9 Q. You're familiar with this document; right?

10 A. Let me find it and tell you. All right. 11:46:37

11 Q. Okay.

12 A. Yes.

13 Q. And you're aware you're --

14 A. Yes.

15 Q. Okay. You're aware you're still under oath, 11:47:10
16 Dr. Berenholz?

17 A. Yes, I'm aware.

18 Q. Okay. So I think I read on your website or
19 possibly your CV that you opened the first laser vaginal
20 rejuvenation institute in the state of Michigan; is that 11:47:32
21 right?

22 A. Yes. Yes.

23 Q. And when was that?

24 A. It was about 28 or 29 years ago.

25 Q. You said 20 or 29? 11:47:44

1 A. No. 28 or 29 years ago.

2 Q. Okay. So back in that 1995, '96 timeframe?

3 A. I believe so, yes.

4 Q. Okay. And how many laser vaginal rejuvenation

5 clinics were there in Michigan -- or sorry, the Midwest 11:48:14

6 at that time?

7 A. None.

8 Q. How about on the East Coast?

9 A. I wouldn't know.

10 Q. The South? 11:48:30

11 A. I believe there was at least one doctor

12 practicing in Florida.

13 Q. Okay. How about the West Coast?

14 A. I know there were several.

15 Q. So maybe is it fair to say maybe around five 11:48:59

16 doctors nationwide practicing in that field at that time?

17 A. I couldn't answer that accurately, Mr. Hector.

18 There weren't a lot. I just don't know the number.

19 Q. Okay. I mean, what if you had to -- like what's

20 a -- just a range of numbers? I mean, not hundreds; 11:49:32

21 right?

22 A. No.

23 Q. Around ten, maybe?

24 A. I'm guessing, but that would be at the most.

25 Q. Okay. And that's as of like '95, '96; correct? 11:49:47

Page 50

1 A. That is correct.

2 Q. And how did the practice progress for you in
3 terms of volume of business? And I'm speaking about your
4 cosmetic gynecology practice.

5 A. It was adequate. 11:50:15

6 Q. But did it blow up right away in '95, '96? By
7 "blow up," I mean expand.

8 A. No. It's Michigan so it was slow starting.

9 Q. How about by maybe ten years later, 2006 --

10 A. Much improved. 11:50:49

11 Q. -- by then?

12 A. Much improved.

13 Q. And what do you mean by "much improved"?

14 A. Greater awareness nationwide so more inquiries,
15 more appointments. 11:51:10

16 Q. And as of that time, were there other doctors in
17 Michigan offering cosmetic gynecology services?

18 A. Not to my knowledge.

19 Q. Not in 2006?

20 A. I don't know. If there was, I didn't know of
21 them. 11:51:32

22 Q. Okay. So likely no, but you can't say for
23 certain?

24 A. I can't say for certain.

25 Q. How about in the Midwest; were there other 11:51:48

1 doctors practicing cosmetic gynecology at that -- as of
2 2006 that you were aware of?

3 A. There might have been.

4 Q. Do you typically know how many -- you know,
5 roughly how many other doctors are practicing in your 11:52:17
6 field as of now?

7 A. A lot.

8 Q. A lot?

9 A. Uh-huh.

10 Q. As of 2006, was it a lot? 11:52:32

11 A. I -- it was far less than today.

12 Q. So in cosmetic -- in the field of cosmetic
13 gynecology in 2006, you said it's far less. Can you
14 quantify that? I mean, I don't need an exact number, but
15 you know, in rough terms nationwide. 11:52:56

16 MR. BEMBEN: Objection. Calls for speculation.

17 THE WITNESS: I can't give you an accurate
18 answer to that question. The knowledge base was much
19 greater then than when I started. So I would imagine
20 with more awareness came more doctors. 11:53:19

21 Q. BY MR. HECTOR: So in 1996, you said there was
22 roughly five, maybe five to ten. How many -- how many
23 more? Like had the number doubled by 2006?

24 MR. BEMBEN: Objection. Mischaracterizes his
25 testimony. 11:53:44

1 THE WITNESS: Again, I want to be accurate, but
2 I -- I would be strictly speculating. I would have no
3 way of knowing.

4 Q. BY MR. HECTOR: Were there like conferences for
5 cosmetic gynecologists as of 2006? 11:54:04

6 A. There might have been. I didn't attend any at
7 that time.

8 Q. Were there other types of meetings where
9 cosmetic gynecologists would have gathered in 2006?

10 MR. BEMBEN: Objection to form and scope. 11:54:27

11 THE WITNESS: There might have been. I didn't
12 attend any.

13 Q. BY MR. HECTOR: As of 2006, who were kind of the
14 thought leaders in cosmetic gynecology nationwide?

15 MR. BEMBEN: Objection to form and scope. 11:55:03

16 THE WITNESS: I don't know who would be
17 considered a leader in the field and on what basis that
18 would be determined.

19 Q. BY MR. HECTOR: Were there some doctors that
20 were more well known than others in the field at that 11:55:23
21 time?

22 MR. BEMBEN: Objection. Calls for speculation
23 and scope.

24 THE WITNESS: I -- I -- I can't answer as to how
25 well known anyone was. 11:55:41

1 Q. BY MR. HECTOR: So you, as of 2006, didn't
2 really have a feel for how many other doctors were
3 practicing in your field of -- core field of cosmetic
4 gynecology?

5 A. Mr. Hector, I was so focused on trying to 11:56:01
6 establish this type of practice in Michigan that I paid
7 little attention as to who were thought leaders in the
8 field at that time.

9 Q. But the thought leaders aside, just other people
10 practicing in the field. You didn't pay attention to 11:56:21
11 that?

12 A. I was trained by Dr. David Matlock some 29 years
13 ago. So for me, he was my expert.

14 Q. Do you know how many other doctors Dr. Matlock
15 had trained by 2006? 11:56:44

16 A. No.

17 Q. Were there other doctors that were trained at
18 the same time you were in 1996?

19 MR. BEMBEN: Objection to form. Scope.

20 THE WITNESS: No. 11:57:05

21 Q. BY MR. HECTOR: What about urogynecologists,
22 people practicing in the field of urogynecology, doctors
23 practicing in the field of urogynecology in 2006, do you
24 have a feel for how many doctors that would be
25 nationwide? 11:57:33

1 A. That's an established specialty. So there were
2 many throughout the country.

3 Q. Probably hundreds?

4 A. I -- perhaps.

5 Q. Were there hundreds of cosmetic gynecologists as 11:57:55
6 of 2006?

7 MR. BEMBEN: Objection. Asked and answered and
8 scope.

9 THE WITNESS: I can't answer that because I have
10 no way of measuring that or knowing that. 11:58:10

11 Q. BY MR. HECTOR: So you weren't aware of, you
12 know, the other doctors practicing in your core field of
13 cosmetic gynecology in 2006?

14 A. I was aware of several doctors throughout the
15 country, but I couldn't tell you what total number of 11:58:34
16 doctors were practicing in the field of cosmetic
17 gynecology.

18 Q. And by "several," what do you mean by "several"?

19 A. Four or five that I knew of.

20 Q. Okay. But there could have been more? 11:59:01

21 A. Could have been more.

22 Q. Okay. What type of doctor would perform the
23 nonsurgical treatment of urogynecological conditions?

24 MR. BEMBEN: Objection. Calls for speculation.

25 THE WITNESS: I would hope it would be performed 11:59:35

1 by anyone who was Board-certified in obstetrics and
2 gynecology or the field of urology or the field of
3 urogynecology.

4 Q. BY MR. HECTOR: What about a doctor that just
5 practiced in the field of obstetrics? 11:59:55

6 MR. BEMBEN: Same objection.

7 Q. BY MR. HECTOR: Would that meet the criteria of
8 a doctor practicing the nonsurgical treatment of
9 urogynecological conditions?

10 A. I'm not sure I understand because we're all 12:00:16
11 Board-certified in obstetrics and gynecology. There is
12 no separate Board certification for just obstetrics.

13 Q. Okay. So anyone that's Board-certified for
14 obstetrics is also certified for gynecology?

15 A. Correct. 12:00:42

16 Q. Okay. And they would be Board-certified for the
17 nonsurgical treatment of urogynecological conditions?

18 A. No. Board-certified, no. That is a
19 sub-specialty that you have to become certified in.

20 Q. Okay. So what type of doctor is, you know, 12:01:06
21 certified or permitted to practice in the nonsurgical
22 treatment of urogynecological conditions?

23 MR. BEMBEN: Objection to form.

24 THE WITNESS: Nonsurgical treatment of -- I
25 didn't understand the question. 12:01:35

1 Q. BY MR. HECTOR: Sure. It was a little garbled.
2 Let me clean it up for you.

3 What type of doctor is certified to practice in
4 the nonsurgical treatment of urogynecological conditions?

5 MR. BEMBEN: Objection to form. 12:01:51

6 THE WITNESS: There is no school of or
7 certification for nonsurgical or non-invasive treatment
8 in urogynecology.

9 Q. BY MR. HECTOR: What type of doctor would
10 perform those procedures, nonsurgical treatment of 12:02:08
11 urogynecological conditions?

12 MR. BEMBEN: Objection to form and calls for
13 speculation.

14 THE WITNESS: It could be an obstetrician,
15 gynecologist, a urogynecologist, a Board-certified 12:02:21
16 physician.

17 Q. BY MR. HECTOR: What type of doctor would you
18 need to be to have a general understanding or ordinary
19 skill related to the technology of the '511 patent?

20 A. Probably any Board-certified physician or 12:03:15
21 urogynecologist or gynecologist, obstetrician, et cetera.

22 Q. Any Board-certified physician?

23 A. Yes.

24 Q. Would that include like an anesthesiologist?

25 A. Doubtful. 12:03:48

1 Q. What type of Board-certified physician?
2 A. Family practitioner, internist.
3 Q. Would a doctor that deals with treatment of
4 conditions related to skin or other tissues?
5 A. For treatment of what again? 12:04:13
6 Q. Of skin -- like the skin. Like would a
7 dermatologist have the requisite skills?
8 A. They certainly would have the ability to be
9 trained in that field, yes.
10 Q. How about a plastic surgeon; would they have the 12:04:34
11 requisite skill to --
12 A. Yes, they --
13 Q. -- understand -- let me. Sorry.
14 Would a plastic surgeon have the requisite skill
15 to understand the technology described in the '511 12:04:47
16 patent?
17 MR. BEMBEN: Object -- objection to form.
18 THE WITNESS: A plastic surgeon would have the
19 requisite skill.
20 Q. BY MR. HECTOR: Okay. Would a plastic surgeon 12:05:09
21 understand the effects on tissue associated with heating
22 and remodeling using RF?
23 A. Yes.
24 MR. HECTOR: Introduce another exhibit. I
25 realize this one, you won't have a printout of this. So 12:05:50

1 I don't know if you want to go print it off, or can you
2 work off the screen, Rick?

3 MR. BEMBEN: Why don't you introduce it, and
4 we'll take a look at it and make a decision.

5 MR. HECTOR: Okay. 12:06:00

6 (Exhibit 3, Neurourology and Urodynamics, Volume
7 41, Issue 6, 2022, was marked for identification
8 by counsel electronically.)

9 MR. BEMBEN: And where are you -- are you
10 introducing it? I need to -- 12:06:14

11 MR. HECTOR: I'm going to put it in the Exhibit
12 Share. Do you have access to that? It should be there
13 now.

14 MR. BEMBEN: Is the Exhibit Share something that
15 you logged into separately? 12:06:50

16 MR. HECTOR: Yeah.

17 MR. BEMBEN: Okay. Hold on. Give me one
18 minute.

19 (Interruption in proceedings.)

20 MR. HECTOR: Should we go off the record? 12:08:57

21 MR. BEMBEN: Yeah, we can go off the record for
22 a moment.

23 THE REPORTER: Off the record at 12:09.

24 (Discussion off the record.)

25 THE REPORTER: Back on the record 12:12 p.m. 12:12:19

1 MR. BEMBEN: Just before you continue, I'm just
2 going to object to this exhibit for our scope. This is
3 not something that's in the record and that Dr. Berenholz
4 has previously seen.

5 MR. HECTOR: All right. Great. 12:12:51

6 Q. So I introduced an exhibit which is labeled
7 Exhibit 3.

8 Have you seen this image before on Exhibit 3,
9 Dr. Berenholz?

10 A. No, I have not. 12:13:03

11 Q. Are you aware of the Neurourology and
12 Urodynamics?

13 A. I am not.

14 Q. Are you aware of Wiley?

15 A. I've never seen this before. 12:13:21

16 Q. All right. Sir, are you aware of the publisher,
17 Wiley?

18 MR. BEMBEN: Objection to scope.

19 THE WITNESS: I don't recall.

20 Q. BY MR. HECTOR: You've never read a scientific 12:13:38
21 article published by Wiley?

22 MR. BEMBEN: Objection to scope.

23 THE WITNESS: Again, I don't recall at this
24 moment.

25 Q. BY MR. HECTOR: Okay. I was turning to some of 12:13:50

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1 the anatomical questions provided in this image just so
2 there's something for us to talk from.

3 Does this image with regard to the anatomy seem
4 accurate to you?

5 MR. BEMBEN: Objection to scope. 12:14:11

6 THE WITNESS: It looks as though it's a fair
7 representation of the anatomy.

8 Q. BY MR. HECTOR: Okay. Is there anything
9 inaccurate?

10 A. I can't comment to categorizations of Level I, 12:14:31
11 II, and III. I just can't comment to TPVL. I mean, I
12 know what that means, but again, I don't know how it's
13 being used here.

14 Q. Okay. But the anatomy, maybe some of the
15 terminology you can't comment on, but the anatomy, does 12:15:00
16 that look accurate to you?

17 MR. BEMBEN: Objection to scope.

18 THE WITNESS: It looks as though it is.

19 Q. BY MR. HECTOR: Okay. So just so we're clear,
20 is there anything inaccurate that you can point out? 12:15:15

21 MR. BEMBEN: Objection to scope.

22 THE WITNESS: With reference to --

23 Q. BY MR. HECTOR: In the figure.

24 A. -- just the anatomy itself?

25 MR. BEMBEN: Same objection. 12:15:30

1 Q. BY MR. HECTOR: Yes, yes. With the anatomy.

2 A. It seems accurate.

3 Q. Okay. But you said that you maybe are not
4 familiar with TPVL or TVL or the levels; is that correct?

5 MR. BEMBEN: Objection to scope. 12:15:51

6 THE WITNESS: There are different terminologies
7 and phrases when it comes to anatomy. I am just not
8 familiar with this diagram short of the -- of course, the
9 anatomy itself.

10 Q. BY MR. HECTOR: Okay. But do you know that 12:16:11
11 TPVL, or total posterior vaginal length is?

12 MR. BEMBEN: Objection to scope.

13 THE WITNESS: I know what that means, yes.

14 Q. BY MR. HECTOR: And do you know what TVL, or
15 total vaginal length means? 12:16:27

16 MR. BEMBEN: Objection to scope.

17 THE WITNESS: I don't know what they're
18 referring to in this diagram.

19 Q. BY MR. HECTOR: But you know what that terms
20 means? 12:16:44

21 MR. BEMBEN: Objection to scope.

22 THE WITNESS: I do know what that term means.

23 Q. BY MR. HECTOR: Would you agree that the vaginal
24 wall can be described as including an anterior wall,
25 lateral walls, and a posterior wall? 12:17:07

1 A. Those are part of the vaginal anatomy.

2 Q. Okay. And in this picture, it says that -- it
3 discusses the posterior vestibule. What is that?

4 MR. BEMBEN: Objection to scope.

5 THE WITNESS: The bottom side of the vestibule 12:17:35
6 in layman's terms.

7 Q. BY MR. HECTOR: What do you mean by "bottom
8 side"?

9 MR. BEMBEN: Objection to scope.

10 THE WITNESS: The vestibule is an area in front 12:17:50
11 of the introitus, and "posterior" means back side in
12 anatomical definitions.

13 Q. BY MR. HECTOR: Okay. So this is saying the
14 back side of the vestibule?

15 A. Yeah, they listed this as the posterior 12:18:19
16 vestibule. The vestibule is not simply a flat surface,
17 but they have labeled it as such here.

18 Q. Okay. So there's a ruler in this diagram, and
19 it lists -- it shows the posterior vestibule being at
20 about 10 centimeters; is that correct? 12:18:50

21 MR. BEMBEN: Objection to scope.

22 THE WITNESS: 10 centimeters. 10 centimeters
23 from what to what? What are we talking about?

24 Q. BY MR. HECTOR: On the ruler there. Can you see
25 the ruler on the figure? 12:19:06

1 A. Yes. Yes, I see it.

2 Q. Okay, okay. And it appears that the hymen is
3 located about 9 centimeters on that ruler? Maybe 8 or 9?

4 MR. BEMBEN: Objection -- objection to scope.

5 THE WITNESS: According -- did you say the 12:19:32
6 hymen?

7 Q. BY MR. HECTOR: Yes.

8 A. It has the hymen at 8.2 centimeters.

9 Q. Okay. And where's -- the vaginal introitus
10 appears to be labeled at about 10 centimeters; is that 12:19:48
11 correct?

12 MR. BEMBEN: Objection to scope.

13 THE WITNESS: I don't see the vaginal introitus
14 being labeled to the measuring device there.

15 Q. BY MR. HECTOR: Do you see -- do you see where 12:20:16
16 it says "vaginal introitus"?

17 A. Uh-huh.

18 Q. And then there's an arrow that points to that
19 blue line?

20 A. Yes. 12:20:25

21 Q. And then that blue line --

22 MR. BEMBEN: Objection.

23 Q. BY MR. HECTOR: That blue line roughly lines up
24 with 10 centimeters; correct?

25 MR. BEMBEN: Objection to scope. 12:20:36

1 THE WITNESS: It lines up with it, yes.

2 Q. BY MR. HECTOR: Isn't it fair to say that the
3 vaginal introitus as labeled in this figure lines up with
4 10 centimeters on that ruler?

