

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

3 MEDTRONIC, INC., AND MEDTRONIC
4 VASCULAR, INC.,

5 Petitioners,

6 vs.

7 TELEFLEX INNOVATIONS S.A.R.L.,

8 Patent Owner.

9 IPR2020-00126 (Patent 8,048,032 B2)
10 IPR2020-00127 (Patent 8,048,032 B2)
11 IPR2020-00128 (Patent RE45,380 E)
12 IPR2020-00129 (Patent RE45,380 E)
13 IPR2020-00130 (Patent RE45,380 E)
14 IPR2020-00132 (Patent RE45,760 E)
15 IPR2020-00134 (Patent RE45,760 E)
16 IPR2020-00135 (Patent RE45,776 E)
17 IPR2020-00136 (Patent RE45,776 E)
18 IPR2020-00137 (Patent RE47,379 E)
19 IPR2020-00138 (Patent RE47,379 E)

20 VIDEOTAPED DEPOSITION OF
21 DEBORAH L. SCHMALZ

22 DATE: November 12, 2020

23 TIME: 10:32 a.m. Central Time

24 PLACE: Veritext Virtual Videoconference

25 REPORTED BY: PAULA K. RICHTER, RMR, CRR, CRC
(By videoconference)

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<p>1 APPEARANCES</p> <p>2 ON BEHALF OF THE PETITIONERS (By videoconference):</p> <p>3 Ms. Emily J. Tremblay, Esq.</p> <p>4 Mr. Cyrus A. Morton, Esq.</p> <p>5 ROBINS KAPLAN, LLP</p> <p>6 800 LaSalle Avenue, Suite 2800</p> <p>7 Minneapolis, Minnesota 55401</p> <p>8 (612) 349-8500</p> <p>9 etremblay@robinskaplan.com</p> <p>10 cmorton@robinskaplan.com</p> <p>11</p> <p>12 ON BEHALF OF THE PATENT OWNER (By videoconference):</p> <p>13</p> <p>14 Ms. Tara C. Norgard, Esq.</p> <p>15 Mr. J. Derek Vandenburg, Esq.</p> <p>16 Ms. Megan E. Christner, Esq.</p> <p>17 CARLSON, CASPERS, VANDENBURGH & LINDQUIST</p> <p>18 225 South Sixth Street, Suite 4200</p> <p>19 Minneapolis, Minnesota 55402</p> <p>20 (612) 436-9600</p> <p>21 tnorgard@carlsoncaspers.com</p> <p>22 dvandenburg@carlsoncaspers.com</p> <p>23 mchristner@carlsoncaspers.com</p> <p>24</p> <p>25 (APPEARANCES continued on next page)</p>	<p>1 INDEX</p> <p>2</p> <p>3 WITNESS: DEBORAH L. SCHMALZ PAGE:</p> <p>4 EXAMINATION BY MS. TREMBLAY..... 7</p> <p>5</p> <p>6</p> <p>7 EXHIBITS REFERRED TO: PAGE:</p> <p>8 EXHIBIT 1110 July 2006 Updates,</p> <p>9 VSIMDT00031726-31746..... 74</p> <p>10 EXHIBIT 1111 April 2007 Updates,</p> <p>11 VSIMDT00031755-31774..... 75</p> <p>12 EXHIBIT 1112 October 2007 Updates,</p> <p>13 VSIMDT00031792-31821..... 76</p> <p>14 EXHIBIT 1113 February 2008 Updates,</p> <p>15 VSIMDT00031851-31877..... 77</p> <p>16 EXHIBIT 2024 Product Requirements for</p> <p>17 GuideLiner,</p> <p>18 VSIMDT00030178-30181..... 55</p> <p>19 EXHIBIT 2025 Clinical Technical Report on</p> <p>20 Use of Catheters in a Coronary</p> <p>21 Application,</p> <p>22 VSIMDT00030139-30167..... 63</p> <p>23 EXHIBIT 2038 July 2008 Updates,</p> <p>24 VSIMDT00031912-31936..... 78</p> <p>25 EXHIBIT 2039 Declaration of Deborah Schmalz.. 35</p>
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<p>1 APPEARANCES (Continued)</p> <p>2</p> <p>3 ALSO PRESENT:</p> <p>4 Adam Wallin - Videographer</p> <p>5 Paul Zalesky</p> <p>6 Greg Smock</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</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>	<p>1 (EXHIBITS continued)</p> <p>2 EXHIBIT 2040 8/26/05 Memorandum to Deborah</p> <p>3 Neymark from Rose Griffith Re:</p> <p>4 Weekly Staff Meeting,</p> <p>5 VSIMDT00030135-30138..... 66</p> <p>6 EXHIBIT 2041 October 2005 Updates,</p> <p>7 VSIMDT00029978-29995..... 70</p> <p>8 EXHIBIT 2109 5/2/06 GuideLiner Team Meeting,</p> <p>9 VSI_00000771..... 81</p> <p>10</p> <p>11 (Original exhibits attached to original transcript;</p> <p>12 copies provided to counsel.)</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>

