UNITED STATES
INTERNATIONAL TRADE COMMISSION

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In the Matter of Investigation No.

CERTAIN DERMATOLOGICAL TREATMENT 337-TA-1356

DEVICES AND COMPONENTS THEREOF

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OPEN SESSIONS

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Serendia, LLC
Exhibit 2125
EndyMed v. Serendia
IPR2024-00844

AFTERNOON SESSION

(In session at 2:00 p.m.)

JUDGE MCNAMARA: Thank you, everyone.

MR. TRZECIAK: Good afternoon, Your Honor. This is Alex Trzeciak on behalf of the Respondents. I will be addressing with Dr. Woloszko invalidity issues regarding the Family Two patents.

May I proceed?

JUDGE MCNAMARA: Yes. Thank you.

CROSS-EXAMINATION

BY MR. TRZECIAK:

Q. Good afternoon, Dr. Woloszko.

A. Good afternoon.

Q. So let's transition to the Family Two patents. Can we go to slide 97?

What was your task as it relates to the Family Two patents?

A. It was to evaluate the '536, '774, and '812 patent, to evaluate whether they are invalid.

Q. And what were your conclusions?

A. That the '536 patent is invalid as anticipated and obvious. The same for '774 was invalid as obvious, and '812 invalid as obvious.

Q. Can we go to slide 98?

What are the earliest effective filing dates of

the Family Two patents?

A. For the three patents, the effective filing date March 3, 2011.

Q. Earlier you testified about the qualifications of the person of ordinary skill in the art.

Were you a POSITA as of March 3rd, 2011?

A. Yes, same definition, same answer.

Q. Can we go to slide 99?

What materials did you consider in forming your opinions as to the Family Two patents?

A. I reviewed the patent. It's RX-0307 by Mehta, patent '737 patent, as well as the Na PCT filing, '848, which is RX-1814, the filing date of August 2008.

Q. And what was the filing date of the application that led to the patent, the '737 patent, which we'll call Mehta?

A. The Mehta patent was filed in April 2009.

Q. Are Mehta and Na '848 prior art to the Family Two patents?

A. Yes, they are.

Q. Slide 100. What does this slide show?

A. This is the claim construction as agreed between the Complainant and defendant.

Q. Did you apply these constructions in forming your opinions?

A. Yes, I did.

Q. Slide 101. What does this slide show?

A. This is the claim construction as defined by the Court.

Q. And did you apply these constructions in forming your opinions?

A. I did as well.

Q. Slide 102, please.

Earlier you testified about some background for the '836 patent. I was hoping you could provide a similar background for the Family Two patents.

A. Yes. The microneedling technology has been described a long time ago in the mid-'90s, the Orentreich and associate first described using some small needles to treat scars in the skin. And then Camirand and Doucet in France in '97 were the first to really describe some kind of a pistol to insert microneedle in the skin. It's called a tattoo pistol.

And from there many, many devices came to market and been used for various uses, including the -- improving skin. And Dr. Na talked about the derma stamp, one of the examples, and those is really the microneedle was thought to create a small injury to the skin, it will induce the formation of growth factor, and that will lead to formation of new collagen and elastin as well and the dermis have a

healing response.

Again, after these -- combining this technology with the microneedle gave birth to many devices, some of the first ones described here is a Miratone, which is shown on the right, figure A, B, C, D, INTRAcel product made by Jeisys, talked about earlier today, and as well as the DeAge from Dashin Enterprise. There were many more of those products prior to the date of the slide RDX-10C.

Q. That depiction of the Miratone device, is that available on Respondents' Exhibit 0277?

A. Yes, it is taken from that.

Q. And that's RX-0277. I apologize.

Could we go to slide 103, please.

One of the prior art references you mentioned a moment ago was the Mehta patent.

Could you give us an overview of what Mehta describes?

A. So the Mehta patent describes a system and method for percutaneous energy delivery using one or several probes. And using your handheld system with microneedle, detachable probe cartridges, with needle modules, those are driven by a motor, and the probe can be inserted at the desired distance, it also mentions pulsed RF, LED on the tip, and other features we will discuss.

Q. On the left part of this slide you've got a

blowup of Fig. 2D. And you have a red arrow pointing from one piece to another.

Could you explain what that red arrow signifies?

A. So the device in Fig. 2D is what is called, I believe, in Mehta the needle cartridge, which is a needle module, that is insertable in the distal end, so proximal end as Mehta defines it, to the handle 2010, and the blowup on the right shows some details of this needle module, and we will review them in more detail later.

Q. Let's go to slide 104. I'd like to get into the specifics of your opinions, and we'll start with the '536 patent.

If we go to slide 105, please, what is your opinion regarding asserted claims 11 and 16 of the '536 patent?

A. So it's my opinion that the claim 11 and 16 are anticipated by Mehta, and that claim 11 and 16 are rendered obvious by Mehta in view of the knowledge of a person of skill in the art.

Q. Let's walk through the limitations of claim 11.

Could we go to slide 106?

What does Mehta disclose about the preamble?

A. The preamble is an apparatus for treating dermatological tissue, which is the skin, and Mehta discloses something, a similar system and a method or

system, to treat tissue in the human body, and later on, on the same column 1, line 14 to 16, in RX-307, which is Mehta's patent, he mentions affecting the skin. So a system to treat the skin.

Q. If we go to slide 107, please.

What does Mehta disclose about the limitation a user holdable device including a proximal end?

A. So I tried to use colors to make it easier to look at the slides. So in blue it is the user holdable, and you can see, I mention three references to that, I won't say the reference because they are all the same, it is all Mehta, so in column 9, line 34-39, a treatment unit, which is the handle, having a handpiece or device body. Further on, column 4, line 1-2, device included device body having a handle portion, or even further, column 9, line 59-62, the device body that has a loop or a curved grip so that -- you know, which it can be grasped by the hand.

Q. And then on the right side of this slide you've drawn a green circle over part of Fig. 2D from Mehta.

Why did you draw that circle?

A. Yeah, the proximal end is not a term used by Mehta, and Mehta, like many of the persons skilled in the art, will actually -- what Mehta calls distal, sorry, proximal, proximal of the patient, we normally call them distal, from the surgeon's point of view.

So if I confuse -- it should not be confused, but it's been a long day, so I apologize for that. This is the proximal end, and I basically highlight it in green to circle that represents the equivalent proximal end of Mehta's device.

Q. Can we go to slide 108, please.

What does Mehta disclose about the highlighted limitation, a releasably couplable deployable needle module?

A. So that's a needle module that can be coupled and released and can have deployable needle. So, first, the middle column in blue, paragraph -- column 15, lines 40-42, Mehta disclose an electrode assembly that includes a coupling portion, and, furthermore, in line -- column 6, line 41-42, it clearly shows that it is also couplable and detachable.

Releasing -- so this is the middle assembly, so it calls them electroassembly, which is an equivalence.

On the right column, it's clearly said that electrode assembly includes any number of electrodes that form an array that are extendable and retractable from the portion 104, so from the cartridge. So they are extendable and retractable.

Q. If they are extendable and retractable, are they deployable?

A. And deployable, yes.

Q. You mentioned a few times the term electrodes. Do these electrodes in Mehta have a particular shape?

A. Yeah, they are needle and -- actually, yeah, they are in the shape of a hypodermic needle. I think it's mentioned somewhere. But it's also somewhere in the text somewhere.

Q. I think maybe you mentioned this, but where is the needle assembly in Mehta vis-α-vis the cartridge?

A. Where are they? Sorry?

Q. Where is the needle module vis-α-vis the cartridge in Mehta?

A. Needle module? I couldn't hear. Within the cartridge, you said? Okay. Yeah, they are inside the cartridge. So inside the cartridge, and they are moved -- they deploy within the cartridge.

Q. Let's go to slide 109, please. What does Mehta disclose about the highlighted limitation, the deployable needle assembly mechanically separatably from the proximal end and including a plurality of extendable needles?

A. So the needle module, so what Mehta discloses is, he mentioned, this is in blue, so column 15, line 31-33, removable coupling of the cartridge body, the cartridge body includes the needle, and I think in the claim construction

it clearly says that if you -- they are together. If you decouple -- if one is coupled, the other one is coupled as well. I forgot the exact words, but they are removable together. And the same thing on paragraph 4, line 63 to 66, the cartridge that are removably coupled to the device body, so it is clearly shown that it's there.

