

## OPEN/CLOSED SESSIONS

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| <p style="text-align: right;">813</p> <p>1 UNITED STATES INTERNATIONAL TRADE COMMISSION</p> <p>2 Washington, D.C.</p> <p>3 Before the Honorable MaryJoan McNamara</p> <p>4 Administrative Law Judge</p> <p>5 -----x</p> <p>6 In the Matter of Investigation No.</p> <p>7</p> <p>8 CERTAIN DERMATOLOGICAL TREATMENT 337-TA-1356</p> <p>9 DEVICES AND COMPONENTS THEREOF</p> <p>10 -----x</p> <p>11</p> <p>12 International Trade Commission</p> <p>13 500 E Street, SW</p> <p>14 Washington, D.C.</p> <p>15</p> <p>16 Evidentiary Hearing</p> <p>17 Tuesday, November 7, 2023</p> <p>18 Volume IV</p> <p>19</p> <p>20 The parties met pursuant to notice of the</p> <p>21 Administrative Law Judge at 9:30 a.m. Eastern.</p> <p>22</p> <p>23</p> <p>24 Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR</p> <p>25</p>                                       | <p style="text-align: right;">815</p> <p>1 A P P E A R A N C E S (continued):</p> <p>2</p> <p>3 Counsel for Respondent EndyMed Medical Inc.; EndyMed Medical</p> <p>4 Ltd.:</p> <p>5 PEARL COHEN ZEDEK LATZER BARATZ LLP</p> <p>6 7 Times Square, 19th Floor</p> <p>7 New York, New York 10036</p> <p>8 (646) 878-0800</p> <p>9 Guy Yonay, Esq.</p> <p>10 Kyle Auteri, Esq.</p> <p>11</p> <p>12 Counsel for Respondent Cutera, Inc.; Ilooda Co., Ltd.:</p> <p>13 COVINGTON &amp; BURLING LLP</p> <p>14 850 Tenth Street, NW</p> <p>15 Washington, DC 20001</p> <p>16 (202) 662-6000</p> <p>17 Kiersten Choi, Esq.</p> <p>18 Brian Nester, Esq.</p> <p>19 Yong Joon Kwon, Esq.</p> <p>20 Alexander Trzeciak, Esq.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 CONTINUED ON FOLLOWING PAGE</p> |
| <p style="text-align: right;">814</p> <p>1 A P P E A R A N C E S:</p> <p>2</p> <p>3 Counsel for Complainant Serendia, LLC:</p> <p>4 LATHAM &amp; WATKINS LLP</p> <p>5 555 11th Street, NW</p> <p>6 Washington, DC 20004</p> <p>7 (202) 637-2200</p> <p>8 Michael A. David, Esq.</p> <p>9 Cecilia Sanabria, Esq.</p> <p>10 Kevin C. Wheeler, Esq.</p> <p>11 Bradley A. Hyde, Esq.</p> <p>12 Charles H. Sanders, Esq.</p> <p>13 Ethan L. Plail, Esq.</p> <p>14 Daniel R. McNeely, Esq.</p> <p>15 David K. Callahan, Esq.</p> <p>16</p> <p>17 Counsel for Respondent Cynosure, LLC; Jeisys Medical Inc.:</p> <p>18 LEYDIG, VOIT &amp; MAYER, LTD.</p> <p>19 Two Prudential Plaza</p> <p>20 Chicago, Illinois 60601</p> <p>21 (312) 616-5600</p> <p>22 David M. Airan, Esq.</p> <p>23 James W. Sanner, Esq.</p> <p>24</p> <p>25 CONTINUED ON FOLLOWING PAGE</p> | <p style="text-align: right;">816</p> <p>1 A P P E A R A N C E S (continued):</p> <p>2</p> <p>3 -and-</p> <p>4 Counsel for Respondent Cutera, Inc.; Ilooda Co., Ltd.:</p> <p>5 COVINGTON &amp; BURLING LLP</p> <p>6 3000 El Camino Real</p> <p>7 Palo Alto, California 94306</p> <p>8 (650) 632-4700</p> <p>9 Anupam Sharma, Esq.</p> <p>10 Robert T. Haslam, Esq.</p> <p>11</p> <p>12 -and-</p> <p>13 COVINGTON &amp; BURLING LLP</p> <p>14 415 Mission Street, Suite 5400</p> <p>15 San Francisco, California 94105</p> <p>16 (415) 591-6000</p> <p>17 Dale A. Rice, Esq.</p> <p>18 Thomas E. Garten, Esq.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 CONTINUED ON FOLLOWING PAGE</p>                                                                                 |

## OPEN/CLOSED SESSIONS

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| <p style="text-align: right;">817</p> <p>1 A P P E A R A N C E S (continued):</p> <p>2</p> <p>3 Counsel for Respondent Aesthetics Biomedical, Inc.; Cartessa</p> <p>4 Aesthetics, LLC; Sung Hwan E&amp;B Co., Ltd. d/b/a SHEnB Co.</p> <p>5 Ltd.:</p> <p>6 JONES DAY</p> <p>7 555 South Flower Street</p> <p>8 Los Angeles, California 90071</p> <p>9 (213) 489-3939</p> <p>10 Steven J. Corr, Esq.</p> <p>11</p> <p>12 -and-</p> <p>13 JONES DAY</p> <p>14 901 Lakeside Avenue</p> <p>15 Cleveland, Ohio 44114</p> <p>16 (202) 879-3939</p> <p>17 Ryan B. McCrum, Esq.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 CONTINUED ON FOLLOWING PAGE</p>                   | <p style="text-align: right;">819</p> <p>1 A P P E A R A N C E S (continued):</p> <p>2</p> <p>3 Counsel for the Office of Unfair Import Investigations:</p> <p>4 U.S. International Trade Commission</p> <p>5 500 E Street, SW</p> <p>6 Washington, DC 20436</p> <p>7 (202) 205-2000</p> <p>8 Aaron D. Rauh, Esq.</p> <p>9 Investigative Attorney</p> <p>10 Jeffrey Hsu, Esq.</p> <p>11 Supervisory Attorney</p> <p>12</p> <p>13</p> <p>14</p> <p>15 **Index appears at end of transcript**</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p style="text-align: right;">818</p> <p>1 A P P E A R A N C E S (continued):</p> <p>2</p> <p>3 -and-</p> <p>4 Counsel for Respondent Aesthetics Biomedical, Inc.; Cartessa</p> <p>5 Aesthetics, LLC; Sung Hwan E&amp;B Co., Ltd. d/b/a SHEnB Co.</p> <p>6 Ltd.:</p> <p>7 JONES DAY</p> <p>8 250 Vesey Street</p> <p>9 New York, New York 10281</p> <p>10 (212) 326-3939</p> <p>11 Yeah-Sil Moon, Esq.</p> <p>12</p> <p>13</p> <p>14 -and-</p> <p>15 JONES DAY</p> <p>16 500 Grant Street, Suite 4500</p> <p>17 Pittsburgh, Pennsylvania 15219</p> <p>18 (412) 391-3939</p> <p>19 Marlee R. Hartenstein, Esq.</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 CONTINUED ON FOLLOWING PAGE</p> | <p style="text-align: right;">820</p> <p>1 O P E N S E S S I O N</p> <p>2 P R O C E E D I N G S</p> <p>3 (In session at 9:30 a.m.)</p> <p>4 JUDGE MCNAMARA: Good morning, everyone. Please</p> <p>5 be seated.</p> <p>6 Let me see. I have here the time, and I guess</p> <p>7 what I need to know also is how you made out in terms of</p> <p>8 carving up another three hours, if I go that direction,</p> <p>9 which, as you know, it sounds like I'm going in that</p> <p>10 direction, and a revision to the original calculations</p> <p>11 that -- well, the ones that you gave me on Monday to account</p> <p>12 for, again, translation and so forth.</p> <p>13 MR. WHEELER: Your Honor, I hate to interject,</p> <p>14 but there is one item of business that impacts the time that</p> <p>15 I'd like to announce to the Court before that, and that is</p> <p>16 that Complainant has reached a settlement with respect to</p> <p>17 some additional Respondents.</p> <p>18 JUDGE MCNAMARA: Yea.</p> <p>19 MR. WHEELER: That's with respect to the SHEnB</p> <p>20 and Cartessa Respondents.</p> <p>21 JUDGE MCNAMARA: Okay. Very good.</p> <p>22 MR. WHEELER: So before we address timing,</p> <p>23 Complainants would like to orally move to suspend the</p> <p>24 procedural schedule until November 20th with respect to the</p> <p>25 SHEnB and Cartessa Respondents. We understand that is</p> |

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| <p>865</p> <p>1 JUDGE MCNAMARA: And you are on slide 4,</p> <p>2 referencing information on slide 4.</p> <p>3 A. Correct.</p> <p>4 Q. You're on slide 4 now. Have you published any</p> <p>5 papers in peer-reviewed publications?</p> <p>6 A. Yes. I published a few papers, but when you work</p> <p>7 for industry, you mostly focus on the patents. But I have</p> <p>8 about 49 peer-reviewed publications, some of them in the</p> <p>9 well-renown magazines, or this is an example of IEEE on</p> <p>10 plasma science where we describe new technology using</p> <p>11 radiofrequency to create plasma to remove tissue, as well as</p> <p>12 several book chapters. This is one book chapter dedicated</p> <p>13 on type of radiofrequency used for coagulation, and plasma</p> <p>14 ablation of tissue in various fields of medicine and</p> <p>15 dentistry.</p> <p>16 Q. Are you an inventor on any U.S. patents?</p> <p>17 A. As I mentioned before, yes, about 114 so far</p> <p>18 issued U.S. patents.</p> <p>19 Q. Can you briefly summarize the subject matter of</p> <p>20 the patents on which you are an inventor?</p> <p>21 A. I believe over a hundred of them are dedicated to</p> <p>22 some type of radiofrequency systems or methods, and here I</p> <p>23 mention three of them. The first one is some work I did</p> <p>24 with a professor where we showed that radiofrequency applied</p> <p>25 in short pulses is able to induce tissue healing.</p> | <p>867</p> <p>1 JUDGE MCNAMARA: Thank you very much. Then</p> <p>2 Dr. Woloszko is accepted as an expert for the topics upon</p> <p>3 which he has been called to testify.</p> <p>4 MR. SHARMA: Thank you, Your Honor.</p> <p>5 Q. Next slide. Your slide number 7 now.</p> <p>6 Dr. Woloszko, what was your task regarding the</p> <p>7 Family One patents in this case?</p> <p>8 A. I was asked to evaluate whether the Family One</p> <p>9 patent, at that time was patent '836, '379 and '444 were</p> <p>10 invalid as under 103. Since then, the patent '444 has been</p> <p>11 called indefinite. The '379 dropped. So I basically</p> <p>12 focused on patent '836.</p> <p>13 Q. And what is your opinion regarding the claims of</p> <p>14 the '836 patent?</p> <p>15 A. My opinion is that it is invalid as obvious under</p> <p>16 103.</p> <p>17 Q. Next slide.</p> <p>18 JUDGE MCNAMARA: Mr. Sharma, would you do me a</p> <p>19 favor and make sure and just mention the slide number?</p> <p>20 Because when you say next slide, sometimes people jump</p> <p>21 around.</p> <p>22 MR. SHARMA: Yes, I will, Your Honor.</p> <p>23 JUDGE MCNAMARA: Thank you very much.</p> <p>24 Q. We're on slide 8 now.</p> <p>25 Dr. Woloszko, what does this slide show?</p>                                                                                                                                                                                          |
| <p>866</p> <p>1 And the second one shows how we can apply similar</p> <p>2 technology to the skin to improve the skin quality and</p> <p>3 generate heating of the dermis.</p> <p>4 And the last one is another patent for a system</p> <p>5 which is less invasive, basically treating what's called the</p> <p>6 stratum corneum, which is a very superficial layer of the</p> <p>7 skin.</p> <p>8 Q. Does Exhibit RX-3211 contain your complete CV?</p> <p>9 A. Sorry? Yes.</p> <p>10 Q. Next slide. Your slide number 5. What does</p> <p>11 slide number 5 show?</p> <p>12 A. This is the definition of a person of ordinary</p> <p>13 skill that has been, I guess, ruled upon recently.</p> <p>14 Q. As of 2010, were you a person of ordinary skill</p> <p>15 according to the definition on slide 5?</p> <p>16 A. Yes.</p> <p>17 MR. SHARMA: Your Honor, we would like to tender</p> <p>18 Dr. Woloszko as an expert in the field of surgical systems</p> <p>19 that employ high frequencies to treat and remodel the dermal</p> <p>20 layer.</p> <p>21 JUDGE MCNAMARA: Who is responding?</p> <p>22 MR. SANDERS: Charles Sanders on behalf of</p> <p>23 Serendia. No objection, Your Honor.</p> <p>24 MR. RAUH: Aaron Rauh for the Staff. No</p> <p>25 objection, Your Honor.</p>                                                                                                                                                                                            | <p>868</p> <p>1 A. This slide shows the patent. We have -- we are</p> <p>2 using as prior art, to show prior art to the '836 patent.</p> <p>3 Mentioned three patents. The so-called Manstein patent that</p> <p>4 was filed in 2005, the Hantash patent filed in 2007, as well</p> <p>5 as the Ganz application, patent application, that was</p> <p>6 published in 2007.</p> <p>7 Q. Were these three references, the Manstein,</p> <p>8 Hantash, and Ganz, available to the public before the</p> <p>9 priority date of the '836 patent?</p> <p>10 A. Yes, '836 priority date has been agreed to be</p> <p>11 June 14, 2011, which was posterior to that.</p> <p>12 Q. Dr. Woloszko, a minute ago you mentioned the Ganz</p> <p>13 patent. You are referring to the Ganz application?</p> <p>14 A. I said Ganz application, yes, that's what I said.</p> <p>15 Q. And for the record, Manstein is at RX-0304,</p> <p>16 Hantash is CX-1089, and Ganz at RX-0329.</p> <p>17 Let's go to slide number 9.</p> <p>18 Dr. Woloszko, what does slide number 9 show?</p> <p>19 A. The slide number 9 shows a summary of my opinions</p> <p>20 for the three claims asserted by Serendia. I believe that</p> <p>21 claim 1 of '836 patent is obvious based on Ganz in view of a</p> <p>22 person of skill in the art.</p> <p>23 Claim 9 is obvious based on Ganz in view of</p> <p>24 knowledge of a person skilled in the art and further in view</p> <p>25 of Manstein.</p> |

