UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JEISYS MEDICAL INC.,

Petitioner,

v.

SERENDIA, LLC

Patent Owner.

Case IPR2024-00386

U.S. Patent No. 9,480,836

REMOTE DEPOSITION of R. JAMES KOCH, M.D.

Saturday, October 19, 2024

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Serendia, LLC
Exhibit 2146
Jeisys v. Serendia
IPR2024-00386
Ex. 2146-001

The deposition of R. JAMES KOCH, M.D., held remotely pursuant to notice before Michelle M. Yohler, CSR, RMR, CRR, a certified shorthand reporter, CSR No. 84-4531.

A P P E A R A N C E S

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ALSO PRESENT:

Mr. Brennan Plummer, Tech

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P R O C E E D I N G S

(Technician read-on.)

MS. REPORTER: Before I swear the witness in, can I please have all attorneys identify themselves and who they represent for the record.

MR. SANDERS: This is Charles Sanders of Latham & Watkins on behalf of patent owner, Serendia.

MR. MUELLER: It's Wes Mueller from Leydig, Voit & Mayer in Chicago on behalf of petitioner, Jeisys Medical.

(WHEREUPON, the witness was duly sworn.)

R. JAMES KOCH, M.D.,

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

EXAMINATION

BY MR. SANDERS:

Q Good morning, Dr. Koch.

A Morning.

Q You understand that this is a deposition in an inter partes review proceeding involving the '836 patent?

A Yes.
Q Is there any reason you cannot testify truthfully and accurately today?
A No.
Q Where are you today?
A I'm in the Leydig Chicago office.
Q Is there anyone else with you there?
A Yes, Mr. Mueller's there.
Q Anyone else?
A No.
Q Other than through the Zoom that we're on together here, are you communicating with anyone else in any other way?
A No.
Q Because this deposition is occurring over Zoom, it's important for us not to speak over one another because Zoom can only record one active speaker at a time. So I'd ask that -- I'll try to do my best to stop speaking when you're speaking, and I'd ask you to do the same. All right?
A Yes.
Q Who did you speak to in the process of

preparing your declaration in this matter?

A For the process of preparing my declaration, I spoke with James Sanner, an attorney here at Leydig.

Q Anyone else?

A No.

Q And can you describe the process of preparing your declaration?

MR. MUELLER: I'll caution the witness not to reveal any attorney-client or work product communications.

BY THE WITNESS:

A Well, he asked me to review the disclosures between the '836 patent and also the Ganz patent, and I sent him my thoughts after reviewing both. And then he formatted it for the attorney purposes.

BY MR. SANDERS:

Q And did you speak with anyone to prepare for your deposition today?

A Not really to prepare. I did meet yesterday to go over the process for what we're

doing today.

Q Who did you meet with?

A I met with Mr. Mueller and Leonard. I -- who I just met yesterday. He was here. And those were the people that I met with.

Q Have you spoken with Dr. Woloszko?

A No.

Q Have you ever been deposed before?

A Yes.

Q How many times?

A I would say probably about 30 times.

Q And what type of cases were those in?

A They're mostly medical malpractice, served as an expert. And then I also worked on patent -- product liability cases with representing CoolSculpting, Allergan/AbbVie.

And then I did do -- sorry to interrupt. I did do a deposition, I testified in front of the ITC in 2019 and did a deposition for that.

Q Other than your testimony in the ITC in 2019, have there been any other proceedings when you've provided testimony regarding patents?

A I don't believe so.

Q And in the ITC proceeding in 2019, you testified for Lumenis and Pollogen; is that correct?

A Yes.

Q And there you testified that a Syneron patent was invalid; is that correct?

A Actually, it was -- I was the noninfringement expert, and the petitioner was Syneron, and we were the respondents. So I guess you could say I was working -- helping to defend Lumenis Pollogen, their VoluDerm device -- Legend, which composed of VoluDerm.

Q Got it.

Do you have any patents of your own?

A No.

Q Did Leydig reach out to you about working on this proceeding?

A Yes.

Q When did that happen?

A For the proceeding, I believe that was -- well, not for -- can you clarify that?

Q What's unclear about my question?
A Well, for this -- what's unclear is when did they first contact me versus whether they -- when they contacted me for my declaration.
Q Got it. All right. I'm focused on the declaration. When did they contact you for your declaration in this proceeding?
A I believe it was -- I can't give you the exact date. I can look when I signed it, but it was several months ago about.
Q Did they contact you shortly before you prepared the declaration?
A No, I wouldn't say that. I don't recall that being shortly.
Q And you're a medical doctor, correct?
A Yes, sir.
Q You have degrees in biology and natural sciences and immunology; is that right?
A Yeah, that's a master's degree.
Q You are not an engineer, correct?
A That's correct.
Q You do not have a degree in physics,

correct?

A No, but I did well in physics. No, but -- sorry about that. No, but I am a -- you'll probably get to this, but I would be considered a POSITA for that time period.

Q Yeah, understood about the POSITA. I just want to be clear, you do not have a degree in physics, correct?

A That is true.

Q And you are offering testimony from the perspective of a medical doctor, correct?

A I would say a POSITA including a medical doctor.

Q You're not --

A It's -- I'm sorry. I'm sorry.

Q Please go ahead.

A Okay. Including someone who's been working with these devices from the very beginning of radiofrequency for skin rejuvenation. And I was involved with the first commercially available device -- or one of the first, Thermage, which was monopolar. It was pre-needle, and it used cooling

to protect the epidermis.

So I've been -- I was on their scientific advisory board. I was their main clinical investigator. So I've been involved with radiofrequency really from the commercial start.

Q Understood.

You are not offering testimony from the perspective of an engineer, correct?

A That is correct.

Q And you're not offering testimony from the perspective of a physics expert, correct?

A No, a POSITA.

Q Have you ever designed a medical device?

A Well, that's a good question. I worked very closely with the engineers at Thermage. In fact, they didn't even have a box when they approached me; it was still in the circuit phase. And if you -- can I give you a little background on that?

Q Sure.