And in green here, column 15, line 45-49, electrode assembly includes any number of electrodes, a plurality of electrodes, number of electrodes, that form an array and are extendable and retractable, so, basically, extendable needles.

Q. At the bottom of this slide 109 you've got, again, a blowup of Fig. 2D. And you have a yellow highlight box that blows up what I believe you described already is a picture of the cartridge.

Could you explain how the cartridge in Mehta is mechanically separatable from the proximal end?

A. So we can see on this graphic that a needle is inserted inside a handle, and the tab in yellow, one of the many embodiment that are allowed and taught by Mehta to do the mechanical coupling of the electrode cartridge, electrode assembly, within the proximal end of the handle.

Q. And is Mehta's disclosure limited to the tab you highlighted in yellow?

A. No. He mentioned many structures can be deployed

into the device --

(Clarification requested by the court reporter.)

A. He mentions any number of structures can be incorporated into the device to permit removable coupling of the cartridge body.

Q. Go to slide --

A. It shows a few different embodiments, different throughout the patent, but this is open-ended to many permutations -- any permutations.

Q. Can we go to slide 110, please?

What does Mehta disclose about the highlighted limitation that reads a plurality of the extendable needles extendable from a deployable needle assembly end surface?

A. So this end surface, which is, you know, has been defined and construed to the surface that is represented by the needles in the retracted position, this is not terminology used in Mehta's patent, but you can see very well in Fig. 4C where the needle -- actually, we don't see actually, but you can guess the needle end just behind the end of this cartridge, and you can see how the needle extends from this plane to the outside of the cartridge on Fig. 4A, so we can see the needle deployable -- sorry -- extendable from the end surface.

Q. Slide 111, please. This is a long limitation so I won't read it, but what does Mehta disclose about the

highlighted -- maybe we can call it the electrical contact coupling limitation?

A. So '536 patent basically in this complex claim describes two implementations of electrical coupling between the handle and the cartridge. And basically one of those two will have a deflectable contact where the other one has the conductive parts. Mehta describes here, and I show here only one of those implementations in which you can see on Fig. 4A, highlighted in yellow, and also colored in yellow are those deflectable contacts, so the triangular contact made of string.

It is also described in paragraph 16, line 12-18, as spring contacts or spring pins, spring pins as we, I think, Mr. Crosby mentioned, can also be called pogo pins. That's trade name, but it's commonly used, pogo pins. So any kind of spring contact deflectable -- a spring is obviously restorably --

I'm going fast again.

JUDGE MCNAMARA: So any kind of spring contact --

A. Restorably deflectable structure.

JUDGE MCNAMARA: Thank you.

A. Sorry. It's my fault.

And in the text of paragraph 15, line 55-65, again, mentions in this case that the electrode assembly has the connection or contact portion, this is the yellow

contact 116, that are basically making contact with a connection board, which is an electric connection board, conductive part, on the treatment unit, which is the proximal part of the handle. Proximal end.

Q. Could we go to slide 112, please?

What does Mehta disclose about the highlighted limitation, a motor coupled to a plurality of extendable needles that causes the plurality of extendable needles to extend?

A. So let's talk about the green portion, and you see on top right Mehta discloses column 4, line 63, to column 5, line 2, in some variations the cartridge and/or energy delivery elements can be coupled to an actuator where the movement of the actuator causes advancement or retraction of the first plurality of electrodes, the electrodes being the needles.

And then this motor, this actuator, is the element 250 on Fig. 5. And you can read in column 15, line 58-65, again, that the actuator within the device body can be coupled to an array of probes, needles, and down, the actuator comprises a motor. So it describes a motor that can be coupled to the needle and extend them.

Q. And earlier when you said column 15, did you mean column 13?

A. Yes, I did. Thank you.

Q. Could we go to slide 113, please?

What does Mehta disclose about the needle extension we just discussed being a desired distance from the needle assembly end surface?

A. So Mehta mentions desired location, desired depth many times throughout the patent. So here, show some example here, in column 32, line 67, to column 33, line 3. He mentions -- basically this is the graphic interface, a display on the system, and said basically the display shows a desired probe location, and he said the array can represent a desired depth.

So obviously Mehta also discloses that the system can have several angles, so this is -- I think 20 degree, I believe, to 90 degrees, so 90 degree, the distance and the depth are the same dimension. Another angle, you will see a linear relationship, it's linear, so it is easy to do.

And then on column 33, line 21 to 34, he mentioned that the system -- basically that the physician would be informed that further advancement of the probes is necessary, and he also -- the system also mentioned some sensing system to actually detect whether you are where you're supposed to be or where you want to be or not, where you desire to be.

And, again, in the same -- in the same paragraph, he says that the system can be adjusted, so there was the

possibility that the physician can adjust the system to guide the probe within the first or third layers or a different distance, different depth, through a layer of the skin being the epidermis.

And the blue rectangle shows it's kind of a -- not very easy to understand the graphic, thank God, engineers don't do graphic design, this is the representation he has for the -- showing the depth and function of the angle of the probe location.

Q. I have more questions about this slide, but just to be clear, earlier when I asked you about the shape of the electrodes, what is the shape of the probes that are described in Mehta here?

A. These are needles, needle with a bevel shape, and the bevel is on top such that the sharp edge is going to easily enter the skin.

Q. I want to focus on the part of the language from columns 33 or column 33, line 21-34, where you've highlighted or underlined in red, therefore, the physician would be informed that further advancement of the probes is necessary to place the probes within the second layer.

In the context of Mehta, does advancement mean the same thing as extension?

A. Yes, definitely, yes, the motor advances the probe, and they make them extend basically from this needle

end surface.

Q. And so when the physician is informed, as it says here, that further advancement -- further advancement -- of the probes is necessary, where are the probes?

A. They are already inside -- inside the tissue, and then at that time the physician is informed that he needs to advance them, he needs to direct the device, the system, to advance the needle further, deeper, further away from the needle assembly end surface.

Q. And so where Mehta describes that it would inform the physician that further advancement may be necessary, what would the person of ordinary skill in the art understand Mehta's device is capable of doing?

A. Mention that the device has some functionality to control advancement of the needle and to have some kind of interface such that the physician can indicate the system to advance the needle further.

Q. And so would that further extension be selected by the physician?

A. Probably, yes, that's what it means. It was advancement that was necessary. Necessary means it doesn't move by itself, but somebody has to give the command to advance them more and basically to the user.

Q. And can the user of the device in Mehta select the desired distance to extend the needles?

A. Yes, obviously the desired distance, and I think Mehta discloses several ways to do that.

Q. All right. I'll go to slide 114, please. You mentioned there are several ways Mehta describes.

Could you elaborate on some of those ways?

A. Yes. So, for instance, in column 15, line 34-42, Mehta mentioned basically the type of actuator, or motor, and he mentioned stepping system or a ratchet system, a stepping motor. A stepping motor is a motor that's controlled by very precise use -- to control very precise movement, can be stepped, micro stepped, and you can control them sometimes a fraction of a millimeter depending on the implement. It is very, very precise with proper controller, and they can be controlled by a specific stepping motor controller.

In paragraph 16, line -- sorry, column 16, line 34-41, he also mentioned that the system can control precisely the electrode. He says the electrodes can be designed to intentionally over-insert and then retract prior to initiating the treatment. The system knows where the needles are, goes further, then pulls them back. So all the circuitry and the feedback in the control system to do that.

And he explains why, later on, over-inserting the partially retracting needles to compensate for the movement and laxity of the skin resulting in a more reliable

insertion. You often do that when you puncture blood.

And in the last -- in the last paragraph, he also mentioned another way to control the distance. He said you can also have different cartridge configuration that have different extensions. So basically the physician could select before the therapy how deep he wants to go and would use the appropriate cartridge for that.

Q. If we can go to slide 115, please.

What does Mehta disclose about the highlighted, when the motor is energized with a particular signal limitation?

A. So we can refer to column 10, line 33-39, two portion of it, he said an actuator as described below for driving the probe array from the cartridge into the target tissue. Target tissue in this case is obviously some layer of the skin.

