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1109 1 UNITED STATES INTERNATIONAL TRADE COMMISSION 2 Washington, D.C. 3 Before the Honorable MaryJoan McNamara 4 Administrative Law Judge 5 -----x 6 In the Matter of Investigation No. 7 8 CERTAIN DERMATOLOGICAL TREATMENT 337-TA-1356 9 DEVICES AND COMPONENTS THEREOF 10 -----x 11 12 International Trade Commission 13 500 E Street, SW 14 Washington, D.C. 15 16 Evidentiary Hearing 17 Monday, December 11, 2023 18 Volume V 19 20 The parties met remotely pursuant to notice of 21 the Administrative Law Judge at 9:30 a.m. Eastern. 22 23 24 Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR 25	1111 1 A P P E A R A N C E S (continued): 2 3 Counsel for Respondent EndyMed Medical Inc.; EndyMed Medical 4 Ltd.: 5 PEARL COHEN ZEDEK LATZER BARATZ LLP 6 7 Times Square, 19th Floor 7 New York, New York 10036 8 (646) 878-0800 9 Guy Yonay, Esq. 10 Kyle Auteri, Esq. 11 12 Counsel for Respondent Cutera, Inc.; Ilooda Co., Ltd.: 13 COVINGTON & BURLING LLP 14 850 Tenth Street, NW 15 Washington, DC 20001 16 (202) 662-6000 17 W. Kiersten Choi, Ph.D., Esq. 18 Brian Nester, Esq. 19 20 21 22 23 24 25 CONTINUED ON FOLLOWING PAGE
1110 1 A P P E A R A N C E S: 2 [All participants appeared via videoconferencing or 3 telephonically.] 4 Counsel for Complainant Serendia, LLC: 5 LATHAM & WATKINS LLP 6 555 11th Street, NW 7 Washington, DC 20004 8 (202) 637-2200 9 Michael A. David, Esq. 10 Cecilia Sanabria, Esq. 11 Kevin C. Wheeler, Esq. 12 Bradley A. Hyde, Esq. 13 14 Counsel for Respondent Cynosure, LLC; Jeisys Medical Inc.: 15 LEYDIG, VOIT & MAYER, LTD. 16 Two Prudential Plaza 17 Chicago, Illinois 60601 18 (312) 616-5600 19 David M. Airan, Esq. 20 James W. Sanner, Esq. 21 Brian Rupp, Esq. 22 Wallace Feng, Esq. 23 Leonard Hua, Esq. 24 Paul Bartkowski, Esq. 25	1112 1 A P P E A R A N C E S (continued): 2 3 -and- 4 Counsel for Respondent Cutera, Inc.; Ilooda Co., Ltd.: 5 COVINGTON & BURLING LLP 6 3000 El Camino Real 7 Palo Alto, California 94306 8 (650) 632-4700 9 Anupam Sharma, Esq. 10 11 -and- 12 COVINGTON & BURLING LLP 13 415 Mission Street, Suite 5400 14 San Francisco, California 94105 15 (415) 591-6000 16 Dale A. Rice, Esq. 17 Thomas E. Garten, Esq. 18 19 20 21 22 23 24 25 CONTINUED ON FOLLOWING PAGE

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1113 1 A P P E A R A N C E S (continued): 2 3 Counsel for the Office of Unfair Import Investigations: 4 U.S. International Trade Commission 5 500 E Street, SW 6 Washington, DC 20436 7 (202) 205-2000 8 Aaron D. Rauh, Esq. 9 Investigative Attorney 10 Jeffrey Hsu, Esq. 11 Supervisory Attorney 12 13 14 15 **Index appears at end of transcript** 16 17 18 19 20 21 22 23 24 25	1115 1 JUDGE MCNAMARA: Jae or Nicole, would you please 2 admit all the participants to the hearing? Please get 3 together and confer. It will be a few minutes. 4 MS. SANABRIA: I'm hearing a lot of feedback. 5 MR. WHEELER: Judge McNamara, can you hear me? 6 JUDGE MCNAMARA: Mr. Wheeler, I now can hear you, 7 yes, but, again, most everybody else seems to be absent. In 8 other words, they haven't turned on their video or perhaps 9 they haven't been admitted yet. 10 Nicole, what's the status? 11 MS. MUHAMMAD: I'm not seeing anyone to be 12 admitted. 13 JUDGE MCNAMARA: Slowly people are coming in. As 14 you check in, would you please identify yourself? 15 Mr. Wheeler, you already have. Who else is on 16 who can hear me? 17 MR. AUTERI: This is Kyle Auteri here for 18 EndyMed, also here with Guy Yonay. 19 MR. YONAY: Good morning, Your Honor. 20 JUDGE MCNAMARA: Good morning. That was 21 Mr. Yonay? 22 MR. YONAY: Yes, it was. 23 JUDGE MCNAMARA: Please identify yourselves. 24 MR. NESTER: Good morning, Your Honor. This is 25 Brian Nester with Ilooda and Cutera, and with me are Mika