5 MR. BEMBEN: Objection to scope. 12:20:52

6 THE WITNESS: On this ruler in this picture,
7 yes.

8 Q. BY MR. HECTOR: Do you think that's accurate to
9 the human anatomy?

10 MR. BEMBEN: Objection to scope. 12:21:03

11 THE WITNESS: This is not the way I understand
12 anatomy.

13 Q. BY MR. HECTOR: How do you understand anatomy?

14 A. Well, I don't know where the arrow pointing to
15 the vestibule -- the vestibule has dimensions to it. 12:21:27
16 This simply points to the vestibule and has it lined up
17 at 7 centimeters according to this picture.

18 Now you have an arrow or a line off to the side,
19 and you have the word "vaginal introitus." That seems to
20 line up with what they call the posterior vestibule and 12:21:53
21 10 centimeters.

22 So you have two different anatomic descriptions
23 lining up at the same location according to this document
24 that you've presented, and that's not accurate.

25 Q. So what's -- what's not accurate? What would 12:22:16

1 you fix to make this accurate?

2 MR. BEMBEN: Objection to scope.

3 THE WITNESS: You're talking about two different
4 structures, Mr. Hector, that are located in two different
5 locations, and yet on this diagram, the implication is 12:22:30
6 they're both at the same place at the same time.

7 Q. BY MR. HECTOR: So I guess can you help me
8 correct the diagram? Like where should the vaginal
9 introitus be and where should the posterior vestibule be
10 in this diagram? 12:22:54

11 MR. BEMBEN: Objection to scope.

12 THE WITNESS: The introitus lies anterior to the
13 vestibule.

14 Q. BY MR. HECTOR: Okay. So where would that be
15 with reference to the ruler? 12:23:09

16 MR. BEMBEN: Objection to scope.

17 THE WITNESS: I would put it somewhere around
18 nine.

19 Q. BY MR. HECTOR: Okay.

20 A. To 8.9, 8.8. 12:23:26

21 Q. Okay. And then where would you put the
22 posterior vestibule, further down? Closer to 10?

23 MR. BEMBEN: Objection to scope.

24 THE WITNESS: I'm going by this picture and the
25 labeling of it. That is closer to 10, yes. 12:23:48

1 Q. BY MR. HECTOR: Okay.

2 A. Although it comes out to really 9.8. I don't
3 want to be too specific. I'm just going by the value.

4 Q. Sure.

5 Where is the cervix located in this image? 12:24:13

6 MR. BEMBEN: Objection to scope.

7 THE WITNESS: Could you clarify about what you
8 mean by where?

9 Q. BY MR. HECTOR: Yeah, that's a good
10 clarification. 12:24:29

11 Like where on the ruler is the cervix, roughly?

12 A. On the ruler. I see.

13 MR. HECTOR: Yeah.

14 MR. BEMBEN: Objection. Objection to scope.

15 THE WITNESS: What part of the cervix are you 12:24:41
16 referring to? The cervix has several parts.

17 Q. BY MR. HECTOR: I guess I'm not familiar with
18 the different parts of the cervix. Maybe you could
19 educate me on that.

20 A. All right. Forgive me. 12:24:58

21 Q. No, thank you for -- for clarifying.

22 A. They have the beginning of the cervix at looks
23 like to be 2.5 centimeters on the ruler.

24 Q. Is there a medical term for the beginning of the
25 cervix? What would you call that? 12:25:25

1 A. Ectocervix, E-C-T-O, cervix.

2 Q. Okay. And then are there other parts of the
3 cervix of note in this diagram?

4 A. Yes.

5 Q. What would those be? 12:25:46

6 A. The ectocervix contains the -- the endocervix or
7 external os, "os" being a hole. Then you have the
8 endocervical canal, and then you have the internal os of
9 the cervix. None of it's depicted here. I'm just
10 telling you what I know. 12:26:22

11 Q. It's all inside of -- like you can't see inside
12 of the --

13 A. Right, right.

14 Q. Yeah, that makes since.

15 So in this figure, the distance from the 12:26:38
16 introitus, which I think you said was around nine, to the
17 cervix would be about six-and-a-half; is that fair?

18 A. Six-and-a-half to seven.

19 Q. Okay. Is that typical --

20 MR. BEMBEN: Objection to the scope. 12:27:08

21 Q. BY MR. HECTOR: -- of patients you see?

22 A. Typical of?

23 Q. Of -- of, you know, across the population of
24 humans, females?

25 MR. BEMBEN: Objection to scope. 12:27:20

1 THE WITNESS: Yes.

2 Q. BY MR. HECTOR: Okay. And all these
3 measurements we've been discussing are typical across the
4 population of females?

5 A. Not the ones displayed here, no. The 12:27:38
6 measurements are all wrong.

7 Q. But the measurements as clarified by, you know,
8 for example, putting the introitus at the nine and --
9 like as clarified by you, those are all typical of -- of
10 the female population? 12:27:59

11 MR. BEMBEN: Objection to form and scope.

12 THE WITNESS: I would assume it's typical. I --
13 I don't know what "typical" means, but I would assume it
14 is.

15 Q. BY MR. HECTOR: Well, I mean, am I using the 12:28:19
16 wrong term? Typical like on average?

17 A. Perhaps average would be more accurate.

18 Q. Is that a term? Okay.

19 So the measurements in this diagram, you know,
20 as clarified by you earlier, would represent the average 12:28:37
21 of those typical of the female -- I used "typical" again.
22 Let me strike that.

23 The measurements in the diagram as clarified by
24 you earlier would represent the average across the female
25 population; is that correct? 12:28:59

1 MR. BEMBEN: Objection.

2 THE WITNESS: Yes.

3 Q. BY MR. HECTOR: Okay. From this diagram, it
4 looks like the posterior vaginal length is longer than
5 the anterior vaginal length; is that -- is that your 12:29:28
6 understanding of the female anatomy?

7 MR. BEMBEN: Objection to scope.

8 THE WITNESS: According to this picture, it is.

9 Q. BY MR. HECTOR: According to your experience, is
10 that also true, that the posterior vaginal length is 12:29:52
11 longer than the anterior vaginal length?

12 A. It is.

13 Q. In this figure, appears that the anterior
14 vaginal length is about seven.

15 A. Approximately, yes. 12:30:34

16 Q. Is that your experience with the population of
17 female anatomy that you've interacted with?

18 MR. BEMBEN: Objection to form and scope.

19 THE WITNESS: Based on my experience, I would
20 say yes. 12:30:52

21 Q. BY MR. HECTOR: Okay. It looks like the total
22 posterior vaginal length is about 10 centimeters. Based
23 on your experience, does that sound correct?

24 MR. BEMBEN: Objection to scope.

25 THE WITNESS: Again, it varies anywhere from 12:31:07

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1 nine to ten.

2 Q. BY MR. HECTOR: Do you use the term "mid-vagina"
3 in your practice?

4 A. We have, yes.

5 Q. This diagram uses Level I, Level II, and Level 12:31:43
6 III. Do you use those terms to describe locations in the
7 vaginal canal in your practice?

8 MR. BEMBEN: Objection to scope.

9 THE WITNESS: I've seen these measurements or
10 these terminologies before, yes. 12:31:59

11 Q. BY MR. HECTOR: So you're familiar with them?

12 A. I'm familiar with them, yes.

13 Q. What is the mid-vagina?

14 A. Middle of the vagina.

15 Q. What's included in the middle of the vagina? 12:32:35

16 A. It's --

17 MR. BEMBEN: Objection to form.

18 Go ahead.

19 THE WITNESS: It's the vagina. Think of a tube.
20 It's the entire tube in the middle of the vagina, in the 12:32:47
21 mid-portion of the vagina. Sorry.

22 Q. BY MR. HECTOR: Where does the mid-portion
23 begin? And I'm speaking superior and inferior.

24 MR. BEMBEN: Objection to form.

25 THE WITNESS: I -- you want to know just as it 12:33:11

1 relates to superior and posterior or anterior-posterior
2 measurements? Because again, it's a tube. So think of
3 circumferential. There is -- there's an anterior,
4 posterior, and lateral.

5 Q. BY MR. HECTOR: Okay. But the tube runs 12:33:38
6 superior-inferior, the axis of the tube; right, roughly?

7 MR. BEMBEN: Objection to form.

8 THE WITNESS: Are you referring to the posterior
9 versus the anterior length?

10 Q. BY MR. HECTOR: I'm just referring to the -- you 12:33:59
11 said the vagina's a tube, and the axis of that tube runs
12 superior-inferior; right?

13 A. Yes.

14 Q. Okay. So along that superior-inferior axis,
15 where does the mid-vagina begin and where does it end? 12:34:21

16 MR. BEMBEN: Objection to form.

17 THE WITNESS: Are you basing -- are you asking
18 me according to this document you've presented?

19 Q. BY MR. HECTOR: I'm asking -- yeah, I guess both
20 according to this document and then both according to 12:34:47
21 your experience. I'm using this document so we have
22 something to talk about -- talk off of to understand your
23 experience and understanding of the female genital
24 anatomy.

25 MR. BEMBEN: Objection to form, still. 12:35:05

1 THE WITNESS: So it looks like it begins
2 inferiorly at about 2-1/2 or so centimeters from the --
3 what they're calling the vestibule or introitus on this
4 document all the way to the 2-1/2 centimeter mark on that
5 ruler. 12:35:59

6 Q. BY MR. HECTOR: Does that seem accurate based on
7 your experience?

8 A. It's approximately where it's located, yes.

9 Q. And can we make it exact? Is there a way to
10 speak an exact about where the mid-vagina would be 12:36:21
11 located? You said approximately.

12 MR. BEMBEN: Objection to form.

13 THE WITNESS: This -- this is a good
14 approximation of where it would be.

15 MR. HECTOR: Okay. Do you want to pull 12:36:46
16 Exhibit 1015 from your IPR petition.

17 (Exhibit 4, Atlas of Human Anatomy, 4th Edition,
18 Frank H. Netter, M.D., was marked for
19 identification by counsel electronically.)

20 MR. BEMBEN: Netter. (Indicating). 12:37:07

21 MR. HECTOR: Netter, yeah. I'm introducing it
22 here. Hold on.

23 Q. If you could turn to -- I guess the pages
24 aren't -- plate 365, which I think is page 16.

25 A. What's the number? 65. Is that 365? That's 12:37:36

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1 362.

2 MR. HECTOR: 365.

3 THE WITNESS: Have it.

4 Q. BY MR. HECTOR: Okay. I want to look at the --

5 I'm going to put it just up on the screen, that top 12:37:59
6 image.

7 Do you see?

8 A. It's the same.

9 MR. BEMBEN: It's the same.

10 MR. HECTOR: Okay. I just want to make sure 12:38:10
11 we're -- we're both reading from the same source
12 material.

13 Q. Okay. So what's depicted here in this image?

14 A. Everything from the abdomen to the anus.

15 Q. BY MR. HECTOR: In a female, I assume; correct? 12:38:47

16 A. That's a female for sure.

17 Q. And so what portions would be categorized as the
18 urogynecological portion of the anatomy?

19 A. Bladder, uterus, vagina, rectum. Urethra.

20 Sorry, I left that out. 12:39:24

21 Q. Okay. I guess we'll work inferior to superior,
22 down then up. So it points to like a labium majus.
23 What's that?

24 A. Those are vulva various structures lateral to
25 the introitus and the labia minora. 12:39:59

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1 Q. And what type of tissue is the labium majus? I
2 guess, first of all -- strike that.

3 Is labium majus the same as labium majora?

4 A. It is.

5 Q. Okay. And does the labium majora include 12:40:21
6 mucosal epithelial tissue?

7 A. The majora; is that what you're asking?

8 Q. Correct.

9 A. It does not contain mucosal tissue.

10 Q. Okay. Above that it says labium minus; is that 12:40:43
11 the labium minora?

12 A. Yes.

13 Q. And is that an accurate representation of the
14 location of the labium minora?

15 A. Yes, it is. 12:41:02

16 Q. Okay. And is the Hart's line visible in this
17 figure?

18 A. It's -- I can approximate it here.

19 Q. Where would -- where would it be?

20 A. It's really where the introitus ends and the 12:41:30
21 labium minus begin.

22 Q. How do you -- how do you find that location?

23 A. Just as I described it to you. If you were
24 looking head on, you could see it. This -- this sagittal
25 view is just a little more difficult. 12:41:57

1 Q. Okay. So you can't really see it in this view?

2 A. Yeah, but...

3 Q. Okay. And then the vaginal canal is depicted'
4 right? The -- strike that.

5 So there's a callout to what -- to the vagina. 12:42:34
6 Is that pointing to the vaginal canal?

7 A. Yes, it is.

8 Q. Then turning to the urinary system, what's --
9 what makes up the urinary system?

10 A. Could you narrow the scope of that question? 12:43:11

11 Q. Yeah.

12 I guess from a high level, what anatomical
13 features make up the urinary system?

14 A. Well, the urinary system is the kidneys, the
15 ureters, the bladder, and the urethra. 12:43:33

16 Q. Okay. So the kidneys and bladder are not shown
17 in this figure?

18 A. No. The bladder is; not the kidneys. Not the
19 ureters. Or at least I don't see it.

20 Q. Sorry. The kidneys and ureter are not shown in 12:43:55
21 this figure, to clean that up.

22 A. No.

23 Q. Okay. So there's several different components
24 on this figure that appear to all be portions of the
25 urinary bladder. Are you familiar with all of those? 12:44:19

1 A. Yes.

2 Q. The fundus, apex, body, ureteric orifice,
3 trigone, and neck?

4 A. Yes.

5 Q. Is that -- is this figure accurate with regard 12:44:29
6 to the location of the fundus?

7 A. The fundus of the uterus?

8 Q. Of the urinary bladder.

9 A. Oh, yes. Yes.

10 Q. Okay. All of those features like the -- the -- 12:44:50
11 there's several feature that seem to be grouped together
12 as urinary bladder. I just listed them a second ago.

13 A. Right.

14 Q. Those are all accurate depictions of the
15 locations of those? 12:45:04

16 A. Yes, they are.

17 Q. Okay. And for the neck, is that the bladder
18 neck that it's referring to?

19 A. Yes.

20 Q. Okay. It's pointing to two different locations. 12:45:18
21 Do you have an understanding of why that would be?

22 A. I'm not really sure, but that's where the neck
23 of the bladder is.

24 Q. What is the "bladder neck"?

25 A. Well, the urethra that has sort of an internal 12:45:44

1 os that enters -- it's an entranceway into the bladder,
2 and it's at that junction that we typically call the
3 bladder neck.

4 Q. You said an "internal os." What is that?

5 A. An internal opening. When I use the word "os," 12:46:10
6 I mean opening.

7 Q. Okay. So the bladder neck is the -- is the
8 bladder neck the superior end of the urethra?

9 A. Yes, the entranceway. It's just at or superior
10 to the internal opening of the urethra into the bladder. 12:46:41

11 Q. Okay. And why is it called a neck?

12 A. Well, I don't know why we call it the bladder
13 neck. We -- we refer to it, when we speak to patients,
14 as the neck because we're treating incontinence, and we
15 illustrate it by saying the neck is falling. So that's 12:47:13
16 the anatomic location of where a sling would be placed to
17 prevent hypermobility.

18 Q. Okay. But the neck, like the shape of the neck,
19 it is conically shaped or -- or is it kind of like a
20 funnel sitting on top of the urethra? 12:47:41

21 A. You could say funnel. It's similar.

22 Q. Okay. So it starts -- the bladder neck or the
23 funnel -- we'll just strike that.

24 We'll call it the bladder -- the bladder neck
25 starts inferior at the end of the urethra, and how far 12:48:00

1 into the bladder does the bladder neck extend?

2 A. Did you say inferior to the urethra?

3 Q. Yes.

4 A. Did you mean superior?

5 Q. I'm not normally a doctor. So, yes, I got that 12:48:17
6 flipped. Let's strike that.

7 So the bladder neck starts at the superior end
8 of the urethra?

9 A. Right.

10 Q. And then extends some distance up into the 12:48:32
11 bladder. Like what would that distance be?

12 A. Half a centimeter. I don't know. Never
13 measured it.

14 Q. Okay. But it's basically just the bottom of the
15 bladder, the inferior portion of the bladder? 12:48:53

16 A. Correct.

17 Q. Okay. And where is the urethral sphincter?

18 A. The urethral sphincter is at about the
19 mid-urethra portion.

20 Q. Okay. Is the endopelvic fascia shown in this 12:49:39
21 image?

22 A. I don't -- well, it's not labeled as such. I
23 don't see it. But it generally surrounds that area.

24 Q. Which -- which area? Let me be more specific.

25 Does it surround the bladder neck, the 12:50:11

1 endopelvic fascia?

2 A. Yes. It's in that area, approximately.

3 Q. Why "approximately"? Why do you use that term?

4 A. That's about where it's located.

5 Q. Okay. On the -- I guess like just below the 12:50:36
6 bladder?

7 A. Yes. I don't see it listed here.

8 Q. What is the function of the endopelvic fascia?

9 A. Well, it supports the area we were talking about
10 as secures it to the pelvis and -- and when things begin 12:51:10
11 to fall, that's what breaks apart and allows the bladder
12 to begin herniating.

13 Q. So it -- you said it supports the area we were
14 talking about. So that by that, you mean it supports the
15 bladder neck? 12:51:38

16 A. Yes. It's a fascial layer.

17 Q. Okay. And then you said, "When things begin to
18 fall, that's what breaks apart." That -- by "that's what
19 breaks apart," you mean the endopelvic fascia?