And he also mentioned that the actuator, the motor, is driven by the control system, or energy system, the control system is a system that will generate a specific signal to control the actuator, and if it is a stepping motor it is a very, very specific type of micro step signal used for that.

Q. If we go to slide 116.

And what does Mehta disclose about the highlighted signal generator limitation?

A. So Mehta shows in Fig. 2A, item 90, which is the supply unit, basically the radiofrequency generator, and he mentioned that those electrode -- so let's stay, again, in column 10, lines 53-65, the bottom right green rectangle, and he said the energy 90 contains software, hardware required to control energy delivery, and he describes the energy delivery is radiofrequency.

And he mentioned that one embodiment had a cable that will be affixed, connecting between the supply unit and the treatment unit, and the handle. We showed before the connection inside the handle to connect to the needles.

And he also shows in, this is the top right, column 16, line 9-11, that the electrodes are energized, obviously there was a connection, I think we discussed it yesterday, the electrodes to send energy you need to have a connection, and the electrode can be energized whether they are in treatment position, which would be extended, or retracted position. So basically this limitation energized the plurality of needle, of extended needle.

Q. Could we go to slide 117, please? So now let's turn to claim 16.

How does claim 16 relate to other claims in the '536 patent?

A. Claim 16 is dependent on claim 11.

Q. What does Mehta disclose about the added

limitations of claim 16?

A. Added limitation is to have restorably deflectable electrical contact that includes a depressible pin. We talked about it a few minutes ago. And Mehta clearly mentions on paragraph 16, line 12-18, spring pins. And spring pins are the -- basically other terms for -- it's basically a depressible pin. So it's obvious.

Q. And have you reviewed the rebuttal expert report of Mr. Peter Crosby?

A. Yes.

Q. Are you aware of his opinion that Mehta does not anticipate claims 11 and 16 of the '536 patent?

A. Yes.

Q. Do you agree with him?

A. No, I don't. We have obviously spring pins here.

Q. Can we go to slide 118, please?

Even if Mr. Crosby were correct about anticipation, would the POSITA have nevertheless been motivated to modify Mehta or combine elements of Mehta in light of a POSITA's knowledge and arrive at the asserted claims?

A. Absolutely.

Q. Why?

A. Sorry. You know, this -- those devices, there was a high degree of similarity of Mehta to the device

described in the claims. Any difference between what Mehta, you know, in terms of this difference of opinion would be a small design implementation that wouldn't be patentable. This is very relevant to the art.

Actually, any connector except a medical connector uses some type of deflectable part to make sure you have contact. So a contact has to have a connector, a depressible, deflectable part of it. And a spring pin is an obvious choice. And basically picking such a feature is obvious. It is really routine optimization.

Q. And --

A. And success of that.

Q. And you mentioned specifically the spring pin in that answer, but would your same opinion apply to any limitation that --

A. Yes, all limitations are mentioned in basically -- this is about claim 11, yes. I talked about claim 16, but the same thing goes for claim 11, there are a lot of similarities between the Mehta device described and the device mentioned in claim 11.

Q. And would a person of ordinary skill in the art have had a reasonable expectation of success in doing these things?

A. This is basic mechanical design, yes.

Q. Let's turn to the '774 patent. Could we go to

slide 119?

Actually we can skip to 120.

What is your opinion regarding asserted claim 14 in the '774 patent?

A. It is my opinion that claim 14 of -- is rendered obvious in view of Mehta and the knowledge of a person of skill in the art.

Q. How does -- let's go to slide 121.

How does asserted claim 14 relate to other claims of the '774 patent?

A. So claim 14 is dependent on claim 12. It is self-dependent on claim 11, so we have to review claim 11, 12, and 14.

Q. Go to slide 122. So we're going to start with claim 11. On the left part of the slide you've highlighted a number of terms in claim 11. You've also highlighted a number of terms in claim 11 in the '536 patent.

Could you explain what you're doing there?

A. Yeah, that's the same construction as we discussed yesterday with Mr. Crosby, to simplify, to safe time obviously -- hopefully. So the words in the same color are supposed to show a similarity between the two patents and the claims. Yellow is about the apparatus for treating skin. I think the language is identical. In green, about the device, about a device that's described clearly, a

holdable device, which is device in '536, plurality of needles extending or extendable a desired distance. We have the same term, extendable needles, so one of them is extendable, causes the plurality of extendable needles to extend a desired distance. And the '774 is generally about end surface. The '536 is more specific about needle assembly end surface, so it's one surface.

And then we have a signal generator electrically coupled to the plurality of extended needles, and exactly the same wording in the '536, claim 11, signal generator electrically coupled to the plurality of extended needles.

Q. Did you rely on the same opinions and evidence for these limitations that you did with respect to the '536 patent?

A. That's exactly the same, the same illustrations.

Q. Are each of the highlighted limitations in claim 11 of the '774 patent disclosed in Mehta?

A. Yes.

Q. Go to slide 123, please. So let's look at the remaining elements of claim 11.

What does Mehta disclose about the desired distance selected to enable the plurality of needles to penetrate dermatological tissue?

A. So I think we discussed extensively already the desired distance, and, again, we have this in the middle

column in blue, in column 32, line 67, 33, line 3, desired location, desired depth, it is the same that we reviewed before. Column 33, line 30-34, desired target layer of tissue, a system can be adjusted to guide the probe placement within the first or third layer.

And column 15, line 34-42, talk about the stepping motor, and the indicator of that on the graphic user interface, GUI, and then, in green, to penetrate the tissue, to penetrate the skin. This is described in column 13, lines 63-65 by Mehta.

In this variation, the actuator that includes a motor, provides sufficient force, speed, or impact to the probe to drive them into tissue. So tissue is here described as the skin.

Q. Just to be clear, when we're talking about the '536 patent, you had maybe two slides covering the desired distance issue.

Does all of that evidence also apply here to claim 11?

A. Yeah.

Q. Okay. Let's go to slide 124.

What does Mehta disclose about the highlighted limitation on this slide?

A. So let's divide this into first he said to produce pulsed radiofrequency signals. This is described in

Mehta, column 20, line 19-24. RF energy with a duty cycle of variations of the present system can be pulsed. So he mentioned pulsed. RF, that has a duty cycle. So it represents that.

And then the second part, which is highlighted in green, across a plurality of needle to affect the tissue near a plurality of needles. So plurality of needle is an array of needles in Mehta, column 37, line 25-34, and array comprising five electrode pairs, that's obviously more than one, inserted into the dermis, which is a piece of the dermatological tissue, a part of the tissue, and then he mentioned to create a series of discrete fractional lesions, meaning discrete lesions. And this is also shown in the Fig. 13A where there were discrete lesions, what we have highlighted here, which is number 2, in this patent, and highlighted in green to better view what those lesions are.

And in the same column 37, line 24-34, he says this is accomplished by passing current between the adjacent electrode of opposite polarity in the electrode pair. So he is passing current between electrodes, part of a plurality of needles is to effect the tissue and to create lesion, you know, the plurality of electrode. Sorry.

Q. What would a person of ordinary skill in the art have thought of pulsing RF energy in 2011?

A. Pulsing RF energy I think was described in the

'70s. This is part of any system that provides a coagulation or hemostasis. It has been described very commonly to control temperature and lesion, how much a lesion grows, basically a sense of energy, and then you let the energy diffuse a bit. So this is -- this is how basically laser surgery works when you do coagulation. It's in -- any book of coagulation talks about it.

Q. Let's go to slide 125 and moving on to claim 12.

What does Mehta disclose about the limitation of claim 12 highlighted on this slide?

A. So the described mentions end surface, the device includes an end surface configured to be placed on the skin, dermatological tissue to be treated.

Mehta mentions in column 2, lines 63, to column 3, line 3, the body -- the device body, which is the device, and this device included tissue engaging surface that allows orientation of the device body on the surface of tissue.

So that's clearly the surface, which is on the tissue to be treated. And this is exemplified in Fig. 2B by the surface 106.

Q. Can we go to slide 126? And on this slide you've highlighted the remaining added limitations of dependent claim 12.

Could you explain your analysis here?