1114 1 P R O C E E D I N G S 2 (In session at 9:30 a.m.) 3 JUDGE MCNAMARA: We're here on the continued 4 hearing. For the Complainant, would you kindly identify 5 yourself and introduce your team again? We've gone through 6 this before, but just to be sure. 7 Hello? No one is speaking up. Counsel for 8 Complainant? Hello? No one is speaking up. 9 Ms. Kinkade, no one is speaking up from the 10 Complainant's side. And I'm also seeing that nobody seems 11 to be available on video. They haven't turned on their 12 video. 13 MR. NESTER: This is Brian Nester. We can start 14 with the Respondents, if you prefer, while the Complainants 15 get their technology together. 16 JUDGE MCNAMARA: That would be great. For the 17 EndyMed Respondents, good morning. 18 MS. SANABRIA: Your Honor, this is Cecelia 19 Sanabria for Serendia. We are waiting to be admitted in the 20 waiting room. 21 JUDGE MCNAMARA: Really? Nicole or Jae, would 22 you please take care of this? You should have been right 23 in. 24 MS. SANABRIA: Apologies. We can't hear 25 anything.	1116 1 Ceta and Kiersten Choi. And I will turn it over to Jeisys. 2 MR. AIRAN: Good morning, Your Honor. David 3 Airan on behalf of Jeisys, and with me in counsel room here is 4 Leonard Hua and Paul Bartkowski, and I also have James 5 Sanner with me as well in the conference room. 6 JUDGE MCNAMARA: Very good. Thank you. 7 There are some other folks on. And I want to be 8 sure that everybody is coming in. Nicole, we're still 9 having problems. 10 MS. MUHAMMAD: Judge, I do not have a feature 11 where we have to let them in. They just come in. There is 12 no one waiting in the waiting room. 13 JUDGE MCNAMARA: Okay. Then I'm not sure what's 14 going on here. 15 Mr. Rupp, are you there? 16 Ms. Rice? 17 Mr. Rauh, I can see that you're there. 18 MR. RAUH: Good morning, Judge McNamara. This is 19 Aaron Rauh on behalf of the Commission Investigative Staff, 20 and with me is Jeff Hsu. 21 JUDGE MCNAMARA: Yes. Good morning, Mr. Hsu. 22 MR. HSU: Good morning, Your Honor. 23 JUDGE MCNAMARA: Good morning. How are you? 24 MR. HSU: Good. Thank you. 25 JUDGE MCNAMARA: I see Mr. Garten is there, but

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1265 1 flood-a-funded study, even the widest thermal zone was not 2 wide enough to extend fully between electrodes; isn't that 3 correct? 4 A. You cannot say that. 5 Q. You can't say that. 6 A. Cannot, that's correct. 7 Q. So let me -- mathematically, the widest observed 8 thermal zone was 785 microns, plus or minus, 212, right? 9 A. That's irrelevant actually because of shrinkage 10 and the coupling -- 11 Q. Dr. Berube, I didn't ask you whether it was 12 irrelevant. And your attorney will have the opportunity to 13 get up here and let you explain why you think that it's not 14 relevant. 15 MR. FARNOLY: Your Honor, we're going to object. 16 Counsel is continuously interrupting the witness. He should 17 be able to at least explain his answer, at least answer the 18 question. 19 JUDGE MCNAMARA: I could not hear you. I'm 20 sorry. Would you repeat your objection? 