A So you might have seen the patents because you're probably involved with all that. So Edward

Knowlton was the founder, and he was a plastic surgeon. He's -- I don't know if he's still practicing, but he wanted to tighten the dermis and not affect the epidermis.

So they came to me -- I think I was -- they were -- I was the first person. I was at Stanford. They came to me, and I told them to come back when they had something I could roll around in the clinic.

So that's the background.

Q And you've used RF microneedling, right?

A Yes, I currently do.

Q It's correct that the device you use most often is the Pollogen Legend?

A Yes.

Q And you mentioned earlier VoluDerm. Is VoluDerm the applicator that has the needles for the Pollogen Legend?

A Yes. Yes.

Q And you state in your declaration that you have no financial interest in Jeisys, right?

A Yes, none that I'm aware of at all.

Q But this proceeding is not the first proceeding where you've worked with Jeisys, correct?

A I have been -- I have been a consultant since 2019. To be honest with you, I'd have to look at my CV. I might help them with certain parts, the law firm, you know, skin anatomy, skin physiology. So I have served as a consultant, not an expert for them in any -- in that capacity.

Q Did you serve as a consultant for Jeisys in a matter adverse to InMode?

A I was a -- I had a contract. I was a consultant. I don't know how that went. Again, it would be the attorney would ask me my opinion about certain things. And I'm not sure how far that went in the process.

Q And is it correct that for purposes of your declaration, you reviewed the '836 patent, its prosecution history, and the Ganz reference?

A I did not review the prosecution history.

Q Okay.

A Okay? And, yes, what I -- I did review

the '836, that was my assignment, and compare it to Ganz. And those were -- that was my assignment.

Q Was there any other material that you reviewed for purposes of your declaration?

A Not for the purposes of declaration.

Q Since preparing the declaration, are there other materials relating to this proceeding that you've reviewed?

A I did -- I briefly read the IPR decision. And I did briefly look at Dr. Goldberg's response, just those areas, but they were not part of my declaration.

Q Any other materials that you reviewed since preparing your declaration related to this proceeding?

A No.

Q Do you know Dr. Goldberg?

A I mean, I'm familiar with him over the years.

Q Have you ever worked together with him?

A I probably have at some meeting. I just

don't -- it's been a long time for both of us, but I'm familiar with him.

Q I'd like to ask you some questions about statements in your declaration. Do you have any materials in the room with you today?

A Just the three items that we just discussed.

Can you see that (indicating)?

Q Now I can. So it looks like the declaration, Ganz, and the '836 patent, correct?

A Yes, sir.

Q So it's up to you what's most convenient for you. I have a copy of your declaration, you have a copy. If you'd like, we can put it on the screen as well, we can download -- you can download it so you can have it on the computer screen. What do you prefer to look at your declaration?

A Well, if it -- maybe it will be -- if we just look at it, we can see how that goes. If that's okay with you? Look at the paper copy.

Q With the paper copy?

A Yeah, instead of doing the...
Q That's fine by me.
A All right. Thank you.
Q So let's take a look at your declaration, Exhibit 1035.
(WHEREUPON, Exhibit No. 1035 was presented to the witness.)
BY MR. SANDERS:
Q And specifically at Paragraph 24, which is on Page 9 of your declaration.
A Yes, I have it.
Q And you state, "The '836 patent is directed to use in skin, reciting 'a skin improvement device' and a method to 'apply energy to achieve coagulation' in skin tissue (especially in the dermis)."
Do you see that?
A Yes.
Q What is your understanding of "coagulation" in the context of the '836 patent?
A It is to heat the tissue and to help promote a more -- a robust healing response with

increased collagen and elastin. That's my interpretation of that.

Q What temperature range would the tissue be heated to to provide that assistance in promoting a robust healing response?

MR. MUELLER: Objection to form.

BY THE WITNESS:

A It would typically be about 60 degrees centigrade.

BY MR. SANDERS:

Q And then going to the next paragraph, Paragraph 25 of your declaration, you state, "The '836 patent states that some embodiments use bipolar needles" -- and the sentence continues.

What is your understanding of bipolar needles?

A Well, bipolar needles, I think there's two general configurations that most people are familiar with, and that would be a needle that has both polarity, positive and negative, on it. And then you can have -- or you have a pair that is positive -- one is positive and the other is

negative.

So usually that's -- those are the configurations of needles if they're considered bipolar.

Q And do you have a view as to which of those two the '836 patent means in referring to bipolar needles?

A I can't remember if it's mentioned in the patent. I just can't remember, sitting here.

Q If it's helpful to take a look at the patent, please feel free to do so. I think you have it there, too.

A Yeah, I have it -- yes, sir, I have it here.

Actually, I recall now so -- that they talk about both types. Na talks about both types, '836. So both types I just mentioned.

Q And where do you, in the '836 patent, do you believe that Na talks about the type where a single needle has both polarities?

And just for clarity, the '836 patent is 1001?

(WHEREUPON, Exhibit No. 1001 was presented to the witness.)

BY THE WITNESS:

A So I have here, under 4, "In an embodiment, adjacent or neighboring needles may be configured to have opposite polarities plus and minus such as shown in Figure 6."

And -- I wish I had the search function here.

BY MR. SANDERS:

Q Well, if you'd like, I'm happy to -- the technician can bring up the electronic version and perform any search you'd like.

A Okay. It's up to you.

Q Well, I --

A I mean, I could look all day so...

Q Whatever's easiest for you, Dr. Koch. I'm just looking for the answer to my question; how you go about answering it is your prerogative.

I just want to understand where in the '836 patent you believe it discloses bipolar needles, with the first possibility you mentioned,

a needle that has both polarities.

A Well, maybe we should do that, the search function.

Q Sure.

MR. SANDERS: Could the technician please bring up Exhibit 1001.

BY MR. SANDERS:

Q And what search would you like the technician to run, Dr. Koch?

A "Bipolar," please.

Q And feel free, Dr. Koch, to tell the technician when you're ready to move to the next one.

A All right.

(Exhibit management discussions were had off the stenographic record.)

BY THE WITNESS:

A Well, I'm not seeing that. I did think that the bipolar with the -- with -- that it was with both poles was described, but I'm not finding it.