A. So your question was to compare -- yeah.

Q. Just explain what you were doing with this slide.

A. Yeah. So the same thing as before, we compared claim 12 from '774 with claim 11 from '536, and you look at the words in green, the end surface including a plurality of needles, and here we have from claim 11 the plurality of extendable needles extendable from a deployable needle module end surface. So needles deploy from a surface.

And in orange, extendable desired distance from the end surface, and this is the same -- basically almost the same words, plurality of extendable needles that cause the plurality of extendable needles to extend a desired distance from the needle assembly end surface. So obviously from the end surface.

Q. Did you rely on the same opinions and evidence for these limitations that you did with respect to the '536 patent?

A. Yes, I did.

Q. Are each of the highlighted limitations in claim 11 of the '774 patent disclosed in Mehta?

A. Yes, they have.

Q. Could we go to slide 127?

So let's turn to asserted claim 14, and could you explain your analysis with respect to this claim?

A. Again, same method, claim 14 of '774 with claim 11 of '536. A motor coupled to the plurality of extendable

needles that may be directed to cause the plurality of extendable needles to extend a desired distance from the end surface.

This is exactly the same wording except one being Mehta, the other -- actually both -- the difference is -- in '774 is to cause -- sorry -- the '774 says may be directed to cause the plurality of the needles, extendable needles to extend, whereas the -- actually the same wording, the '536 says that -- the motor that causes a plurality of extendable needles to extend. So it's the same, same wording.

Q. And did you rely on the same opinions and evidence for the added limitation of claim 14 that you did with respect to the '536 patent?

A. Yes, I did.

Q. And are each of the highlighted limitations in claim 14 -- are each of the limitations in claim 14 disclosed in Mehta?

A. Yes.

Q. Go to slide 128. Would the person of ordinary skill in the art have been motivated to modify Mehta or combine the elements of Mehta and arrive at claim 14?

A. Yes, there was -- absolutely. There was a high similarity between the claims and the Mehta, devices described by Mehta. The difference are just small design options, probably not represent any patentable -- not have

any patentable significance. This is basic mechanical engineering, so the relevant art is very predictable, and the implementation is obvious and doesn't require much experimentation, you can do some CAD drawing, and routine optimization for manufacturing, production, and so on. So very high level, very high gravity of success expected.

Q. Can we go to the '812 patent? Let's go to slide 129.

Could you tell us your opinions regarding asserted claims 5, 13, and 18?

A. It is my opinion that claim 5, 13, and 18 are obvious in view of Mehta and the knowledge of a POSITA, or obvious in view of Mehta, and knowledge of a POSITA, and in view of Na '848.

Q. Go to slide 131. Start with claim 5.

How does claim 5 relate to other claims in the '812 patent?

A. Claim 5 is department on claims 1, 2, 3, and 4.

Q. Let's talk about claim 1. Can we go to slide 132?

A. Same method as before, compare the wordings, I'm not going to go through all the words. They are similar wording all along. I forgot if this was anything different. I think they are all the same.

Q. So for claim 1 of the '812 patent, the terms that

you highlighted, did you rely on the same opinions and evidence for these limitations that you did with respect to highlighted limitations shown with respect to the '536 patent?

A. Yes, I did.

Q. And are each of the highlighted limitations in claim 1 of the '812 patent disclosed in Mehta?

A. Yes.

Q. Go to slide 133. So we'll look at the remaining elements of claim 11, and we'll start with the preamble.

What does Mehta disclose about a method for treating dermatological tissue?

A. '812 is a method patent, and in column 1, Mehta discloses a system and a method.

Q. Go to slide 134.

What does Mehta disclose about the highlighted limitation, placing a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated?

A. So let me make sure. So Mehta mentions, as we discussed previously, the tissue engaging surface 106, which is the surface near the tissue, and so this was in column 10, line 43. And in column 4, line 63-66, it discloses that the cartridges are removably coupled to the device body, and the plurality of electrodes and the tissue engaging surface

are located on or in the cartridge body.

Q. And are the needles in Mehta's needle module deployable?

A. Yes. Yes, it's -- where is it here -- yes, they are deployable. We discussed this several times before. We have this in this text.

Q. And what does Fig. 2B show as you've got on this slide?

A. Fig. 2B? 2B you said?

Q. Yes, B as in boy.

A. The surface 106 in which the needles are deployed inside the skin.

Q. And is the surface 106 part of the device body or is it part of the cartridge in Mehta?

A. Actually it's both here. As you can see that -- the way the cartridge aligned with the device body, so on Fig. 2D you see surface 106, which exactly aligns with the surface basically and aligned with the part 216, which is a part of the handle. So -- and you have an edge that continues. So the surface is part of both.

Q. As shown in Fig. 2D, is 106 part of the cartridge?

A. Yes.

Q. Let's go -- one moment. Just to be clear, for purposes of your analysis of Mehta, how does your analysis

of the needle module end surface compare to your analysis of the needle assembly end surface we talked about before?

A. So we show before where how they are located, and the needle module is sliding within the needle module, and the end surface is really very close to the end surface 106 and they are basically mechanically linked, they are dependent from each other, so if you relate to one, you relate to the other.

Q. Let's go to slide 135.

What does Mehta disclose about the highlighted releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end limitation?

A. So this is very similar to what we reviewed before. We can see on the Fig. 2D the needle module that is separated from the handle, and he mentions in column 15, line 31-33, any number of structures can be incorporated into the device to permit removable coupling of the cartridge body.

And as we discussed, the needle module being part of the cartridge body, if you decouple the cartridge -- the needle module, you will decouple or couple the needle assembly.

Q. Slide 136.

A. This is -- yeah, okay.

Q. What does Mehta disclose about the limitation the needle assembly movable within the releasably couplable deployable needle module limitation?

A. So I took the liberty to make some kind of animation on Fig. 4A. Fig. 4A is normally when the needles are extended, you can see readily extended, and make the same picture when taken from another figure how the movement happens. It makes it clear, and you can see that the whole needle assembly is sliding on some kind of a tracks within the needle module, and this is explained on paragraph -- sorry -- column 14, line 15-19. The probe assembly, needle assembly, that is slidable relative to the cartridge body.

Q. Go to slide 137.

And what does Mehta disclose about the highlighted limitation, which includes the needle assembly remains electrically coupled limitation?

A. So Mehta discloses an ingenious way to make this contact. It took me sometime to understand, and really it took me a long time to understand what he was doing. So he shows those contacts 116 that spring out of this 118, which is a needle assembly, and basically those are sliding on the track, on the board, and they are maintaining contact because the elastic, actually all the contacts, were sliding on this track, on this connection board, which is a trace, and the contact is sliding along it, so they maintain

contact during the movement of the electrodes.

So here he has about 16 times -- 32 contacts, so it's many contacts, each of them has a deflectable pin to maintain contact, maintain pressure on the contact, and he is sliding over probably gold plating trace on the PCBA to maintain contacts between electrodes. And this is explained as well in column 16, line 13-18, the connection portion can maintain contact with a corresponding contact point, trace, this trace we talked about, on a connection board during movement of the electrode assembly.

Q. Let's move on to claim 2. Now you've highlighted -- I'm sorry. Let's go to slide 138.

You've highlighted the added limitations of claim 2 and also some language from claim 1 of the '812 patent and also from the '536 patent.

Could you explain what you're doing on this slide?

A. So same things as before, we looked at '812 and '536 to compare the language, the module end surface, this is taken from claim 1 of '812, needle module end surface that we discussed previously, so they are identical language. And the motor -- the energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the couplable deployable needle.

So this is, I think, similar language in claim 11 of the '536. Motor coupled to -- motor coupled to the plurality of extendable needles that causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface when the motor is energized with a particular signal.

Q. And is the -- in addition to what we've already discussed with this claim, did you rely on the same opinions and evidence for these limitations that you did with respect to the '536 patent?

A. Absolutely.

Q. And in the case of Mehta, if the motor is extending the needles a desired distance from the needle assembly end surface, is it obvious also to have the needles extendable a desired distance from the needle module end surface?

A. Yeah, we just discussed, I think in the previous claim, that the needle assembly end surface and the module end surface are mechanically rigidly linked, so if you move from one you move from the other.