<p style="text-align: right;">Page 6</p> <p>1 PROCEEDINGS</p> <p>2 THE VIDEOGRAPHER: We are going on</p> <p>3 the record at 10:32 a.m. Central Time on November</p> <p>4 12th, 2020.</p> <p>5 This is Media Unit 1 of the video</p> <p>6 recorded deposition of Deborah L. Schmalz being</p> <p>7 taken via Zoom and taken in the matter of</p> <p>8 Medtronic, Incorporated and Medtronic Vascular,</p> <p>9 Incorporated versus Teleflex Innovations,</p> <p>10 S.A.R.L., in the United States Patent and</p> <p>11 Trademark Office before the Patent Trial and</p> <p>12 appeal board; Case Number IPR2020-00128.</p> <p>13 My name is Adam Wallin from the firm</p> <p>14 Veritext, and I am the videographer. The court</p> <p>15 reporter is Paula Richter from the firm Veritext.</p> <p>16 Will counsel please identify</p> <p>17 themselves for the record.</p> <p>18 MS. TREMBLAY: Good morning. My</p> <p>19 name is Emily Tremblay. I'm an attorney with</p> <p>20 Robins Kaplan. Also with me today from Robins</p> <p>21 Kaplan is Cy Morton on behalf of Medtronic, Inc.</p> <p>22 and Medtronic Vascular, Inc. Also on the phone</p> <p>23 today is our expert, Paul Zalesky.</p> <p>24 MS. NORGDARD: Good morning. I'm</p> <p>25 Tara Norgard on behalf of the witness and the</p>	<p style="text-align: right;">Page 8</p> <p>1 First, as you know, I'm going to ask</p> <p>2 you a series of verbal questions, and you're going</p> <p>3 to do your best to answer them truthfully and</p> <p>4 completely. We're going to do our best to speak</p> <p>5 one at a time for the court reporter's benefit,</p> <p>6 and I'd just ask that you make sure that your</p> <p>7 answers are given verbally as opposed to by</p> <p>8 nodding your head yes or shaking your head no and</p> <p>9 that you do your best to speak slowly and clearly</p> <p>10 for the record. Is that fair?</p> <p>11 A. Yes.</p> <p>12 Q. And then before we get started today, is</p> <p>13 there anyone in the room with you today?</p> <p>14 A. No, there is not.</p> <p>15 Q. As we go through the questions today, if you</p> <p>16 don't understand my question, please ask me to</p> <p>17 rephrase it. I will assume that if you do answer</p> <p>18 my question, that you heard it and you understood</p> <p>19 it. Is that fair?</p> <p>20 A. Yes.</p> <p>21 Q. We will be taking breaks, but if you need or</p> <p>22 want one, please just let us know. I only ask</p> <p>23 that if I've asked you a question, that you answer</p> <p>24 it before we go on break so that there's not a</p> <p>25 question pending on the record. Is that fair?</p>
<p style="text-align: right;">Page 7</p> <p>1 respondents in this action. With me today is</p> <p>2 Derek Vandenburg and Megan Christner, also with</p> <p>3 Carlson Caspers. And also joining us is</p> <p>4 Greg Smock, in-house counsel for Teleflex.</p> <p>5 THE VIDEOGRAPHER: Will the court</p> <p>6 reporter please swear in the witness.</p> <p>7 DEBORAH L. SCHMALZ,</p> <p>8 duly sworn, was examined and testified as follows:</p> <p>9 EXAMINATION</p> <p>10 BY MS. TREMBLAY:</p> <p>11 Q. Good morning, Ms. Schmalz.</p> <p>12 A. Good morning.</p> <p>13 Q. Could you please -- could you please state</p> <p>14 your full name for the record and spell your last</p> <p>15 name.</p> <p>16 A. Deborah Lynn Schmalz. The last name is</p> <p>17 spelled S-C-H-M-A-L-Z.</p> <p>18 Q. My name is Emily Tremblay. I'm an attorney</p> <p>19 with Robins Kaplan and I represent Medtronic, Inc.</p> <p>20 and Medtronic Vascular, Inc. Have you given a</p> <p>21 deposition before, Ms. Schmalz?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. So you're familiar with the process.</p> <p>24 I'm going to go over just a few ground rules</p> <p>25 before we get started here.</p>	<p style="text-align: right;">Page 9</p> <p>1 A. Yes.</p> <p>2 Q. Have you consumed any alcohol today?</p> <p>3 A. No, I have not.</p> <p>4 Q. Have you taken any controlled substances or</p> <p>5 prescription medication?</p> <p>6 A. No.</p> <p>7 Q. Is there any reason that you will not be able</p> <p>8 to answer my questions truthfully and completely</p> <p>9 today?</p> <p>10 A. No.</p> <p>11 Q. Do you have any questions about the process</p> <p>12 before we begin?</p> <p>13 A. Not at this time.</p> <p>14 Q. What did you do to prepare for your</p> <p>15 deposition today? And before you answer, I want</p> <p>16 to be clear that I'm not interested in any advice</p> <p>17 that you may have received from your attorneys,</p> <p>18 but I am interested in general in what you did to</p> <p>19 prepare.</p> <p>20 A. I reviewed the -- my prior statement that had</p> <p>21 been prepared in March, the documents that were</p> <p>22 referenced in that, and spoke to the attorneys in</p> <p>23 this matter.</p> <p>24 Q. Did you review any documents that aren't</p> <p>25 cited in your declaration?</p>