BY MR. SANDERS:

Q So let me just ask the question again so we have it clearly on the record.

Do you believe that the '836 patent discloses bipolar needles where a single needle has both polarities?

A Not at this point, no.

Q Okay. Do you believe the '836 patent discloses bipolar needles where one needle is positive and the other needle is negative and vice-versa?

A Yes.

Q In that bipolar configuration, current flows between the bipolar needles, right?

A Yes.

Q Have you used an RF microneedling device with bipolar electrodes?

A Yes, the Syneron Profound.

Q And does that device have bipolar electrodes where one electrode is positive and the other is negative and vice-versa?

MR. MUELLER: Objection. Beyond the

scope.
BY THE WITNESS:
A I really don't remember. That was several years ago, but I remember it was bipolar.
BY MR. SANDERS:
Q When did you start using the Syneron Profound?
A Probably about -- I used it as a demonstration. As mentioned, the -- my main microneedling device is the Pollogen Legend VoluDerm component. So I think I said it was about 2020.
Q When did you start using RF microneedling devices with bipolar electrodes?
A The VoluDerm has bipolar electrodes, so I've been doing that since, I would say, 2018.
Q Prior to 2011, did you use any RF microneedling devices with bipolar electrodes?
A I don't believe so.
Q Going back to your declaration, Exhibit 1035, same paragraph we were on, Paragraph 25, you point out that the '836 patent

also references a monopole needle, right?

A Yes.

Q The way a monopolar needle works is that current flows from the needle to something else that serves as a ground, such as a grounding pad, correct?

A That's correct.

Q And have you used an RF microneedling device with monopolar electrodes?

A Not a microneedling device, but the Thermage device was obviously monopolar.

Q Just to be clear, the Thermage device was a monopolar device, but it was not a needling device, correct?

A That is correct, yeah.

Q You have a website where you market your expert witness services, right?

A Yes.

Q Let's take a look at that website.

MR. SANDERS: This is document "Website 1" is the file name.

THE TECHNICIAN: One moment.

(WHEREUPON, Koch Exhibit No. 1 was presented to the witness.)

BY MR. SANDERS:

Q And we've dropped the document into the chat, too, Dr. Koch, so if you want to open it up yourself, if that's easier, feel free to do so.

A Okay.

Q This document shows the home page of your website where you market your expert witness services, right?

A Yes.

Q If we go down to the fourth page -- yes, fourth page.

A Okay.

Q At the upper right, you see a U.S. Patent Number 9,510,899, right?

A Yes.

Q And you have below that on your web page Figure 3 from that patent, right?

A Yes.

Q And this is the patent that you opined on in the 2019 ITC case, correct?

A You know, I honestly don't remember. I think I pulled this off of Google. That's my recollection.

It looks like something I -- that might be familiar to me, but I don't remember pulling it from any case that I worked on.

Q Why did you pick this particular patent figure to use on your expert witness website?

A Nothing nefarious. I just wanted to have something that looked like a microneedling device, to be honest with you. I mean, I'm being honest the whole time, but to be really honest with you, it looks like something I would be able to describe. But I don't think I took it from a case, and, if I did, it would be a case that has been done so...

Q Let's take a look at this patent, U.S. 9,510,899.

And just for recordkeeping purposes today, we'll assign your website that we just looked at as Koch 1 and the patent we're now going to look at as Koch 2.

(WHEREUPON, Koch Exhibit No. 2 was presented to the witness.)

BY MR. SANDERS:

Q You see this is the patent that was on your website, U.S. 9,510,899, right?

A Yes.

Q And on the front page of the patent is the same figure you had on your website, right?

A It appears to be, yes.

Q And if we actually go up and zoom in on the upper left portion, you can see that the inventor's name is Dieter Manstein?

A Yes.

Q Did you address a Manstein patent in the 2019 case?

A I did, but I still believe I didn't -- I still believe that I downloaded it from Google, and maybe it looked familiar to me but...

Q And do you know Dr. Manstein?

A I mean, I know -- I met him. I know some of the things that he's done, you know.

Q So let's focus in on Figure 3 of the

patent, the one that you've got on the website. It's on Page 6 of the PDF.

And you see this shows an RF microneedling device, right?

A Yes.

Q And in this device, the electrodes are in a monopolar configuration, correct?

A Yeah, it's -- I believe so. Like, this was not what I was tasked to do in the current case. My memory of this is not really good, but...

Q Let me help then. We can go to the description on Figure 3, which is on PDF 10 at 6-34 to 38.

If you'll look, you'll see at lines -- the sentence that starts at line 39 here confirms that the apparatus is in a monopolar configuration, right?

A Yes.

Q And the item 370 that's shown in Figure 3 are the thermal damage regions around the tip of each monopolar electrode, right?

A That's what it appears to show, yes.

Q In Figure 3, those thermal damage regions do not extend into the regions between the electrodes, right?

A That's what it shows in the diagram, yes.

Q Let's take a look at Figure 4 in this patent.

Figure 4 shows electrodes 410 and 415, right?

MR. MUELLER: Objection. Outside the scope.

BY THE WITNESS:

A Yes.

BY MR. SANDERS:

Q And this patent describes those electrodes as operating in a bipolar configuration, right?

MR. MUELLER: Objection. Outside the scope.

BY THE WITNESS:

A Well, I'd like to see the description like you just showed me before.

BY MR. SANDERS:

Q Of course.

MR. SANDERS: If we could go to Page 11 of the PDF, starting column 7 at line 27.

Perfect.

BY MR. SANDERS:

Q If you look at the sentence that's at line 27 to 28, confirms that the needles 410 and 415 are shown operating a bipolar mode, right?

A That's what it states, yes.

Q And Figure 4 shows the thermal damage regions 425 around and between the tips of the two needles, right?

MR. MUELLER: Objection. Outside the scope.

BY THE WITNESS:

A Yes.

BY MR. SANDERS:

Q So you agree this Manstein patent shows different thermal damage for monopolar and bipolar configurations?