20 A. Yes. 12:52:08

21 Q. How does it break apart?

22 A. Childbirth, trauma, aging.

23 Q. What do you mean by break apart?

24 A. It begins to separate. It begins to separate.

25 Q. Like separate from the bladder neck? 12:52:27

1 A. Yes. It helps hold the bladder in place.

2 Q. So it separates the -- by "separate," you mean
3 it separates from the bladder neck during childbirth?

4 A. Bladder neck and parts that surround that lower
5 portion of the bladder, too. 12:52:49

6 Q. It's kind of like a hammock for the bladder?

7 A. That's a fair description.

8 Q. Okay. And after childbirth that -- you know,
9 that hammer -- strike that.

10 After childbirth, that hammock would become more 12:53:07
11 lax?

12 A. Weakened.

13 Q. Weakened. So the bladder would dip down further
14 in the hammock?

15 A. Correct. 12:53:20

16 Q. Like putting a bowling ball in the hammock or
17 something like that?

18 A. I've heard these described as bowling balls,
19 yes.

20 MR. HECTOR: Okay. 12:53:46

21 MR. BEMBEN: Bill, we're getting close to
22 1 o'clock. I don't know if you have additional questions
23 on this line.

24 MR. HECTOR: Yeah. I mean, it's up to you. If
25 the witness wants to take a break now, that's fine. 12:54:01

1 Maybe finish up this kind of theme, if you're willing,
2 but up to you.

3 MR. BEMBEN: Do you want to continue or?

4 THE WITNESS: I'd like to continue if you do.

5 MR. BEMBEN: Okay. 12:54:14

6 MR. HECTOR: Okay.

7 Q. Would you flip back to or turn back on that --
8 the image with the ruler, Exhibit 3.

9 Where on this image would the bladder neck be
10 located, using the ruler as a rough estimate? 12:54:48

11 MR. BEMBEN: And again, just objection to scope
12 with respect to this exhibit in general.

13 THE WITNESS: If you could be a little more
14 specific, Mr. Hector, I -- because, of course, the
15 bladder's not displayed on this image and -- and I don't 12:55:07
16 know how to answer you accurately. Maybe you could be
17 more specific.

18 Q. BY MR. HECTOR: Yeah.

19 I'm just wondering like where along that ruler
20 would the bladder neck align with? 12:55:34

21 A. I -- around -- I'm guessing now because I don't
22 see all the structures here, but I -- it could be around
23 six, seven -- five, six, seven, in that range there.

24 Q. Okay. You said in the range of five, six,
25 seven. Okay. 12:56:20

1 What's the average length of the urethra in
2 females?

3 MR. BEMBEN: Objection to scope and calls for
4 speculation.

5 THE WITNESS: Could be anywhere from 1-1/2, 12:56:52
6 2 centimeters, 3 centimeters.

7 Q. BY MR. HECTOR: And what's the basis for that
8 knowledge?

9 A. Well, you're measuring from the internal os of
10 the urethra to the urethra -- urethral opening or orifice 12:57:15
11 external to the external world. So it varies, maybe
12 about 3 -- 2 to 3 centimeters.

13 Q. I mean, you practice in urogynecology. Are you
14 aware of any, you know, medical references that would
15 provide a, you know, average length of the female 12:57:49
16 urethra?

17 A. I've never read anything about the average
18 length so, again, I'm speculating on your behalf.

19 Q. Turning back to the Exhibit 1015, that portion
20 we were looking with the cross-section of the anatomy. 12:58:13

21 A. Uh-huh.

22 Q. Given your understanding of the length of the
23 anterior and posterior vaginal walls, what would -- what
24 would you estimate the urethral length in this figure to
25 be? 12:58:49

1 MR. BEMBEN: Objection. Calls for speculation.

2 MR. HECTOR: And for the record, this is the
3 figure on plate 365 of Exhibit 1015.

4 MR. BEMBEN: Objection. Calls for speculation.

5 And scope. 12:59:01

6 THE WITNESS: Looks -- it could be around 3,
7 3-1/2 centimeters. I have nothing to measure or scale
8 the diagram on plate 365 so...

9 Q. BY MR. HECTOR: So in your practice as a
10 urogynecologist, the length of the urethra never is 12:59:35
11 important or something that, you know, you would need to
12 know off the top of your head?

13 MR. BEMBEN: Objection to form.

14 THE WITNESS: I am not a practicing
15 urogynecologist. I am a gynecologist who practices 12:59:55
16 urogynecology. There is a Board certification for
17 urogynecologists formally.

18 Q. BY MR. HECTOR: So your expertise isn't in
19 urogynecology such that you would need to know the length
20 of the female urethra on average? 13:00:19

21 A. I'm not saying that, no. I'm just trying to
22 clarify the statement I'm a urogynecologist. In this day
23 and age when one's called that, that means they're
24 Board-certified. Almost every gynecologist practices
25 some form of urogynecology. But there is a sub-specialty 13:00:39

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1 certification.

2 Q. And in your sub-specialty, the length of the
3 female urethra would be less important such that, you
4 know, you wouldn't look to medical sources to understand
5 that geometry?

13:01:02

6 A. That's --that's not accurate. What I'm trying
7 to say, in the -- that's not what I'm trying to say.

8 My surgical experience in that realm teaches me
9 approximately the length of the urethra. I've never
10 taken a ruler or a urethral sound and measured the
11 internal os to the external orifice. So that's how we
12 know approximately how long it is.

13:01:30

13 Q. Okay. So you're speaking kind of based on, you
14 know, eyeballing it during various surgical procedures
15 over the years?

13:01:56

16 A. Over 40-plus years, yes. Not eyeballing it, but
17 there's a variety of surgical experiences over the course
18 of decades where you have a pretty good feel as to the
19 length of the urethra.

20 Q. But you've never measured it?

13:02:19

21 A. Nobody does. Even a nurse who inserts a
22 catheter doesn't measure the urethra but knows how long
23 it is, approximately.

24 Q. And how does the nurse know?

25 A. She inserts --

13:02:35

1 MR. BEMBEN: Objection. Calls for speculation.

2 THE WITNESS: She inserts a Foley catheter, for
3 example, to have to drain the bladder and inflate a
4 balloon. And once she pulls back on the balloon, she
5 sees how much of that catheter is in the urethra, and it 13:02:51
6 looks like about 3, 4 centimeters.

7 Q. BY MR. HECTOR: Okay. So you're -- okay. So
8 just a few more questions on the anatomy and then we can
9 take a break.

10 I just want to understand the tissue layers that 13:03:12
11 make up the vaginal wall. Could you describe that for
12 me?

13 A. Yeah. It's a mucosal epithelial layer,
14 non-keratinized epithelium. And beneath that layer,
15 mucosal layer, is what we know as the lamina propria. 13:03:40
16 And below that, muscularis, and sometimes fascial layer
17 of adventitia. That's the classic understanding, but
18 varies anatomically from person to person based on trauma
19 secondary to childbirth.

20 Q. And what would vary based on trauma, like which 13:04:11
21 layers would vary?

22 A. Well, sometimes you may have trouble spotting
23 adventitia, but you're not really working in those
24 layers; you're treating them internally from the vaginal
25 mucosa with thermal energy. So you don't see the layers 13:04:33

1 per se.

2 Q. And so the adventitia layer, is that endopelvic
3 fascia or is there no endopelvic fascia?

4 A. It's not really endopelvic fascia. It's a type
5 of fascia. 13:04:53

6 Q. Okay. So where does -- you provided those
7 layers, the epithelial, mucosal epithelial layer, lamina
8 propria, muscularis, adventitia. What's below that down
9 to the endopelvic fascia?

10 A. Oh, it depends what direction you're going. If 13:05:12
11 you're going posterior, you're -- you're well past all
12 that and into the pelvic floor.

13 Q. What about anterior?

14 A. Well, anterior you can't go far because you have
15 the urethra at 12:00 running along the mid-axis. 13:05:38

16 Q. So the urethra would be right below the
17 adventitia layer?

18 A. No, I never said that.

19 Q. I'm just trying to understand.

20 A. Think of -- think of above the -- think of the 13:05:53
21 anterior wall of the vagina and sitting -- think -- think
22 of the orifice of the vagina, the orifice of the urethra
23 is just above that, and the urethra is running along the
24 axis.

25 Q. Do they run parallel? 13:06:14

1 A. Yeah.

2 Q. Exactly parallel, or is there any deviation?

3 A. I wouldn't know how much an individual
4 variations are, but it's midline.

5 Q. Okay. Yeah. So I'm just trying to understand 13:06:32
6 from -- you know, we're speaking anterior. You have --
7 speaking about the vaginal wall and the tissues layers
8 that make up the vaginal wall.

9 Here's my question: You have the, you know,
10 mucosal, epithelial layer, the lamina propria, 13:06:46
11 muscularis, adventitia, and then below that would be the
12 urethra, or is there anything in between there?

13 A. The -- again, the urethra sits above the vagina.
14 It's above the anterior wall of the vagina. So when you
15 go through the lamina propria, when you go through the 13:07:16
16 vaginal mucosa, there's some lamina propria, but there
17 isn't much beyond that because you have the urethra
18 sitting there right on top running down from the bladder
19 and out to the urethra where the woman urinates. It
20 literally sits atop the vagina. 13:07:41

21 Q. You don't -- you wouldn't have the muscularis
22 layer or the adventitia layer. You just run straight
23 into the urethra?

24 A. Yeah, you wouldn't find much up there, no.

25 Q. Okay. How thick is the mucosal epithelium on 13:08:01

1 average?

2 A. I've never measured it. About 4 -- zero
3 point -- .04 millimeters.

4 Q. Okay. How about the muscularis?

5 A. Oh, I wouldn't know. It's thin. 13:08:23

6 Q. And the depth, do you know the depth from the
7 surface of the vaginal wall down through the muscularis
8 layer?

9 A. I'm just guessing, 4, maybe a half a centimeter
10 less -- less than that. 13:09:03

11 MR. HECTOR: Okay. I think that's a good place
12 to stop. We can go off the record.

13 THE REPORTER: Off the record at 1:09 p.m.

14 (Recess.)

15 THE REPORTER: Back on the record at 1:41 p.m. 13:41:43

16 Thank you.

17 Q. BY MR. HECTOR: Good afternoon, Dr. Berenholz.

18 A. Good afternoon.

19 Q. What's your understanding of hyperthermia?

20 MR. BEMBEN: Objection to scope. 13:42:29

21 THE WITNESS: Hyperthermia is elevated
22 temperature.

23 Q. BY MR. HECTOR: And are there particular
24 temperature ranges associated with hyperthermia?

25 A. I don't know what context you're talking about. 13:42:42

1 Q. Just in the context of your medical practice and
2 medical experience.

3 A. Again, are we referring to vaginal treatments or
4 fever that a patient has from influenza? What type of
5 hyperthermia are you talking about? 13:43:12

6 Q. Yeah, as applied to vaginal treatments.

7 A. Can you be specific? What's my understanding of
8 it?

9 Q. Yeah. So what is your definition of
10 hyperthermia? 13:43:28

11 A. I don't have a set definition in general. If
12 you give me a specific situation, I can answer you.

13 Q. Well, we're speaking about, you know, your
14 medical practice and use the term "hyperthermia," what
15 would you mean in the context of, for example, cosmetic 13:43:52
16 gynecological surgery?

17 A. Well, we treat women vaginally with devices that
18 are hyperthermic.

19 Q. What devices are --

20 A. That create hyperthermia within the vagina. 13:44:15

21 Q. So when you create hyperthermia within the
22 vagina, what does that -- what does that mean?

23 A. We're usually directing thermal energy into the
24 walls of the vagina.

25 Q. And is there a certain level of thermal energy 13:44:36

1 that would be required to result in hyperthermia?

2 A. It varies from device to device.

3 Q. How does it vary?

4 A. Different devices have different ranges of
5 hyperthermia which result in a predictable outcome, and
6 so it varies from modality to modality.

13:45:04

7 Q. How would it vary, for example, in RF versus
8 lasers?

9 A. Laser is burning. RF is transmission of energy
10 through tissue walls. Laser is by micro cutting, micro
11 burning.

13:45:36

12 Q. Is cutting or burning hyperthermia?

13 A. It definitely causes an effect like that, yes.

14 Q. Does RF cause an effect like hyperthermia?

15 A. Sure, yes.

13:46:03

16 Q. So they both -- RF and lasers cause
17 hyperthermia. Is it the degree to which you're burning?
18 Is that the difference, the distinction?

19 MR. BEMBEN: Objection to form.

20 THE WITNESS: Could you repeat that again? I'm
21 sorry.

13:46:26

22 Q. BY MR. HECTOR: Yeah.

23 I think you said earlier that hyperthermia
24 varies from modality to modality. I'm trying to
25 understand how hyperthermia varies from the modality of

13:46:46

1 lasers to the modality of RF. Can you explain that,
2 please.

3 A. I -- I don't have experience using laser in
4 vaginal rejuvenation myself. But laser, you're burning
5 directly -- you're burning into the tissue, whereas RF 13:47:10
6 you're transmitting heat through the vaginal walls.

7 Q. You said you don't have experience using laser
8 for vaginal rejuvenation. What does that mean?

9 A. Well, some of these products, like Mona Lisa,
10 which are laser-based treatments of the vagina, my 13:47:38
11 experience was with diode lasers, and the ones that are
12 now being used are much different, and I don't use them.

13 Q. How are they different? How is Mona Lisa
14 different from a diode laser?

15 A. Well, there's -- it's micro cutting. It's very, 13:48:04
16 very fine incisional-type treatment of the vaginal mucosa
17 versus diode laser, which is a much deeper, in-depth
18 cutting.

19 Q. So the diode laser is the scalpel --

20 A. Yes. 13:48:29

21 Q. -- like modality you referred to earlier? The
22 Mona Lisa would be a -- like a finer-point scalpel?

23 A. Very fine. Burning. It's -- it's a burning.

24 Q. What about what's your understanding of the term
25 "erythema"? "Erythema"? 13:48:55

1 A. Erythema?

2 MR. HECTOR: Yeah.

3 MR. BEMBEN: Objection to scope.

4 THE WITNESS: Inflammation, redness.

5 Q. BY MR. HECTOR: Does -- is hyperthermia the same 13:49:07

6 thing as erythema?

7 A. No.

8 Q. How are they different?

9 A. Just so I understand, you asked me if

10 hypothermia. 13:49:33

11 Q. I'm sorry. Hyperthermia.

12 A. All right. Hypertherm --

13 Q. How is that different from erythema?

14 A. Erythema is the result of heating an area

15 meaning it becomes inflamed and red. 13:49:49

16 Q. Why do you not use the Mona Lisa device?

17 MR. BEMBEN: Objection to scope.

18 THE WITNESS: I just find RF therapy safer.

19 Q. BY MR. HECTOR: Why is it -- why is RF therapy

20 safer? 13:50:24

21 A. Never been associated with burning or scarring.

22 Q. But lasers have been associated with burning or

23 scarring?

24 A. According to the FDA, yes.

25 Q. How about according to your experience? 13:50:42

1 A. Again, my experience is with RF therapy and
2 diode laser.

3 Q. In diode laser, there's burning and scarring; is
4 that correct?

5 A. Well, intentionally, yes. 13:51:01

6 Q. So with Mona Lisa, it's unintentional?

7 A. The problems that arose that the FDA warned us
8 about mostly arose with the laser therapy of vaginal
9 rejuvenation like Mona Lisa.

10 Q. Why do you want to avoid burning or scarring? 13:51:29

11 A. To avoid depositions.

12 Q. So you're saying it leads to malpractice?

13 A. Well, if someone comes in for treatment and ends
14 up having pain secondary to burning or scarring, they're
15 going to be unhappy. 13:51:50

16 Q. So in laser vaginal rejuvenation, would it be
17 frequent that someone would come in with pain secondary
18 to burning or scarring?

19 MR. BEMBEN: Objection. Calls for speculation
20 and form. 13:52:09

21 THE WITNESS: With what I did, you mean?

22 Q. BY MR. HECTOR: Yes, with regard to your
23 experience.

24 MR. BEMBEN: Same objections.

25 THE WITNESS: I -- I've never had that complaint 13:52:21

1 about the diode laser.

2 Q. BY MR. HECTOR: But there was burning and
3 scarring with the diode laser; correct?

4 A. Again, the -- I don't want to conflate what I
5 did with diode laser with a Mona Lisa device, which it 13:52:40
6 causes intentional burning and scarring on a minimalist
7 basis to treat the vagina. But if there is an adverse
8 event such as pain afterwards, that's reported to the
9 FDA.

10 Q. But it wouldn't be a -- pain or scarring 13:53:13
11 associated with a diode laser would not be reported to
12 the FDA?

13 A. I'm not saying that. I'm just saying that,
14 again, remember we're using it as a scalpel. We've never
15 had anyone complain of an untoward effect afterwards. 13:53:28

16 Q. And why do you think that is?

17 MR. BEMBEN: Objection. Calls for speculation.

18 THE WITNESS: I -- I can't --

19 MR. HECTOR: Counsel, I believe the PTAB rules
20 limit objections to form and several other and do not 13:53:44
21 include speaking objections of -- as to speculation. I'd
22 just like to point that out.

23 Go ahead.

24 MR. BEMBEN: Same objection.

25 THE WITNESS: Are we dealing with the same 13:54:04

1 question again? Could you repeat it?

2 Q. BY MR. HECTOR: I asked you why you think that
3 you've never had a complaint of untoward effects from
4 using the laser as a scalpel.