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<p style="text-align: right;">Page 10</p> <p>1 A. No, I did not. 2 Q. Did you speak with anyone other than your 3 attorneys? 4 A. No. 5 Q. Did you do anything else to prepare for 6 today? 7 A. No. 8 Q. Ms. Schmalz, I'd just like to discuss your 9 background briefly before we get going. Where do 10 you currently work? 11 A. I currently am employed at a company called 12 Ablative Solutions. 13 Q. And what is your position with Ablative 14 Solutions? 15 A. My position is the vice president of 16 regulatory affairs and clinical research. 17 Q. Could you briefly describe some of your 18 responsibilities in that role? 19 A. Sure. My responsibilities include all 20 corporate matters relative to clinical trial 21 conduct and design, and negotiations with the 22 associated regulatory agencies that we're dealing 23 with. 24 Q. And how long have you been with Ablative 25 Solutions?</p>	<p style="text-align: right;">Page 12</p> <p>1 and ended my time with them in February because 2 the company ceased to operate. They had lost 3 their funding. 4 Q. And before you joined NeuroTronik in 2019, 5 where were you employed? 6 A. At a company called ReShape Lifesciences. 7 Q. And what was your role with ReShape 8 Lifesciences? 9 A. My role at ReShape was as the vice president 10 of regulatory affairs, clinical research, quality 11 and compliance. 12 Q. Were some of your responsibilities in that 13 role similar to those that you've described with 14 respect to your positions with NeuroTronik and 15 Ablative Solutions? 16 A. Yes, with the addition of compliance-related 17 matters in terms of overarching compliance outside 18 of the regulatory agency issues, like FDA matters. 19 Q. And how long were you with ReShape? 20 A. I joined ReShape in October of 2017 and 21 remained there until I began my position at 22 NeuroTronik. 23 Q. We're just going to keep working our way 24 backwards here. 25 A. Okay.</p>
<p style="text-align: right;">Page 11</p> <p>1 A. I joined Ablative Solutions in June of this 2 year. 3 Q. And where were you before you joined Ablative 4 Solutions? 5 A. Prior to working for Ablative Solutions, I 6 was employed at a company called NeuroTronik, Inc. 7 Q. What was your position with NeuroTronik, 8 Inc.? 9 A. My position at NeuroTronik was the vice 10 president of clinical research, regulatory 11 affairs, and quality. 12 Q. Could you just briefly describe some of your 13 responsibilities in that role? 14 A. Certainly. In that role at NeuroTronik, my 15 responsibilities, again, included all of the 16 overall corporate responsibilities for clinical 17 research, the regulatory affairs, interactions 18 with agencies that governed our product, and in 19 addition, I had responsibilities for the quality 20 systems and quality functions within the 21 organization. 22 Q. And how long have you -- or excuse me. How 23 long were you with NeuroTronik, Inc.? 24 A. I started with them in February -- I'm sorry. 25 I apologize. I started with them in June of 2019,</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. Where were you before you joined ReShape? 2 A. Before that I was at a company called 3 Medpace. 4 Q. And what was your title when you were with 5 Medpace? 6 A. My title was the executive director of the 7 medical device group. 8 Q. And what were some of your responsibilities 9 in that role? 10 A. My responsibilities included the overall 11 business direction for the medical device group 12 within Medpace. Medpace is a contract research 13 organization, so we provided clinical trial 14 management services and regulatory affairs support 15 services for companies that needed our assistance. 16 So I had the overarching responsibilities for all 17 of the staff members that supported sponsors. 18 Q. And when did you join Medpace? 19 A. I joined Medpace in May of 2013. 20 Q. And before you joined Medpace in May of 2013, 21 where were you employed? 22 A. I worked for a company called Veniti. That's 23 spelled V-E-N-I-T-I. And I was employed as their 24 vice president of clinical, regulatory and 25 quality.</p>