MR. MUELLER: Objection. Outside the

scope.
BY THE WITNESS:
A That's what the schematics show, but I don't recall this patent -- I don't recall this patent having any histology associated with it.
BY MR. SANDERS:
Q And you -- do you review histology?
A Oh, yes.
Q Okay. We'll take --
A If you don't mind me saying, Mr. Sanders, I actually have done a lot of clinical research with lasers and skin samples and also had a wound healing lab at Stanford where I worked with fibroblasts -- different types of fibroblasts and trying to generate favorable collagen for healing.
Q Can you describe what you mean by "working with fibroblast to generate favorable collagen for healing"?
A Yeah, so what I was doing in my wound healing lab was I was getting specimens, all approved by the IRB, from normal skin, irradiated skin, and keloid-forming tissue.

Also, I had a fetal cell line that I was using, and I was taking various -- doing different manipulations to try to get favorable growth factor production to generate collagen -- to improve collagen and elastin. And that included RF.

I did do -- and I think it's in my declaration, I did -- we did present that using RF on fibroblast. Not full skin, but the fibroblast part.

Q So you -- were you growing the collagen on the fibroblast?

A We were measuring it when it was produced after stimulating it.

Q Let's go back to your declaration, which is Exhibit 1035, and specifically Paragraph 26, the next one.

You state in the first sentence of that paragraph, "The '836 patent distinguishes between carbonization, vaporization, and coagulation and states that the present invention achieves skin condition by primarily using coagulation," right?

A Yes.

Q What's your understanding of carbonization?

A My understanding of carbonization is -- as a person -- a POSITA from that time period, is a small zone -- a zone of thermal necrosis or tissue necrosis. And that's what's left after the area has been ablated.

Q You just used the term "ablated." What do you mean by that?

A Well, in terms of microneedling, it's when the heat is applied, the skin -- the tissue moves away from -- it shrinks away from the needle. It's not -- I don't look at it as removal of tissue, okay?

And then the edge of that shows the -- what I think Na means is the residual tissue debris and what we were talk -- what those of us were talking about back then was a zone of thermal necrosis.

Q What is your understanding of vaporization?

A Well, that -- my understanding of vaporization is heating tissue and basically having the water -- targeting the water primarily, and it evaporates the tissue.

I think "ablation" is a better word, and it's more consistent with the time period. We were talk -- if you don't mind me saying, we were talking back then about -- we were doing fully ablative lasers and peeling off layers of skin leaving a little zone of thermal necrosis, which, in many cases, we believed was favorable; hence using CO2 over erbium YAG, okay?

So that was the terminology that we were using going into, for example, what I believe Ganz was talking about.

Q How does carbonization differ from vaporization?

A I think the carbonization is the end result of ablation at the edges. And if -- can I say that I understand that the '836 is primarily using coagulation, that's preferred, but it does state that carbonization is one of the three

phenomena that occur, so I actually think that's an agreement with Ganz.

Q Do you believe that the techniques of the '836 patent cause carbonization?

A Yes.

Q And do you believe that the techniques of the '836 patent cause vaporization?

A Well, I think that he -- they -- he calls it vaporization. I think, at the time, "ablation" is more an accurate term, consistent with what we were transitioning from lasers to RF.

Q Do you believe that the techniques of the '836 patent cause ablation?

A I do.

Q And is carbonization ablation, or do you draw a distinction between them?

A I draw --

MR. MUELLER: Objection to form.

BY THE WITNESS:

A I draw a distinction between them.

BY MR. SANDERS:

Q What distinction do you draw between

carbonization and ablation?

A Carbonization is the residual carbon debris after the heat treatment.

Q And what is the ablation?

A Ablation, as I think I defined it in my declaration, is when the -- when the energy is applied to the needle, the tissue shrinks away from it. And -- so it doesn't remove the tissue, but the tissue shrinks, and then there's a rim, I think appropriately called thermal necrosis -- a zone of thermal necrosis.

But that's different from the coagulation, which persists. And that's not death of the tissue; that's just stimulation of the tissue.

Q So is coagulation different from thermal necrosis?

A Yes.

Q What is the distinction between carbonization and vaporization?

MR. MUELLER: Objection. Asked and answered.

BY THE WITNESS:

A Can you read back what I said? So I'm consistent. I'm not asking you to do that, Mr. Sanders; can the stenographer do that?

MS. REPORTER: Is there an answer you'd like me to read back? I don't know specifically what you're looking for.

BY MR. SANDERS:

Q Yeah, Dr. Koch, I didn't actually ask you that question before. I did ask a question that was similar, and you answered in terms of coagulation, and that's why I'm asking again because I didn't get an answer to the difference --

A Okay.

Q -- between vaporization and --

A All right. Fair enough. I'm sorry. Go ahead.

THE WITNESS: Is that okay with you, Wes?

MR. MUELLER: Sure.

THE WITNESS: Okay.

BY MR. SANDERS:

Q So I'll ask just to be clear. What's the distinction between carbonization and vaporization?

A My understanding of the '836 is that carbonization is the residual product after what the '836 describes as vaporization.

Q What do you mean by "residual product"?

A The -- like, in broad -- well, in broad terms, the -- as I said, the tissue necrosis, the zone of thermal necrosis, you could call it micro-eschar if you wanted to. It's the -- I guess you could say the final product where the vaporization stops.

Q Does vaporization result in tissue necrosis?

MR. MUELLER: Objection to form.

BY THE WITNESS:

A I believe that there's always some peripheral tissue necrosis.

BY MR. SANDERS:

Q Let me ask it a different way.

Is tissue that has been vaporized not necessarily in a necrotized state?

A Well, see, the point I was trying to make earlier was I'm not -- I don't think "vaporization" is a good term as -- I think -- that's why I'm talking about ablation, and it fits with the terminology that we were using, POSITAs, at the time.

But you can repeat the question if you want.

Q I'll come back to it.

Why do you think "ablation" is a better term?

A Because you're using -- one is using energy heat to shrink tissue, and that's how -- just putting the needle in will cause a micro-hole, but when you apply the energy, that tissue will -- the tissue loss will expand.