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| <p style="text-align: right;">869</p> <p>1 Claim 22 is obvious based on Ganz in view of</p> <p>2 knowledge of a person skilled in the art and also in view of</p> <p>3 Hantash.</p> <p>4 Q. Let's go to slide number 10.</p> <p>5 Dr. Woloszko, what does slide 10 show?</p> <p>6 A. These are the latest claim construction</p> <p>7 agreed-upon terms.</p> <p>8 Q. Let's go to slide 11.</p> <p>9 What does slide 11 show?</p> <p>10 A. This is the Court's issued claim construction for</p> <p>11 Family One.</p> <p>12 Q. Did you apply the construction shown on slide 10</p> <p>13 and slide 11 in coming up with your opinions?</p> <p>14 A. Yes, I did.</p> <p>15 Q. Next slide. Dr. Woloszko, what does slide 12</p> <p>16 show?</p> <p>17 A. It's kind of a summary what happened over the</p> <p>18 past, you know, between the '90s and the late 2010 in this</p> <p>19 field. It's a very high level skin -- treatment for skin</p> <p>20 system.</p> <p>21 Q. What trends were going on in the industry in the</p> <p>22 '90s?</p> <p>23 A. So 1990s it was the technology used, and I think</p> <p>24 Dr. Goldberg talked about it where invasive, what we call</p> <p>25 skin resurfacing, whether it was driven by laser or</p>                                                                                                                                                                                                                                                                                    | <p style="text-align: right;">871</p> <p>1 some healing.</p> <p>2 So from those two aspects I mentioned before,</p> <p>3 people understood that you want to be less invasive on the</p> <p>4 skin, and the notion of fractional lesion came up, so why,</p> <p>5 for the older skin, if you can only treat specific lesions,</p> <p>6 that would basically have an effect on the overall skin,</p> <p>7 such that you don't have any downtime, you reduce the risk,</p> <p>8 you basically make therapy much easier, less complicated,</p> <p>9 less risky, and also patients don't have to hide their face</p> <p>10 for weeks or months.</p> <p>11 Q. And what trends were going on in 2000s and in the</p> <p>12 decade ending in 2010?</p> <p>13 A. So many techniques has been developed, as I</p> <p>14 mentioned, basically, based on those things, and I show here</p> <p>15 on the right, this is one of the patents on which I'm an</p> <p>16 inventor that describes several systems, and you can see in</p> <p>17 the Fig. 6, this was one of the precursors of microneedle.</p> <p>18 This was a system using small, sharp, needle-type electrodes</p> <p>19 in a bipolar fashion moving inside the dermis to generate</p> <p>20 such healing response with some shrinking as well.</p> <p>21 Q. And the patent is U.S. 6,766,202; is that</p> <p>22 correct?</p> <p>23 A. Yes, from July 2004.</p> <p>24 Q. And the '202 patent, is that RX-0303?</p> <p>25 A. That's correct.</p>                                       |
| <p style="text-align: right;">870</p> <p>1 radiofrequency or was making a product removing the skin,</p> <p>2 both were effective, but had a long downtime and risk of</p> <p>3 scarring and a lot of risk of coloration changes in, you</p> <p>4 know, Asian skin, darker skins. So not very popular because</p> <p>5 of that.</p> <p>6 Q. And what was going on in the industry in the late</p> <p>7 1990s? I request you to speak slowly on behalf of the court</p> <p>8 reporter.</p> <p>9 A. Sorry?</p> <p>10 Q. I would request that you slow down on behalf of</p> <p>11 the court reporter.</p> <p>12 A. Sure. I will try. I'm sorry. I will slow down.</p> <p>13 In the '90s it was, as I mentioned previously, a</p> <p>14 lot of work on the effect of radiofrequency on tissue, and</p> <p>15 there were really two things that are relevant here. Number</p> <p>16 one, when you apply heat to tissue, it will shrink, same way</p> <p>17 if you wash a sweater too hot it will shrink. So the</p> <p>18 molecule contracts. This used first to shrink tendon,</p> <p>19 ligament when you have a joint, but people realize use on</p> <p>20 the skin, it would put the skin under tension and basically</p> <p>21 reduce the effect of wrinkles.</p> <p>22 Also, as I mentioned also, there was a lot of</p> <p>23 work and I was one of the pioneers in this field with my</p> <p>24 colleagues showing that radiofrequency and actually many</p> <p>25 other type of micro control injury to tissue could induce</p> | <p style="text-align: right;">872</p> <p>1 Q. Next slide. Slide 13, Dr. Woloszko, what does</p> <p>2 this show?</p> <p>3 A. As we said before, we believe that claim 1 of</p> <p>4 patent '836 is invalid in view of the knowledge -- it is</p> <p>5 obvious, sorry, in view of Ganz and with the knowledge of a</p> <p>6 person skilled in the art.</p> <p>7 Q. Let's go to slide 14. What is shown here on</p> <p>8 slide 14?</p> <p>9 A. This is -- it shows basically the first page of</p> <p>10 the Ganz patent, which is RX-0329. And also mentioned the</p> <p>11 field of the invention, which says a device for treating one</p> <p>12 or more layers of the skin, and it is a healing response.</p> <p>13 Q. One clarification. When you mentioned the Ganz</p> <p>14 patent, you meant Ganz application; is that correct?</p> <p>15 A. Oh, you're correct. This is Ganz application.</p> <p>16 Q. Next slide. Dr. Woloszko, on slide 14 what do</p> <p>17 Fig. 1 and 4 depict?</p> <p>18 A. This is some excerpt of the patent, and basically</p> <p>19 paragraph 51 shows that the patent is using electrode pins</p> <p>20 or needles that penetrate all the way into tissue, that they</p> <p>21 are connected to paragraph 11, to an energy source</p> <p>22 connecting to the plurality of electrodes, mentioned</p> <p>23 radiofrequency, and paragraph 10 clearly said that the</p> <p>24 electrode patent is also selected to create a zone of</p> <p>25 coagulative tissue surrounding each perforation, each</p> |

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| <p>873</p> <p>1 needle.</p> <p>2 JUDGE MCNAMARA: You're on slide 15.</p> <p>3 A. Slide 15.</p> <p>4 MR. SHARMA: Thank you. I'll be careful next</p> <p>5 time, Your Honor.</p> <p>6 Q. In summary, what is the subject matter of the</p> <p>7 Ganz application?</p> <p>8 A. The Ganz application is related to</p> <p>9 multi-electro-microneedle system that penetrates into the</p> <p>10 skin to generate coagulation around each needle. And this</p> <p>11 was to improve upon laser that do not penetrate in the skin.</p> <p>12 Q. Let's go to slide 16. What does the Ganz</p> <p>13 application disclose about the preamble of claim 1 of the</p> <p>14 '836 patent?</p> <p>15 A. Sorry?</p> <p>16 Q. What does the Ganz application disclose about the</p> <p>17 preamble of claim 1?</p> <p>18 A. Oh, the preamble is -- claim 1 of the preamble is</p> <p>19 about a skin treatment apparatus, and Ganz, in paragraph 1,</p> <p>20 disclosed that this is a device and all methods for treating</p> <p>21 one or more layers of the skin, so to treat the skin.</p> <p>22 Q. Let's go to slide 17.</p> <p>23 What does the Ganz application disclose about a</p> <p>24 plurality of electrodes as required by claim 1?</p> <p>25 A. Ganz clearly mentions in paragraph 10 that this</p>                                                                   | <p>875</p> <p>1 current alternates between them.</p> <p>2 Q. Does the Ganz application disclose anything about</p> <p>3 applying energy to bipolar electrodes?</p> <p>4 A. Yes, Ganz -- Ganz mentions bipolar, and</p> <p>5 radiofrequency electrodes, so yes.</p> <p>6 Q. And what kind of energy is applied to the bipolar</p> <p>7 electrodes in the Ganz application?</p> <p>8 A. In the Ganz application, radiofrequency</p> <p>9 alternating current is applied.</p> <p>10 Q. Does the alternating current in the Ganz</p> <p>11 application flow back and forth between the electrodes?</p> <p>12 A. Yes. When the electrodes -- when the alternating</p> <p>13 current is applied to electrodes, the flow will -- polarity</p> <p>14 will alternate with the current between positive or</p> <p>15 negative.</p> <p>16 Q. A person of ordinary skill in the art reading the</p> <p>17 Ganz application in 2010 would understand that the RF energy</p> <p>18 refers to alternating current, is that your testimony?</p> <p>19 A. Without any doubt.</p> <p>20 Q. Next slide. You're on slide 20.</p> <p>21 Dr. Woloszko, are you aware of any references in</p> <p>22 the art that talk about a relationship between</p> <p>23 radiofrequency and alternating current in the field of</p> <p>24 medical devices?</p> <p>25 A. There are many, many books, and articles. This</p> |
| <p>874</p> <p>1 patent is about a plurality of electrodes.</p> <p>2 Q. The Court has construed the term plurality of</p> <p>3 electrodes.</p> <p>4 Did you apply the Court's construction in forming</p> <p>5 your opinions?</p> <p>6 A. Yes, I did.</p> <p>7 Q. Next slide. On slide 18, what does the Ganz</p> <p>8 application disclose about the electrodes being bipolar as</p> <p>9 required by claim 1?</p> <p>10 A. So in paragraph 55, Ganz clearly mentioned that</p> <p>11 his invention can be used either with a monopolar or bipolar</p> <p>12 electrodes. Reinforced in paragraph 56, where it says in</p> <p>13 other embodiments electrodes are provided as a bipolar</p> <p>14 electrode arrangement.</p> <p>15 Q. And the Court has construed the term a plurality</p> <p>16 of electrodes, the electrodes being bipolar.</p> <p>17 Did you apply the Court's construction in forming</p> <p>18 your opinion?</p> <p>19 A. Yes, I did.</p> <p>20 Q. Slide 19, please. What does slide 19 show?</p> <p>21 A. This is the Court's claim construction related to</p> <p>22 a plurality of electrodes, the electrodes being bipolar, and</p> <p>23 excluded the INTRAcel configuration, and said that two or</p> <p>24 more electrodes, which can be needles or pins, that change</p> <p>25 or alternate between being positive or negative as the</p> | <p>876</p> <p>1 is an example of a medical journal, annals of internal</p> <p>2 medicine published in 1994 by Manolis and colleagues, where</p> <p>3 he defines clearly radiofrequency energy is a form of</p> <p>4 alternating currents.</p> <p>5 Q. What is the subject matter of the article shown</p> <p>6 on slide 20?</p> <p>7 A. This article is about radiofrequency catheter</p> <p>8 ablation for cardiac tachyarrhythmias for electrosurgeries.</p> <p>9 Q. Are you familiar with the journal called the</p> <p>10 Annals of Internal Medicine?</p> <p>11 A. Yes.</p> <p>12 Q. Is it a reputable journal?</p> <p>13 A. It's a -- it's a pretty reputable journal, yes.</p> <p>14 Q. Okay. And what is the date on which the article</p> <p>15 authored by Manolis was published?</p> <p>16 A. September 1994.</p> <p>17 Q. And for the record, the Manolis article is at</p> <p>18 CX-2657.</p> <p>19 Next slide.</p> <p>20 Dr. Woloszko, on slide 21, what does the Ganz</p> <p>21 disclose about the arrangement of electrodes required by</p> <p>22 claim 1?</p> <p>23 A. So the claim 1 mentions bipolar, Ganz mentioned</p> <p>24 that the electrode can be arranged as an array of</p> <p>25 electrodes, and it also mentions the electrode pairs.</p>                                                                                                                  |