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<p style="text-align: right;">Page 14</p> <p>1 Q. And could you just briefly describe some of 2 your responsibilities in that role? 3 A. I had the overarching corporate 4 responsibilities for clinical trial matters, 5 quality, and regulatory matters. 6 Q. And I apologize if this is getting a bit 7 iterative. I just want to make sure we have your 8 full history here. Before you -- excuse me. When 9 did you join Veniti? 10 A. I started with them as a consultant in 11 November of 2010 and formally joined them as an 12 employee in March of 2011. 13 Q. And before you joined Veniti in November of 14 2010, where were you employed? 15 A. For a short time I was working as an 16 independent consultant, supporting a variety of 17 different small companies based in the Twin 18 Cities. 19 Q. And before your time as an independent 20 consultant, where were you employed? 21 A. At a company called Entellus, 22 E-N-T-E-L-L-U-S. 23 Q. And what was your title when you were with 24 Entellus? 25 A. It was as the vice president of regulatory</p>	<p style="text-align: right;">Page 16</p> <p>1 before -- I think you joined Vascular Solutions in 2 September of 2000; is that correct? 3 A. That is correct. Before that time -- 4 Q. Before September -- 5 A. Oh, yeah. 6 Q. Sorry, go ahead. Before September of 2000, 7 where were you employed? 8 A. The company that I worked at before Vascular 9 Solutions was called Empi. That is spelled 10 E-M-P-I. I was hired by Empi in -- I think in 11 September of 1995. The months -- the months are a 12 bit of a blur at this point. And I was hired as 13 the director of regulatory affairs, clinical 14 research, and quality for the company. 15 In 1997 I was then promoted to the 16 vice president role, overseeing those corporate 17 functions. 18 Q. And before Empi, where were you employed? 19 A. Boston Scientific. 20 Q. And what was your role with Boston? 21 A. Regulatory affairs manager. 22 Q. And how would your responsibilities as a 23 regulatory affairs manager have differed from some 24 of the responsibilities we've discussed so far? 25 A. Well, this was more of an individual</p>
<p style="text-align: right;">Page 15</p> <p>1 affairs, clinical research, and quality and 2 reimbursement. 3 Q. That is such a surprising answer. 4 A. I know. 5 Q. Could you briefly just describe some of your 6 responsibilities in that role for Entellus? 7 A. I had the overarching corporate 8 responsibilities for regulatory affairs matters, 9 clinical research matters, reimbursement matters, 10 and quality matters. 11 Q. And when did you join Entellus? 12 A. July of 2008 and I left in July of 2010. 13 Q. And before you joined Entellus, where were 14 you employed? 15 A. Vascular Solutions. 16 Q. I do want to come back and we'll obviously 17 spend a fair amount of time today talking about 18 your time at Vascular Solutions, but before you 19 joined Vascular Solutions, could you give me kind 20 of a high level sense of your experience coming 21 into Vascular Solutions? 22 A. Certainly. Would you like me to continue to 23 work backwards or just generally -- generally 24 discuss that? 25 Q. Sure, let's just keep working backwards. So</p>	<p style="text-align: right;">Page 17</p> <p>1 contributor role, although I did have someone 2 reporting to me, but I had responsibilities for 3 projects -- specific projects that Boston 4 Scientific was working on, specifically with 5 respect to securing approval through either 6 510(k)s or PMAs through FDA. 7 Q. And when did you join Boston? 8 A. Probably May of 1991, spring of 1991. 9 Q. Let's go back to Vascular Solutions. 10 A. Sure. 11 Q. So I believe you mentioned that you joined 12 VSI as vice president of regulatory and clinical 13 affairs; is that correct? 14 A. I also had responsibilities for quality. 15 Q. Quality systems? 16 A. All aspects of quality, so that would have 17 been the quality engineering group, plus quality 18 systems. 19 Q. And did you remain in that role until you 20 left VSI? 21 A. At some point in time, and I do not recall 22 the exact date, the company brought in a vice 23 president of quality because the job had grown so 24 much. And so I retained the responsibilities for 25 clinical regulatory and added reimbursement to my</p>

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