But I don't consider it tissue removal. It's not like a curette or a punch biopsy or something like that; it's all heat-related, and it can be controlled to some extent.

Q Is there a difference in your view between tissue that has been subject to vaporization and tissue that's been subject to coagulation?

A Can you repeat that, please?

Q Sure. I'll state it a little differently.

Is there a difference between vaporized tissue and coagulated tissue?

A Yes, vaporized tissue is the term that the '836 uses for, I believe, around where the needle treatment occurred.

And then coagulation is present in the area -- the tissue that's in the periphery of that, that is the -- I'm sorry, the coagulated tissue is -- you could say that it's damaged to some extent, but it's not -- it's still there. And the fibroblast don't like that, and they think it's been injured, and that's when they start to, you know, make new collagen.

So the coagulation is different from, you know, the -- and, again, the '836 distinguishes between three phenomena. I agree that coagulation is the -- is desirable. I just think the

terminology is a little different with the vaporization versus ablation.

Q So would you substitute "ablation" for "vaporization"?

MR. MUELLER: Objection to form.

BY THE WITNESS:

A I think with RF microneedling, unless there's something extremely unique about the device, I think you could.

BY MR. SANDERS:

Q And at what temperature in skin does carbonization occur?

A Well, I didn't -- just from memory, I think it's above 100, maybe close to 200. So it's tissue -- it's tissue death. It's the residual.

Q Is there a temperature range between the temperature range for coagulation and the temperature range for carbonization where you believe ablation occurs?

A Yes, but I can't give you that number sitting here today.

Q We'll move on to the '836 patent to Ganz.

We've been going about an hour. Let me know if you're okay to proceed, or do you want to take a break at this point? Since we're switching topics, it's a good point.

MR. MUELLER: I could use a five-minute break.

MS. REPORTER: I was going to ask for the same.

MR. SANDERS: Let's do it.

(WHEREUPON, a recess was had.)

BY MR. SANDERS:

Q Doctor, before we get into Ganz, just some general questions. Do you believe that RF microneedling devices, by their nature, cause ablation?

A I believe that a proper RF microneedling device does cause ablation.

Q And how would you expect to see that ablation appear in histology of tissue?

A It would be absence of tissue.

Q Outside of this case, have you reviewed histology of tissue that's been subject to

RF microneedling?

A Yes, it's been a while, but the -- I did review the histology with the VoluDerm device.

Q Did the histology of the tissue that had been subject to RF microneedling with the VoluDerm device show the absence of tissue that you referenced a couple moments ago?

A Yes.

Q Let's turn to Ganz now.

Going back to your declaration, Exhibit 1035, focusing on Paragraph 28. You state in the second sentence in that paragraph that Ganz involves creating a zone of coagulative tissue surrounding each perforation, right?

A That's correct.

Q Is it your understanding that Ganz discloses creating zones of coagulative tissue that surround perforations?

A Yes.

Q Ganz discloses making that perforation through use of energy, correct?

A Yes.

Q And Ganz discloses creating ablation holes, right?

A Yes. And if -- these are micro-holes.

Q What's your understanding of an ablation hole?

A Again, it's -- and I believe it's in my declaration. The ablation hole, micro hole, occurs when the heat is delivered to the needle and the tissue moves away, shrinks away from the needle.

Q Are ablation holes shown in Ganz's figures?

A Yes.

Q Let's take a look at Figure 9 of Ganz, which you copied in your declaration on Page 13.

Do you have that there?

A Yes.

Q Is what is marked as 4 an ablation hole?

A Yes.

Q Ganz also refers to area 4 as a perforation, right?

A Yes. But it is a very tiny perforation,

okay? It's such -- that's such a big word. It's a micro-hole, but, yes, it's -- yes, sir, it's a perforation.

Q Is there tissue remaining in what's marked as "Treated Area 4" on Figure 9?

A No.

Q What happened to that tissue?

A It melted away.

Q What word would you use to describe that process of the tissue melting away?

A It was ablated. And this is -- again, this is consistent with the -- going from ablative lasers and trying to preserve -- you brought up Manstein. I remember that the -- his -- describing his -- what he wanted to do, he was interested in preserving the epidermis and heating the dermis, just like the Thermage was trying to preserve the epidermis, but not in a truly efficient way with the cooling.

So we were -- at that time, the people that were POSITAs, including Dr. Zelickson, Dr. Rox Anderson -- who developed the Fraxel is my

understanding -- we were trying to minimize damage to the epidermis but heat the dermis.

So it's the terms that kind of continue, and that's really where I stand on that.

Q Appreciate the explanation.

A Okay.

Q Just to confirm, in Ganz, in area 4, both epidermis and dermis material has been melted away, right?

MR. MUELLER: Objection to form.

BY THE WITNESS:

A "Ablated" is the term I would use. And you want me to be more specific, but I think "ablation" is a better term, and it's consistent with the way we were describing heat applied to the skin at that time.

BY MR. SANDERS:

Q Just to be clear then, I'll ask it a little different way.

In Ganz, in treated area 4, both epidermal and dermal tissue has been ablated, correct?

A Yes. But I would like to point out, if I

may, that looking at the measurements of the depth, this is -- would be above the mid-reticular dermis in human facial skin. So completely safe.

My VoluDerm needles, they go deeper than that, and never had a problem with scarring, never heard of a problem with scarring or healing.

Q What's the scale on this image?

A Well, I -- it's hard to tell what the scale is, but there are measurements given in the example.

Q Is treated area 4 where the electrode was inserted?

A Yes, most likely the center of that.

Q And is it correct that what we see here as treated area 4 shows the tissue that was around the electrode was ablated?

A Yes, now it's absence of tissue.

Q You say in the paragraph below Figure 9, Paragraph 32 of your declaration, that there are smaller darker areas showing limited tissue necrosis?

A Yes.

Q Are those what is shown in Figure 9 as the areas that have the highest contrast that appear the darkest?

A Yes. And they're where you would expect them to be, you know, on the edge.

Q Are those the areas that you believe show coagulation?

A No, the coagulation is, say, lateral to that, denoted by number 2.