## OPEN/CLOSED SESSIONS

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| <p>877</p> <p>1 Q. You know the Court has construed the term to</p> <p>2 exclude the INTRAcel configuration.</p> <p>3 A. It is when you -- when you read the electrode</p> <p>4 pairs, you think of a pair connecting -- related to each</p> <p>5 other independent from the other ones, and in no fashion is</p> <p>6 the INTRAcel configuration -- in no fashion would those</p> <p>7 claims be limited to the INTRAcel configuration.</p> <p>8 Q. And so just to clarify, are you aware that the</p> <p>9 Court has construed the claims to exclude the INTRAcel</p> <p>10 configuration; is that correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Is the Ganz reference limited to the INTRAcel</p> <p>13 configuration?</p> <p>14 A. As I said, there was no limitation whatsoever to</p> <p>15 this type of configuration.</p> <p>16 Q. And when you mention no limitation whatsoever,</p> <p>17 are you referring to the disclosure of the Ganz application?</p> <p>18 When you mention no limitation whatsoever, are</p> <p>19 you referring to the disclosure of the Ganz publication?</p> <p>20 A. This is the Ganz patent application, yes.</p> <p>21 Q. Next slide. Slide 22.</p> <p>22 What does the Ganz reference disclose about the</p> <p>23 electrodes that are configured to be insertable into the</p> <p>24 skin to be treated?</p> <p>25 A. So Ganz mentioned several parts in the patent.</p>                                                                                               | <p>879</p> <p>1 Q. Next slide. What does slide 24 depict?</p> <p>2 A. Fig. 24 on the left you have the claim 1 of the</p> <p>3 '836 patent that mentions configured to provide an</p> <p>4 alternating current RF current. What I'm showing on the</p> <p>5 right side is similar to what Mr. van der Weide --</p> <p>6 Dr. van der Weide showed. Basically this is what you would</p> <p>7 call an alternating current, basically a radiofrequency</p> <p>8 delivered to bipolar electrodes through alternating current.</p> <p>9 And you can see that the current oscillates</p> <p>10 around neutral value, that is zero. And what's important to</p> <p>11 define alternating current is that the same number of charge</p> <p>12 go one way and then come back the other way so that the</p> <p>13 surface area of what's in yellow here is similar to what's</p> <p>14 in green.</p> <p>15 Q. Does the graph on slide 24 show the type of</p> <p>16 current that is delivered to the electrodes in the Ganz</p> <p>17 application when RF energy is applied?</p> <p>18 A. Absolutely.</p> <p>19 Q. Next slide.</p> <p>20 Dr. Woloszko, we are on slide 25. What do the</p> <p>21 graphs on the left-hand side under the legend alternating</p> <p>22 current depict?</p> <p>23 A. So it shows -- basically the figure top left</p> <p>24 shows the same figure we saw before, alternating current,</p> <p>25 does not have to have a sinusoidal shape. You can have any</p>                    |
| <p>878</p> <p>1 I've put here two excerpts that I think are typical. So</p> <p>2 paragraph 1, he mentioned that it's important here that all</p> <p>3 the electrodes are inserted together as compared to one by</p> <p>4 one, and so to create perforation, perforation being, you</p> <p>5 know, puncture is a perforation, and to reinforce that, in</p> <p>6 paragraph 51, he mentioned the electrode pins are placed all</p> <p>7 the way into the tissue. And even furthermore, he said, if</p> <p>8 you want to have a deeper -- if you want to have a deeper</p> <p>9 lesion, you will place the tip even deeper into tissue</p> <p>10 layers. This is all in paragraph 51.</p> <p>11 Q. Next slide. On slide 23, what does the Ganz</p> <p>12 reference disclose about a radiofrequency RF generation</p> <p>13 module, the RF generation module electrically coupled with a</p> <p>14 plurality of electrodes?</p> <p>15 A. So paragraph 11 mentions the device includes an</p> <p>16 energy source coupled -- electrically coupled obviously to a</p> <p>17 plurality of electrodes. Later on in the same paragraph he</p> <p>18 says in preferred cases, the electrodes are radiofrequency</p> <p>19 electrodes and are configured to receive -- for receiving</p> <p>20 radiofrequency energy.</p> <p>21 Q. And the Court has construed the term</p> <p>22 radiofrequency generation module.</p> <p>23 Did you apply the Court's construction in forming</p> <p>24 your opinions?</p> <p>25 A. Yes.</p> | <p>880</p> <p>1 shape you want. This is an example of something that I've</p> <p>2 used for many, many years. Some people call it voltage</p> <p>3 pulses, but it's clearly -- basically other people call it a</p> <p>4 square wave. What's important is, and we disclose why</p> <p>5 this -- the fact that the current goes up very quickly and</p> <p>6 provides various benefit --</p> <p>7 (Clarification requested by the court reporter.)</p> <p>8 A. Sorry. And provides various benefits for</p> <p>9 specific type of electrosurgery. I apologize. I will slow</p> <p>10 down.</p> <p>11 But once again, what's important is the current</p> <p>12 oscillates around the line and you have some number of</p> <p>13 charge going one way, some number of charge going the other</p> <p>14 way.</p> <p>15 Q. And what does this slide 25 on the right-hand</p> <p>16 side depict under the legend direct current (DC)?</p> <p>17 A. They would be what people would call (DC) RF, and</p> <p>18 basically what happens here, you still have some type of</p> <p>19 oscillation, but the charges goes only one way. And you</p> <p>20 accumulate the charge, so basically on the alternating</p> <p>21 current, there is no transfer of charge, they oscillate,</p> <p>22 they go back and forth.</p> <p>23 When you have a (DC) component you will</p> <p>24 accumulate charge that will transfer from one side to the</p> <p>25 other side, basically the same thing, if you charge a</p> |

## OPEN/CLOSED SESSIONS

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| <p>881</p> <p>1 battery, you accumulate charges, and this can be, again,<br/>2 sinusoidal type of signal, or square wave, but then the<br/>3 charge don't oscillate in the same fashion.<br/>4 Q. Sometimes in the art is the direct current (DC)<br/>5 depicted by a straight line?<br/>6 A. Yes. You need to have a higher frequency.<br/>7 Q. Will a person of ordinary skill reading the Ganz<br/>8 patent in 2010 understand that the RF energy is deployed on<br/>9 the electrodes using direct current (DC)?<br/>10 A. Yes. At that time and still currently I don't<br/>11 know of any radiofrequency electrosurgical system that does<br/>12 not use alternating current. They would be illegal. They<br/>13 would be dangerous. And they would have many, many negative<br/>14 things that's very well known and also would lead to<br/>15 electrocorrosion. So if you connect microneedle, they would<br/>16 be gone within seconds and leaving tattoos of metal, of iron<br/>17 inside the skin of patient, and they wouldn't be very happy.<br/>18 Q. Are you aware of any medical systems in 2010 that<br/>19 are used for the skin treatment that use direct current<br/>20 (DC)?<br/>21 A. For skin treatment, I don't know any, no.<br/>22 Q. And a person of skill in the art would understand<br/>23 that the Ganz system delivers RF energy using alternating<br/>24 current?<br/>25 A. Without any doubt.</p> | <p>883</p> <p>1 called phoresis where you try to use a charge to push a drug<br/>2 or something into the tissue. There is another technology<br/>3 that FDA has issued a new guidance, a very low frequency,<br/>4 low power, no thermal ablation, and they show that having<br/>5 basically this current will lead to what is called cell<br/>6 apoptosis or called as programmed death. Basically you send<br/>7 current to the cell and they will not survive, and within<br/>8 minutes or hours, the dye that is used to treat cancers, it<br/>9 is very toxic to the cells, very well-defined.<br/>10 And some nerve stimulator are not designed for<br/>11 chronic stimulation, but you test whether you're close to a<br/>12 nerve, some of them use (DC), but the good one use a<br/>13 capacitor to prevent a (DC) component, but it can be used.<br/>14 Q. Next slide. What does slide 26 show?<br/>15 A. So this is -- this is a Korean patent<br/>16 application, Patent 10-2011-7005052, which is the original<br/>17 is RX-0124, the translation is RX-0125.<br/>18 Q. Who is the inventor on the patent shown,<br/>19 Dr. Woloszko? Who is the inventor on the application shown<br/>20 on slide 26?<br/>21 A. The author is Dr. Na, and I believe it is the<br/>22 same Dr. Na as the patent asserted in this case.<br/>23 Q. And what does slide number 26 show about radio<br/>24 waves?<br/>25 A. Basically, in paragraph 16, Dr. Na explained</p> |
| <p>882</p> <p>1 Q. And why would (DC) current not be used in a<br/>2 system like the one disclosed in Ganz?<br/>3 A. Where would --<br/>4 Q. Let me repeat the question.<br/>5 A. Repeat, yes.<br/>6 Q. Why would the (DC) current not be used in a<br/>7 system like Ganz?<br/>8 A. I think I answered the question a few seconds<br/>9 ago. It would be, first, illegal. You would not be able to<br/>10 put it on the markets in any country. FDA would not accept<br/>11 it. It would be dangerous. And he would really be -- not<br/>12 work very well.<br/>13 Q. Are there regulations promulgated by the<br/>14 government that limit the use of direct current in devices<br/>15 like one disclosed in Ganz application?<br/>16 A. Yes, the IEC 60601-2-2, which has been defined by<br/>17 the MT 17 committee and released by the IEC committee, this<br/>18 defines the international standard that is accepted by all<br/>19 European regulation, Japan and everywhere and obviously the<br/>20 FDA.<br/>21 Q. Broadly speaking of medical devices, sometimes<br/>22 (DC) current is used in medical devices?<br/>23 A. In very specific indications. They are usually<br/>24 either for very, very short time, and also low power. So<br/>25 few applications, the most common right now is something</p>                                                                                                             | <p>884</p> <p>1 that, given that high frequencies such as radio wave --<br/>2 radios waves, sorry, are basically alternating currents.<br/>3 Q. In other words, Dr. Na equated high frequencies<br/>4 such as radio waves to alternating current, correct?<br/>5 A. Yes, he did.<br/>6 Q. Do you know what kind of electrodes are used in<br/>7 the patent disclosed -- in the application shown here on<br/>8 slide 26?<br/>9 A. This is what is defined by the FDA or IEC<br/>10 standard as monopolar electrode where there is an electrode<br/>11 applied on one side of the body, that's the device 320,<br/>12 which is a microneedle system, and the current is closed by<br/>13 a neutral electrodes, which is in that case the ground, but<br/>14 neutral so the current closes a loop such that the<br/>15 alternating current can go between the electrodes.<br/>16 Q. The fact that the electrodes are used, monopolar<br/>17 electrodes, does that change your opinion in any manner?<br/>18 A. No. It is alternating polarity.<br/>19 Q. Next slide. We're on slide number 27.<br/>20 Dr. Woloszko, what does the Ganz application<br/>21 disclose about electrodes that are configured to cause<br/>22 coagulation around each electrode rather than coagulating<br/>23 between the electrodes?<br/>24 A. Paragraph 10 in Ganz application is clearly said<br/>25 the electrode pattern can also be selected to create a zone</p>                      |