21 MR. FARNOLY: Yes, Your Honor. Dan Farnoly 22 behalf of the Respondents. We're going to object to this 23 constant interruption from counsel. If the witness -- the 24 witness is trying to answer the question, and he is 25 repeatedly cutting him off. He should be at least be able	1267 1 reasons -- 2 A. I would not word it that way. I would not have 3 worded it that way. 4 Q. Okay. Well, so let's pull up your slide here. 5 This is, again, I believe the one we just had up, 18. 6 On the bottom left you said "cross-section 7 slicing." So you said one reason why you don't think these 8 measurements should be trusted is they might have been 9 sliced in the wrong cross-section. Is that a fair 10 representation of your testimony? 11 A. That's fair. 12 Q. Okay. But you don't actually cite to any piece 13 of evidence showing that they were sliced in a configuration 14 that would not show any of this coagulation between, do you? 15 A. No, because I cannot cite evidence, because it 16 was not provided. 17 Q. That's my point. You don't point to anything 18 saying that in every single one of these tests they sliced 19 it in apparently the wrong way so that you just wouldn't see 20 these results that you say might exist of coagulation 21 between electrodes, right? 22 A. The contrary is also true. The contrary is also 23 true in the fact that you cannot -- there's nothing in this 24 report to suggest that the maximum width and length of those 25 thermal zones were cut.
1266 1 to answer the question. 2 MR. HYDE: Your Honor -- 3 JUDGE MCNAMARA: Hold on just a moment. I agree 4 that you should not try to cut him off. On the other hand, 5 I do think it's appropriate to redirect the witness and ask 6 him to answer the question as posed, and I think it was a 7 narrowly structured question. 8 MR. HYDE: I appreciate that, Your Honor. I'm 9 doing my best -- I apologize. I think sometimes there is 10 also a little bit of delay in the feed, Your Honor, so I'm 11 trying not to interrupt the witness. 12 Q. Dr. Berube, I do respect you and I don't want to 13 interrupt you. I'm trying to ask my specific question, and 14 I'm looking for questions for my specific answer, and your 15 counsel will have the opportunity to allow you to explain 16 using their time. 17 A. Sure. 18 Q. Okay. Now I think you were actually just about 19 to talk about this, Dr. Berube. Mathematically, these 20 thermal zone widths didn't extend fully between electrodes, 21 but your opinion is, is that that's not really relevant, and 22 one reason is because, well, you can't trust the tissue 23 stains. They could have been sliced in a different 24 orientation, which wouldn't have shown really the electrodes 25 in the right configuration, right? That's one of your	1268 1 Q. So there's nothing in this report -- 2 A. So it's unknown. You cannot say anything. It is 3 unknown. 4 Q. It's unknown. You actually don't have any basis 5 for how it was sliced; is that correct? 6 A. Well, I stand with what I just said. It's 7 unknown. 8 Q. It's unknown. Okay. 9 So the patents in this investigation do not 10 involve ablation; is that correct? You would agree with 11 that? 12 A. You said the patents in this investigation do not 13 involve ablation. 14 Q. Correct. 15 A. Well, yeah, ablation is not, correct. 16 Q. And they are instead trying to generate a thermal 17 injury to generate a wound response, a wound-healing 18 response? 19 A. Who are you referring to? 20 Q. The patents. 21 A. The patents? 22 Q. I'll just rephrase the question here just to 23 clarify. 24 The patent, the '836 patent investigation, does 25 not involve ablation, correct?