Q. And is it your opinion that the added limitation of claim 2 as a whole is disclosed in Mehta?

A. Yes.

Q. Moving on to claim 3, slide 139, what does Mehta disclose about claim 3?

A. So this is the claim 2 energizing the plurality of needles via a signal generator and electrically coupled to the user holdable device proximal end, the generator.

So I think we kind of talked about this. So '536 mentions a single generator electrically coupled to the plurality of needles to energize the plurality of extended needles. So we'll extend the plurality of needles. We don't only talk about extended needles, generator coupled to the needles. And we can see in Fig. 2A the generator and cables 96 that couples the generator to the needles by the sliding connector.

And then so this is also in green, a device, holdable device, including a proximal end. This is -- so the '536. And as discussed already before, in column 10, line 57-65, mentioned a cable -- noting there's a cable 96 may be permanently affixed to the supply unit and the treatment unit. So coupled to the generator.

Q. And does the energy from the signal generator to the needles in Mehta pass through the proximal end?

A. Yes. Via the connector we described -- -- via the sliding connector.

Q. In addition to what we've already discussed about this claim 3, did you rely on the same opinions and evidence for these limitations you did with respect to the '536 patent?

A. Yes, I did.

Q. And is it your opinion that the added limitation of claim 3 is disclosed in Mehta?

A. Yes.

Q. Let's talk about claim 4. Slide 140, please.

What does Mehta disclose about the highlighted limitations on slide 140?

A. So Mehta disclosed that on the device body there would be transfer element, comprised sources of light at the distal end, so distal for Mehta is proximal for Na, the distal end, the proximal end following Dr. Na's nomenclature, there is this light, sources of light, and this is in column 11, line 36-39. And in column 11, line 24-30, this is Mehta, RX-0307, he mentions that the radiant energy may be supplied by the energy source or supply that is coupled to a diode. A diode is basically light-emitting diodes, diode is a light emitting diode, and called a LED.

Q. Could we go to slide 141?

What does Mehta disclose about the remaining limitation, which is highlighted on slide 141?

A. So this is claim 4 where the LEDs, when they are energized, will -- the embedded LED will illuminate the releasably couplable deployable needle module.

So Mehta discloses in column 11, line 36-39, that a transfer element may comprise sources of light at the

distal end of the treatment unit. Treatment unit is the handle, so it is basically the proximal -- proximal end.

He also mentions that the -- this is in column 11, line 24-30, that the energy source can be variable to transfer element -- transfer elements are within the energy -- within the so-called needle module, so the unit is transferred to this transfer module, so transfer light, you would illuminate transfer module by the energy source.

And furthermore he also mentions a window to permit direct visualization of the advancement of the energy transfer elements. So he mentions the need to view the needle advancing, forces of light, illuminate through the needle module, so it is obvious, you have light to view something, and you have -- the light goes through something that it will illuminate something here, the needle module, the needle assembly.

Q. Can we go to slide 142?

Earlier you testified that you also considered the Na '848 prior art.

Could you tell us, what is the field of technology in Na '848?

A. So '848 is a PCT application from Dr. Na filed on August 2008, which describes microneedle system that is energized, one is vibration energy on the needles, and another embodiment is to use RF energy on the needles to

1 treat the skin.
2 Q. Can we go to slide 143?
3 What does Na '848 disclose about LEDs?
4 A. So in paragraph 34, in an embodiment, the LEDs,
5 light-emitting diode 32A may be configured to emit energy of
6 a first particular frequency range and the second to -- one
7 color and another frequency another color, so two different
8 colors.
9 And then he mentioned in paragraph 38 that the
10 LED can be coupled to lens via fiber-optic pathways, and
11 that it is transmitted to the skin via the lenses and
12 fiber-optic. And, again, so basically we have those LEDs
13 that are directed to the skin, light of various colors.
14 And look at Mehta, again, mentioned direct
15 visualization of advancement of the energy transfer element,
16 electrodes, into the entry point, so the transfer into the
17 skin. Obviously you don't see through the skin.
18 Q. All right. So would claim 4 also have been
19 obvious in view of Mehta knowledge and Na '848?
20 A. Yes.
21 Q. Let's move on to asserted claim 5. Can we go to
22 slide 144?
23 What does Mehta disclose about claim 5?
24 A. So claim 5 is the same basically LED to -- LED
25 that illuminates the plurality of needle, the limitation

here to use a needle assembly translucent section.

So number one, translucent is an interesting word because a transparent material like Plexiglass, if you look through it, but if you look through the cross-section it becomes translucent. This is used all the time. This is what is called light pipes. It is used in many, many systems, like this microphone, the green stuff is a light pipe. Clear plexiglas, because the thickness is enough, it becomes -- we don't see through it because it doesn't have a perfect transparency. So there is a really gray area between transfer and translucent depending on how you look at the material.

However, Mehta mentioned, again, direct visualization of the -- sorry -- direct visualization of the advancement of the energy transfer elements. He mentioned the window with transparent material, having an outline, so the outline is actually -- yeah, it's a line, so, again, the transfer material, if you have the line going, not through the thinner surface but oblique, suddenly the transfer material becomes translucent by definition until we find a fully transparent material. Doesn't exist yet.

So this is how Mehta basically makes obvious the art to use the transfer material to translucent material light path, direct the light where you want it.

Q. Is the transparent window of Mehta on the needle

assembly or is it somewhere else?

A. So that's interesting. Mehta put the window on the -- on the handle. And that's a big mistake, because this is patient contact material. Somebody who is used to make any disposable device with a reusable part, you would never -- if you had the potential to put all the patient contact on the disposable part, you don't have to sterilize or clean the rest. So it is totally obvious to move that. I saw that and I said this is -- I would have done this right away.

Q. And so if you have an LED embedded in the proximal end, as we talked about with claim 4, why would the POSA make the needle assembly translucent as required by claim 5?

A. We talked about the window with the Plexiglass, with a thing you want to -- the light to go from the LED to the needle, this was discussed, this is to illuminate the needles. We talked about the transparent window. We talked about this window being on the wrong part of the device. You move it to the disposable part. And the light to illuminate the needles have to go through a needle assembly, so the window would be -- part of it would be on the window assembly as well.

Q. If you have an LED on one side of a translucent material, does some light pass to the other side via the

translucent material?

A. Absolutely. This is the concept of light pipe.

Q. Would claim 5 have been obvious based on Mehta and the knowledge of a POSA?

A. For me it is absolutely obvious, so I believe it would be obvious for any person skilled in the art.

Q. Can we go to slide 145?

What does Na '848 disclose about claim 5?

A. Na discloses in paragraph 35 the pin section, which is the pin section where the pins, the electrodes, are basically the needle assembly, comprised of polyurethane, medical silicon, or other pliable translucent material. So he discloses this translucent material already. So you look at -- you look at the prior art and the translucence, which is already obvious, is even more obvious for a device for the same indication, same type of use using transition part, which transmits the light to the needles and needle module.

Q. Would claim 5 also have been obvious based on Mehta, knowledge of a POSITA and Na '848?

A. Definitely.

Q. Slide 146, and let's talk about claim 13.

What's the relationship between claim 13 and other claims of the '812 patent?

A. Claim 13 is department on claim 12.

Q. Go to slide 147. So we'll start with claim 12.

Could you explain your analysis here?

A. Same construction. We compare '812 claim 12 to claim 1. They are equivalent claim. One is -- 12 being the apparatus. One is the method. So except the apparatus and method, we highlighted all the language in claim 12 and highlighted the equivalent language in claim 1. I don't think we need to go through all of them, but you can see the wording are identical.

Q. All right. So are each of the highlighting limitations in claim 12 disclosed in Mehta?

A. Yes.

Q. Would you rely on the same opinions and evidence for these limitations as we covered earlier?

A. Yes.

Q. And what does Mehta disclose about an apparatus?

A. Mehta discloses -- do we have a slide for that? He mentions that he discloses a method apparatus or -- a system or method.

Q. Can we go to slide 148? And we'll go to claim 13 now.

I'll let you explain your analysis for claim 13.

A. So claim 13 describes something we have already discussed, a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface

when the motor is energized with a particular signal.