## OPEN/CLOSED SESSIONS

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| <p style="text-align: right;">885</p> <p>1 of coagulative tissue surrounding around each perforation,<br/> 2 as you mentioned, a perforation is around each needle that<br/> 3 is inserted in the tissue. So obviously the coagulation is<br/> 4 surrounding around the needles.</p> <p>5 Q. And is there any coagulation between the<br/> 6 electrodes in the system disclosed in the Ganz reference?</p> <p>7 A. They can be, but the way it is discussed here,<br/> 8 it's surrounding each electrode, and he shows an example<br/> 9 where they are not between electrodes.</p> <p>10 Q. Next slide. Slide number 28, what does this<br/> 11 show?</p> <p>12 A. So this shows basically an excerpt from paragraph<br/> 13 48, 47, and 47. The paragraph 47 mentions how big the zone<br/> 14 of coagulation would be around each perforation, around each<br/> 15 electrode, 5 to 100 microns or a tenth of a millimeter.<br/> 16 This is in blue.</p> <p>17 In green he mentions that the perforation itself<br/> 18 is 30 to 100 microns -- 30 microns is -- you cannot see, you<br/> 19 know, it's much smaller than a hair, not visible obviously,<br/> 20 it's very small. And then he mentions that the space<br/> 21 between the perforation is 50 to 400 microns. So the figure<br/> 22 at the bottom, we basically showed that, in blue is a<br/> 23 needle, the white space around the blue would be the space<br/> 24 basely around the needle that is basically the space in the<br/> 25 perforation, and the space in red would show the zone of</p> | <p style="text-align: right;">887</p> <p>1 reference in 2010, would have knowledge to follow the Ganz<br/> 2 principles and be able to create larger or wider<br/> 3 perforations; is that correct?</p> <p>4 A. He mentioned somewhere the patent perforations<br/> 5 are closely related to the needle size, so obviously using a<br/> 6 larger needle would make a larger perforation.</p> <p>7 Q. Next slide. Slide 29, Dr. Woloszko, were you in<br/> 8 the courtroom when Serendia and Staff made the opening<br/> 9 statements last week?</p> <p>10 A. Yes, I was there.</p> <p>11 Q. Did you -- do you recall the Staff made some<br/> 12 comments about the Ganz reference in the opening statement?</p> <p>13 A. Yes, I do.</p> <p>14 Q. What is your understanding of Staff's position<br/> 15 regarding the Ganz reference?</p> <p>16 A. What I heard was that the needle was blasting<br/> 17 high energy, creating a hole in tissue, without spreading<br/> 18 into tissue and created an area of thermal damage or<br/> 19 ablation, which I don't disagree.</p> <p>20 Q. Why don't you agree with the Staff's position?</p> <p>21 A. I think we mentioned clearly several times that<br/> 22 the needle penetrates all the way to tissue, so needle is<br/> 23 inside tissue. A lesion of 5 micron, 30 -- a perforation of<br/> 24 30 microns, so we would say thermal damage of 5 microns is<br/> 25 very small, so you really need to be very precise, and it's</p> |
| <p style="text-align: right;">886</p> <p>1 coagulation.</p> <p>2 So here we took perforation of 100 microns, this<br/> 3 is the maximum perforation size mentioned by Ganz, we took<br/> 4 the maximum zone of coagulation of 100 microns mentioned in<br/> 5 this paragraph, and, as well as a maximum distance between<br/> 6 needles, and you can see very well that in this case there<br/> 7 would be a zone of 200 microns of healthy, noncoagulative<br/> 8 issue, between the needles showing clearly in this example<br/> 9 using the parameters, the limitations taught by Ganz, that<br/> 10 you would have coagulation around electrodes and not between<br/> 11 the electrodes.</p> <p>12 Q. And did you draw the figure shown on slide 28<br/> 13 based on disclosures in the Ganz reference?</p> <p>14 A. Yes.</p> <p>15 Q. And how are the perforations created in the Ganz<br/> 16 reference?</p> <p>17 A. The perforation is created, I mean, by inserting<br/> 18 the needle in the tissue together, and assisted with some<br/> 19 energy in this case is RF energy.</p> <p>20 Q. Does the Ganz reference place any limit on the<br/> 21 size of the perforations?</p> <p>22 A. No. He gives an example, but it's only in<br/> 23 certain cases, so he doesn't exclude making this perforation<br/> 24 larger or using larger needles.</p> <p>25 Q. So a person of skill in the art reading the Ganz</p>                                                                                                                                          | <p style="text-align: right;">888</p> <p>1 a low amount of energy, so this is not blasting energy, it<br/> 2 is very controlled perforation puncture in tissue assisted.<br/> 3 Ganz also mentioned using energy in the patent we mentioned<br/> 4 before, the '848, energy to vibrate the needle to create<br/> 5 bigger lesions. So this is in the same spirits, you know,<br/> 6 create micro injury to tissue.</p> <p>7 But the coagulation is obvious around the needle,<br/> 8 once the needle, the current, pass through tissue creating<br/> 9 the coagulation. Thermal ablation, thermal damage is what<br/> 10 is known in the art as coagulation necrosis, or basically<br/> 11 tissue coagulation. That's exactly what Na is describing in<br/> 12 the patent.</p> <p>13 Q. What does Ganz reference disclose about creating<br/> 14 zones of coagulation?</p> <p>15 A. What --</p> <p>16 Q. What does the Ganz reference disclose about the<br/> 17 zones of coagulation?</p> <p>18 A. They say that they are surrounding the<br/> 19 perforation, therefore, the needle.</p> <p>20 Q. Is that disclosed in paragraph 10 and paragraph<br/> 21 48 on slide 29?</p> <p>22 A. Paragraph 48 and the paragraph 10.</p> <p>23 Q. And reference to Staff's slide is at RX-0329.</p> <p>24 Dr. Woloszko, based on the disclosures in the<br/> 25 Ganz reference, in 2010, would a person of skill in the art</p>                                                               |

## OPEN/CLOSED SESSIONS

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| <p>889</p> <p>1 understand that any limitations that are not disclosed in</p> <p>2 the Ganz reference, they would have been obvious to a person</p> <p>3 of ordinary skill?</p> <p>4 A. Yes, definitely, yeah.</p> <p>5 Q. And if a person of ordinary skill were to modify</p> <p>6 the teachings of Ganz reference in 2010, would -- he or she</p> <p>7 would be able to rely upon his own knowledge to make the</p> <p>8 modifications?</p> <p>9 A. Yes, a person in the art would rely on his own --</p> <p>10 on his or her own experience and knowledge as well as</p> <p>11 applications and the knowledge of a product or patent's</p> <p>12 publication in the same field.</p> <p>13 Q. And the person of ordinary skill, if making the</p> <p>14 modifications to Ganz in 2010, would have reasonable</p> <p>15 expectation of success in making the modification?</p> <p>16 A. Yes, that's a pretty well defined in changing</p> <p>17 the -- one or two single parameters on that would be --</p> <p>18 would probably -- a good chance of success, yes.</p> <p>19 Q. And a person of skill would be using known</p> <p>20 techniques and known ways?</p> <p>21 A. Totally.</p> <p>22 Q. Next slide. Dr. Woloszko, what does slide number</p> <p>23 30 show?</p> <p>24 A. This is related to claim 9, and my opinion</p> <p>25 it's -- claim 9 is obvious in view of Ganz and the knowledge</p>                                                                                              | <p>891</p> <p>1 radiofrequency, to understand really what makes sense. And</p> <p>2 here we mention Manstein that mentions the actual needle</p> <p>3 diameter, and he said needles less than 500 microns in</p> <p>4 diameter may be used if they are mechanically strong enough.</p> <p>5 Mechanically they are. It's a manufacturing methodology.</p> <p>6 But there are other known products that are using actually</p> <p>7 smaller needles than that.</p> <p>8 Q. Are you aware of the state of the art in the</p> <p>9 microneedle industry in 2010?</p> <p>10 A. Somewhat, yes.</p> <p>11 Q. And what microneedles that were less than 500</p> <p>12 microns in diameter but were still strong enough to be used</p> <p>13 in the application like Ganz were available?</p> <p>14 A. Yes.</p> <p>15 MR. SANDERS: Objection, Your Honor.</p> <p>16 JUDGE MCNAMARA: And the basis?</p> <p>17 MR. SANDERS: This is Charles Sanders for</p> <p>18 Serendia. I don't believe that there were identifications</p> <p>19 of materials that you can make needles out of in his report</p> <p>20 other than -- in other words, the question is it is</p> <p>21 soliciting information that was not in his report. He</p> <p>22 relied on the Manstein for this.</p> <p>23 JUDGE MCNAMARA: Your response?</p> <p>24 MR. SHARMA: I'm simply asking the knowledge of</p> <p>25 what someone would have in the industry based on</p>                        |
| <p>890</p> <p>1 of a person skilled in the art, and in view of Manstein</p> <p>2 patent.</p> <p>3 Q. Next slide. What is shown on slide 31?</p> <p>4 A. So this is RX-0304, what we call the Manstein</p> <p>5 patent, that was in 2010, we mentioned previously, and this</p> <p>6 patent is also another apparatus for skin treatment using an</p> <p>7 array of needles penetrating into the skin and powered by</p> <p>8 radiofrequency current.</p> <p>9 Q. Again, what's shown in Fig. 3 on slide 31?</p> <p>10 A. That's a schematic of needles in the skin</p> <p>11 controlled with a control module and energy RF module.</p> <p>12 Q. Next slide. On slide 32, what does the Ganz</p> <p>13 reference disclose about the diameter of needles as required</p> <p>14 by claim 9?</p> <p>15 A. So Ganz doesn't give formal limitation on the</p> <p>16 electrode pins on the needle diameter. He mentioned some</p> <p>17 size for the -- some size for the puncture, although it's</p> <p>18 not limited to that.</p> <p>19 Q. So if a person of skill in the art were trying to</p> <p>20 limit the Ganz application in 2010, how would the person of</p> <p>21 skill in the art decide what diameter of needles to use?</p> <p>22 A. A person skilled in the art would look at the</p> <p>23 existing technology and products as well as various kind of</p> <p>24 needle used to perforate the skin, whether they are</p> <p>25 hypodermic needles or needles used that are powered with</p> | <p>892</p> <p>1 Dr. Woloszko's experience. He testified that he is familiar</p> <p>2 with the microneedle industry in 2010.</p> <p>3 JUDGE MCNAMARA: Right, I understand that, but I</p> <p>4 think the issue is scope of the report and what was</p> <p>5 testified to in his expert report and I assume the</p> <p>6 deposition.</p> <p>7 MR. SHARMA: Yes.</p> <p>8 JUDGE MCNAMARA: So I think, though, that since</p> <p>9 he is also relying on a person of skill in the art --</p> <p>10 Well, first of all, Mr. Sanders, was there any</p> <p>11 mention at all certainly of this paragraph in Manstein</p> <p>12 together with the Ganz application?</p> <p>13 MR. SANDERS: Yes, Your Honor. We're not</p> <p>14 objecting to the use of these paragraphs in Ganz and the</p> <p>15 paragraphs from Manstein. But we are objecting to filling</p> <p>16 in with what people would have known about other needle</p> <p>17 materials. That was never disclosed in his report. So I</p> <p>18 had no opportunity to ask him about it at his deposition,</p> <p>19 because that information was not disclosed.</p> <p>20 JUDGE MCNAMARA: So my question to you is, during</p> <p>21 the course of the deposition, was the doctor asked about a</p> <p>22 person of skill in the art at the time and the nature of the</p> <p>23 needles that would have been used?</p> <p>24 MR. SANDERS: Your Honor, to my recollection, he</p> <p>25 was not.</p> |