Q So in this Ganz Figure 9, is the coagulation shown by the areas of least contrast that are in white?

A Yes, where the number 2 is pointing to. It looks to me like it's coagulation, and it should be coagulation, too, but it does look like it.

Q If we move to the left of where arrow number 2 points, is that tissue coagulated, in your view?

A Yes.

Q And if we keep on moving to the left from where the arrow for number 2 points, toward the

other area where tissue has been removed, where would you say the coagulation stops?

A I would say that it stops when you -- well, I'm not sure if it goes completely all the way over, but I can see it in the slide, and it's consistent with the physics of these devices.

But it would not go all the -- it doesn't go to where -- it might go to where the thermal necrosis is on the other perforation.

Q So is it correct to say that it goes at least half the distance between where the tissue has been removed and may go the full distance?

A I can't say looking at this, but I do think the 2 represents an area of coagulation, and that's consistent with the way these devices work.

Q So is it correct that for each of the areas where tissue has been removed, there's coagulation that is toward the middle of the area that is in between the removed tissue?

A Can you rephrase that, please?

Q Sure. So let me break it down.

In Figure 9, we see two areas where tissue

has been removed, right?

A Yes.

Q And there is coagulation between those two areas, right?

A Yes.

Q Do those areas of coagulation between the removed tissue areas reach each other; in other words, intercept?

A It would depend on the power setting, whether they connect.

Q In this figure, do you see them connecting?

A It's difficult for me to say.

Q Can you tell where the coagulation ends moving from the edges of the removed tissue areas?

A Well, I think it's going to be just outside the zone of the thermal necrosis, but I can't -- on this, I can't give you a definite stop and start location.

Q So is it correct that one boundary for the coagulated areas is the zone of thermal necrosis that's next to the removed region?

A Can you repeat that?

Q Sure. Is it correct that one boundary of the zone of coagulation is where there's thermal necrosis next to the region where the tissue has been removed?

A Yes. And that actually is probably explained better than the way I was trying to explain it. It is -- that would be what you would expect. That's tissue that has survived, but it's kind of upset because it's been heated.

And these devices, including now, you know, ultrasound devices, they -- like the -- I don't want to jump around, sorry, but, like, the SoftWave uses ultrasound. It does coagulation in the mid -- mid -- well, it's 1.5 millimeters in. So that gives you a little zone of coagulation. The tissue doesn't die, it doesn't slough, it doesn't open up, but that's what stimulates the collagen.

So it would be next to the zone of thermal necrosis, but I can't say for sure that it extends all the way over. That's all I'm saying.

Q So sort of anticipating where I'm going. So for the zone of coagulation that extends -- let me start again.

For the zone of coagulation that has one boundary that is next to the tissue necrosis that's at the edge of the removed region 4, where is the other lateral boundary of that zone of coagulation?

A Of 2?

Q Of region 2, yeah.

A Okay. I think I said it's hard for me to tell you the exact boundary, but I do think the 2 is what it describes, looking at this.

Q Roughly what percentage of the distance between the two removed areas do you believe that zone of coagulation 2 extends?

A Can you repeat that, please?

Q Roughly what percentage of the distance between the two removed areas do you believe that the zone of coagulation 2 extends?

A Well, I think it's a small area of coagulation, looking at the whitish or whiter area

that you mentioned earlier.

And that's also consistent with some of the whiter areas on the other side of the microperforation that we've been discussing.

I'm just trying to be really, you know, covering, but I don't think it extends. It wouldn't -- the other perforation is going to handle its own coagulation zone.

Q Let me ask a little different way.

In looking at Figure 9, there are white regions that go from the edge of one removed area to the edge of another removed area; would you agree with that?

A Well, it looks like there's -- I wouldn't agree with that.

Q Would you agree that there are white regions in the middle of the area between the two regions?

A They're not purely white, and it wouldn't be -- just -- I mean, 2 is a good example to me of coagulation, and there's other examples you can find, but -- and I don't think it goes all the way

across. It is a low resolution, you know, so...

But at least he's got histology.

Q You believe that using the approach in the '836 patent you would get histology that looks like what's shown in Ganz Figure 9?

MR. MUELLER: Objection to form.

BY THE WITNESS:

A It's hard to say because an -- well, there's -- some of the figures show that as coagulation across between needle sites, and then other -- another figure shows it just under the needle.

But, again, there's no histology given; it's just a schematic, which doesn't -- to me, doesn't prove anything.

So let me -- can I -- I'm sorry. You've been very patient, but I don't believe that this goes all the way across. I believe it surrounds the zone -- the zone of -- limited thermal necrosis, and that's why we -- that is with each microperforation. So it doesn't extend.

BY MR. SANDERS:

Q Do you have a view as to whether using the approach in the '836 patent that you would get removed areas of tissue like is shown here designated by 4 in Figure 9 of Ganz?

A I'm sorry. Can you repeat that?

Q Do you have a view as to whether using the approach in the '836 patent, whether you would get removed areas of tissue like is shown as designated by 4 in Figure 9 of Ganz?

A That's what it claims.

Q Can you explain what you mean by "that's what it claims"?

A Well, as I said, there are schematics that show a zone of coagulation between the electrodes and also just around -- I'm sorry, underneath one electrode. So if what the '836 is saying is actually doable and proven by histology, then I would say yes.

Q Let's take a look at Figure 10 of Ganz, which you have on the next page.

And in Figure 10, we see designated 4 a

hole through the epidermis, right?

A Yes, a microperforation.

Q Is that an ablation hole where skin was removed?

A Where skin was ablated.

Q And --

A Or I should say this: Where epidermis has been -- a microperforation where the epidermis has been ablated for access to place the needle electrode and then the subsequent energy that's placed.

Q And, just to be clear, the area that's shown as 4, the needle would have been inserted within that area, right?

A Yes, most likely in the center. With a needle that configuration would be most likely in the center.

Q In your view, does Ganz teach that a desirable coagulation result is zones of coagulation that are around the microneedles and do not extend between the microneedles?

A Yes.

Q Let's take a look at Ganz, which is Exhibit 1005.