5 MR. BEMBEN: Same objection. 13:54:34

6 THE WITNESS: I can't answer that. I don't know
7 why.

8 Q. BY MR. HECTOR: Are they not complaining because
9 your -- strike that.

10 Would your patients not be complaining because 13:54:52
11 they're aware of the risk for pain and scarring after the
12 surgery with the diode laser?

13 MR. BEMBEN: Objection. Form. Calls for
14 speculation.

15 And, you know, since he's talking about your 13:55:09
16 patients, if there's anything confidential that is
17 covered by your privilege with your patients, you don't
18 need to answer this question.

19 THE WITNESS: I -- we've just never had the
20 experience of that type of adverse event. 13:55:22

21 Q. BY MR. HECTOR: How -- what's your understanding
22 of how a collagen denaturation works?

23 A. Well, there's a breakdown of collagen that
24 involves denaturation secondary to thermal injury, and
25 the bonds that hold this helical structure or matrix 13:56:04

1 repairs itself, goes through stages of healing,
2 fibroplasia, rematrixing, and eventually more durable
3 scar or matrix of collagen, which tightens the tissue.
4 That's all I know.

5 Q. And what are the typical temperature ranges 13:56:32
6 necessary to denature collagen?

7 A. I -- I believe you have to get -- depending,
8 again, on device, you have to get anywhere from 45 to
9 65 degrees.

10 Q. So what happens below 45 degrees? 13:57:02

11 A. Not a whole lot.

12 Q. And then what would happen above 65 degrees?

13 A. You would start getting a breakdown. Again, I
14 don't know what devices we're talking about. I don't
15 know what parameters. If you could point me to 13:57:21
16 something, I might be more helpful.

17 Q. What parameters would you need?

18 A. If you have a particular device in mind, a
19 particular modality. I'm not aware of something that I
20 could -- every device has their own protocols and ranges 13:57:41
21 of temperature.

22 Q. And why does it vary from device to device,
23 those ranges of temperature?

24 A. Well, I can't answer that.

25 Q. Why not? 13:58:01

1 A. For example, the device that I'm currently
2 using, the research behind it showed a parameter that is
3 different from other devices. So it -- it delivers heat
4 in a different range and still affects the expected
5 result. 13:58:25

6 Q. What device are you referring to?

7 A. Right now, EMFEMME 360.

8 Q. And what are the temperature ranges for the
9 EMFEMME 360?

10 MR. BEMBEN: Objection to scope. 13:58:42

11 THE WITNESS: EMFEMME 360 works best between
12 40 degrees and 45 degrees Celsius.

13 Q. BY MR. HECTOR: Well, you said earlier that not
14 much happens below 45 degrees Celsius.

15 A. It's a general statement, but this is nuanced. 13:59:03
16 Every device has a different modality of penetrating
17 tissue. One may be more effective than another.

18 The researchers of the device that I'm using
19 prescribed these parameters to the clinician, namely
20 myself, and I follow those protocols. 13:59:29

21 Q. And what is the temperature that you're
22 referring to? Is that the temperature of the electrode,
23 40 to 45 degrees?

24 MR. BEMBEN: Objection to scope.

25 THE WITNESS: Not the -- it's a transducer. I 13:59:41

1 guess we could substitute the word "electrode." But
2 nevertheless, it's the temperature being transmitted to
3 the vaginal mucosa.

4 Q. BY MR. HECTOR: And how is that measured?

5 A. As I told you, you have to get to this 14:00:02
6 therapeutic range of 40 to 45 degrees Celsius.

7 Q. Therapeutic --

8 A. Yeah.

9 Q. The therapeutic range refers to the temperature
10 of the tissue? 14:00:21

11 A. Right. That's where you'll get maximal effect.

12 Q. Okay. But you wouldn't -- you don't go over
13 that?

14 A. The device won't let you go past 45. It will
15 shut off. 14:00:35

16 Q. Why is that?

17 A. Again, because the parameters set with the
18 thermocouple device that goes along with the device
19 will -- the AI will shut you off, and you'll have to
20 adjust power in order to continue. 14:00:54

21 Q. What's the preparation for a treatment using
22 that device?

23 MR. BEMBEN: Objection to scope. Objection to
24 scope.

25 THE WITNESS: Object -- what is the preparation? 14:01:09

1 Q. BY MR. HECTOR: Yes. How do you prepare the
2 patient for a treatment?

3 MR. BEMBEN: Same objection.

4 THE WITNESS: Could you be more specific,
5 Mr. Hector?

14:01:24

6 Q. BY MR. HECTOR: I mean, just walk me through a
7 treatment, the steps that, you know, a patient comes into
8 your office. What happens up to when you start treating?

9 A. Before I do anything, I --

10 MR. BEMBEN: Same objection.

14:01:37

11 THE WITNESS: Before I do anything, I examine
12 the patient to make sure they're a candidate, and then if
13 they are a candidate, I would explain to them the
14 mechanism of action, and then all risk, benefits, and
15 alternates. And then we would schedule a date for
16 treatment.

14:01:55

17 Q. BY MR. HECTOR: And then once that date is
18 scheduled, what are the steps that are performed in the
19 treatment?

20 A. She signs a consent, and we proceed with the
21 treatment by putting her in dorsal lithotomy
22 presentation.

14:02:07

23 THE REPORTER: In dorsal what, sir?

24 THE WITNESS: Sorry. D-O-R-S-A-L. And
25 lithotomy, L-I-T-H-O-T-O-M-Y.

14:02:26

1 THE REPORTER: Thank you.

2 Q. BY MR. HECTOR: And then you directly after that
3 apply the electrode?

4 A. We set our parameters, our time, and we start.

5 Q. Is there any other preparation of the patient's 14:02:50
6 tissue?

7 A. No.

8 Q. Do you use gel with the EMFEMME device?

9 A. Yes, we use -- sorry.

10 MR. BEMBEN: Objection to scope. 14:03:05

11 Go ahead.

12 THE WITNESS: We use an ultrasound gel,
13 water-based gel.

14 Q. BY MR. HECTOR: What's the purpose of that?

15 A. Lubrication and ease of transmission of the RF 14:03:17
16 waves.

17 Q. Any other reasons?

18 A. No.

19 Q. What's your understanding of the term "lesion"?

20 MR. BEMBEN: Objection to form. 14:03:44

21 THE WITNESS: Oh, it's very broad, Mr. Hector.
22 Can you narrow the scope?

23 Q. BY MR. HECTOR: I mean, I think it's a common
24 medical term; right? Lesion?

25 A. It's a common medical term that encompasses 14:04:01

1 everything from acne on your face to a burn on tissue.

2 So I would need to know where you're using it and how
3 you're using it.

4 Q. As to tissue.

5 MR. BEMBEN: Objection to form. 14:04:25

6 Q. BY MR. HECTOR: What does it mean?

7 A. Tissue of the -- tissue of the where?

8 Q. Let's say the vagina.

9 MR. BEMBEN: Objection to form.

10 THE WITNESS: Well, a lesion would be a 14:04:45
11 disruption of tissue caused by thermal energy.

12 Q. BY MR. HECTOR: What's a disruption of tissue?

13 A. It would be an area of -- a treatment area
14 that's been treated and becomes, let's say, erythematous
15 due to heat. 14:05:08

16 Q. Is a first-degree burn a lesion?

17 MR. BEMBEN: Objection to form.

18 THE WITNESS: It would be a lesion, but again,
19 we -- we just never see things like that.

20 Q. BY MR. HECTOR: What about a second-degree burn 14:05:44
21 would be a lesion?

22 MR. BEMBEN: Same objection and scope.

23 THE WITNESS: A second-degree burn called a
24 lesion would really be downplaying something like that.
25 That's an injury. 14:05:56

1 Q. BY MR. HECTOR: What happens at the cellular
2 level in a lesion?

3 MR. BEMBEN: Objection to scope. Form.

4 THE WITNESS: I -- I don't know what you mean by
5 "cellular level." I don't know what -- what you're 14:06:15
6 referring to.

7 Q. BY MR. HECTOR: A lesion in the vagina, what is
8 happening in a cellular level?

9 MR. BEMBEN: Objection to form and scope.

10 THE WITNESS: You're going to get thermal injury 14:06:36
11 of some kind. Cell walls may be disrupted. You can have
12 cellular breakdown.

13 MR. HECTOR: Do you have a copy of the '511
14 patent handy? I'm going to go ahead and introduce that.
15 I think it's Exhibit 1001. 14:07:14

16 (Exhibit 5, United States Patent Number
17 8,961,511 B2, 02/24/15, was marked for
18 identification by counsel electronically.)

19 THE WITNESS: Yes.

20 Q. BY MR. HECTOR: What is your understanding of -- 14:07:36
21 or let me know when you're ready, rather.

22 A. I'm ready.

23 Q. What is your understanding of the technology
24 described in the '511 patent?

25 A. You have to be more specific so I can give you a 14:08:07

1 more accurate answer.

2 Q. What do the claims of the '511 patent cover?

3 A. Well, there are many claims, all of them
4 involving remodeling of the vagina.

5 Q. What does that entail? 14:08:46

6 A. What we talked about earlier, denaturation of
7 collagen and the lower tissues below the mucosa and
8 subsequent stiffening, tightening, et cetera.

9 Q. Let's take claim 1, for example. Are you
10 familiar with claim 1 of the '511 patent? 14:09:22

11 A. I am.

12 Q. What is that describing?

13 A. "A method for remodeling a therapeutic zone
14 within a target tissue, the target tissue comprising
15 tissue underlying an epithelium of female genital tissue 14:09:40
16 comprising at least one of vulva, introitus, and vagina
17 tissue, the method comprising heating the target tissue
18 and remodeling the therapeutic zone of target tissue
19 wherein the heating includes heating a portion of the
20 vagina extending from the introitus inwardly to a 14:10:02
21 location from 1 to 3-1/2 centimeters from the introitus."

22 Q. That's the language. Thank you.

23 But generally, like if you're explaining that
24 treatment to -- or that method to a layman, how would you
25 describe it? 14:10:25

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1 MR. BEMBEN: Objection. Form. Asked and
2 answered.

3 THE WITNESS: To a simple layman and nonmedical
4 person, you mean?

5 MR. HECTOR: Sure. 14:10:36

6 MR. BEMBEN: Same objections. Form and asked
7 and answered.

8 THE WITNESS: We're using a heating device to
9 cause collagen production to tighten the vagina, and
10 other tissues related, such as vulva and the entrance of 14:10:52
11 the vagina, and that the depth could go as far as 3-1/2
12 centimeters from the opening.

13 Q. BY MR. HECTOR: So what is your understanding of
14 the meaning of the term "heating the target tissue"?

15 A. Well, my understanding is heating the layer 14:11:17
16 beneath the vaginal mucosal or epithelial layer.

17 Q. What about the mucosal layer?

18 A. Well, we're transmitting through it to the
19 target tissue.

20 Q. But is the mucosal layer heated? 14:11:43

21 A. It may be heated somewhat, but for the most
22 part, the heat is -- the thermal energy is directed to
23 the lamina propria which lies below.

24 Q. You say it may be heated somewhat. So is it
25 substantially affected in any way, the mucosal layer? 14:12:10

1 MR. BEMBEN: Objection to form.

2 THE WITNESS: It can be.

3 Q. BY MR. HECTOR: What do you mean "it can be"?

4 A. You asked me if it could possibly be heated, and
5 it can be. There are ways to protect it. 14:12:26

6 Q. You said it may be heated somewhat. What do you
7 mean by "heated somewhat"?

8 A. Well, their surrounding tissue may feel -- may
9 experience a little warming, but where the tip of the
10 device is, is where you're directing the energy. There 14:13:11
11 isn't much thermal spread, is what I'm saying.

12 Q. I think you said you said -- you said the
13 mucosal epithelium is heated somewhat, but for the most
14 part, the heat -- the thermal energy is directed to the
15 lamina propria. 14:13:36

16 What do you mean by "the mucosal epithelium is
17 heated somewhat"?

18 A. You put something warm on the vaginal mucosal
19 tissue, it's going to be heated somewhat. It's not
20 impervious. It is going to have some reaction. But the 14:13:54
21 energy is directed through the mucosa to the underlying
22 layers.

23 Q. And what would -- you said it's going to have
24 some reaction. What do you mean by "some reaction"?

25 A. It's just going to experience some warmth. 14:14:16

1 Q. What -- what do you mean by "some warmth"?
2 A. Well, anytime you apply energy to tissue, there
3 is something called thermal spread, but it is like just
4 collateral thermal energy that has no impact because it
5 never rises to a temperature to be harmful. 14:14:40
6 Q. It never rises to a temperature to be harmful to
7 the mucosal epithelium?
8 A. Correct.
9 Q. So how does that work that it rises to a
10 temperature in the lamina propria and muscularis to 14:15:00
11 result in denaturation of collagen, but it doesn't rise
12 to a harmful temperature in the mucosal epithelium?
13 MR. BEMBEN: Objection to form.
14 THE WITNESS: Well, again, depending on what
15 device you're using, but some devices have cooling 14:15:24
16 mechanisms simultaneously cooling the mucosa to prevent
17 any damage. Some devices use lower temperatures for
18 longer periods of time, and so it avoids damaging the
19 mucosa that way.
20 Q. BY MR. HECTOR: And that -- are both of those 14:15:53
21 types of devices covered by this claim of the '511
22 patent?
23 MR. BEMBEN: Objection to form.
24 THE WITNESS: I don't know if they're both
25 covered. I just know what's covered here in the '511 14:16:11

1 patent.

2 Q. BY MR. HECTOR: Yeah. We're speaking about
3 the -- you know, the -- what this claim, claim 1 of the
4 '511 patent, means, and you described, you know, one --

5 A. Uh-huh. 14:16:25

6 Q. -- one type of device that has a cooling
7 mechanism and then another type of device that uses lower
8 temperature for longer periods of time.

9 Could use of both of those types of devices meet
10 the elements of claim 1? 14:16:38

11 MR. BEMBEN: Objection to form.

12 THE WITNESS: I'm sorry. I don't understand the
13 question.

14 Q. BY MR. HECTOR: So we're talking about -- I
15 mean, you're testifying as an expert as to the '511 14:17:00
16 patent relative to prior art references, and I'm trying
17 to understand your understanding, what you will be
18 testifying, as to the scope of this, you know, claim 1.

19 And in your answer you just provided -- maybe if
20 we break it down it will be a little bit simpler, but you 14:17:21
21 said that --

22 MR. BEMBEN: He knows why he's here. Do you
23 have a question?

24 MR. HECTOR: Yeah, I do. Yes, I do, Counsel.

25 Q. You said -- so we're discussing the scope of the 14:17:38

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1 claim 1 -- of claim 1 and your understanding of claim 1.

2 And you said that one type of device has a cooling

3 mechanism. So a -- use of a device with a cooling

4 mechanism, could you meet the elements of claim 1 with

5 that -- that type of device?

14:17:57

6 MR. BEMBEN: Objection. Form. Calls for

7 speculation.

8 MR. HECTOR: Again, I think calls for

9 speculation is an improper speaking objection, Counsel.

10 It makes the appearance that you're coaching the witness.

14:18:14

11 THE WITNESS: Again, as it relates to patent

12 '511, I -- I had cooling mechanisms in response to how

13 does the mucosa -- I remember you asking -- avoid being

14 affected adversely by this transmission. I brought up

15 the issue of cooling the mucosa.

14:18:54

16 So what is the question?

17 Q. BY MR. HECTOR: So, yeah, you brought it -- fair

18 enough.

19 So you brought up the issue of a cooling

20 mechanism to avoid, in your words, affecting the mucosa.

14:19:06

21 So it sounds like one way to carry out the steps of this

22 claim would be to use a device with a cooling mechanism

23 to, as you said, not affect the mucosa; is that correct?

24 A. Correct.

25 MR. BEMBEN: Objection. Form and scope.

14:19:28

1 Q. BY MR. HECTOR: And then you said that -- I
2 think you said that was one type, and then the other type
3 of device using lower temperature for longer periods of
4 time. How would that --

5 A. I -- that's just thermodynamics. I'm sorry. I 14:19:39
6 wasn't speaking about anything specifically that it --
7 for patient comfort, sometimes you tone down temperature
8 and do it for a longer period of time to get the expected
9 effect without causing any not only discomfort but
10 burning, et cetera, or thermal damage to the mucosa and 14:20:04
11 still penetrate it.

12 Q. Okay. And that would be without cooling, in
13 that scenario that you just described?

14 A. That could be without cooling, yes.

15 Q. Okay. And how -- so my question is: How -- how 14:20:22
16 were the layers below the mucosal epithelium heated to a
17 temperature where collagen denaturation occurs while not
18 substantially affecting the mucosal epithelium in that
19 treatment you just described with, you know, a lower
20 temperature, longer period of time device? 14:20:46

21 MR. BEMBEN: Objection to form.

22 THE WITNESS: I think the -- the mucosal layer
23 is protected with cooling mechanisms so that there is a
24 bit of a gradient between the temperature on the surface
25 of the mucosa versus the penetrated tissues or target 14:21:03

1 tissues.

2 Q. BY MR. HECTOR: I think you also -- so we
3 discussed the -- you were discussing two separate
4 devices. I understood one had a cooling mechanism and
5 then another used a lower temperature; right? 14:21:21

6 A. I wasn't referring to any specific device. I
7 was just referring, as I said, to thermodynamics where
8 cooler temperatures at longer timeframes could do the
9 same thing versus hotter temperatures that require
10 immediate cooling to affect the predictable result. 14:21:45
11 That's all I'm saying. I wasn't referencing a specific
12 device.

13 Q. Oh, no, I'm not saying that you're referencing a
14 specific device. I'm just trying to understand the
15 thermodynamics of that -- that second scenario where 14:22:01
16 you're not using a cooling mechanism, how that would work
17 and how heat would be applied to the various layers, the
18 mucosal epithelium, the lamina propria, the muscularis?