## OPEN/CLOSED SESSIONS

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| <p style="text-align: right;">893</p> <p>1 JUDGE MCNAMARA: Interesting.</p> <p>2 Mr. Rauh, were you at the deposition?</p> <p>3 MR. RAUH: I was, Your Honor. Aaron Rauh for the</p> <p>4 Staff. I don't recall that specifically -- it was a two-day</p> <p>5 deposition. It was a long deposition. I don't recall that</p> <p>6 specifically either, Your Honor. I think this does get to</p> <p>7 an issue that came up in the MILs where some of the opinions</p> <p>8 were limited to what was in the report or not in the report.</p> <p>9 And I think your order and your ground rule were if</p> <p>10 something is going to be challenged, then the person putting</p> <p>11 on the examination had to be able to point to as in ground</p> <p>12 rule 9.5.6 --</p> <p>13 JUDGE MCNAMARA: Right.</p> <p>14 MR. RAUH: -- point to the expert report or</p> <p>15 transcript on the spot.</p> <p>16 JUDGE MCNAMARA: Mr. Sharma, I'm going to take a</p> <p>17 brief break. It will only be five minutes. I have to get</p> <p>18 my realtime back on track. And I'd like you to find if</p> <p>19 there is something in the report that corresponds or in the</p> <p>20 deposition that where Dr. Woloszko talked about what would</p> <p>21 have been known in the art about the strength or type of</p> <p>22 materials used in needles. Please pull that up.</p> <p>23 (Whereupon, the proceedings recessed at 12:04</p> <p>24 p.m.)</p> <p>25 (In session at 12:06 p.m.)</p>                                                          | <p style="text-align: right;">895</p> <p>1 never mentioned at all in his opinions about claim 9 of the</p> <p>2 '836 patent for which he is combining Ganz and Manstein. He</p> <p>3 wasn't combining with us. He didn't refer back to this. He</p> <p>4 didn't mention any needle material. This, respectfully,</p> <p>5 Your Honor, we believe is an attempt to backfill the</p> <p>6 opinions that were not expressed for claim 9 by now bringing</p> <p>7 in technology background that was never discussed and</p> <p>8 addressed in the claim.</p> <p>9 JUDGE MCNAMARA: Mr. Rauh?</p> <p>10 MR. RAUH: Aaron Rauh for the Staff. Your Honor,</p> <p>11 I would just add that the figure doesn't have a citation to</p> <p>12 where it's from, the date of what it's representing, whether</p> <p>13 it's in the relevant time frame.</p> <p>14 JUDGE MCNAMARA: Is there a time frame on this</p> <p>15 figure, Mr. Sharma? I don't see one either.</p> <p>16 MR. SHARMA: Well, Your Honor --</p> <p>17 JUDGE MCNAMARA: Paragraph 87.</p> <p>18 MR. SHARMA: I don't have a time frame on the</p> <p>19 figure, but the section is from section 8, technology</p> <p>20 background, and that's the background of the technology that</p> <p>21 was before the patent.</p> <p>22 JUDGE MCNAMARA: Right, but the problem is that</p> <p>23 in this particular paragraph it doesn't refer to time, and</p> <p>24 it doesn't refer to -- unless you can show me where it</p> <p>25 specifically is referencing the background, I don't see it</p> |
| <p style="text-align: right;">894</p> <p>1 MR. SHARMA: In Dr. Woloszko's report he had</p> <p>2 about a 40-page section on technology background, and on</p> <p>3 page 45 -- on page 45 of Dr. Woloszko's report in paragraph</p> <p>4 57 he has a description and a figure of the microneedles.</p> <p>5 JUDGE MCNAMARA: Can you put it up on the ELMO?</p> <p>6 Mr. Sharma, would you point out, please, I know what I'm</p> <p>7 looking at, but would you point out where, in fact, in this</p> <p>8 diagram there is a discussion of the different types of</p> <p>9 materials?</p> <p>10 MR. SHARMA: Yes, Your Honor. If you see here,</p> <p>11 on page 45 of Dr. Woloszko's report, it shows the outside</p> <p>12 diameter, tungsten stainless steel, 350 to 400 microns, and</p> <p>13 the needles are different materials, platinum and Iridium,</p> <p>14 350 to 630 microns, and they are talking about different</p> <p>15 portions of the needles, tungsten and stainless steel</p> <p>16 portion, 126 to 218 micron and the same with platinum and</p> <p>17 Iridium, and it goes on, talks about the different materials</p> <p>18 and compositions of the microneedles.</p> <p>19 JUDGE MCNAMARA: And that's paragraph 87,</p> <p>20 correct?</p> <p>21 MR. SHARMA: Yes, Your Honor.</p> <p>22 JUDGE MCNAMARA: Okay. So Mr. Sanders, would you</p> <p>23 like to expound upon your objection?</p> <p>24 MR. SANDERS: I would, Your Honor. To be clear,</p> <p>25 this is a figure from the technology background that was</p> | <p style="text-align: right;">896</p> <p>1 in 87, certainly, and I think Mr. Sanders's objection is in</p> <p>2 part to the fact that this was never discussed with</p> <p>3 materials used for the needle tips, it was never discussed</p> <p>4 in Dr. Woloszko's report.</p> <p>5 So can you show me where -- just show me that at</p> <p>6 least a figure was taken from the background of the patent?</p> <p>7 It still doesn't deal with the issue of whether or not</p> <p>8 Dr. Woloszko actually discussed the use of materials as a</p> <p>9 person of skill in the art would have back in the day.</p> <p>10 MR. SHARMA: No, Your Honor, he did not</p> <p>11 discuss -- I'll refer back to this figure -- when he made</p> <p>12 the combinations of Ganz and Manstein, but he did mention</p> <p>13 that he was applying his opinion of Ganz reference,</p> <p>14 knowledge of a person of skill in the art, and the</p> <p>15 disclosure of the Manstein patent.</p> <p>16 JUDGE MCNAMARA: You have to get more explicit</p> <p>17 than that when you're providing an opinion about combining</p> <p>18 for obviousness.</p> <p>19 Mr. Rauh, where are you on this?</p> <p>20 MR. RAUH: Aaron Rauh for the Staff. You took</p> <p>21 the words out of my mouth, Your Honor. Looking at the</p> <p>22 portion of the report that goes to this prior art invalidity</p> <p>23 theory, and it is not in that part of the report for the</p> <p>24 claim.</p> <p>25 JUDGE MCNAMARA: I'm going to have to strike --</p>                  |

## OPEN/CLOSED SESSIONS

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| <p>897</p> <p>1 I'm going to have to agree with the objection on this one,</p> <p>2 Mr. Sharma. When you're dealing with obviousness</p> <p>3 combinations, you have to be very explicit about what you</p> <p>4 are putting together, which of the claims, how you're</p> <p>5 putting it together. So that stands. The objection stands.</p> <p>6 MR. SHARMA: I'll move on, Your Honor. Thank</p> <p>7 you.</p> <p>8 Q. Let's come back to where we were on slide 31. I</p> <p>9 need to go back to -- let's go to slide number 33.</p> <p>10 So in the 2010 time frame, if a person -- let me</p> <p>11 start again.</p> <p>12 Do the -- Ganz application and the Manstein</p> <p>13 patent are from the same field of dermatological treatment</p> <p>14 and devices?</p> <p>15 A. Yes, they do.</p> <p>16 Q. And the person of skill in the art making the</p> <p>17 combination of Ganz and the Manstein would be combining them</p> <p>18 according to known methods?</p> <p>19 A. Yes.</p> <p>20 Q. And that would require a simple substitution of</p> <p>21 one known element for the other?</p> <p>22 A. They would in this case, yes.</p> <p>23 Q. And making the combination, would the person of</p> <p>24 ordinary skill in 2010 have a reasonable expectation of</p> <p>25 success?</p>                                                                                          | <p>899</p> <p>1 A. So claim 22 is dependent on claim 14.</p> <p>2 Q. Next slide. On claim 37, have you compared the</p> <p>3 relationship between claim 14 and claim 1 of the '836</p> <p>4 patent?</p> <p>5 A. Yes. This is a very similar representation of</p> <p>6 what we saw yesterday with Mr. Crosby's presentation.</p> <p>7 Basically, claim 14 and 1 are very similar, 1 being a</p> <p>8 method, the other one being an apparatus. We have</p> <p>9 highlighted in similar colors the words that are either</p> <p>10 exactly the same or equivalent. So in yellow, treatment for</p> <p>11 the skin, in green, inserting a plurality of electrodes,</p> <p>12 inserted bipolar electrodes basically in the skin, and this</p> <p>13 is the same language.</p> <p>14 And in blue he is providing an alternating</p> <p>15 current radiofrequency signal to the plurality of electrodes</p> <p>16 configured to cause coagulation around each electrode rather</p> <p>17 than coagulating between electrodes. The exact same</p> <p>18 language except "applying" is replaced with "providing." I</p> <p>19 think each one is similar, one for the method, the other for</p> <p>20 the apparatus.</p> <p>21 Q. And does the Ganz reference disclose claim 14 of</p> <p>22 the '836 patent?</p> <p>23 A. Yeah. We discussed this previously during claim</p> <p>24 1, and the same explanation as before.</p> <p>25 Q. Next slide. We're on slide 38. What does the</p> |
| <p>898</p> <p>1 A. Yes, very high.</p> <p>2 Q. Next slide. Dr. Woloszko, what does slide 34</p> <p>3 show?</p> <p>4 A. This is claim 22 -- this is about claim 22, and</p> <p>5 my opinion is that claim 22 is invalid in view of Ganz and</p> <p>6 the knowledge of a person skilled in the art and also in</p> <p>7 view of Hantash.</p> <p>8 Q. Let's go to slide 35. What does slide 35 show?</p> <p>9 A. That shows on the left the Hantash patent with --</p> <p>10 that we discussed previously, and on the left -- on the</p> <p>11 right this is -- the Fig. 1 shows microneedle RF powered</p> <p>12 apparatus, basically used for revitalizing aging skin, same</p> <p>13 thing as the other product, using the electromagnetic</p> <p>14 energy, using a plurality of needles and, again, that</p> <p>15 penetrate the skin to a desired depth.</p> <p>16 Q. And what does Fig. 1 on slide 35 show?</p> <p>17 A. Fig. 1 shows the array of needles penetrating</p> <p>18 inside the skin and connected to an RF generator, which is,</p> <p>19 I believe, 140. The needles in the skin are in yellow and</p> <p>20 in the blue square, number 115.</p> <p>21 Q. And does the Hantash patent disclose use of RF</p> <p>22 energy?</p> <p>23 A. Yes, he does.</p> <p>24 Q. We're on slide 36. What is the relationship</p> <p>25 between claim 22 and claim 14 of the '836 patent?</p> | <p>900</p> <p>1 Ganz reference disclose about the range of RF frequency as</p> <p>2 required by claim 22?</p> <p>3 A. So claim 22 provides two limitations, one in the</p> <p>4 frequency from 05 to 10 MHz, and the other one is about the</p> <p>5 interval time application. This slide is about the</p> <p>6 frequency.</p> <p>7 So, again, Ganz mentions in paragraph 58 that</p> <p>8 this is about radiofrequency electrodes, and Hantash, in the</p> <p>9 very similar, describes in paragraph 40, highlighting at the</p> <p>10 bottom the frequency range is from 0.1, basically 100 kHz,</p> <p>11 0.1 MHz or 10 MHz, which is very similar, slightly broad on</p> <p>12 the low end, but still as broad and very similar to 05 to 10</p> <p>13 MHz taught by Na.</p> <p>14 Q. The frequency range that you referred to, .1 to</p> <p>15 10 MHz, or .4 to 3 MHz, is that limited to certain</p> <p>16 embodiments in the Hantash patent?</p> <p>17 A. No. This is a preferred embodiment, and in the</p> <p>18 other part he mentions -- he mentions, actually, it can be</p> <p>19 from 04 to 3. So showing clearly that 04 to 3 may be -- in</p> <p>20 some condition may be a better use, but he has also this 0.4</p> <p>21 MHz.</p> <p>22 Q. Because the Ganz reference does not disclose the</p> <p>23 RF frequency, if a person of ordinary skill were --</p> <p>24 JUDGE MCNAMARA: I think you just need to slow</p> <p>25 down a little bit, Mr. Sharma.</p>  |