(WHEREUPON, Exhibit No. 1005 was presented to the witness.)

BY MR. SANDERS:

Q Where do you believe Ganz teaches that a desirable coagulation result is a zone of coagulation that is around the microneedles but does not extend between the microneedles?

A I'm sorry. Did I -- I don't know if I used the word "desirable," did I?

Q Well, that was the word in my question. So I'll ask the question again, and you can tell me what your view is.

In your view, does Ganz teach that a desirable coagulation result is zones of coagulation that are around the microneedles and do not extend between the microneedles?

A Well, let me -- I've got to preface that. And this is related to '836, too.

I'm not convinced that it's desirable to just have coagulation under a -- below one of the

needles. I can tell you that the device I use, which is -- I was exposed, as you know, to 13 other devices, and that one has coagulation that extends to the needles.

So I think Ganz shows that that can be done by the histology, but I'm not -- I don't think Ganz states that that's desirable is I think clearer. But it's capable because it's proven its capable.

Q Why are you not convinced that it's desirable to have coagulation that's just around the microneedles that does not extend?

A Well, I don't see how it prevents scarring or interferes with healing in any way.

And, as I said, I'm currently using the device after being exposed to 13 -- to a total of 14 in my ITC case, and I like it. And I don't get complications with it.

And that goes -- so I'm not -- I'm not convinced that that is a desirable effect. It might be in some cases, but I don't think that's necessarily a -- something that's desirable for

sure.

Q When you're referring to the device that you like, is that the Pollogen Legend?

A Yes.

Q I'd like to direct your attention to some of the disclosures in Ganz, Exhibit 1005. First, Paragraph 57, which is on Page 12 of the PDF or of the document.

A All right. I'm here.

Q You see Ganz discloses in Paragraph 57 electrodes configured to provide power in the range of about 50 to about 200 watts per square centimeter?

A Yes.

Q Does the amount of energy applied to tissue depend on how long the RF electrodes are delivering RF energy when they're in the tissue?

A Yes.

Q Does Ganz say how long the electrodes of his device are inserted into the tissue?

MR. MUELLER: Objection to form.

BY THE WITNESS:

A I don't recall that.

BY MR. SANDERS:

Q Would you agree that, based on Ganz's disclosure, the electrodes would be inserted into the tissue long enough to use the energy to create ablation holes?

A Yes.

Q At the end of Paragraph 57, Ganz states, "In other cases, the electrodes are configured to provide an energy of at least about 1 joules per square centimeter."

Do you see that?

A Yes.

Q Do you have a view as to what temperature the tissue would reach if 1 joule per square centimeter were applied?

A From my review, I can't tell you that.

Q Is there other information you would need to determine that?

A Well, the watts and the time would be necessary.

Q Any other information?
A Probably something I'm not thinking of but...
Q At least watts and time; is that --
A Yeah.
Q We'll now go to Paragraph 41 of Ganz.
I'm sorry. I misspoke. I meant Paragraph 41 of your declaration.
A Okay.
All right.
Q You mention in Paragraph 41 of your declaration that Ganz discloses perforations of 30 to 100 microns in diameter, right?
A Yes.
Q In millimeters, that's 0.03 to 0.1 millimeters, right?
A Yes.
Q And you mentioned before that the perforations were quite small that Ganz creates, right?
A Yeah, microperforations is what would my -- so if I -- I'm sorry to interrupt you,

Charles, but -- and, just for reference, a human hair width is about 70 microns. And Ganz does state that these perforations are not visible to the naked eye, so, yes, I think it's a very small perforation.

Q Would you agree that larger perforations would present greater risk of scarring?

A It would -- I can't tell you what that limit is as someone who does facial plastic surgery, but if there was a -- even with -- I can say that, yes, you're -- yes. But I can't -- I think with these devices, it could be quite -- relatively quite wide.

And the -- even with fractional resurfacing, which a lot of us do now, we ablate the epidermis, and those holes are visible to the naked eye. Maybe -- you know, they're actually -- they can see the pattern. And they heal up seven days.

So, yes, a huge hole that would require stitches would be -- that might cause a healing problem, but I don't think in the context of these

devices, that you'd probably have the microperforations running into each other.

Q Do you review literature in peer-reviewed journals?

A Yes.

Q And you publish in peer-reviewed journals, right?

A Yes.

Q Have you ever published in any of the "Nature" journals?

A No.

Q Are you familiar with "Nature's" scientific reports?

A No.

Q Is it correct you've had no contact with the inventor of the '836 patent, Dr. Na, so far as you're aware?

A Yeah, not that I'm aware of.

Q Have you reviewed any publications by Dr. Na?

A No.

Q Let me show you Exhibit 2032, which is

Dr. Na's publication in "Nature" Scientific Reports.

(WHEREUPON, Exhibit No. 2032 was presented to the witness.)

BY MR. SANDERS:

Q And we dropped it in the chat, too, so if it's easier for you to download it and open it up yourself, you're welcome to do that.

A All right.

Did you have a specific area you wanted me to look at?

Q Yeah, first -- my first question is have you seen this publication before?

A No.

Q I'd like to direct you to Figure 1, which is on Page 3.

Probably have to make it smaller for you to be able to see the caption, and the caption is printed small. So feel free to tell the technician to move if it's helpful or open it up on your end on the PDF that's in the chat. Whatever's easiest for you to look at it.

Figure 1 shows histology, correct?

A Yes, I'm just trying to read this real quick.

Q Sure. Just let me know when you're ready.

A Okay.

Q You see Figure 1 shows RF-induced coagulation columns indicated by broken lines?

A That's what it states, yes.

Q It states that those RF-induced coagulation columns were generated separately around each microneedle electrode, correct?

A Yes.

Q In the histology that's shown in Figure 1, do you see a hole where the microneedle was inserted?

A Well, I don't see a distinct hole.

Q Do you see ablation holes in Figure 1?

A No.

But do you -- can I ask a question since this is the first time I've seen this? Do you know when the samples were taken?

Q Sorry, Dr. Koch, it's a one-way exercise.