This is similar language that is in '536, claim 11, a motor coupled to a plurality of extendable needles that causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface when the motor is energized with a particular signal.

Q. All right. Is it your opinion that each of the highlighted limitations in claim 13 of the '812 patent is disclosed in Mehta?

A. Yes.

Q. Did you rely on the same opinions and evidence for claim 13 as we covered with claim 11 in the '536 patent?

A. Yes, I did.

Q. Is there any difference between coupling to the plurality of extendable needles versus coupled to the needle assembly for purposes of analyzing Mehta?

A. By their claim construction, when you couple to one you couple to the other. We're not going to go into details.

Q. So let's go --

A. It is equivalent for this purpose.

Q. Can we go to slide 149. Let's finally talk about asserted claim 18.

What's the relationship between claim 18 and other claims?

A. Claim 18 is dependent on claim 12.

Q. And did we already cover claim 12?

A. We covered claim 12.

Q. Let's go to slide 150.

What does Mehta disclose about the apparatus of claim 12 wherein one of the -- at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles?

A. Yes. So the pins are those element 116 in yellow on the needle assembly, and this is basically moving together with the needle. So when the needle extend from the needle end surface, those elements extend towards the end surface, same movement, same direction, because they are on the same assembly.

Q. And did you create an animation showing movement of the needles and the electrical contact?

A. Yeah, I think I did, yes.

Q. Can we show that?

A. Yeah, you can see they are moving together, same direction.

Q. Can we go to slide 151?

Would the POSITA have been motivated to modify Mehta or combine elements of Mehta in light of a POSITA's knowledge and arrive at the claims?

A. Yes.

Q. And why is that?

A. Basically, again, the device described in Mehta has a high degree of similarity with the device described by the patent '812. The differences are minor and probably not subjectable to a patent. I'm not a patent lawyer. The art is, again, basic mechanical design, highly predictable. There was nothing complicated about it. And this is just basic implementation, obvious, easy to optimize, can be done on a CAD model, and with a pretty high -- very reasonable expectation of success.

Q. And let's go to slide 152. In addition to what we talked about before, and with respect to claim 5, why would the POSITA have been motivated to combine Mehta with Na '848?

A. Again, this is the same field of the --

This is the same field of dermatological treatment, basically of microneedles used to treat the skin, combination would be done with known methods, disclosed this translucent material. It's a simple LED, very simple substitution of known equivalent, one element for another. Follow the market force in the industry, and --

Q. Would a person of ordinary skill in the art had a reasonable expectation of success in combining these references?

A. Again, these are basic -- basic limitation that

may require one or two experimentation, but you don't expect any big surprises.

Q. Thank you, Dr. Woloszko.

I don't have any questions on these topics.

A. Thank you.

MR. SHARMA: Good afternoon, Your Honor.

JUDGE MCNAMARA: Good afternoon. Anupam Sharma on behalf of Ilooda and Cutera.

I have a few questions on inventorship on behalf of the Respondents.

DIRECT EXAMINATION (continued)

BY MR. SHARMA:

Q. Dr. Woloszko, were you in the court when Mr. Kim testified?

MR. SANDERS: Your Honor, we have an objection to this line of inquiry, inventorship.

JUDGE MCNAMARA: And what's the basis, Mr. Sanders?

MR. SANDERS: Charles Sanders. This witness is not qualified to give an opinion as to inventorship. Has not done so. And we respectfully submit this is the province of Your Honor to weigh the testimony, and that, from what I can see from the slide presentation, it's simply presenting across eight slides the fact that there are a number of claim elements, and that Mr. Kim claims to have

invented them, which is the subject of fact testimony, not expert testimony, Your Honor.

JUDGE MCNAMARA: Mr. Sharma, do you have a response to Mr. Sanders?

MR. SHARMA: Yes, Your Honor. Serendia had filed a MIL on it and withdrew. The second part was trying to prevent Dr. Woloszko's testimony on this issue. The MIL was withdrawn.

(Clarification requested by the court reporter.)

JUDGE MCNAMARA: Start again.

MR. SHARMA: And the opposition to the MIL, Serendia withdrew. We mentioned that Dr. Woloszko would not testify on the issue of inventorship. He would not testify whether Dr. Na or Mr. Kim is credible or not. He will simply say if Mr. Kim's testimony is to be true, which claims of asserted patent would be impacted. So he would simply be connecting the dots between what Mr. Kim said and what the claims impacted based on Mr. Kim's statement. He will not say whether Mr. Kim is right or Mr. Kim is wrong or whether Mr. Kim is the inventor.

JUDGE MCNAMARA: Mr. Rauh?

MR. RAUH: Aaron Rauh for the Staff, Your Honor.

I'd like to see where the Q&A goes. I think this might be venturing into a weight rather than admissibility issue, but, again, without hearing where this is going, it's

hard for me to say what is right or what is wrong.

MR. SHARMA: May I add something?

JUDGE MCNAMARA: Yes of course.

MR. SHARMA: These slides were disclosed to opposing counsel a few days ago.

JUDGE MCNAMARA: I'm sorry. You disclosed these slides to counsel?

MR. SHARMA: Yes, Your Honor.

JUDGE MCNAMARA: Was there an objection?

MR. SHARMA: No, Your Honor.

JUDGE MCNAMARA: Mr. Sanders?

MR. SANDERS: We're objecting to the subject matter of the testimony, not the particular slides. We're objecting to his testimony about inventorship. We did withdraw the MIL, but we did not waive our objection. We're asserting our objection here to his testimony about inventorship.

JUDGE MCNAMARA: Did you tell Mr. Sharma and his team that you were still objecting to the content of inventorship? I had some issues with this, but did you tell the other side that you were still objecting to the content? Was that transmitted either in writing or orally?

MR. SANDERS: Your Honor, we never withdrew the objection. We did not voice the objection again in the meet and confer.

JUDGE MCNAMARA: Mr. Nester?

MR. NESTER: My understanding, Your Honor, is they didn't raise it.

MR. SHARMA: Yeah.

JUDGE MCNAMARA: Okay. Here's the problem I'm having. I don't think you can comment on someone else's testimony, Dr. Woloszko. If you have facts that help support the Respondents' problem with inventorship, that's one thing. But the problem that I have is that you were not a contemporary of Dr. Na or Mr. Kim. They have provided facts, and I don't think it's within your expertise, as great as your expertise is, to comment on either what Mr. Kim or what Dr. Na said with respect to inventorship. The facts are the facts. So your ability to comment on what they say is not possible.

THE WITNESS: And I don't intend to make any such comments.

JUDGE MCNAMARA: Okay. Mr. Sharma, let's start there.

Mr. Sanders, if it's going into a territory where it goes beyond simple facts that explain why or why not something contributed to inventorship, then you're free to stand up and object, and I'll consider that. I did have problems when I saw the MILs with Dr. Woloszko testifying about inventorship based on what I saw then. So that still

1 remains. He can't testify about the application of law to
2 fact. He can't give an ultimate conclusion of law.
3 Same thing was true, again, with another witness
4 who was withdrawn who was going to testify on inequitable
5 conduct. You can't testify on the elements to which -- when
6 you don't have that expertise. So let's see where this
7 goes. Let me keep this short. Let's see where this goes.
8 But if -- Mr. Sharma, can you get around, since
9 they had objections to all of, as I understand, all of the
10 slides on inventorship -- Mr. Sanders?
11 MR. SANDERS: Yes, Your Honor. In particular, I
12 mean, it starts on the first one stating that Mr. Kim
13 created a presentation... this is disputed territory about
14 whose drawings are in the presentation.
15 JUDGE MCNAMARA: Absolutely. Absolutely. He
16 cannot comment on what Mr. Kim said or did not say or the
17 timing of it. The timing is -- we know what the time frame
18 is. We know what the contemporaneous meetings were, so he
19 cannot comment on that.
20 So the slides you object to are 157 through what,
21 Mr. Sanders?
22 MR. SANDERS: It is through 161, Your Honor.
23 JUDGE MCNAMARA: Okay. I'm going to take a quick
24 look.
25 MR. SANDERS: It starts at 155 actually,

Your Honor.

JUDGE MCNAMARA: I'm not going to take too long with this. I can go through quickly.