## OPEN/CLOSED SESSIONS

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| <p>901</p> <p>1 Q. Because the Ganz reference does not disclose the</p> <p>2 RF frequency range, how would a person of ordinary skill in</p> <p>3 the art in 2010 implementing the Ganz system figure out the</p> <p>4 frequency range?</p> <p>5 A. Once again, a person of skill in the art would</p> <p>6 use his own experience and knowledge of frequency system</p> <p>7 being between 450 and -- 450 kHz and over, and as well look</p> <p>8 at published literature, and a system in the same field,</p> <p>9 like a system using microneedle for the skin, Hantash is one</p> <p>10 of them, and would be obvious to apply Hantash for this</p> <p>11 application.</p> <p>12 Q. Next slide.</p> <p>13 JUDGE MCNAMARA: Which slide number, Mr. Sharma?</p> <p>14 MR. SHARMA: We will be on slide 39.</p> <p>15 JUDGE MCNAMARA: Thank you.</p> <p>16 Q. What does the Ganz reference disclose about the</p> <p>17 time interval as required by claim 22 of the '836 patent?</p> <p>18 A. So the limitation provided by claim 22 for the</p> <p>19 time interval, which is the time of RF application, is</p> <p>20 between 50 to 800 milliseconds or 0.05 to 08 seconds.</p> <p>21 Q. Does the Ganz reference disclose the time</p> <p>22 interval of the RF frequency to be applied?</p> <p>23 A. Not directly. But he mentions to select the</p> <p>24 appropriate treatment time.</p> <p>25 Q. So if somebody were to limit the Ganz reference</p> | <p>903</p> <p>1 A. Absolutely.</p> <p>2 Q. Next slide.</p> <p>3 JUDGE MCNAMARA: I think you -- please mention</p> <p>4 the number.</p> <p>5 MR. SHARMA: Yes, I've been doing that</p> <p>6 Your Honor. I'll keep doing that.</p> <p>7 Q. Dr. Woloszko, what does slide 41 show?</p> <p>8 A. Slide 41 shows the patent '836 on the left, and</p> <p>9 this is a summary of my opinion that we discussed over the</p> <p>10 past few minutes.</p> <p>11 Q. Okay. Let me bring up RX-0303. If you can zoom</p> <p>12 in on the top portion of the exhibit.</p> <p>13 A. Yes.</p> <p>14 Q. Dr. Woloszko, do you know what this exhibit is?</p> <p>15 A. This is the patent I mentioned before that I</p> <p>16 wrote with my colleague Ron Underwood. We are relating to a</p> <p>17 system method to treat the skin basically.</p> <p>18 Q. And is that Jean Woloszko mentioned, is that you?</p> <p>19 A. I don't know any others, yes.</p> <p>20 Q. What is the subject matter of the patent?</p> <p>21 A. Again, that's a system method for intradermal</p> <p>22 collagen stimulation using various methods, including</p> <p>23 microneedling.</p> <p>24 Q. Can we go to column 6, line 42 to 52? Will you</p> <p>25 highlight the first two sentences?</p>                                                                           |
| <p>902</p> <p>1 in 2010, how would that person figure out what time interval</p> <p>2 to employ?</p> <p>3 A. There are a lot of disclosure, I mention in my</p> <p>4 report, for decades about pulsing frequency and various</p> <p>5 application time. Once again, you would look at example of</p> <p>6 similar application, the needle in the skin, Hantash being</p> <p>7 one of them, and Hantash provide full examples and</p> <p>8 parameters, and this is mentioned in paragraph 77 of</p> <p>9 Hantash, where he mentioned a pulse duration of 400</p> <p>10 milliseconds, and the second example with another pulse</p> <p>11 duration of 200 milliseconds, 0.4 seconds and 0.2 seconds,</p> <p>12 which is within the range taught by Na, middle of the range.</p> <p>13 Q. Next slide. We're on slide 40 now.</p> <p>14 Dr. Woloszko, are the Ganz and Hantash references</p> <p>15 from the same field of dermatological treatment and devices?</p> <p>16 A. Definitely.</p> <p>17 Q. And if a person of ordinary skill made the</p> <p>18 combination of Ganz and Hantash in 2010, would the person be</p> <p>19 combining them according to the known methods?</p> <p>20 A. Absolutely.</p> <p>21 Q. Would the combination require a simple</p> <p>22 substitution of one known element for another?</p> <p>23 A. That's a simple software change, yes.</p> <p>24 Q. Would the person have reasonable expectation of</p> <p>25 success?</p>  | <p>904</p> <p>1 Dr. Woloszko, when you were drafting this patent,</p> <p>2 or as shown in this patent, what do the terms series of</p> <p>3 voltage pulses or alternating current of time denote?</p> <p>4 A. This patent is a family of serial patents in 1995</p> <p>5 where we discussed using square waves. As we described</p> <p>6 previously, square waves for radiofrequency, and to -- it's</p> <p>7 really a --</p> <p>8 (Clarification requested by the court reporter.)</p> <p>9 A. Sorry. Voltage pulses for alternating current</p> <p>10 was really to reinforce the alternating current, in this</p> <p>11 case was a synonymous of pulses, voltage pulses.</p> <p>12 Q. You were questioned about this patent in your</p> <p>13 deposition, correct?</p> <p>14 A. Yes.</p> <p>15 Q. Dr. Woloszko, in the patents and applications you</p> <p>16 use the phrase radiofrequency alternating current; is that</p> <p>17 correct?</p> <p>18 A. Radiofrequency, sorry, alternating current, yeah,</p> <p>19 uh-huh.</p> <p>20 Q. And what do you imply by that term?</p> <p>21 A. As I just said, in this case to reinforce it, it</p> <p>22 was, you know, a synonym, all meant basically that it's a</p> <p>23 synonym, not an alternative.</p> <p>24 MR. SHARMA: Your Honor, that concludes the</p> <p>25 questions.</p> |

## OPEN/CLOSED SESSIONS

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| <p>1 Q. Slide 176, please.</p> <p>2 Can you explain to Judge McNamara and the</p> <p>3 Commission what tissue shrinkage is?</p> <p>4 A. I think we talked before, the tissue shrinkage,</p> <p>5 and it's been described in other studies, tendon tissue can</p> <p>6 shrink over 50 percent. So it can be very significant.</p> <p>7 JUDGE MCNAMARA: You're going very fast.</p> <p>8 A. I'll start again.</p> <p>9 When you coagulate tissue, you heat tissue,</p> <p>10 tissue can shrink, and has been described for other tissue,</p> <p>11 for instance, tendons, that the length can be reduced by 50</p> <p>12 percent.</p> <p>13 So when you put those needles in tissue, the</p> <p>14 lesions around them will affect tissue. The lesion is, you</p> <p>15 know, basically, it's probably smaller than the volume of</p> <p>16 tissue you had originally, but, furthermore, the tissue in</p> <p>17 between, which may be intact, is going to be put under</p> <p>18 tension.</p> <p>19 When you remove the needles, it will contract</p> <p>20 again, because you put tension on the tendon, then the</p> <p>21 distance between needles will have a different value.</p> <p>22 Q. And the histological measurements are taken after</p> <p>23 shrinkage?</p> <p>24 A. Yes.</p> <p>25 MR. AIRAN: Pass the witness, Your Honor.</p> | <p>1 Q. Were you here during the opening when Respondents</p> <p>2 called you the preeminent authority in this industry and in</p> <p>3 this technology?</p> <p>4 A. Yes, I was.</p> <p>5 Q. You would know whether the art relevant to the</p> <p>6 '836 patent is predictable or unpredictable, true?</p> <p>7 A. Correct.</p> <p>8 Q. And you understand that the words predictable and</p> <p>9 unpredictable have opposite meanings, right?</p> <p>10 A. I understand that.</p> <p>11 Q. In your opinion the relevant art is predictable,</p> <p>12 right?</p> <p>13 A. I think I mentioned that during my -- during my</p> <p>14 testimony. At a high level, we know you can predict what</p> <p>15 will happen at high level, but this patent is very precise,</p> <p>16 by a fraction of millimeters, and the conductivity is not</p> <p>17 that precise.</p> <p>18 Q. Well, to be precise, in your opinion, a person of</p> <p>19 ordinary skill in the art would have recognized that the</p> <p>20 relevant art is predictable and that achieving the claimed</p> <p>21 subject matter of the '836 patent merely requires merely</p> <p>22 routine optimization, right?</p> <p>23 A. To implement -- to implement one embodiment to</p> <p>24 make it work in one fashion, yes.</p> <p>25 Q. Now I'll represent to you that on page 25 of</p>     |
| 1002                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 1004                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <p>1 JUDGE MCNAMARA: Thank you, Mr. Airan.</p> <p>2 MR. RAUH: Your Honor, Aaron Rauh for the Staff.</p> <p>3 Would it be an opportune time to take the afternoon break?</p> <p>4 JUDGE MCNAMARA: Yes. Let's take ten minutes.</p> <p>5 (Whereupon, the proceedings recessed at 3:50</p> <p>6 p.m.)</p> <p>7 (In session at 4:05 p.m.)</p> <p>8 JUDGE MCNAMARA: Thank you, everybody. You're</p> <p>9 up.</p> <p>10 MR. SANDERS: Thank you, Your Honor. Charles</p> <p>11 Sanders for the Complainant.</p> <p>12 CROSS-EXAMINATION</p> <p>13 BY MR. SANDERS:</p> <p>14 Q. Good afternoon, Dr. Woloszko.</p> <p>15 A. Good afternoon, Mr. Sanders.</p> <p>16 Q. Now you agree credibility is important for a</p> <p>17 witness or a party, right?</p> <p>18 A. I agree.</p> <p>19 Q. Let's start by talking about your opinions</p> <p>20 relating to enablement and written description for the '836</p> <p>21 patent.</p> <p>22 You understand that one of the questions for</p> <p>23 enablement is whether the art is predictable or</p> <p>24 unpredictable, right?</p> <p>25 A. I understand.</p>                                                                                                                                                                                                                                          | <p>1 Respondents' prehearing brief they cited your deposition</p> <p>2 testimony for the following statement:</p> <p>3 Furthermore, a person of ordinary skill in the</p> <p>4 art would have considered controlling the lesion size of an</p> <p>5 RF microneedling device to be limited to between the</p> <p>6 electrodes to be predictable.</p> <p>7 Do you agree with that statement?</p> <p>8 A. This was -- this was in my -- in my report?</p> <p>9 Q. It was actually in Respondents' prehearing brief,</p> <p>10 the brief that they submitted to Judge McNamara.</p> <p>11 A. I haven't seen the brief. I haven't read it, so</p> <p>12 I don't know.</p> <p>13 Q. Okay. Well, why don't we take a look.</p> <p>14 Do we have Respondents' prehearing brief at page</p> <p>15 25?</p> <p>16 Do you agree with the statement: A person of</p> <p>17 ordinary skill in the art would have considered controlling</p> <p>18 the lesion size of an RF microneedling device to be limited</p> <p>19 to between electrodes to be predictable?</p> <p>20 A. Yes.</p> <p>21 Q. Tell us, do you agree with the following</p> <p>22 statement:</p> <p>23 Because this art is so unpredictable, a person of</p> <p>24 ordinary skill in the art would have to make and test every</p> <p>25 candidate to determine whether it achieves the claim result?</p> |