19 MR. BEMBEN: Objection to form.

20 THE WITNESS: I don't know how to answer it any 14:22:20
21 differently than that. It's -- again, it's an issue of
22 temperature times time equals X amount of penetration.
23 And you reach a temperature that's much hotter, you may
24 have to spend less time over the target area but have
25 some type of cooling mechanism to prevent collateral or 14:22:53

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1 thermal spread to the mucosa.

2 Q. BY MR. HECTOR: Okay. But if you don't use the
3 cooling mechanism, you use lower temperatures and longer
4 time to prevent any sort of affect on the mucosal
5 epithelium? 14:23:14

6 A. It could do that --

7 MR. BEMBEN: Objection to form.

8 Q. BY MR. HECTOR: Okay. If you created scarring
9 in the mucosal epithelium using a treatment, would that
10 treatment meet the elements of the '511 patent? 14:23:43

11 MR. BEMBEN: Objection to scope.

12 THE WITNESS: Repeat that again, Mr. Hector.

13 Q. BY MR. HECTOR: I'm asking -- we're -- again,
14 about the scope and your understanding of the '511
15 patent. If you performed a treatment where there was 14:23:59
16 damage to the mucosal epithelium, would that meet the
17 elements of the '511 patent, claim 1?

18 MR. BEMBEN: Objection to scope and incomplete
19 hypothetical.

20 THE WITNESS: I am just guessing that that's not 14:24:17
21 the scope of the '511 patent or what it wants to
22 accomplish in terms of you describing damage to the
23 mucosa.

24 Q. BY MR. HECTOR: So the goal of the '511 patent
25 is to not have damage to the mucosa -- 14:24:37

1 A. The scope -- yeah --

2 Q. -- while --

3 A. Affect the target tissue, but not the mucosa.

4 Q. If you wanted to treat for circumferential
5 tightening of the vaginal wall, how would you do so? 14:25:17

6 MR. BEMBEN: Objection. Incomplete
7 hypothetical.

8 THE WITNESS: What scenario, Mr. Hector, are you
9 referring to?

10 Q. BY MR. HECTOR: Based on your medical practice 14:25:32
11 using RF devices to achieve circumferential tightening of
12 the vaginal canal, how would you treat that?

13 A. Are you talking opening or full length of the
14 canal? Are you talking about the full vaginal length?

15 Q. We can start with the opening in the vaginal 14:25:57
16 canal.

17 A. Well, that's -- you would treat it with the
18 heating device, again, but to a limited depth, because
19 you're focusing on the introitus, the entranceway.

20 Q. And where would you treat -- 14:26:23

21 A. All --

22 Q. -- along the vaginal wall?

23 A. Well, you're treating the vaginal wall that
24 encompasses the introitus, usually impacting the hymen --
25 remnants of the hymen, too. 14:26:39

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1 Q. So would you treat at just one point to achieve
2 circumferential tightening?

3 MR. BEMBEN: Objection. Incomplete
4 hypothetical.

5 THE WITNESS: Just treat one point? 14:26:59

6 Q. BY MR. HECTOR: Yeah.

7 A. Like just treat 7 o'clock?

8 Q. Yeah.

9 A. Well, you could affect tightening because you
10 have a circumferential anatomy, so anywhere you shorten 14:27:15
11 it or contract it is going to impact the diameter of that
12 round canal. If you treat it in multiple areas, you'll
13 get multiple contractions and further reduction in the
14 diameter.

15 Q. So you can achieve circumferential tightening by 14:27:43
16 just treating in one location?

17 A. You can. Again, if you think of it
18 mathematically, it's a 360-degree circle, and you remove
19 or shorten one portion of that circle, the entire
20 diameter reduces. 14:28:05

21 Q. Would that be circumferential tightening,
22 though?

23 MR. BEMBEN: Objection. Asked and answered.

24 THE WITNESS: I -- I'm assuming your definition
25 of circumferential tightening is shrinking the diameter 14:28:28

1 of a tubular structure, which is a circle.

2 Q. BY MR. HECTOR: So to treat circumferentially,
3 you would just heat at one point?

4 MR. BEMBEN: Objection. Asked and answered.

5 THE WITNESS: I think I was addressing your 14:29:00
6 question of what could happen if you did one point, and I
7 answered that.

8 Q. BY MR. HECTOR: But to treat -- for you to treat
9 and to get circumferential tightening, would you treat
10 just one point -- 14:29:17

11 MR. BEMBEN: Objection --

12 Q. BY MR. HECTOR: -- around the vaginal wall?

13 MR. BEMBEN: Objection. Incomplete
14 hypothetical.

15 THE WITNESS: I think hypothetically that could 14:29:27
16 happen. I would probably defer to more points than one.

17 Q. BY MR. HECTOR: How many points?

18 A. I think as many points as I felt necessary to
19 tighten and get the effect that I wanted.

20 Q. What would be, like, the lower bound? 14:29:53

21 A. Be what?

22 MR. BEMBEN: Objection. Calls for speculation.

23 THE WITNESS: What? Could you repeat that one
24 quickly?

25 Q. BY MR. HECTOR: You said you would -- 14:30:06

1 A. Oh, I see it.

2 Q. -- I think as many points as I felt necessary to
3 tighten.

4 What would be the lower bound of as many points?

5 MR. BEMBEN: Same objection and incomplete 14:30:21
6 hypothetical.

7 THE WITNESS: I -- I don't have a -- a number
8 for you.

9 Q. BY MR. HECTOR: Would it be two?

10 MR. BEMBEN: Same objections. 14:30:33

11 THE WITNESS: I would try to get whatever I felt
12 would be the maximum benefit to the patient, so I would
13 want to administer the therapy accordingly.

14 Q. BY MR. HECTOR: And to get the maximum
15 benefit -- I mean, would you get the maximum benefit with 14:30:52
16 two -- treating two points?

17 MR. BEMBEN: Objection. Incomplete
18 hypothetical.

19 THE WITNESS: Again, mathematically, I don't
20 think you would get the maximum result. 14:31:04

21 Q. BY MR. HECTOR: Would it be, like, four points
22 to get the maximum result? I'm just trying to get a feel
23 for --

24 MR. HECTOR: Objection. Incomplete
25 hypothetical. 14:31:19

1 THE WITNESS: Again, that -- I would want to get
2 the most desired area heated as possible to obtain
3 tightening.

4 Q. BY MR. HECTOR: And that's probably not two
5 points, not three points, but it's some number more than 14:31:48
6 that? Is that fair to say?

7 MR. BEMBEN: Same objections.

8 THE WITNESS: I would suspect.

9 Q. BY MR. HECTOR: How far apart would you -- would
10 these points be? You know, if you're -- let's say you do 14:32:06
11 four points. Like how far apart would you make those
12 points?

13 MR. BEMBEN: Objection. Incomplete
14 hypothetical.

15 THE WITNESS: I have no way of knowing. I'd 14:32:16
16 want it to be as close to contiguous as possible.

17 Q. BY MR. HECTOR: What do you mean by
18 "contiguous"?

19 MR. BEMBEN: Same objections.

20 THE WITNESS: Just segmentally each segment 14:32:33
21 being contiguous to the next to be heated.

22 Q. BY MR. HECTOR: Like anterior, lateral,
23 posterior, lateral as your four points, is that what
24 you're explaining?

25 MR. BEMBEN: Same objections. 14:33:00

1 THE WITNESS: That would be good.

2 Q. BY MR. HECTOR: Are there portions -- and
3 still -- we're still talking about the -- around the
4 vaginal wall circumferentially.

5 Are there portions of the vaginal wall that are 14:33:20
6 particularly receptive to remodeling as opposed to other
7 portions of the vaginal wall?

8 MR. BEMBEN: Objection to form.

9 THE WITNESS: I have no way of knowing that in
10 my experience. 14:33:37

11 Q. BY MR. HECTOR: Are the lateral walls more
12 susceptible to circumferential tightening than the
13 anterior wall, for example?

14 MR. BEMBEN: I'm sorry. Objection. Asked and
15 answered. 14:33:54

16 THE WITNESS: What do you mean "susceptible"?

17 Q. BY MR. HECTOR: Receptive. I should have used
18 the term "receptive," so let me restate that again.

19 Are the lateral walls more receptive to
20 circumferential tightening than the interior wall? 14:34:09

21 A. Lateral walls and anterior walls don't go
22 together, so...

23 Q. Sorry. I'm wrapped around the actual -- the
24 terminology. Let me try that again.

25 Would it be more effective to treat the lateral 14:34:36

1 walls of the vagina than the anterior wall?

2 MR. BEMBEN: Objection. Incomplete
3 hypothetical.

4 THE WITNESS: I -- I don't know. I can't answer
5 that. 14:34:53

6 Q. BY MR. HECTOR: What's your understanding of
7 obviousness as it pertains to this proceeding?

8 A. It is something that would be -- to a person
9 of -- who's involved in the similar art of this type of
10 procedures that we're talking about, that the impact of 14:35:32
11 the thermal energy is well-known and just obvious to
12 people who practice in the realm of this specialty.

13 Q. You said "the impact of thermal energy is
14 well-known." What do you mean by that?

15 A. Just what I said, people who are practicing this 14:36:14
16 form of -- it's well-known what the impact of thermal
17 energy has on these structures and it's obvious to them,
18 and it's been known for quite some time. So that's my
19 understanding of obviousness.

20 Q. Okay. What's your understanding of, like, the 14:36:47
21 doctrine of obviousness in patent law?

22 A. Are you referring to claim structure? Or what
23 are you referring to? Obvious, as I had mentioned, is
24 something that's well-known and obvious. If I can use
25 the acronym POSA instead of repeating it many times, if 14:37:15

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1 that's all right with you.

2 Q. That's fine.

3 A. The people who are practicing this form of
4 cosmetic gynecology. It invalidates non-obviousness.

5 Q. What invalidates non-obviousness? 14:38:02

6 A. When something is well-known and obvious to
7 POSAs in the field.

8 Q. And what would be well-known and obvious to
9 POSAs in the field?

10 A. What we talked about, the impact of thermal 14:38:17
11 energy on the vagina and its structures.

12 Q. What's your understanding of the term "prior
13 art"?

14 A. Something that has been used previously in the
15 realm of this field. 14:38:43

16 Q. What's your understanding of claim construction?

17 A. Well, may I refer to my declaration?

18 Q. Sure.

19 A. Thank you.

20 Q. And a summary would be fine. You don't 14:39:15
21 necessarily need to read to me from it.

22 A. I'm not a patent attorney, so my counsel has
23 counseled me on these claim terms. They construe the --
24 are in a controversy and only to the extent necessary to
25 resolve the controversy. As discussed, it's my opinion 14:39:44

1 that the cited prior art teaches all the elements of the
2 claim in this '511 patent when giving its ordinary and
3 customary meaning in view of the '511 patent
4 specification. And accordingly, that's my opinion, that
5 no claim term requires an express construction. 14:40:09

6 I was told by my counsel that there have been
7 prior -- several proceedings prior, including IPRs and in
8 district court, and that there has been certain
9 constructions that weren't adopted.

10 I address these claim constructions in my 14:40:32
11 analysis of invalidity in the context of the claim
12 element in which the claim term is recited.

13 As I demonstrate below, it's my opinion that the
14 prior art disclosures or renders obvious the claim
15 elements under the various prior constructions, including 14:40:49
16 those proposed by the Patent Owner and those that were
17 not adopted by the Court or Board.

18 Q. Okay. Does your understanding extend beyond
19 that, those paragraphs you just read?

20 A. That's pretty much my understanding of patent 14:41:07
21 laws that addresses claim construction.

22 MR. HECTOR: Okay. I think it would be a good
23 time to take a break, if it's okay with you all. We've
24 been going about an hour.

25 THE WITNESS: Sure. 14:41:25

1 MR. BEMBEN: Let's go for 15 minutes, if you
2 don't mind.

3 MR. HECTOR: Fine with me.

4 Go off the record.

5 THE REPORTER: Off the record at 2:41. 14:41:38

6 (Recess.)

7 THE REPORTER: Back on the record at 2:37 p.m.

8 MR. HECTOR: Great. I'm going to go ahead and
9 introduce the Edwards, Mosher and Ingle references, just
10 so you have them. I'm going to pull those up. 14:57:55

11 (Exhibit 6, United States Patent Number

12 6,463,331 B1, 10/8/02, was marked for

13 identification by counsel electronically.)

14 (Exhibit 7, United States Patent Application

15 2004/0193238 A1, 9/30/04, was marked for

16 identification by counsel electronically.)

17 (Exhibit 8, United States Patent Number

18 6,216,704 B1, 4/17/01, was marked for

19 identification by counsel electronically.)

20 MR. HECTOR: It will be just a second while I 14:58:38
21 uploaded them.

22 Q. Okay. Do you have those three references,
23 Dr. Berenholz?

24 A. Yes, I do.

25 Q. Are you familiar with those three patents, the 14:59:15

1 Edwards, Ingle and Mosher?

2 A. Yes.

3 Q. And just to be clear, by Edwards I mean US
4 Patent 646,331. You're familiar with that?

5 A. Yes. 14:59:38

6 Q. And by Mosher I'm referring to US Patent
7 Publication Number 2004/0193238.

8 A. Yes.

9 Q. And by Ingle I'm referring to US Patent Number
10 6,216,704. 14:59:55

11 A. Yes.

12 Q. What are these patents generally directed to?

13 MR. BEMBEN: Objection. Form.

14 THE WITNESS: What are they directed to?

15 MR. BEMBEN: Objection -- 15:00:19

16 Q. BY MR. HECTOR: Correct.

17 A. I think they're all directed towards some
18 nonsurgical treatment with the use of energy and treating
19 urogenitale disorders as well as shrinking tissue and
20 treating for incontinence. 15:00:48

21 Q. Okay. You said "treating for incontinence," the
22 last one?

23 A. Uh-huh. Uh-huh.

24 Q. Tell me -- tell me about that condition,
25 incontinence. Is that the same as stress urinary 15:01:05

1 incontinence? Or are there differences?

2 A. Yeah -- I'm sorry.

3 MR. BEMBEN: Objection. Form.

4 Go ahead.

5 THE WITNESS: There are different incontinences. 15:01:18

6 Q. BY MR. HECTOR: What type of incontinence --

7 A. You had mentioned urinary stress incontinence,
8 and then there is urge incontinence. U-R-G-E
9 incontinence. There is overactive bladder incontinence.

10 There's overflowing incontinence. Neurogenic 15:01:48
11 incontinence. So there are several forms of
12 incontinence.

13 Q. And are these patents directed to a particular
14 type of incontinence from those -- from that list?

15 A. Mostly towards, I believe, stress incontinence. 15:02:11

16 Q. And what is stress incontinence?

17 A. Stress incontinence is the involuntary loss of
18 urine with various Valsalva maneuvers -- V-A-L-S-A-L-V-A,
19 for the transcriptionist -- such as laughing, sneezing,
20 coughing, jumping, exercising, et cetera. 15:02:43

21 Q. Okay. So it's like urine leaves the bladder
22 involuntarily when one of those Valsalva maneuvers occur;
23 is that correct?

24 A. Yeah. Yes.

25 Q. Okay. And what controls urine leaving the 15:03:09

1 bladder?

2 A. It's usually caused by laxity around the
3 mid-urethra allowing for hypermobility, meaning the
4 urethra, mid-urethra falls with the strenuous activities,
5 like coughing and sneezing, and when that falls, the 15:03:41
6 urine is allowed to spiral out as you lose your angle
7 between the bladder and the bladder neck, and they become
8 one level, one line, if you can picture it. Urine is
9 then able to escape.

10 Q. You said the angle between the bladder and the 15:04:13
11 bladder neck become one level?

12 A. In other words, you have an angulation between
13 the bladder as it meets the urethra and then it helps
14 constrict that opening. When somebody coughs and that
15 angle falls and becomes, let's say, not 40 degrees but 15:04:35
16 suddenly becomes parallel with 180 degrees, just as an
17 example, urine is allowed to pass freely.

18 Q. Okay. And so how do you fix that with these
19 treatments?

20 A. There are -- there are numerous modalities to 15:05:00
21 fixing it.

22 Q. But I'm speaking with regard to the Edwards,
23 Mosher and Ingle --

24 MR. BEMBEN: Objection. Objection to form.

25 THE WITNESS: In relation -- 15:05:17

1 MR. HECTOR: So let me correct that.

2 Q. So how do the Edwards, Mosher and Ingle patents
3 address stress urinary incontinence?

4 A. Well, by strengthening the tissues surrounding
5 that juncture and by bulking, as you would think of a 15:05:43
6 neck -- that junction as the neck, and by bulking that up
7 with collagen, some elastin. That bulking procedure
8 reduces the hypermobility of that area so when you laugh,
9 sneeze, cough or jump, it doesn't move as much down as it
10 could, and thus maintains an angle and keeps that opening 15:06:16
11 closed or more resistant to the pressure.

12 Q. You're treating the fascia around the bladder
13 neck?

14 A. Yeah, essentially.

15 Q. Okay. The focus is keeping that bladder neck up 15:06:34
16 in the hammock.

17 A. Right.

18 Q. Okay. And Edwards, Mosher and Ingle all
19 describe, kind of, different modalities of treating that
20 fascia to keep the -- to support the bladder neck? 15:06:54

21 MR. BEMBEN: Objection to form.

22 Q. BY MR. HECTOR: Is that fair?

23 A. I believe so, yes.

24 Q. And so if you hold the bladder neck in place
25 during the laughing, coughing, Valsalva maneuver, it 15:07:20

1 wouldn't result in urine inadvertently passing into the
2 urethra?