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1269 1 A. That's correct. 2 Q. Okay. So rather than ablating tissue, in RF 3 microneedling devices, like the accused Secret products, the 4 thermal injury is designed to trigger a wound-healing 5 sequence in the skin stimulating new collagen, right? 6 A. That's my scientific understanding of it, 7 although it is not in the patent, agreed. 8 Q. So I have a few quick questions here on this, and 9 then I want to move to the other patents. 10 You mentioned a little bit about marketing 11 materials and how there are cartoons and such. You agree 12 it's important to avoid misleading people in marketing an 13 FDA-approved device to the public, right? 14 A. Well, you're using the word "misleading," and 15 misleading involves an intent to deceive people. And so you 16 can communicate wrong information. I don't believe that 17 that's what Ilooda and Cutera is doing. 18 Q. Dr. Berube, did I ask you whether Ilooda and 19 Cutera were communicating wrong information, or did I ask 20 you a very specific question here? Do you agree that it's 21 important to avoid misleading people in marketing an 22 FDA-approved device? 23 A. Certainly the FDA -- you don't want to deceive 24 the FDA and marketing -- I mean, marketing is not -- is 25 intended to create a demand for the product.	1271 1 they don't deploy. Nobody will say they deploy from there. 2 Q. Dr. Berube, again, I'm asking you to answer my 3 specific question. You don't dispute that the needles will 4 move past that green line when they are moving into the 5 skin, right? 6 A. The needle will pass the green line. They will, 7 yes. 8 Q. Okay. You don't dispute that a user can select 9 the depth of the needle insertions, right? 10 A. I don't dispute that. 11 Q. But, again, your opinion is that needles do not 12 extend a desired distance from the needle assembly end 13 surface. Do I understand that correctly? It's just a yes 14 or no question. 15 A. I'm thinking about what you just said. Can you 16 repeat, please? 17 Q. Once again, it's still your opinion that the 18 needles do not extend a desired distance from the needle 19 assembly end surface. 20 A. That's correct. 21 Q. Okay. So Ms. Sullivan, can we pull up RDX-12C at 22 11, slide 11? 23 This is your other noninfringement opinion. You 24 say the needle assembly does not include a translucent 25 section. Do you remember that?
1270 1 Q. Let's try this a different way. Yes or no, Dr. 2 Berube, you agree that it's important to avoid misleading 3 people in marketing an FDA-approved device to the public, 4 right? 5 A. Yes. 6 Q. Okay. And you agree that the audience for 7 marketing FDA approved RF microneedling devices includes 8 medical professionals and potential patients, right? 9 A. Right. 10 Q. Let's talk about your opinions for the '812 and 11 '536 patent real quick. Can we pull up slide 10 from Dr. 12 Berube's deck? 13 Now this slide shows your noninfringement 14 opinions for the needles do not extend a desired distance 15 from the needle assembly end surface, right? 16 A. Yes. 17 Q. You don't dispute that the needles extend from 18 the needle module end surface, right? 19 A. I believe the needle module is the cartridge, 20 right, and they extend from the -- from the blue line over 21 there, from the cartridge patient interface. 22 Q. Okay. And in the Secret products you don't 23 dispute that the needles deploy past that green line in 24 operation to be inserted in the skin, right? 25 A. They move in relationship with the line, but --	1272 1 A. Mm-hmm. Yes, I do. 2 Q. And that's because you've limited the needle 3 assembly to just the PCB item here that you labeled in 4 yellow; is that correct? 5 A. Yeah, because that's the only assembly. 6 Q. Okay. So that was a yes? 7 A. Of course. 8 Q. Okay. So, Ms. Sullivan, can we pull up the '536 9 patent? That's JX-1, Fig. 11C. Next to that can we pull up 10 the specification, column 13, lines 1-5. 11 And I assume that you've read the '536 patent, 12 Dr. Berube? 13 A. A little while ago, yes. 14 Q. Okay. So we see the portion in the specification 15 on the right here that's describing the figure on the left 16 and it says, as shown in Figs. 11B and 11C, the needle 17 assembly 924F may include a pin cover, drive arm module, 18 needles, pins with bases, and needle printed circuit board, 19 the PCB. Do you see that? Do you see the text that I just 20 read? 21 A. Yeah. I'm making the link between the numbers. 22 I see the text, of course I do, so I'm trying to see line 23 924G. Let me read that, please. Give me a moment, please. 24 I cannot locate 924G. Where is that? 25 Q. So my question, Dr. Berube, was did you see the