## OPEN/CLOSED SESSIONS

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| <p style="text-align: right;">1005</p> <p>1 A. I think you are -- this is not what I -- I mean,</p> <p>2 this is what I said, but we talked in the 112, we said to</p> <p>3 show the full scope of the -- of the invention, not to make</p> <p>4 it work once or twice.</p> <p>5 So you can predict -- some parameters are</p> <p>6 predictable, not all of them. For instance, needle shape is</p> <p>7 complicated to predict because it depends on a lot of</p> <p>8 things. So you can fix some parameters and make it a way --</p> <p>9 you can relatively easily predict, increase frequency,</p> <p>10 lesion slows down, you increase power, time, it would</p> <p>11 increase -- although, if you increase power, it's not</p> <p>12 predictable because increasing power, for instance, and you</p> <p>13 increase power --</p> <p>14 Q. Dr. Woloszko --</p> <p>15 A. -- the tissue -- some things are predictable to</p> <p>16 some extent, not the full extent of the range of the</p> <p>17 limitation provided in the '836 patent.</p> <p>18 Q. Dr. Woloszko, my question was a simple one,</p> <p>19 whether you agree with this statement.</p> <p>20 Can you answer me yes or no, do you agree with</p> <p>21 this statement:</p> <p>22 Because the art is so unpredictable a person of</p> <p>23 ordinary skill in the art would have to make and test every</p> <p>24 candidate to determine whether it achieves the claim result?</p> <p>25 A. Once again, you take a piece of a statement, when</p> | <p style="text-align: right;">1007</p> <p>1 technical people, you know what to do. It's not simple. It</p> <p>2 takes a lot of time. But I would assume they would know or</p> <p>3 they would get the help of somebody to do that. To do a set</p> <p>4 of histology takes a few weeks. You know how to do it. It</p> <p>5 doesn't mean it's simple. It's routine, but it's tedious,</p> <p>6 expensive, yes.</p> <p>7 Q. Do you recall I took your deposition in this</p> <p>8 matter?</p> <p>9 A. I do.</p> <p>10 Q. And you were under oath like you are today?</p> <p>11 A. I do.</p> <p>12 Q. And you reviewed your deposition transcript and</p> <p>13 acknowledged that the transcript of your testimony was true,</p> <p>14 correct, and complete, right?</p> <p>15 A. I made a few errors and I stopped because there</p> <p>16 were many, many transcription errors, but I did sign it,</p> <p>17 yes.</p> <p>18 Q. If we go to your deposition, it's CX-3063 at 42,</p> <p>19 161, 1-4, and at your deposition I asked you:</p> <p>20 "In 2011, would a person of ordinary skill in the</p> <p>21 art have known how to perform histology to determine where</p> <p>22 coagulation occurred in tissue?"</p> <p>23 A. Yeah.</p> <p>24 Q. You answered, "definitely."</p> <p>25 A. Yes.</p>                                                                                                                                                         |
| <p style="text-align: right;">1006</p> <p>1 I say to predict to the full extent, the full scope of the</p> <p>2 invention, you have to do all of that, that is</p> <p>3 unpredictable, and I agree with that.</p> <p>4 Q. Do you agree with that statement?</p> <p>5 A. Yes, to -- the full scope of the embodiments,</p> <p>6 yes.</p> <p>7 Q. So we now understand your opinions about the art</p> <p>8 being predictable and unpredictable.</p> <p>9 Let's focus on your opinions about the art being</p> <p>10 predictable. A person of ordinary skill in the art would</p> <p>11 have known the experimental methodology to determine whether</p> <p>12 unconnected coagulation zones were achieved, right?</p> <p>13 A. Repeat? I know I wrote that. Can you repeat?</p> <p>14 Q. Sure. A person of ordinary skill in the art</p> <p>15 would have known the experimental methodology to determine</p> <p>16 whether unconnected coagulation zones were achieved, right?</p> <p>17 A. Yes.</p> <p>18 Q. A person of ordinary skill also would have known</p> <p>19 how to select the RF frequency, right?</p> <p>20 A. Frequency, yes.</p> <p>21 Q. In 2011 a person of ordinary skill in the art</p> <p>22 would have known how to perform histology to determine where</p> <p>23 coagulation occurred in the tissue, right?</p> <p>24 A. I think the definition of a person skilled in the</p> <p>25 art has evolved, but if you use that with the help of</p>                                                  | <p style="text-align: right;">1008</p> <p>1 Q. Is that the question that you were asked and the</p> <p>2 answer you gave?</p> <p>3 A. I mean, yes, I mean, I don't expect the POSITA to</p> <p>4 do the slicing, but they know how to do that, send it to a</p> <p>5 lab, yes.</p> <p>6 Q. A person of ordinary skill in the art would have</p> <p>7 known that, among other parameters, the frequency range of</p> <p>8 the RF source can be chosen based on the desired effects on</p> <p>9 various types of tissue and its influence on lesion size and</p> <p>10 geometry based on the intended application?</p> <p>11 A. Yes, I agree.</p> <p>12 Q. The '836 patent discloses that frequencies below</p> <p>13 500 kHz have a broader energy field and frequencies of over</p> <p>14 10 MHz have a narrower energy field, correct?</p> <p>15 A. That's all energy frequency, yes.</p> <p>16 Q. In 2011 a person of ordinary skill in the art</p> <p>17 would have known how to adjust the RF energy level to create</p> <p>18 more or less coagulation, right?</p> <p>19 A. They know how to adjust. It doesn't mean it's</p> <p>20 trivial.</p> <p>21 Q. The '836 patent discloses using 20 to 40 volts in</p> <p>22 a particular embodiment, right?</p> <p>23 A. That's typical range in some kind of -- in some</p> <p>24 type of -- some type of coagulation necrosis systems, yes.</p> <p>25 Q. And that's in the '836 patent. You recall that,</p> |

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| <p style="text-align: right;">1009</p> <p>1 right?</p> <p>2 A. Yeah.</p> <p>3 Q. It was well-known that the energy dissipated in</p> <p>4 tissue is a function of the voltage applied and the tissue</p> <p>5 impedance, right?</p> <p>6 A. Yeah.</p> <p>7 Q. In an embodiment the '836 patent discloses RF</p> <p>8 energy delivery or between .1 and .4 seconds and in a</p> <p>9 particular embodiment between .1 and .2 seconds, right?</p> <p>10 A. Not typical, as I mentioned before. These are</p> <p>11 not unconventional.</p> <p>12 Q. In 2011 a person of ordinary skill in the art</p> <p>13 would have known what temperature is needed in the skin to</p> <p>14 achieve coagulation, right?</p> <p>15 A. Temperature and time, yes.</p> <p>16 Q. Tissue coagulation is induced when tissue reaches</p> <p>17 a temperature of 60 to 65 degrees, correct?</p> <p>18 A. More or less, yes.</p> <p>19 Q. In 2011 a person of ordinary skill in the art</p> <p>20 would have been able to use computer model to obtain a very</p> <p>21 good approximation of how much energy needs to be delivered</p> <p>22 to achieve a certain amount of heating in the skin, right?</p> <p>23 A. Approximation, not measurement.</p> <p>24 Q. Indeed, a very good approximation, correct?</p> <p>25 A. Depends what you call very good. It's still an</p>                                                                                               | <p style="text-align: right;">1011</p> <p>1 A. I have a patent on this, I think, in 2002.</p> <p>2 Q. In fact, you believe the state of the art in the</p> <p>3 area of the invention, as you just referenced, is well-known</p> <p>4 and extensive, correct?</p> <p>5 A. To use RF in the skin, yeah, the theory, but it</p> <p>6 is well-known, yes.</p> <p>7 Q. You believe that in 2011 a person of ordinary</p> <p>8 skill in the art would have known how to adjust the distance</p> <p>9 between the needles to create more isolated coagulation</p> <p>10 zones, right?</p> <p>11 A. Obviously, if you have the same lesion, the</p> <p>12 closer they are, the closer the lesions are, so that's --</p> <p>13 Q. The further apart the electrodes are, the lower</p> <p>14 the energy concentration between them, and the lower the</p> <p>15 chances are to have any coagulation in the gap all the way</p> <p>16 between them, right?</p> <p>17 A. That's in general terms, yes.</p> <p>18 Q. The '836 patent discloses a range of distances</p> <p>19 for needle separation of 1.3 to 3 millimeters, correct?</p> <p>20 A. This was not in the asserted claim that we</p> <p>21 discussed. This is not part of the asserted claim we have</p> <p>22 reviewed.</p> <p>23 Q. To be clear, I'm asking about the '836 patent</p> <p>24 specification. The '836 --</p> <p>25 A. Oh, specification, okay. Probably so, yeah, it</p> |
| <p style="text-align: right;">1010</p> <p>1 approximation that needs to be validated.</p> <p>2 Q. Well, very good, according to what you call very</p> <p>3 good. Do I have that right?</p> <p>4 A. Yes.</p> <p>5 Q. Thank you. Indeed, modeling of current flow</p> <p>6 around electrodes has been performed for decades using a</p> <p>7 technique called finite element analysis, correct?</p> <p>8 A. Yes.</p> <p>9 Q. In view of this, a person of ordinary skill in</p> <p>10 the art was able to predict how small changes to bipolar RF</p> <p>11 microneedling will affect the results, correct?</p> <p>12 A. Small changes, yes.</p> <p>13 Q. That's interesting. Respondents didn't cite you</p> <p>14 when they said the opposite in their prehearing brief at 31.</p> <p>15 In 2011 a person of ordinary skill in the art</p> <p>16 would have known how to make a skin treatment apparatus with</p> <p>17 an RF generator that produces an alternating current RF</p> <p>18 signal supplied to bipolar electrodes insertable into skin,</p> <p>19 right?</p> <p>20 A. In what -- I didn't hear the last two words.</p> <p>21 Q. Of course. Let me repeat.</p> <p>22 In 2011 a person of ordinary skill in the art</p> <p>23 would have known how to make a skin treatment apparatus with</p> <p>24 an RF generator that produces alternating current RF signal</p> <p>25 supplied to bipolar electrodes insertable into skin, right?</p> | <p style="text-align: right;">1012</p> <p>1 was a claim, yes.</p> <p>2 Q. Let's confirm. Let's take a look at JX-7 at 14,</p> <p>3 9, 63-67, please.</p> <p>4 And you see there, the '836 patent discloses a</p> <p>5 range of distances for needle separation of 1.3 to 3</p> <p>6 millimeters, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And the '836 patent also discloses use of an AC</p> <p>9 signal of 2 MHz with needle spaced 2 millimeters apart in an</p> <p>10 embodiment, correct?</p> <p>11 A. I don't have the text in front of me, but --</p> <p>12 Q. Let's take a look.</p> <p>13 A. It's probably somewhere in --</p> <p>14 JUDGE MCNAMARA: Please don't crosstalk.</p> <p>15 MR. SANDERS: Understood, Your Honor.</p> <p>16 Q. Let's take a look at the '836 patent, JX-7 at 12</p> <p>17 at 6, 63-65.</p> <p>18 Do you see there the '836 patent discloses use of</p> <p>19 an AC signal of 2 MHz with needles spaced 2 millimeters</p> <p>20 apart in an embodiment?</p> <p>21 A. Yes.</p> <p>22 Q. And you believe that in 2011 a person of ordinary</p> <p>23 skill in the art would have known how to adjust the</p> <p>24 thickness or diameter of the needles to adjust the</p> <p>25 coagulation zones, right?</p>                                                                                                                                                                                                |