3 A. Yeah, it helps. You may not get 100 percent
4 result, but you get a tremendous mitigation of those
5 symptoms. 15:07:40

6 Q. So kind of -- by treating the -- or by, you
7 know, tightening those tissues that support the bladder
8 neck, you kind of keep the horse from getting out of the
9 barn, so to speak, is that --

10 MR. BEMBEN: Objection to form. 15:07:58

11 Q. BY MR. HECTOR: -- the --

12 A. That's close.

13 Q. The fluid getting out of the tank, the bladder?

14 A. Yes.

15 Q. Turning to the Edwards reference, as I 15:08:28

16 understand -- I'm going to focus on Figures 4 and 9,
17 which I believe you rely on predominantly in your
18 declaration, correct me if I'm wrong on that. It speaks
19 to treatment of the anterior and posterior walls of the
20 vagina; is that correct? 15:09:02

21 A. Figure 4? Did you say figure --

22 Q. Yeah, I think Figure 4 is the --

23 A. Yes.

24 Q. -- is the RF device contemplated by Edwards, and
25 then Figure 9 is a flowchart. 15:09:19

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1 A. Did you say 9 is the flowchart?

2 Q. Yeah, Figure 9.

3 So, yeah, starting with Figure 4.

4 A. Uh-huh.

5 Q. Do you see that? 15:09:54

6 A. I do.

7 Q. So there's, like, two or, depending on how you

8 count it, three devices there. In the upper portion of

9 that figure, is that a speculum picture in the upper

10 portion? 15:10:11

11 A. It is.

12 Q. Okay. And then the bottom -- the lower item

13 is -- it's called the -- like a handle or a blade?

14 A. Yes.

15 Q. And so as -- starting with -- I assume these two 15:10:36

16 devices are -- would be used together, the speculum and

17 the handle/blade?

18 A. Yes.

19 Q. Okay. So why would you need to use the

20 speculum? 15:10:56

21 A. To give exposure to the walls of the vagina.

22 Q. Okay. Yeah. What do you mean by "exposure"?

23 Is that a medical term or --

24 A. Well, the purpose of the speculum is to open the

25 vagina so the clinician can see the walls of the vagina, 15:11:26

1 otherwise they would collapse upon each other.

2 Q. Okay. So how would the -- how would the
3 speculum be applied in this case?

4 A. If you maybe imagine a duckbill type of motion,
5 so it's closed, the duckbill is closed, you insert it and 15:11:59
6 then open it, and it opens anterior and posterior walls
7 of the vagina.

8 Q. So it's a -- the one duckbill is contacting
9 the --

10 A. Anterior -- 15:12:20

11 Q. -- anterior wall, the other is the posterior?

12 A. Correct.

13 Q. Okay. And then -- so, yeah, what's the purpose
14 of that, just kind of opens up the vaginal cavity? Is
15 that the reason why you use the speculum? 15:12:41

16 A. Right. You want to see the area that you wish
17 to treat.

18 Q. Okay. And typically do you -- what -- if you
19 put the speculum in, it kind of stays in place, or do you
20 move it around? 15:13:01

21 MR. BEMBEN: Objection to form.

22 THE WITNESS: Are you talking about me or with
23 regards to Edwards?

24 Q. BY MR. HECTOR: I guess let's start with you.

25 MR. BEMBEN: Objection to form. 15:13:18

1 THE WITNESS: Mr. Hector, it depends on the
2 clinical situation. If I'm trying to view various areas
3 of this circumferential organ, initially putting a
4 duckbill speculum in, you can see the cervix and the
5 walls of the vagina. If I need to see more, I can simply 15:13:39
6 close the speculum and rotate it.

7 Q. BY MR. HECTOR: Okay. With your understanding
8 of Edwards, how does Edwards use the speculum, from your
9 understanding of this reference?

10 A. I believe that they used it in both manners 15:14:05
11 of -- it's rotatable and can be adjusted to target
12 lateral walls, posterior walls, anterior walls.

13 Q. The reference speaks to treating the anterior
14 and posterior walls, is that correct, your understanding
15 of Edwards? 15:14:39

16 A. Yes.

17 Q. So if you're treating those surfaces, you would
18 put the speculum in contact with the anterior and
19 posterior walls?

20 A. In treating it? You put the -- not the 15:14:54
21 speculum, the treatment tip. If I was trying to treat
22 anterior and posterior, you would be blocked by putting
23 in the duckbill speculum up and down. You would have to
24 rotate it sideways to allow the clinician to see both the
25 top and bottom or anterior and posterior of the walls. 15:15:16

1 Q. But -- so turning back to Figure 4 and the
2 description thereof, it speaks about, you know, the
3 handle/blade engaging the speculum. What's your
4 understanding of how that works?

5 A. It's -- it has, I guess, an ability to lock in 15:15:40
6 with the speculum.

7 Q. And how would that work?

8 MR. BEMBEN: Objection to form.

9 THE WITNESS: They have some type of mating
10 feature that's engaged with the speculum, and that's what 15:16:10
11 locks it into position. They refer to it as a lock pin,
12 but then they can go forward and treat the patient.

13 Q. BY MR. HECTOR: The speculum has those, like,
14 rectangular shapes in -- does the retractable lock pin,
15 like, slide into those rectangular shapes? 15:16:40

16 A. The openings, you mean? Those --

17 Q. Yeah. On the speculum there's those rectangular
18 openings; right?

19 A. Yeah. I believe those are the -- where you
20 would insert and lock in. 15:16:54

21 Q. Okay. So then the blade would extend into the
22 vagina from the end of the speculum once it's locked in;
23 right?

24 A. Well, it first -- yeah. The duckbill speculum
25 has to be closed before you insert it. 15:17:21

1 Q. Yeah. So I guess so what's -- yeah, what's your
2 understanding of the order of how this would be done?

3 MR. BEMBEN: Objection to form.

4 THE WITNESS: I visualize it and understood it
5 to mean that it is introduced into the vagina and they 15:17:45
6 try to mate up the tip -- the treatment tip to the
7 speculum, and that way they can deliver both heat and
8 cooling fluid to whatever area they want to treat.

9 Q. BY MR. HECTOR: But how is -- how is the blade
10 mated up with the speculum? 15:18:21

11 A. It's lock pinned through the number 431 to the
12 speculum. I've never used the device myself, so I'm --
13 I'm understanding it two dimensionally instead of how
14 I -- I've never used it.

15 Q. Yeah. So I'm asking from -- yeah, from your 15:18:48
16 understanding of this reference as a -- you know, an
17 expert in this case as to how -- how that handle would be
18 mated to the speculum. It seems like that retractable
19 lock pin portion would engage with the rectangular
20 portion of the speculum? 15:19:11

21 A. Right. And that lock pin was on top of a
22 handle.

23 Q. Yeah.

24 A. Handle 430.

25 Q. So, yeah, with -- with reference to that and 15:19:30

1 then Figure 9, which talks about -- so, I think, you
2 know, step 904, you would insert the duckbills of the
3 speculum into the vagina. The speculum was placed in an
4 open position, and then the -- and then the blade is
5 inserted into the vagina through the speculum. 15:19:57

6 A. Correct.

7 Q. So from your understanding, would the -- would
8 the portion like 420, like, stick out from the front into
9 the vagina from the speculum?

10 A. It would go further past it, I think, is what 15:20:20
11 they're saying.

12 Q. Yeah. Further -- by further past, you mean
13 further into the vagina?

14 A. Further into the vagina, yeah.

15 Q. Than the end of the duckbill? 15:20:36

16 A. Yes.

17 Q. Okay. And then just understanding what the --
18 when you place the speculum into the vagina, typically
19 how far into the vagina is the end of those duckbills,
20 the speculum? 15:20:59

21 MR. BEMBEN: Just objection.

22 THE WITNESS: I can't tell you because of the
23 variable sizes of the speculum, so I don't know the
24 dimensions in terms of length of the duckbill.

25 Q. BY MR. HECTOR: But from, you know, looking at 15:21:21

1 Figure 4, how would you think that speculum would be
2 placed in terms of the length into the vagina of those
3 duckbills?

4 A. I would have to match them up on the drawing and
5 measure if these are true to form, which I don't think 15:21:45
6 they are actual measurements, but it looks like it takes
7 up half the length of the both handle and tip, allowing
8 the tip to proceed further.

9 Q. So which -- I'm sorry. What takes up half the
10 length -- 15:22:10

11 A. You asked me --

12 Q. -- of the handle?

13 A. -- how much of the duckbill speculum would take
14 up the length of the device, is what I understood your
15 question. 15:22:17

16 I don't have an exact measurement. I'm just
17 eyeballing the diagram that looks as though the treatment
18 probe is twice the length of the duckbill speculum.

19 Q. So then how far would you typically insert the
20 speculum into the vagina? 15:22:48

21 A. It depends where you want to treat. If you want
22 to go more deeply, you would go deeper. More shallow,
23 you would proceed more shallow.

24 Q. But you would need -- you need to be at least
25 some portion into the vagina, right, to have tissue to 15:23:09

1 push it on?

2 A. Sure.

3 Q. Okay. The speculum has to be at least some
4 portion into the vagina; is that correct?

5 A. Yes. 15:23:26

6 Q. Okay. And this figure doesn't make clear in
7 terms of what those dimensions would be --

8 A. Not to me.

9 Q. -- is that correct?

10 It doesn't provide dimensions for the speculum; 15:23:46
11 correct?

12 A. I don't see that in Figure 4.

13 Q. And it doesn't provide dimensions for the
14 blade/hand piece?

15 I think I asked you -- it may not have come 15:24:29
16 across -- it doesn't provide dimensions for the
17 blade/hand piece; correct?

18 A. Not what I'm looking at, no. Sorry.

19 Q. How far would you need to insert the speculum in
20 to engage tissue? 15:24:48

21 A. What tissue are we aiming for, Mr. Hector?

22 Q. Like vaginal wall tissue. Like I'm talking
23 about -- you could push the speculum all the way in and
24 maybe you're, you know, in contact with tissues that are
25 deeper into the vaginal canal, is one end of the 15:25:13

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1 spectrum. Now I'm asking you about the other end of the
2 spectrum.

3 Like how far in would you -- is the furthest, I
4 guess, interior that you could place the speculum such
5 that you would make contact with tissue in -- 15:25:30

6 MR. BEMBEN: Objection --

7 Q. BY MR. HECTOR: -- a manner to be able to hold
8 the vagina open --

9 MR. BEMBEN: Objection to form.

10 THE WITNESS: I'm just reading your question. 15:25:43
11 I'm sorry.

12 Q. BY MR. HECTOR: Like what's the minimum
13 insertion depth of a speculum that you could use where
14 you engage tissue?

15 A. You'd want to go at least a centimeter in. 15:26:03

16 Q. But probably more than that to be able to
17 meaningfully engage tissue?

18 MR. BEMBEN: Objection to form.

19 THE WITNESS: I don't -- I don't know what you
20 mean by meaningful. You engage the tissue of the vagina 15:26:20
21 whether you're shallow, slightly more than shallow,
22 deeper. You're engaging the vagina at various lengths,
23 depending on what you're trying to accomplish.

24 Q. BY MR. HECTOR: Okay. But the most shallow
25 would be, you said, one centimeter? 15:26:45

1 A. If you don't want the speculum to pop out, yeah.

2 Q. It seems like -- I mean, like, one centimeter is
3 pretty small, even there --

4 A. One --

5 Q. -- you have a risk of -- I'm sorry. 15:27:00

6 Go ahead.

7 A. No. One centimeter's not even a half inch.

8 Q. Yeah, so if the ends of the duckbills were only
9 one centimeter in, it seems like it would even pop out at
10 that depth; right? 15:27:18

11 A. That's what I said, yes.

12 Q. Okay. So what's the -- like what's the minimum
13 depth, like, where the speculum would not pop out?

14 A. Yeah. I've never researched that question
15 before, so I don't know. I mean, common sense is you 15:27:33
16 want to be in far enough to support the tissue so that it
17 opens without losing it.

18 Q. So maybe like an inch, based on your practice as
19 a medical doctor?

20 A. I don't think I've ever gone that shallow. But 15:27:52
21 probably a little further than that.

22 Q. What's the most shallow you think you've gone?

23 A. I don't know, Mr. Hector. I really don't.

24 Q. Okay. But beyond -- beyond an inch, maybe two
25 inches? 15:28:12

1 A. Perhaps.

2 Q. Okay. Taking a look at this hand piece a little
3 bit further, the electrodes 423 are like lined up in a
4 row. I guess that'd be, I don't know, longitudinally on
5 that device. Why would you have, like, those electrodes 15:28:45
6 lined up in a row like that?

7 A. Well, I think those -- you called them
8 electrodes? You're referring to, what, 423?

9 Q. 423, yeah.

10 Yeah. Let me just clarify, too, that -- 15:29:29
11 speaking clearly about the geometry here. You know, you
12 have the length of the, you know, handle and blade. It's
13 longer in one direction than it is wide. When I speak
14 along the length, I mean along the, you know, long
15 length. 15:29:45

16 Those electrodes 423, there's two of them kind
17 of lined up along the length of the blade, and I'm
18 wondering, you know, from your perspective as an expert
19 in this case, why those would be lined up next to each
20 other along the length like that? 15:30:03

21 MR. BEMBEN: Objection to form.

22 THE WITNESS: I would guess it has to do with
23 showing a plurality of areas to treat or cool.

24 Q. BY MR. HECTOR: But would those -- I don't think
25 those electrodes would cool, though; right? 15:30:36

1 A. No, but rather than -- you want to cover some
2 areas so you have a plurality of electrodes setting
3 there. It just covers more treatment area if you have
4 two or three electrodes in a row.

5 Q. Okay. And why would you -- why would you want 15:31:02
6 to do that --

7 MR. BEMBEN: Objection to form.

8 Q. BY MR. HECTOR: -- in terms of the procedures
9 described in the Edwards patent?

10 A. I think to be efficient in terms of manipulating 15:31:14
11 and treating the area, covering surface area.

12 Q. Okay. And how big would you estimate those
13 electrodes to be, based on your experience as an expert
14 in this field?

15 A. I have no experience with the sizing of these 15:32:04
16 electrodes, so I can't answer that accurately.

17 Q. Like how big are electrodes, you know, for -- I
18 realize you don't have experience with this device, but
19 for other devices, like how big are the electrodes
20 typically? By other devices, I mean devices similar to 15:32:26
21 this.

22 MR. BEMBEN: Objection to form.

23 THE WITNESS: Just there is quite a range in
24 size, so very hard to -- there are pluralities, and then
25 there's contiguous electrodes in a circular 15:32:46

1 circumferential manner, so I -- it varies from a single
2 electrode to multiple electrodes to a continuous line of
3 electrodes, so there's just no way for me to answer your
4 question intelligently.

5 Q. BY MR. HECTOR: Okay. Do you have a feel for, 15:33:07
6 like, the smallest size of an electrode that you've
7 encountered in your years of experience with similar
8 devices?

9 A. I couldn't give you a measurement. I never
10 bothered to measure. 15:33:27

11 Q. Like would they be as small as a centimeter?

12 MR. BEMBEN: Objection. Asked and answered.

13 THE WITNESS: It could be. I'm speculating.

14 Q. BY MR. HECTOR: When the handle is -- is engaged
15 with the speculum, do you have any feel from this picture 15:34:03
16 how far that blade would stick out into the vagina?

17 A. I would be willing to guess several centimeters.

18 Q. Okay. Like two or three centimeters?

19 A. Possibly. But, again, I have no experience with
20 this device. 15:34:31

21 Q. And with regard to Figure 9 -- or 9A, in the
22 first step it talks about, you know, placing the patient
23 on the treatment table and then cleansing the external
24 genitalia and surrounding anatomy with Betadine and
25 benzalkonium chloride. Do you see that language? 15:35:16

1 A. Yes. That's figure 901 in the 9A figure; right?

2 Box 901?

3 Q. That's right, yeah.

4 Why would you use Betadine or benzalkonium

5 chloride? 15:35:41

6 A. Well, they're antiseptics, so you are doing an

7 invasive procedure, and that would help prevent

8 infection.

9 Q. What do you mean by "invasive procedure"?

10 A. Well, you're placing an object -- a foreign 15:36:00

11 object -- and I'm assuming that the doctor is using a

12 sterilized speculum, but if they're not, once again,

13 you're introducing a foreign object into the vagina.

14 Q. Do you use Betadine or benzalkonium when you

15 treat using the EMFEMME 360 device? 15:36:30

16 MR. BEMBEN: Objection to scope.

17 THE WITNESS: We don't.

18 Q. BY MR. HECTOR: Why not?

19 MR. BEMBEN: Objection to scope.

20 THE WITNESS: We've just never had a problem, 15:36:44

21 because all of our probes are sterile packaged, and --

22 and we've just never had an infection in all the years

23 that we've used them.

24 Q. BY MR. HECTOR: Is there an increased risk of

25 infection with the Edwards treatment? 15:37:12

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1 A. I wouldn't know. I think they're just
2 attempting to produce a sterile field on the outside of
3 the vagina, and so that's their methodology.

4 Q. And would you -- would you use Betadine and
5 benzalkonium in performing, like, surgical procedures -- 15:37:41
6 as prep for a surgical procedure?

7 A. Surgical procedures, yeah. We use Betadine
8 extensively for literally cutting open a patient.

9 Q. But for a non-surgical procedure would you use
10 Betadine? 15:38:00

11 A. I haven't with my device, but I'm sure others
12 have with theirs. I just can't speak to it. I can only
13 offer you my experience.

14 Q. In the discussion of Figure 9, in column 13 of
15 Edwards, and specifically with column 13, line 14 to 16, 15:39:01
16 it says, "A method is performed to create a series of
17 lesions in either" -- "A method is performed to create a
18 series of lesions in either the anterior vaginal wall,
19 the posterior vaginal wall or both."