There's no problem with the first -- with 155. It's merely a statement of fact.

MR. SHARMA: Yes, Your Honor.

JUDGE MCNAMARA: Hold on. It's not necessarily. There are disputes about some of the presentation elements.

So I think if you reword that, Mr. Sharma, but this slide would be out as is. And I'm referencing 155, that's out.

MR. SHARMA: Your Honor, may I seek a clarification?

JUDGE MCNAMARA: I'm sorry?

MR. SHARMA: On slide --

JUDGE MCNAMARA: 55 is out as it is. That slide is out because there is a comment here on an ultimate -- there is more to it than just Mr. Kim's presentation. It was a combined presentation based on the facts, or there was -- there were two people involved here. That's out, as it is. As it stands. I'm not necessarily saying the evidence is all out. This slide is out. Okay?

I'm looking at slide 161. He cannot comment, 161. The first point of 161 is out. He cannot comment on the numbers of claims that are identified as significant or

not significant.

He can't comment on what is considered -- we know what the elements of the claims are. I'm going to have to match those. We're going to have to sit down. He is not -- he cannot comment on the parts that are or aren't central because of the kind of analysis that we have to do. We have to go claim by claim, compare side by side, so that's out.

MR. SHARMA: Okay. Sure, Your Honor.

JUDGE MCNAMARA: At least that slide is out. If there's a different way that you can present it, that's fine. Let's see where you go with starting at slide 157.

MR. SHARMA: Your Honor, slide 156 is simply facts that were recited when -- Dr. Woloszko was present in the room and Mr. Kim was testifying.

JUDGE MCNAMARA: I'm sorry. You're going fast again.

I know what facts were presented. I do not -- Dr. Woloszko is not in a position to basically comment on what was described or not described. There are still some issues about that.

MR. SHARMA: I can go straight to slide 157, Your Honor.

JUDGE MCNAMARA: Great. Let's see where it goes. I'm not saying that the facts necessarily are out. I'm just saying his comment, any comments on the facts or what they

1 did or didn't say to one another, given that he wasn't there
2 contemporaneously.
3 MR. SHARMA: Okay, Your Honor. I'm going to
4 simply ask him what did he and Mr. Kim testify, but if you
5 don't want me to go there, I won't ask him. I'm not going
6 to ask him whether good or bad, simply what did he hear
7 Mr. Kim testify. That's on slide 156.
8 JUDGE MCNAMARA: There is a problem with that. I
9 heard Mr. Kim's testimony.
10 MR. SHARMA: Then we don't need to have Dr.
11 Woloszko repeat it.
12 JUDGE MCNAMARA: He does not need to repeat
13 facts. They are already in evidence. And the problem is
14 there is still, Mr. Sharma, there's still a dispute about
15 who presented what in that series of meetings. So this is
16 just not territory for --
17 MR. SHARMA: Yes. Dr. Woloszko is not going to
18 testify whether he was right or wrong.
19 JUDGE MCNAMARA: I don't need to rehear the
20 facts. They are in evidence.
21 MR. SHARMA: Okay. Your Honor, then slide 157,
22 158, 159, and 160, I'll just deal with those, and on
23 those --
24 JUDGE MCNAMARA: Let's see where they go.
25 MR. SHARMA: Thank you, Your Honor.

JUDGE MCNAMARA: Mr. Sanders?

MR. SANDERS: Your Honor, the content of the slide is quite separate, I think, here from the titles. The titles are regurgitating the facts.

JUDGE MCNAMARA: I agree, but the problem is that the way some of this is worded is a problem. Like Mr. Kim's presentation, we don't know to state the obvious, we don't know entirely what was part of a written presentation, an oral presentation, some of this language is too broad and may not apply. There are disputes.

So go ahead. Let me see where you're going, Mr. Sharma.

MR. SHARMA: Let's go to slide 157.

JUDGE MCNAMARA: Let's start there.

Q. Dr. Woloszko, do you see on slide 157 on the top is claims from the '836 patent?

A. Yes.

Q. And we have certain claims -- 1, 7, 8, 19, and 22 highlighted?

A. Yes.

Q. What's unique about those claims?

A. All those claims are mentioning either radiofrequency or a specific frequency of 2 MHz or a range including 2 MHz of --

(Clarification requested by the court reporter.)

-- all those claims mention either alternating radiofrequency or gave a limitation in the frequency at either 2 MHz or a range of 05 to 10 MHz.

Q. On slide 157, on the bottom, do you see claims from the '379 patent?

A. Yes.

Q. And do you see the claims 1, 6, and 15 of the '379 patent contain?

A. Yes. These are the claims --

MR. SANDERS: Your Honor, we object. The '379 patent has been terminated from this investigation.

JUDGE MCNAMARA: Mr. Sharma?

MR. SHARMA: I withdraw the question, Your Honor.

JUDGE MCNAMARA: Thank you.

Q. Next slide. On slide 158, you have claims from the '836 patent?

A. Yes.

Q. Do you see slides 27, 28, and 29 contain highlights?

A. Yes.

Q. What's unique about claims 27, 28, and 29 of the '836 patent?

A. Those three claims of the '836 patent include the limitation of a drive module.

Q. Moving to the left on the 158 slide, you have

claims 1 and 11 of the '536 patent that contain highlights. Do you see that?

A. Yes.

Q. What's so special about claims 1 and 11 of the '536 patent?

A. Both those claims mention a motor.

Q. I didn't hear that. Would you repeat it?

A. Both those claims mention the limitation of a motor.

Q. Thank you. On the left-hand side of slide 158 we have claims from the '379 patent, and claims 3, 4, 12, and 13 contain highlights. Do you see that?

A. Yes.

JUDGE MCNAMARA: Pardon me, Mr. Sharma. There is an objection again from Mr. Sanders.

MR. SANDERS: Yes. Thank you, Your Honor. It's the same objection. The '379 patent has been terminated from the investigation.

JUDGE MCNAMARA: Mr. Rauh? I didn't call on you before.

MR. RAUH: Thank you, Your Honor. Aaron Rauh for the Staff. I agree, the '379 is out.

MR. SHARMA: I withdraw my question to the '379, Your Honor.

JUDGE MCNAMARA: Okay. But you can keep going

with respect to the '836, of course.

MR. SHARMA: Yes, Your Honor.

JUDGE MCNAMARA: And the '536 to the extent that you can.

MR. SHARMA: Yes.

Q. Next slide?

Slide 159, on the top, Dr. Woloszko, do you see claims from the '536 patent?

A. Yes.

Q. And you have claims 4, 5, 14, 15, containing highlights?

A. Yes.

Q. What's special about claims 4, 5, 14, 15 of the '536 patent?

A. These four claims mention the limitation of embedded LED in the handpiece -- in the handpiece.

Q. And, finally, on the bottom half of this slide, 159, you have claims of the '812 patent, and claims 4, 5, 17 contain highlights on them.

What is special about the claims that have been highlighted from the '812 patent?

A. The same as before. Those three claims have a limitation of using at least one embedded LED within the user holdable device.

JUDGE MCNAMARA: Mr. Sharma, what you're saying

is that at least those -- the same mention is made in RX-1731.2? It's the same thing at CX-0250C, without going into commentary about the accuracy or not, but they are mentioned in what was labeled or what's called the Full Automatic RF MTS; is that correct? Is that what you're getting at or saying?

MR. SHARMA: Your Honor, may I confer with my colleagues?

JUDGE MCNAMARA: Yes.

MR. SHARMA: Yes, Your Honor. Okay. I'm not asking Dr. Woloszko --

JUDGE MCNAMARA: I understand. I just wanted to make sure that that was the correlate.

MR. SHARMA: Yes, Your Honor.

Q. Next slide, please. We're on slide 160.

Dr. Woloszko, we have claims 1, 11 from the '536 patent that have been highlighted.

A. Yes.

Q. And we also have claims 1 and 12 from the '812 patent that have been highlighted.

What's unique about these claims from the '536 and '812 patent?

A. So with claim 1 and 11 of the '536 have the limitation of releasably couplable deployable needle assembly --

(Clarification requested by the court reporter.)