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| <p style="text-align: right;">1013</p> <p>1 A. They would know how the changing diameter would</p> <p>2 affect the coagulation with the model, yes.</p> <p>3 Q. The '836 patent discloses needle thicknesses of</p> <p>4 .25 to .3 millimeters, correct?</p> <p>5 A. Yes.</p> <p>6 Q. You believe that in 2011 a person of ordinary</p> <p>7 skill in the art would have known how to adjust the needle</p> <p>8 length or depth to obtain coagulation at the right depth in</p> <p>9 the dermis, right?</p> <p>10 A. That's kind of obvious, yes.</p> <p>11 Q. The '836 patent discloses using needles 1 to 4</p> <p>12 millimeters in length, correct?</p> <p>13 A. That's -- this is where the dermis is, so</p> <p>14 that's -- that's correct.</p> <p>15 Q. In 2011 a person of ordinary skill in the art</p> <p>16 would have known how to design an RF microneedling device</p> <p>17 that could use both insulated and non-insulated needles,</p> <p>18 right?</p> <p>19 A. To design it, not to predict the effect, yes.</p> <p>20 Q. A person of ordinary skill in the art would have</p> <p>21 had the knowledge to design an RF microneedling device that</p> <p>22 produces coagulation regions between the needles, right?</p> <p>23 A. Providing some experimentation you can get there,</p> <p>24 yes.</p> <p>25 Q. A person of ordinary skill in the art also would</p>                                                                     | <p style="text-align: right;">1015</p> <p>1 your opinion you could stand here in court today and say</p> <p>2 falls within what you call the very broad claims, correct?</p> <p>3 A. Correct.</p> <p>4 Q. Now do you recall testifying about the INTRAcel</p> <p>5 device?</p> <p>6 A. Yes.</p> <p>7 Q. INTRAcel was a prior Jeisys device that you</p> <p>8 discussed during your testimony, right?</p> <p>9 A. Briefly, yes.</p> <p>10 Q. And INTRAcel is an example of a device that</p> <p>11 produced coagulated regions between the needles, right?</p> <p>12 A. I don't know the details of what it does, so if</p> <p>13 you say so, I don't know.</p> <p>14 Q. Well, let's take a look at one of the exhibits</p> <p>15 that you cited on your slides, CX-2907.</p> <p>16 Do you see this is a Cynosure document? Do you</p> <p>17 know who Cynosure is?</p> <p>18 A. Yes.</p> <p>19 Q. It's Jeisys's distributor, right?</p> <p>20 A. I understand.</p> <p>21 Q. And this is an evaluation of the Potenza, the</p> <p>22 Jeisys device, that Cynosure performed?</p> <p>23 A. Okay.</p> <p>24 Q. Now let's go to page 18 of the document. And</p> <p>25 could we please blow up the text on the left? Thank you.</p> |
| <p style="text-align: right;">1014</p> <p>1 have had the knowledge to design an RF microneedling device</p> <p>2 that produces coagulated regions around the needles and not</p> <p>3 between them based on the '836 patent, right?</p> <p>4 A. Knowing how to do it doesn't mean it doesn't take</p> <p>5 undue experimentation and doesn't mean it's trivial.</p> <p>6 Q. Just to make sure I understand your testimony,</p> <p>7 your testimony, do I have this clear, a person of ordinary</p> <p>8 skill can understand how to do something but it requires</p> <p>9 undue experimentation?</p> <p>10 A. I know how to build a car. It doesn't mean I</p> <p>11 can build a car in five minutes. It can take me a year to</p> <p>12 do it, undue work and experimentation.</p> <p>13 Q. Now you mentioned also as part of your testimony</p> <p>14 about enablement, the claims are very broad. Do you recall</p> <p>15 that?</p> <p>16 A. Yes.</p> <p>17 Q. And just to be clear, you didn't identify in your</p> <p>18 testimony a single reference that you assert anticipates any</p> <p>19 of the claims, right?</p> <p>20 A. During my deposition, you mean?</p> <p>21 Q. During your direct testimony, you did not</p> <p>22 identify a single reference that you're opining anticipates</p> <p>23 any of the claims, right?</p> <p>24 A. That was not part of my task there.</p> <p>25 Q. So you didn't identify a single reference that in</p> | <p style="text-align: right;">1016</p> <p>1 Do you see in the first sentence it states, "We</p> <p>2 cannot duplicate the lesions we have seen in the literature,</p> <p>3 (INTRAcel paper at LMS) showing coagulated regions between</p> <p>4 the needles"? Do you see that?</p> <p>5 MR. AIRAN: Your Honor, David Airan on behalf of</p> <p>6 Jeisys and Cynosure. We are in the public record right now.</p> <p>7 This is referencing a confidential document.</p> <p>8 JUDGE MCNAMARA: Thank you, Mr. Airan.</p> <p>9 MR. HYDE: Bradley Hyde, we're clear.</p> <p>10 (Whereupon, the hearing proceeded in confidential</p> <p>11 session.)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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| <p style="text-align: right;">1033</p> <p>1 the technology that would spare the epidermis and not</p> <p>2 require any downtime would represent a better option, right?</p> <p>3 A. Correct.</p> <p>4 Q. And you agree that there are many devices</p> <p>5 described in patents that are never commercialized, right?</p> <p>6 A. Yes.</p> <p>7 Q. Now let's talk about the Ganz reference. Were</p> <p>8 you here when Respondents called Ganz a silver bullet in the</p> <p>9 opening?</p> <p>10 A. I was there. I don't remember the exact wording</p> <p>11 was used, but probably said that. I'm not sure. I don't</p> <p>12 remember exactly the context, though.</p> <p>13 Q. Ganz is a published patent application, right?</p> <p>14 A. Correct.</p> <p>15 Q. Ganz never issued as a patent, correct?</p> <p>16 A. Never issued as a patent?</p> <p>17 Q. Never actually went through the examination</p> <p>18 process at the Patent Office and came out as an issued</p> <p>19 patent, right?</p> <p>20 A. I'm not familiar with the full history of the</p> <p>21 patent, so I cannot say yes or no.</p> <p>22 Q. Are you aware that Ganz abandoned the patent</p> <p>23 application?</p> <p>24 A. Possibly.</p> <p>25 Q. Ganz discloses creating perforations, right?</p>                                                                           | <p style="text-align: right;">1035</p> <p>1 perforations of vertical holes into the skin, right?</p> <p>2 A. He compares a laser with his approach, which is</p> <p>3 different.</p> <p>4 Q. And in doing so, Ganz distinguishes the approach</p> <p>5 of only creating coagulation from his approach of creating</p> <p>6 perforations of vertical holes into the skin, right?</p> <p>7 A. In order to have the source of energy inside the</p> <p>8 skin, yes.</p> <p>9 Q. And the '836 patent distinguishes coagulation</p> <p>10 from vaporization and carbonization, right?</p> <p>11 A. Yes.</p> <p>12 Q. None of the claims of the '836 patent relate to</p> <p>13 producing vaporization or carbonization, correct?</p> <p>14 A. They don't include it or exclude it. It's not</p> <p>15 mentioned.</p> <p>16 Q. Let's take a look at --</p> <p>17 A. In my deposition I explained to you Ganz actually</p> <p>18 created plasma and tissue is removed without vaporization.</p> <p>19 This is a term I use because I describe --</p> <p>20 (Clarification requested by the court reporter.)</p> <p>21 A. -- described another method of removing tissue at</p> <p>22 low temperature by basically energizing particle in the</p> <p>23 water of the cellular tissue, that we remove tissue and</p> <p>24 induce actually a very active heating response. It had</p> <p>25 nothing to do with vaporization or carbonization.</p> |
| <p style="text-align: right;">1034</p> <p>1 A. Yes.</p> <p>2 Q. Those perforations are vertical holes</p> <p>3 perpendicular to the surface of the skin, right?</p> <p>4 A. Yes.</p> <p>5 Q. Ganz teaches removing tissue to create those</p> <p>6 holes that extend vertically from the surface of the skin</p> <p>7 into the tissue, right?</p> <p>8 A. He doesn't use -- does he use the word</p> <p>9 "removing"? It's been a long day. Is he using the actual</p> <p>10 "remove" term, "removing" in the patent? It's been a long</p> <p>11 day. So if you show me where it is, I will say yes or no.</p> <p>12 Q. Well, let's see -- taking a look at your</p> <p>13 deposition testimony helps refresh your recollection.</p> <p>14 CX-3063 at 60. It's the September 14th</p> <p>15 deposition, 236, 9-14.</p> <p>16 I'll ask my question again.</p> <p>17 A. Okay. I said some, which, you know, some means a</p> <p>18 very small amount, yes.</p> <p>19 Q. Just to make the record clear, you agree Ganz</p> <p>20 teaches removing some tissue to create those holes that</p> <p>21 extend vertically from the surface of the skin into the</p> <p>22 tissue, right?</p> <p>23 A. My word, not Ganz' word, okay.</p> <p>24 Q. You agree that Ganz distinguishes the approach of</p> <p>25 only creating coagulation from his approach of creating</p> | <p style="text-align: right;">1036</p> <p>1 Q. In fact, you testified that Ganz is infringing</p> <p>2 your patent, right?</p> <p>3 A. Yeah, which is fine, because I, you know --</p> <p>4 Q. Let's take a look at Fig. 8 of Ganz, which is on</p> <p>5 RX-329 at 5.</p> <p>6 Fig. 8 of Ganz is labeled prior art, correct?</p> <p>7 A. It's about laser.</p> <p>8 Q. And you don't -- you didn't mention Fig. 8 of</p> <p>9 Ganz in your direct testimony, right?</p> <p>10 A. Because it's not about his product, yeah.</p> <p>11 Q. Exactly. Fig. 8 is not using Ganz' approach.</p> <p>12 A. That's correct.</p> <p>13 Q. Now let's take a look at a demonstrative that we</p> <p>14 prepared, CDX-24 at 2, which shows side by side, for</p> <p>15 convenience, paragraph 28 of Ganz with Ganz' Fig. 8.</p> <p>16 In paragraph 28, Ganz explains that Fig. 8 shows</p> <p>17 zones of coagulation produced using the Fraxel laser system,</p> <p>18 correct?</p> <p>19 A. That's correct.</p> <p>20 Q. Now let's take a look at CDX-24 at 3.</p> <p>21 And this, for convenience, shows a side by side</p> <p>22 of paragraph 28 of Ganz and Figs. 9 and 10 of Ganz.</p> <p>23 A. Yes.</p> <p>24 Q. Ganz distinguishes the approach that's shown in</p> <p>25 Fig. 8 from what he shows in Figs. 9 and 10, correct?</p>                                                                                                            |

## OPEN/CLOSED SESSIONS

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| <p style="text-align: right;">1037</p> <p>1 A. Yeah, he is using Fig. 10 to show the coagulation<br/>2 around the perforation, yes.</p> <p>3 Q. In Figs. 9 and 10, Ganz is showing perforations<br/>4 produced using a monopolar configuration, correct?</p> <p>5 A. The patent -- I know I said yes in my deposition.<br/>6 And I read it again. And he mentioned monopolar in the<br/>7 example he gave to show parameters, but there was nothing to<br/>8 show whether the histology shows it mono or bipolar.</p> <p>9 I checked afterwards because I was -- I wasn't<br/>10 sure, so I -- I think at the deposition I said it was<br/>11 monopolar. That's what I believed at that time. But I<br/>12 checked again. It's undefined in the Ganz application,<br/>13 patent application.</p> <p>14 Q. Well, just to confirm, Figs. 9 and 10 in Ganz<br/>15 were obtained by delivering RF energy to monopolar<br/>16 electrodes, correct?</p> <p>17 A. I don't know that. I don't think he said that.<br/>18 I know this is what I told you during the deposition, and I<br/>19 don't disagree with that, but I checked again, and maybe I<br/>20 was wrong, but I couldn't find anyplace where he showed that<br/>21 those figures were obtained with the monopolar<br/>22 configuration. He mentioned in the example where he gave<br/>23 the 1 joule for -- the 1 joule at 60 watts, 50 watts,<br/>24 whatever it was.</p> <p>25 Q. You recall you checked again at your deposition</p> | <p style="text-align: right;">1039</p> <p>1 into the tissue, right?</p> <p>2 A. Surrounding -- it's not clear. It's not clear.<br/>3 It can be diameter. It can be the depth. It's not clear.<br/>4 I assume it was in the diameter. My assumption it was in<br/>5 the diameter.</p> <p>6 Q. So just to be clear, you assume that zones can<br/>7 extend from the perforation site into the tissue for a<br/>8 length ranging from about 5 microns to about 100 microns was<br/>9 a width?</p> <p>10 A. That was my assumption, yes.</p> <p>11 Q. Okay.</p> <p>12 A. Actually on this slide, one of the slides I<br/>13 presented today.</p> <p>14 Q. Let's take a look at that slide now. Why don't<br/>15 we take a look at RDX-10 at 28.</p> <p>16 A. Mm-hmm.</p> <p>17 Q. So to be clear, what you colored in red shown as<br/>18 a width for zones of coagulation at the bottom of that page<br/>19 is described in the text of Ganz as a length into the tissue<br/>20 of about 5 microns to about 100 microns; is that right?</p> <p>21 A. That was and -- that was and is my understanding,<br/>22 yes.</p> <p>23 Q. Let's turn to Manstein. Can we agree that the<br/>24 Examiner had Manstein before him during prosecution?</p> <p>25 A. Before -- yes, he did, yes.</p> |
| <p style="text-align: right;">1038</p> <p>1 on this very issue?</p> <p>2 A. I remember that, and I checked again recently,<br/>3 and it's what I said. At the deposition, it's a stressful<br/>4 situation where somebody asks you, a nice person, asked me<br/>5 questions, under pressure. And, you know, I'm human. I<br/>6 make mistakes, like everybody makes mistakes. So I checked<br/>7 again, and I cannot confirm now whether this is under mono<br/>8 or bipolar. I'm sorry.</p> <p>9 Q. Okay. Just to make sure I understand your<br/>10 testimony clearly today, you don't know whether Figs. 9 and<br/>11 10 in Ganz are monopolar or bipolar. Do I have that right?</p> <p>12 A. Correct.</p> <p>13 Q. So you don't know whether Ganz shows any outcome<br/>14 or results using bipolar electrodes, right?</p> <p>15 A. That's correct.</p> <p>16 Q. Now let's take a look at paragraph 48 of Ganz.<br/>17 It was shown on your RDX slide, but I think it would<br/>18 probably be easiest to take a look at it in Ganz. Let's<br/>19 take a look at RX-329 at 11.</p> <p>20 Do you see the second sentence states, "the zones<br/>21 can extend from the perforation site into the tissue for a<br/>22 length ranging from about 5 microns to about 100 microns"? </p> <p>23 A. Yes.</p> <p>24 Q. And just to make sure we're on the same page,<br/>25 that's describing the length of the coagulation zones down</p>                                                          | <p style="text-align: right;">1040</p> <p>1 Q. The Examiner had the opportunity to review<br/>2 Manstein during prosecution, right?</p> <p>3 A. Yes.</p> <p>4 Q. Indeed, the Examiner was supposed to review and<br/>5 interpret the prior art of record, including Manstein,<br/>6 correct?</p> <p>7 A. That's correct.</p> <p>8 Q. Now during prosecution of the '836 patent, the<br/>9 applicant distinguished Manstein because Manstein has<br/>10 intersecting damage in what it calls bipolar mode, correct?</p> <p>11 A. Possible, yes.</p> <p>12 Q. You don't remember?</p> <p>13 A. I don't remember this exactly. It's been a few<br/>14 months. I haven't read my statements. I don't agree or<br/>15 disagree. I don't remember the details of that, yeah.</p> <p>16 Q. Well, let's take a look at the figure you showed<br/>17 for Manstein. RX-304 at 5.</p> <p>18 Do you recall showing this figure from Manstein<br/>19 in your slides?</p> <p>20 A. Yes, I do.</p> <p>21 Q. The thermal damage regions 370 in this figure,<br/>22 Fig. 3 of Manstein, are showing the result of using a<br/>23 monopolar configuration, right?</p> <p>24 A. That's correct.</p> <p>25 Q. Let's talk for a moment about your</p>                                                    |