20 What does that statement mean? 15:39:30

21 A. It means that they're heating the anterior wall
22 and the posterior vaginal wall. The lesion, I believe --
23 I interpret it as a point of thermal energy treatment.

24 Q. A point of thermal energy treatment?

25 A. Uh-huh. 15:39:59

1 Q. So Figure 9 discusses the use of, like,
2 irrigating fluids. What's your understanding as to why
3 irrigating fluids would be used in this procedure?

4 A. My understanding, it is to cool the mucosal
5 layer before and during the treatment of vaginal mucosa. 15:40:44

6 Q. So the irrigating fluid, if you look at Figure
7 4, it looks to be delivered from a location 425. Is that
8 your understanding?

9 A. Yes.

10 Q. So the fluid -- or possibly 433 as well? 15:41:14

11 A. Correct. That seems to remove the fluid.

12 Q. 433?

13 A. Yeah.

14 Q. So the fluid delivery pours are -- it's -- it's
15 expelling fluid at a different location than what is 15:41:38
16 being heated by the thermal couple; correct?

17 A. Correct.

18 Q. So this is kind of like creating a flow of water
19 or a flow of irrigating fluid in the vagina during the
20 treatment? 15:41:59

21 A. That's the way I interpret it, yes.

22 Q. So you're kind of heating and then flowing water
23 over at the same time?

24 A. And removing water.

25 Q. And why would you be removing the water? 15:42:19

1 A. Well, you're only removing water temperature so
2 you can replace it with cooler temperature.

3 Q. And why do you think it uses the term
4 "irrigating"?

5 A. It seems appropriate. 15:42:46

6 Q. By irrigating, does that mean it's clearing away
7 tissue?

8 A. I don't see that. I mean, irrigating means
9 utilizing fluid, not clearing it away.

10 Q. Okay. So you're, in this device here, kind of, 15:43:12
11 you know, heating while running fluid past --

12 A. Right.

13 Q. -- the heating site?

14 A. Right.

15 Q. Like welding under water or something -- welding 15:43:23
16 in a river or something like that?

17 A. Another thing I have no experience with either.

18 Q. Do you have any understanding about the
19 intensity of the heat applied with Edwards?

20 A. I would have to refer to the patent or to the 15:43:57
21 claims. I think there was a mention of cooling, and so
22 at this time I can't remember. You'd have to give me
23 time to review it.

24 Q. Yeah. We can move on rather than having you
25 read the whole patent. 15:45:06

1 A. All right.

2 Q. At step 908 it speaks about dividing energy to
3 discrete areas.

4 A. I'm sorry. Where are you? Where are you,
5 Mr. Hector? 15:45:21

6 Q. Figure 9A, step 908.

7 A. All right.

8 Q. It says, "discrete areas of the vaginal wall."
9 What does that mean to you?

10 A. I think those are intended areas that the 15:45:36
11 clinician wants to treat.

12 Q. And what does it mean by "discrete"?

13 A. I think it's synonymous with specific.

14 Q. I guess reading Edwards here, you don't have a
15 feel for the intensity of the heating that would be 15:46:26
16 applied to the vaginal wall?

17 A. Again, I'd need to go over it again.

18 Yeah, I don't see reference to a specific
19 temperature.

20 Q. Or intensity of heating? 15:48:01

21 A. That's correct. I mean, I briefly skimmed
22 through it.

23 Q. Would you -- would the device in Figure 4, would
24 you categorize that as a radio frequency surgery device?

25 A. Surgery -- 15:48:51

1 MR. BEMBEN: Objection to form.

2 Sorry. Go ahead.

3 Q. BY MR. HECTOR: Yeah. In Figure 4, a radio
4 frequency surgery device?

5 MR. BEMBEN: Objection to form. 15:48:59

6 THE WITNESS: We call it non-invasive. Even
7 though it is put in the vagina, it's --

8 Q. BY MR. HECTOR: Why is it called non-invasive?

9 A. Because we're not doing surgery. We're not
10 cutting the patient. 15:49:19

11 Q. Okay. You're creating lesions.

12 Okay. We can move to Mosher, if you have that
13 one.

14 Are you familiar with the Mosher patent?

15 A. Yes. 15:50:06

16 Q. And this one is also directed to treatment of
17 stress urinary incontinence?

18 A. Correct.

19 Q. Does Mosher discuss improving sexual function in
20 any way? 15:52:18

21 A. I don't see it mentioned here.

22 Q. Okay. Would treatment of endopelvic fascia be
23 used to enhance sexual function?

24 MR. BEMBEN: Objection to form, calls for
25 speculation. 15:52:48

1 THE WITNESS: I -- I don't know if that would
2 work or not.

3 Q. BY MR. HECTOR: Okay.

4 A. Anything that affects the vagina, if you're
5 doing that to the endopelvic fascia, could or couldn't. 15:53:03
6 I just don't know how to answer that.

7 Q. Okay. But you're not aware of that being done?

8 A. Not here, no.

9 Q. What do you mean "not here"?

10 A. You were referring, I believe, to Mosher and 15:53:21
11 endopelvic fascia, or were you not?

12 Q. Just generally. Mosher speaks about treatment
13 of endopelvic fascia, and I was asking, you know, just
14 generally, based on your experience as an expert in this
15 case, would treatment of endopelvic fascia be used -- 15:53:43
16 would you treat endopelvic fascia to increase sexual
17 function?

18 A. Well, that's not the primary target tissue. The
19 original primary target tissue, again, is the lamina
20 propria and collagen producing and scarring and 15:54:06
21 contracting, et cetera.

22 Q. You're not aware of any reason to treat
23 endopelvic fascia for sexual function; correct?

24 A. I just don't recall that being a target tissue
25 specifically for sexual function. 15:54:26

1 Q. Does Mosher disclose treatment of external
2 vaginal tissue?

3 A. I don't see it here.

4 Q. Okay. And would -- would there be any reason to
5 treat external vaginal tissue to improve stress urinary 15:56:44
6 incontinence?

7 A. No.

8 Q. Take a look at Figure 4C of Mosher.

9 A. Yes.

10 Q. What -- what tissue is being treated here? 15:57:28

11 A. Well, that looks like mid-urethral tissue. The,
12 I'm sorry, anterior wall of the vagina.

13 Q. Okay. So you said that that -- that's treatment
14 of the mid -- okay. That's -- you clarified that the
15 answer is that's the treatment of the anterior wall of 15:58:02
16 the vagina?

17 A. Yeah, just below the -- yeah.

18 Q. And is that the bladder?

19 A. Above it?

20 Q. Yeah. 15:58:16

21 A. Yes.

22 Q. Okay. And that -- that tip, 24, is a needle;
23 correct?

24 A. Yes.

25 Q. That would puncture the -- put a hole in the 15:58:27

1 surface of the mucosa epithelium?

2 A. Yes.

3 Q. Okay. Would -- would that leave behind a scar
4 after treatment?

5 A. I doubt it. And that's all of a dimension. 15:58:49

6 Q. Is there a potential for bleeding?

7 A. If there is, it's minimal.

8 Q. Would -- would you typically use some sort of
9 anesthetic --

10 MR. BEMBEN: Objection to form. 15:59:16

11 Q. BY MR. HECTOR: -- in performing a treatment
12 like this?

13 A. No. I've never used this device.

14 Q. Is that -- is that percutaneous treatment? Is
15 that the correct terminology? 15:59:41

16 A. Not really. But the -- it's similar to
17 percutaneous. It's very shallow. I think of skin when I
18 think of percutaneous. But this is just shallow.

19 Q. How deep is that -- how deep is that electrode
20 going? 16:00:04

21 A. I would guess less than a millimeter.

22 Q. But there would be some -- some damage to the
23 mucosal epithelium?

24 A. I'm not sure what you mean by "damage."

25 Q. I mean you're poking a hole through it with a 16:00:27

1 needle. That's -- creates some sort of damage to the
2 mucosal epithelium, does it not?

3 A. Oh, I don't think it elevates to that level of
4 description, no.

5 Q. So what is happening to the mucosal epithelium? 16:00:45

6 A. It's being perforated or interrupted with the
7 needle but to such minimal depth that it's hardly causing
8 damage -- or residual damage.

9 Q. How do you -- how do you know the depth from
10 this picture? 16:01:14

11 A. I think the point of the depth of this needle is
12 to deliver heat, not to inject it into the bladder walls
13 so as to heat it up. It's transmitting heat. So it's
14 very superficial.

15 Q. And what tissue is it transmitting heat to? 16:01:42

16 A. Well, you're going through the mucosal, the
17 anterior wall of the vagina. I think we discussed that
18 as being a fraction of a fraction of a millimeter.

19 Q. But to your understanding, this is -- it's
20 heating the endopelvic fascia -- 16:02:05

21 A. There -- there isn't a pelvic fascia there.
22 There is lamina propria there. There's collagen
23 production there.

24 Q. Okay. Is there any means for protecting the
25 mucosal epithelial surface in -- in this device? 16:02:33

1 A. Protecting how?

2 Q. Protecting it from injury.

3 A. What type of injury are you referring to?

4 Q. From being stabbed with a needle.

5 MR. BEMBEN: Objection to form. 16:02:58

6 THE WITNESS: Again, I think I've answered this.

7 This is something that would heal immediately, within a

8 day or two.

9 Q. BY MR. HECTOR: But there would be healing?

10 A. Yes. 16:03:17

11 Q. Some discomfort?

12 A. Discomfort? I don't know.

13 MR. BEMBEN: So we've been going for over an

14 hour again. Do you want -- or would you like to take a

15 break? 16:03:37

16 THE WITNESS: What time is it?

17 MR. BEMBEN: It is 4:03.

18 THE WITNESS: Okay.

19 MR. HECTOR: Would you like to take a quick

20 ten-minute break? 16:03:44

21 THE WITNESS: All right.

22 MR. BEMBEN: Sure. That sounds good. Thank

23 you.

24 (Recess.)

25 THE REPORTER: Back on the record at 4:15 p.m. 16:15:25

1 Q. BY MR. HECTOR: Will you turn to Ingle, which is
2 Exhibit 1007, Exhibit 8 to this deposition?

3 Are you familiar with Ingle --

4 A. I am.

5 Q. -- Dr. Berenholz? 16:16:30

6 A. I am.

7 Q. And what does Ingle generally describe?

8 A. It's just a non-invasive manner of heating
9 collagenous tissue and with an emphasis on incontinence
10 and other support tissue in that the -- there is a 16:17:06
11 precooling and preheating protocol to modulate the amount
12 of temperature reaching the target tissue, as I
13 understand it.

14 Q. Does Ingle describe the target tissue as the
15 lamina propria anywhere? 16:17:43

16 A. He mentions collagenous tissue.

17 Q. But he doesn't specifically say lamina propria?

18 A. No, I don't remember that.

19 Q. And does he specifically identify the muscularis
20 as a target tissue? 16:18:07

21 A. He mentions fascia, which is not muscularis.

22 Q. Okay. But he doesn't mention muscularis?

23 He does not mention muscularis; correct?

24 A. I don't recall seeing it.

25 Q. Does Ingle disclose heating tissue for the 16:18:47

1 improvement of sexual function?

2 A. Mr. Hector, you mean specifically; correct?

3 Q. I'm not sure what -- yeah, the question was:

4 Does Ingle disclose heating tissue for the improvement of
5 sexual function? 16:19:23

6 A. I don't see that here specifically.

7 Q. Does Ingle describe any treatments of the labia
8 minora?

9 A. I didn't see that.

10 Q. Does Ingle describe any treatments of the 16:21:00
11 introitus?

12 A. I don't see that.

13 Q. Ingle describes treatments using a probe in the
14 bladder or a -- or a rectal probe. Why -- why does it
15 use those modalities? 16:21:59

16 A. I think what he's trying to accomplish is he
17 wants to -- I guess he wants to enhance both top and
18 below the supporting structure tissue for the bladder
19 neck.

20 Q. And using a -- a bladder probe or a rectal probe 16:22:43
21 would -- would more advantageously allow you to heat
22 those tissue areas?

23 A. Would it add more --

24 MR. BEMBEN: You kind of trailed off, and we
25 lost audio for a second. Can you just repeat that 16:23:13

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1 question?

2 MR. HECTOR: Okay. Yeah.

3 Q. So you said Ingle has described treatments of
4 the bladder neck and up in the bladder; is that correct?

5 A. From above and below, yes. 16:23:31

6 Q. From above and below the bladder neck?

7 A. Huh? Sorry.

8 Q. You mean -- you mean above and below the bladder
9 neck; correct?

10 A. Bladder neck, yes. 16:23:55

11 Q. Okay. I think you cite to Figure 11 in your --

12 Do you see that, Figure 11?

13 A. Yeah, I just got to it.

14 Q. So in that -- in that image, the device is
15 treating above the bladder neck; is that correct? 16:25:04

16 A. Yes.

17 Q. And that's to treat symptoms of stress urinary
18 incontinence?

19 A. Yes.

20 Q. Why would you treat above the bladder neck for 16:25:28
21 stress urinary incontinence?

22 A. Well, I -- I think it -- it's not that far above
23 that it wouldn't be effective, the best I can tell. It
24 would support the structure so that there's no prolapse
25 of either the bladder or the bladder neck. 16:26:01

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1 Q. Okay. I think you cite to some passages of
2 Ingle that describe treatment of -- of breasts and
3 abdominal wall.

4 A. Yes.

5 Q. And are those mucosal epithelium -- 16:26:43

6 A. No.

7 Q. -- tissues that would be treated?

8 A. No, those --

9 Q. What type of -- what type of tissue is that in
10 those structures -- 16:26:54

11 A. I'm sorry --

12 Q. -- in those treatment areas? What type of
13 tissue is in those treatment areas?

14 A. Are we talking breasts and abdomen, you mean?

15 Q. Breasts and abdomen, correct. 16:27:06

16 A. Yeah. That's just squamous epithelium that
17 you're treating.

18 Q. And squamous epithelium is the skin that's all
19 over your body; right?

20 A. Right. 16:27:23

21 Q. That treatment of squamous epithelium is --
22 there are different protocols for treating squamous
23 epithelium as opposed to mucosal epithelium; correct?

24 A. Different protocols is --

25 Q. Yeah, different protocols. 16:27:44

1 A. There are different protocols, both depending on
2 application of heat to layers below the skin to lift up
3 and contract. I think that's what he's trying to say.

4 Q. So you would have to determine different amounts
5 of heat to apply to either breast or abdominal wall as 16:28:11
6 opposed to the vaginal wall?

7 A. Yes, you would.

8 Q. And how else would the treatment be different,
9 applying RF energy to the breasts, abdominal wall versus
10 the vaginal wall? 16:28:38

11 A. I think it would just be dependent on modulation
12 of temperature and time and a delivery system.

13 Q. By "delivery system," that means like the
14 treatment tip -- the RF generator?

15 A. Right. Right. 16:29:00

16 Q. You would use different treatment tips,
17 different RF generators, different temperatures,
18 different times when treating the breasts or abdominal
19 wall as opposed to the vaginal wall?

20 A. Right. 16:29:15

21 Q. What about treating the cervix versus the
22 vaginal wall? Would that be different in any way?

23 A. I'm not sure what you mean by "treating the
24 cervix."

25 Q. Heating using RF. 16:30:01

1 A. I'm not sure what you would try to accomplish by
2 doing that.

3 Q. Do you ever use RF to heat the cervix in your
4 practice?

5 A. No. 16:30:22

6 Q. Are you aware of any doctors who would use RF to
7 heat the cervix for any reason?

8 A. There may be some doctors who use it as an
9 ablative modality. I've just never used it.

10 Q. Why would they use it as an ablative modality? 16:30:40

11 A. Somebody had a high-grade lesion of the cervix,
12 meaning an abnormal Pap smear, pre-cancerous, you'd want
13 to destroyed that part of the cervix.

14 Q. If you would open Ollivier.

15 MR. HECTOR: Add that to the marked exhibits. 16:31:28

16 (Exhibit 9, Designer Vaginas by Debra Ollivier,
17 was marked for identification by counsel
18 electronically.)

19 Q. BY MR. HECTOR: Are you familiar with this
20 document, Dr. Berenholz? 16:32:05

21 A. I -- I am.

22 Q. And on the cover, it says this article is -- or
23 strike that.

24 On the first page, it appears this article is
25 from a website called Salon.com. 16:32:29

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1 Do you see that?

2 A. Salon -- where is that, Mr. Hector?

3 Q. Upper left corner.

4 A. Ah, Salon.com Sex, yeah.

5 Q. Are you -- are you aware of the Salon.com 16:32:50

6 website?

7 A. Not at all.

8 Q. Not at all?

9 A. No.

10 Q. You've never visited the Salon.com website? 16:33:01

11 A. No. I'm happily married. That was an attempt

12 at humor. Nothing else.

13 Q. Okay. Is it -- I'm not sure it's a dating

14 website. You may know more than I do.

15 A. I'm married. Thank you. 16:33:17

16 Q. Did you find this article, the Ollivier article?

17 A. Did I find it? No, it was given to me.

18 Q. Okay. So, yeah, I take it you were not aware of

19 Salon.com until two minutes ago?

20 A. That is correct. 16:33:43

21 Q. Okay. And you --

22 A. I read -- excuse me. I read the article. I

23 just never bothered to look in the upper left-hand

24 corner.

25 Q. Okay. Are you aware of any other doctors that 16:33:58

1 read Salon.com?