A. -- the claim 1 and 11 from the '536 patent mention releasably couplable deployable needle assembly, basically a needle assembly that can be releasably and couplable from the --

-- releasably and couplable from the device, and patent '812, claim 1 and 12, both have a limitation of releasably couplable needle module.

Q. That's all on that issue. Thank you.

JUDGE MCNAMARA: Thank you, Mr. Sharma.

MR. AIRAN: Good afternoon, Your Honor. Dave Airan on behalf of Jeisys and Cynosure. I have a few final questions for this witness.

DIRECT EXAMINATION (continued)

BY MR. AIRAN:

Q. Dr. Woloszko, have you prepared some slides relating to your responses to Drs. van der Weide and Goldberg?

A. Yes, I have.

Q. And if we can have slide 165, please.

Dr. Woloszko, did Dr. van der Weide test the products at issue?

A. No, he did not. He only tested a small part of it.

Q. Did he use a different power supply than those

for Woloszko Innovations Consulting relate to RF microneedling?"

You answered, "No."

Did I read that correctly?

A. That's correct, but I work in a product very similar. It is not microneedling, but the technology is very similar.

Q. Let's now turn to the '536 patent family. The specification discloses that the user can adjust the distance that the needles extend, right?

A. Say it again? Repeat the words?

Q. Sure. The specification discloses that the user can adjust the distance that the needles extend, correct?

A. They said -- I believe so. Show me the wording, if you don't mind, where it says that. I know they mentioned a desired distance.

Q. Perhaps your deposition will refresh you. Let's go to CX-3064 at 33, your September 15th deposition, page 456, 7-10.

A. Okay.

Q. And I'll ask my question again.

The specification discloses that the user can adjust the distance that the needles extend, right?

A. I said so then. It is probably true.

Q. Okay. You agree that a user can set operational

parameters to select a desired extension of the needles in the '536 patent, right?

A. Yes.

Q. Now let's talk about the Mehta reference. You testified about Mehta today, right?

A. Yes.

Q. You understand that the Mehta reference was considered by the Patent Office, right?

A. I believe so, yes.

Q. You understand that Examiners are assumed to have some experience in interpreting the references before them, right?

A. Supposedly.

Q. Let's take a look at one of your slides about Mehta, RDX-10 at 112, is what you showed in blue on Fig. 5 on this slide what you believe is the motor in Mehta?

A. Sorry, it's number 250, which is called the actuator, and later on the actuator comprises a motor, yes. So 250 is part of the motor assembly. It is difficult to see. Difficult to -- the motor -- the motor is probably part of 250 or vice versa.

Q. Is what you colored in blue with the label 250 intended to indicate where the motor is?

A. It is where the motor is, yes.

Q. Now let's take a look at Fig. 2D in Mehta. We

can see it on RDX-10 at 140.

A. Yes.

Q. And in this slide is the area that's -- let me actually start that again.

Am I correct that you would expect the LED in Mehta to be in the area of item 216?

A. Yeah. He mentioned that the LED is, you see on the distal end of the treatment unit. The distal end, as Mehta mentioned, is proximal, as Mehta mentioned, so it's somewhere in this area.

Q. And 216 is that window, right?

A. The window, yes, mm-hmm.

Q. Now let's take a look at RDX-10 at 107.

Is it your opinion that what's circled in green on Fig. 2D on that slide is the proximal end of Mehta's user holdable device?

A. Yep. It's -- it should have been the same dimension if in the same position as the previous circle, but, yes, it's the same area.

Q. And now let's take a look at Mehta itself, which is RX-307, and specifically at 54 of the exhibit. There is text right at the top of column 33, lines 1-7.

A. Okay. This is Mehta, okay.

Q. Yes, it is. And do you recall testifying in your direct about this array 342?

A. Yes.

Q. That array 342 is a virtual array, right?

A. Yeah. This is not an image. This is not a camera. This is a representation, a poor representation.

Q. The array 342 is not the array of needles themselves, right?

A. That's correct.

Q. Now let's talk about the Na '848 reference. The Na '848 publication does not mention radiofrequency, correct?

A. It mentioned energy. I read it yesterday again. I thought it did, but -- do I have a copy of it here? I would like to read it.

Q. It was one of the references you addressed on direct. It should be in your binder.

A. I don't know what's where. If you can help me where it is.

JUDGE MCNAMARA: Mr. Sanders, can you help Dr. Woloszko?

MR. SANDERS: May I approach, Your Honor?

JUDGE MCNAMARA: Yes.

It's a long day and there are a lot of paper.

A. It mentions a waveform including multiple pulses. He doesn't exclude RF but -- he mentioned delivering energy to the needles. In an example, he said, high frequency that

vibrates the needles -- will vibrate the needle without any kind of actuator to make the wound bigger, as Ganz discloses, but it's a general -- he doesn't mention or include or exclude RF.

Q. Just to be clear. The Na '848 publication does not mention radiofrequency, correct?

A. No.

Q. The Na '848 publication does not mention supplying a radiofrequency signal to needles, correct?

A. That's correct.

Q. There is no motor or other active mechanism for moving the needles in the Na '848 patent, right?

A. I disagree. You mentioned vibrating the needles. Again, if you say current, the needle vibrates, you need some kind of actuator to vibrate them or it's magic.

Q. There's no motor or other active mechanism for moving the needles into the skin and out of the skin in Mehta, correct? In Na '848. I misspoke.

A. He said that the vibration can have -- you know, it's energy assisted. The vibration can assist to penetrate into the skin but does not provide any longitudinal movement of the needle to penetrate the skin.

Q. In your view, Na '848 does not have both a needle module and a needle assembly, correct?

A. It doesn't have a needle assembly, but it would

have a needle module, which is the whole device, which is disposable.

Q. Do you recall testifying about written description in your direct testimony?

A. Yes.

Q. According to the understanding you applied for the purposes of reaching your opinions on written description, verbatim description of the claimed subject matter is required to meet the written description requirement, correct?

A. Yes.

Q. The '774 patent discloses pulsed RF signals, right?

A. Correct.

Q. In your view an RF generator is generic machinery. Do I have that right?

A. I won't call it machinery, but medical generator can be generic. Some of them are, some are not, but, yeah.

Q. In your view there's nothing inventive about selecting an RF generator, correct?

A. I said, if you select an existing system, you don't invent a new system.

Q. Can we take a look at RX-10 at 94, please?

I have the wrong one. I'll move on.

In your view there's nothing technologically

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DEVICES AND COMPONENTS THEREOF

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A. It does, yes.

Q. Is it your view that a user selecting a cartridge with a particular needle length would satisfy the desired distance claim limitations in the Family Two patents?

A. This -- this, yes, this would be one -- one -- one embodiment that would satisfy this, this specification. Doesn't mean adjustable, it means a desired distance.

Q. Would a motor extending a plurality of needles to a predetermined distance constitute extending extendable needles a desired distance as claimed in the Family Two patents?

A. As long as you can program this distance, yes.

Q. Does the ability of a user to check where the needles are located in the skin and then adjust needle depth sufficient to meet the desired distance claim limitations in the Family Two patents in your view?

A. It would also satisfy as long -- yes, it will also satisfy the claim.

Q. In your view the fact that an actuator can advance and retract needles necessarily means that the motor controls -- let me withdraw that and start over. I apologize.

In your view the fact that a motor can advance and retract needles necessarily means that the motor controls the desired distance of needle extension from an

end surface as recited in the Family Two patent claims?

A. No. It does not. Motor, the type of motor, some motor --

Q. You're fine, Dr. Woloszko. There's no question pending.

A. Okay.

Q. Mehta discusses changing the angle of insertion of a needle cartridge, right?

A. He also described that, yes.

Q. Changing the angle of insertion does not adjust the distance that Mehta's needles are extended from the needle assembly end surface, correct, just the angle of insertion?

A. Yes. It would change the depth but not the distance.

Q. Right. So it just changes the angle at which the needles are fully extended, right?

A. Yes, so the depth of the needle. It doesn't change the distance from the end surface.

Q. Okay.

MR. RAUH: I pass the witness.

JUDGE MCNAMARA: Thank you.

Is there any redirect examination?

MR. SHARMA: Good morning, Your Honor. Anupam Sharma for the Respondents. No questions for Dr. Woloszko.