A All right. Well, then I can at least say that it would depend on when the samples were taken whether -- because they have to put the needle in, there's going to be a hole, even if it's -- one considers it a special device.

So I'm just saying that even when we fully ablate the epidermis with rough lasers like carbon dioxide, it -- I did a study where the epidermis was completely healed in seven days.

Q And would you agree what's shown in Figure 1 here is different than what's shown in Ganz?

A You don't want me to use the apples to oranges, do you? You get sick of that analogy?

But, no, I'm sorry, to be serious, it is different. But, again, I don't know the background regarding when the needles were removed, when the samples were taken. There's processing issues sometimes with these samples.

But yes is the answer.

MR. SANDERS: Thank you, Dr. Koch. No further questions.

THE WITNESS: Thank you.

FURTHER EXAMINATION

BY MR. MUELLER:

Q I just have a couple of follow-up questions, Dr. Koch. Can you direct -- or directing your attention to Paragraph 19 of your declaration.

Do you see that?

A Yes.

Q It says there that you reviewed the prosecution history of the '836 patent?

A Yes.

Q Do you have any reason to believe that was incorrect at the time you wrote the declaration?

A No, I -- I must have looked at it briefly. I just didn't review it before the deposition, but I must have seen it.

Q And then looking at Paragraph 33 of your declaration where you quote from Ganz in the second, third, and fourth sentences of that paragraph.

Paragraph 33.

A Yes.

Q And, again, directing your attention to the second, third, and fourth sentences of the paragraph; do you see that?

A Yes.

MR. SANDERS: Objection. Beyond the scope.

BY MR. MUELLER:

Q What is your understanding from that quote as to what Ganz is teaching a person skilled in the art with respect to the zones of coagulation that are disclosed in Ganz?

A That they're --

MR. SANDERS: Objection to form.

BY THE WITNESS:

A -- surrounding the perforation.

BY MR. MUELLER:

Q Anything else?

A And that they extend in all directions originating from the perforation site.

Q Anything else with respect to whether the zones of coagulation are beneficial?

A Yes.
Q Can you explain that?
A Well, the zones of coagulation are beneficial because the tissue has been heated, it's been wounded, but it's still viable, and it mounts a wound-healing response.
Q And is that according to the disclosure in Ganz, to your understanding?
A Yes.
Q All right. Let me direct your attention to the first page of Ganz, which is Exhibit 1005.
And do you see number 76 at the top where it identifies the inventors? At the first page.
A Yes. Yes. Sorry.
Q You mentioned earlier a Dr. Zelickson --
A Yep.
Q -- do you recall that?
A Yes.
Q And do you see on the listing of inventors a Brian D. Zelickson?
A Yes.
Q Is that the same Dr. Zelickson you were

referring to?

A Yes.

Q And who is he?

A So Dr. Zelickson is a -- I'm not sure if he's still practicing, to be honest, but he was, or is, a very prominent science-based dermatologist, I believe M.D./Ph.D., and we both served together on the Thermage advisory board.

And he -- so with what he's trying to do here, it fits with what was -- as a POSITA, what was going on at the time.

And, also, interestingly, Rox Anderson, he -- as I mentioned earlier, I believe he was the developer of the Fraxel, which is the prior art, and it's true prior art in this patent.

That was -- we were trying to get away from -- here we are, RF people at Thermage, we were trying to get a way of getting better heating of the dermis with minimal disruption of the epidermis.

Q So, to your understanding, are Dr. Zelickson's teachings in the Ganz reference

theoretical?

MR. SANDERS: Objection.

BY THE WITNESS:

A No.

BY MR. MUELLER:

Q They relate to a real-world device?

A Yes.

MR. MUELLER: Thank you. No more questions.

MR. SANDERS: I have follow-up to that.

FURTHER EXAMINATION

BY MR. SANDERS:

Q Did Thermage introduce an RF microneedling device?

A No, it was surface heating with cooling.

Q So --

A But that's where we all were, and that's why I was saying that I know where we were heading.

Q Okay.

A From a POSITA point of view.

Q So when you just said that the teachings

relate to a real-world device, did you see any device from Dr. Zelickson or Thermage that implemented what's described in Ganz?

A Well, I see the histology here from the device that Ganz used, but not for Thermage. They're still doing -- you probably know this, they're still using pretty much the same machine.

Q So, just to be clear, you never saw an RF microneedling device that implemented what's taught in Ganz from Dr. Zelickson, right?

A I never saw -- have seen a commercial device, but obviously he had a device.

Q Whatever device he had, it wasn't one that you witnessed, correct?

A Yes, I didn't witness it.

MR. SANDERS: No further questions.

THE WITNESS: All right.

MR. MUELLER: Okay. Thank you.

THE WITNESS: Thank you. Nice to meet you.

(WHEREUPON, the deposition was concluded at 11:02 a.m. CST.)

ACKNOWLEDGMENT OF DEPONENT

I, R. JAMES KOCH, M.D., do hereby acknowledge that I have read and examined the foregoing testimony and the same is a true, correct, and complete transcription of the testimony given by me and any corrections appear on the attached errata sheet signed by me.

_____ _____

(SIGNATURE) (DATE)

CERTIFICATE OF SHORTHAND REPORTER

I, MICHELLE M. YOHLER, Certified Certified Shorthand Reporter within and for the State of Illinois, do hereby certify:

That R. JAMES KOCH, M.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition and that such deposition was taken before me and is a true record of the testimony given by such witness.

I further certify that the adverse party, JEISYS MEDICAL INC., was represented by counsel at the deposition.

I further certify that the deposition of R. JAMES KOCH, M.D., was conducted virtually via Zoom, on Saturday, October 19, 2024, commencing at 9:01 a.m. to 11:02 a.m.

I further certify that I am not related to any of the parties to this action by blood or marriage, I am not employed by or an attorney to any of the parties to this action, and that I am in no way interested, financially or otherwise, in the outcome

of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 24th day of October, 2024.

Michelle M. Yohler

Michelle M. Yohler, CSR, RMR, CRR
Certified Shorthand Reporter
CSR No.: 84-4531

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