2 A. I don't know of any, no.

3 Q. And is it -- is Salon.com directed to the
4 medical community?

5 A. I don't know. 16:34:22

6 Q. Do you know who Debra Ollivier is?

7 A. Dr. Ollivier?

8 Q. Is she a doctor?

9 A. Debra? No, I don't know her personally.

10 Q. Who do you understand that Debra Ollivier is? 16:34:51

11 A. I just know that she contributed this article to
12 this site.

13 Q. Okay. You don't know -- does Debra Ollivier
14 write technical medical literature?

15 A. I don't know. 16:35:15

16 Q. So this article references laser vaginal
17 rejuvenation. I think we discussed that earlier. But
18 kind of from a layman's terms -- I'm not a doctor -- what
19 is this article saying about laser vaginal rejuvenation?

20 A. It addresses modality for tightening vagina 16:36:09
21 and vulvar structures, sculpting vulvar structures,
22 et cetera.

23 Q. Does the article, like, discuss -- strike that.

24 So laser vaginal rejuvenation is, I think we
25 discussed earlier, using a laser as a scalpel; is that 16:36:37

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1 correct?

2 A. Yes.

3 Q. And they used another term, "designer laser
4 vaginoplasty." Is that also using a laser as a scalpel?

5 A. Yes. 16:36:53

6 Q. And does this article discuss, like, what lasers
7 to use?

8 A. It doesn't discuss it, but it's a diode laser.

9 Q. How do you know that?

10 A. I was trained by Dr. Matlock. 16:37:26

11 Q. So you know that based on your personal
12 experience?

13 A. Correct.

14 Q. But from reading the article, you couldn't
15 determine what type of laser is being used? 16:37:39

16 A. No. She didn't get into that.

17 Q. Does the article instruct you how to perform
18 either of the procedures, laser vaginal rejuvenation or
19 designer laser vaginoplasty?

20 A. I see no mention of it. 16:38:35

21 Q. So the specifics of the treatment are not
22 provided?

23 A. No, it's not.

24 Q. Does the article discuss treating the mucosal
25 surface of the labia minora? 16:39:07

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1 A. It doesn't mention the mucosal surface of the
2 labial minora.

3 Q. Does it mention the heart line?

4 A. Heart line? No, I didn't see that.

5 Q. This article says that, "Curious that Matlock 16:40:38
6 has not applied" -- sorry. Strike that.

7 The sentence before starting there. This is on
8 page 2, the fourth paragraph.

9 It says, "There are standard pre- and
10 post-operative intervention tests and tools that could be 16:41:02
11 applied here to substantiate his claims. It's curious
12 that Matlock has not applied any of them to his own work,
13 nor published any scientific material relating to his
14 work."

15 Are you aware -- 16:41:18

16 A. You're on page 2, Mr. Hector?

17 Q. That's right.

18 A. How many paragraphs down?

19 Q. I guess it's the fourth down. The first one
20 might be a partial paragraph, but... 16:41:26

21 A. Oh, so one, two, three -- four? "I think this
22 is the way"?

23 Q. Yeah. And I was focused on the last two
24 sentences of that paragraph.

25 A. All right. 16:41:39

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1 Q. Feel free to read that.

2 A. Yes, I see that sentence.

3 Q. So she's talking about that Dr. Matlock has not
4 published any scientific material related to -- to his
5 work. Is that your understanding?

16:42:02

6 A. Yes.

7 Q. So it seems like he keeps the specifics -- "he"
8 being Dr. Matlock -- the specifics of the treatment
9 confidential; is that correct?

10 MR. BEMBEN: Objection to form, calls for
11 speculation.

16:42:18

12 THE WITNESS: I -- I don't know what his
13 motivation is.

14 Q. BY MR. HECTOR: You -- you studied under
15 Dr. Matlock; correct?

16:42:34

16 A. Yes.

17 Q. And did you pay Dr. Matlock for that training?

18 A. Yes, I did.

19 Q. How much?

20 MR. BEMBEN: Objection to scope.

16:42:50

21 THE WITNESS: This was nearly 30 years ago. I
22 think it was \$10,000.

23 Q. BY MR. HECTOR: And did you -- were there any
24 requirements that you keep the details of the treatment
25 confidential?

16:43:08

1 MR. BEMBEN: Objection to scope.

2 THE WITNESS: I -- I can't answer that.

3 Specifically there was a contract about not training, not
4 divulging treatment, surgical techniques, et cetera. So
5 in that regard, I guess it was confidential. 16:43:34

6 Q. BY MR. HECTOR: And you were required to sign
7 that before being trained?

8 A. Yes, I was.

9 Q. And these procedures cut and coagulate tissue;
10 correct? 16:43:58

11 A. Yes, it does.

12 Q. So you're effectively cutting away portions of
13 vaginal tissue?

14 A. Yes.

15 Q. So two paragraphs down from the one we were just 16:44:21
16 reading on page 2, it talks about -- well, I'll let you
17 read that first. It starts with "Brubaker."

18 A. I read it.

19 Q. And she says that there are risks associated
20 with laser vaginal rejuvenation and -- and designer laser 16:44:54
21 vaginoplasty, including hemorrhage, infection, loss of
22 sensitivity, lingering pain and nerve damage. Is that a
23 correct statement?

24 A. Yes, that's what I'm reading here.

25 Q. But do you agree with that statement, from your 16:45:18

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1 experience --

2 A. No.

3 Q. -- as a medical --

4 A. No. This article was written 24 years ago, and
5 those complications just so rarely, if ever, arise. 16:45:29

6 Q. But they do arise? You said rarely, but they
7 do --

8 A. It's possible. It's possible.

9 Q. There's a risk of those complications?

10 I think I asked: There is a risk of those 16:46:12
11 complications; correct?

12 A. There is a possibility of a complication. I
13 said yes.

14 Q. And for when you use a -- a diode laser, as
15 described -- or strike that. 16:46:32

16 When you use a laser to perform laser vaginal
17 rejuvenation or designer laser vaginoplasty, are there
18 other precautions that you have to take when performing
19 the procedure as a doctor?

20 A. What are you referring to as reference to 16:46:57
21 precautions?

22 Q. I think I've read that you have to have a
23 special laser room with signage, wear glasses, smoke
24 evacuators; is that correct?

25 A. That is correct. That is correct. 16:47:19

1 Q. Do you have -- do you need those precautions
2 when using RF devices?

3 A. No.

4 Q. I've heard another precaution is you need to
5 wear a mask to prevent against venereal wart viruses that 16:47:42
6 may slough off from the tissue. Is that your
7 understanding?

8 A. That's general protocol. And every OR, if
9 you're doing gynecologic surgery and you're using any
10 coagulation device, monopolar, bipolar. The fumes is 16:48:01
11 what they're referring to. And we have smoke evacuators
12 now.

13 Q. When did you first meet Dr. Matlock?

14 A. Twenty-nine years ago.

15 Q. And are you still in contact with Dr. Matlock? 16:48:34

16 A. Once a year we wish each other a Merry
17 Christmas.

18 Q. I think I asked you before. You're not sure how
19 many people he's trained to do these procedures, LVR or
20 DLV? 16:49:03

21 A. I would just venture a guess to answer that
22 question.

23 Q. And do you still -- if -- if a doctor wanted to
24 learn these procedures from Dr. Matlock today, would they
25 have to pay a fee and sign a confidentiality agreement? 16:49:29

1 A. I assume so.

2 Q. Do you know if Dr. Matlock has ever faced
3 malpractice claims for LVR surgical procedures?

4 MR. BEMBEN: Objection to scope.

5 THE WITNESS: I have no way of knowing that. 16:50:03

6 MR. HECTOR: Can we take a short break? Does
7 that work for you? Like 5, 10 minutes.

8 MR. BEMBEN: Are we wrapping up? Is that what
9 you're looking at?

10 MR. HECTOR: In the near term. I think I just 16:50:56
11 want to look over my notes. But, yeah, not too much
12 longer.

13 MR. BEMBEN: Okay.

14 (Recess.)

15 (Exhibit 10, Administrative Complaint against
16 Joseph Berenholz, M.D., was marked for
17 identification by counsel electronically.)

18 (Exhibit 11, Consent Order and Stipulation
19 against Joseph Berenholz, M.D., was marked for
20 identification by counsel electronically.) 17:03:18

21 (Recess.)

22 THE REPORTER: Back on the record at 5:03 p.m.

23 MR. HECTOR: Great. Thank you.

24 Q. Dr. Berenholz, with regard to your declaration
25 that we've looked at a bit today, could you describe 17:03:39

1 how -- the process of how that was drafted?

2 A. How it was drafted or by whom or...

3 Q. Yes.

4 A. It was drafted by the attorneys who represent
5 me. 17:04:02

6 Q. Okay. And did you -- what was your contribution
7 to the declaration?

8 A. My expertise just in thermal energy and
9 non-invasive vaginal rejuvenation.

10 Q. So is that -- is that particular sections of the 17:04:22
11 declaration that you're referring to?

12 A. No. My experience was -- was known through the
13 client who hired this firm. And they --

14 MR. BEMBEN: Let me just caution the witness not
15 to divulge any attorney-client privileged information 17:04:46
16 when you're answering this question.

17 So, yeah, maybe you can ask your question again,
18 Bill.

19 Q. BY MR. HECTOR: So you said that -- I asked what
20 your contribution was to the declaration, and you said, 17:05:06
21 "My expertise in thermal energy and non-invasive vaginal
22 rejuvenation."

23 Do you recall that?

24 A. Yes.

25 Q. And are you referring to particular sections of 17:05:17

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1 the declaration in making that statement?

2 A. I -- I'm not sure where it was utilized in the
3 declaration, but these are my summaries of reviewing
4 references given to me by my attorneys.

5 Q. And you wrote those summaries? 17:05:49

6 A. I participated in them.

7 Q. How did you participate?

8 A. Just providing knowledge base about the
9 technology.

10 Q. And that knowledge base was phone calls? Over 17:06:13
11 email? How did you provide that knowledge? Without
12 disclosing the contents of those communications.

13 A. Just discussions, meetings, Zoom meetings. And
14 anatomy discussions, et cetera.

15 Q. Okay. Did you actually -- did you edit any 17:06:38
16 portion of the declaration?

17 A. Edit the -- no.

18 Q. Okay. Did you change any portion of the
19 declaration?

20 A. No. 17:07:01

21 Q. Okay. Have you ever been subject to any
22 administrative proceedings related to your medical
23 practice?

24 A. Yes.

25 Q. And how many? 17:07:26

1 A. Just once.

2 MR. HECTOR: Okay. I've introduced two
3 exhibits, Exhibit 10 and Exhibit 11.

4 Do you want to pull those up, Rick, just for...

5 MR. BEMBEN: Sure. Give me a minute to review 17:07:48
6 these, please.

7 MR. HECTOR: Sure.

8 THE WITNESS: Okay.

9 Q. BY MR. HECTOR: Do you recognize these
10 documents, Exhibit 10 and 11, Dr. Berenholz? 17:08:33

11 MR. BEMBEN: So I'll pull up Exhibit 10 right
12 now he's looking at.

13 MR. HECTOR: Okay.

14 MR. BEMBEN: And before he answers this
15 question, I'm going to object to scope and just -- also 17:08:45
16 just mention that --

17 Continue. Go ahead.

18 So, Dr. Berenholz, have you seen this before?

19 THE WITNESS: Yes. It's been about a decade
20 since I've looked at this, I think. 17:09:02

21 Q. BY MR. HECTOR: And what -- what generally does
22 this document describe?

23 MR. BEMBEN: Objection to scope.

24 THE WITNESS: It was a disciplinary complaint
25 for a boundary violation. 17:09:32

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1 Q. BY MR. HECTOR: And what does that mean?

2 MR. BEMBEN: Objection to scope.

3 THE WITNESS: I had a relationship with a
4 patient about a decade ago.

5 Q. BY MR. HECTOR: And did the relationship involve 17:09:53
6 laser vaginal rejuvenation surgery?

7 MR. BEMBEN: Objection to scope.

8 THE WITNESS: I -- I don't know if it was -- I
9 can't remember if it was general gynecologic surgery or
10 laser vaginal surgery. But it did involve vaginal 17:10:21
11 surgery, yes. I think, yes.

12 Q. BY MR. HECTOR: Okay. And were there any other
13 aspects of the administrative complaint?

14 MR. BEMBEN: Objection to scope.

15 THE WITNESS: Could you be more specific what 17:10:41
16 you're referring to?

17 Q. BY MR. HECTOR: So I think you said it was a
18 disciplinary complaint for a boundary violation. And
19 then following up on that, and you said you had a
20 relationship with a patient about a decade ago. 17:11:00

21 Did the complaint involve any other allegations,
22 other than the relationship?

23 MR. BEMBEN: Objection to scope.

24 THE WITNESS: There, I believe, was another
25 allegation involving prescription -- just to give you a 17:11:17

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1 backdrop. I was going through a divorce of a
2 40-year-long marriage, and I was being treated for
3 depression. I did not pursue this relationship. But,
4 nevertheless, I stipulated to the allegations. And in
5 return, I was given a one-year probation. 17:11:54

6 Q. BY MR. HECTOR: And so turning to Exhibit 11, if
7 you would, please.

8 MR. BEMBEN: For Exhibit 11, again, I'm going to
9 object to scope.

10 Q. BY MR. HECTOR: Do you recognize this document? 17:12:22

11 A. I do.

12 Q. Is this the stipulation that you just
13 referenced?

14 MR. BEMBEN: Objection to scope.

15 THE WITNESS: I believe so. 17:12:55

16 Q. BY MR. HECTOR: And what were the terms of the
17 stipulation?

18 A. Well, I paid a fine, and I was on probation for
19 a year. I retook my Boards successfully and my medical
20 assistant monitored me for one year during every -- we 17:13:26
21 had to sign off every visit. The ethics class was my
22 idea.

23 Q. And what did the ethics class entail?

24 MR. BEMBEN: Objection to scope.

25 THE WITNESS: It was just a general course -- I 17:13:53

1 can't -- I think it was North Carolina -- about medical
2 ethics and examination. And I graduated with the highest
3 score in the class.

4 Q. BY MR. HECTOR: And then after the one-year
5 probation, this -- the subject matter of this allegation 17:14:17
6 was resolved?

7 A. Yes.

8 Q. Okay. And you said this was the one -- the -- I
9 guess the one administrative complaint you've been
10 subject to? 17:14:41

11 A. Yes.

12 MR. HECTOR: Okay. Well, thank you very much
13 for your time today.

14 Pass the witness.

15 MR. BEMBEN: Okay. We're going to -- can we go 17:14:53
16 off the record, and I'm going to consult with my
17 colleagues? And if you give us, like, 20 minutes, we'll
18 be back.

19 MR. HECTOR: Twenty minutes? Okay.

20 MR. BEMBEN: Thank you. We may be back sooner, 17:15:03
21 but let's plan for 20 minutes.

22 (Recess.)

23 THE REPORTER: Back on the record at 5:29 p.m.

24 MR. BEMBEN: So we have no questions for
25 Dr. Berenholz, and we will close the deposition. 17:29:50

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MR. HECTOR: Great. Thank you very much for
your time and being a good sport, Dr. Berenholz.

THE WITNESS: Thank you.

(Time noted: 5:30 p.m. Eastern Standard Time.)

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I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on _____, 2025, at _____.

SIGNATURE OF THE WITNESS

1 STATE OF CALIFORNIA) ss:
2 COUNTY OF MARIN)
3

4 I, LESLIE ROCKWOOD ROSAS, RPR, CSR NO. 3452, do
5 hereby certify:

6 That the foregoing deposition testimony was
7 taken before me at the time and place therein set forth
8 and at which time the witness was administered the oath;

9 That testimony of the witness and all objections
10 made by counsel at the time of the examination were
11 recorded stenographically by me, and were thereafter
12 transcribed under my direction and supervision, and that
13 the foregoing pages contain a full, true and accurate
14 record of all proceedings and testimony to the best of my
15 skill and ability.

16 I further certify that I am neither counsel for
17 any party to said action, nor am I related to any party
18 to said action, nor am I in any way interested in the
19 outcome thereof.

20 IN WITNESS WHEREOF, I have subscribed my name
21 this 10th day of January, 2025.
22
23

24

25



LESLIE ROCKWOOD ROSAS, RPR, CSR NO. 3462

1 WILLIAM A. HECTOR, ESQ.

2 wahector@venable.com

3 JANUARY 10, 2025

4 RE: BTL Industries, Inc. v. Inmode Ltd.

5 1/9/2025, Joseph Berenholz , M.D. (#7095421)

6 The above-referenced transcript is available for
7 review.

8 Within the applicable timeframe, the witness should
9 read the testimony to verify its accuracy. If there are
10 any changes, the witness should note those with the
11 reason, on the attached Errata Sheet.

12 The witness should sign the Acknowledgment of
13 Deponent and Errata and return to the deposing attorney.
14 Copies should be sent to all counsel, and to Veritext at
15 (PRODUCTION-CA@VERITEXT.COM).

16 Return completed errata within 30 days from
17 receipt of testimony.

18 If the witness fails to do so within the time
19 allotted, the transcript may be used as if signed.

20
21
22 Yours,

23 Veritext Legal Solutions
24
25

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BTL Industries, Inc. v. Inmode Ltd.

Joseph Berenholz, M.D. (#7095421)

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REASON_____

Joseph Berenholz, M.D.

Date

1 BTL Industries, Inc. v. Inmode Ltd.

2 Joseph Berenholz , M.D. (#7095421)

3 ACKNOWLEDGEMENT OF DEPONENT

4 I, Joseph Berenholz , M.D., do hereby declare that I
5 have read the foregoing transcript, I have made any
6 corrections, additions, or changes I deemed necessary as
7 noted above to be appended hereto, and that the same is
8 a true, correct and complete transcript of the testimony
9 given by me.

10

11

12 _____
Joseph Berenholz , M.D.

_____ Date

13

*If notary is required

14

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_____ DAY OF _____, 20____.

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[& - 4]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate.

The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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