

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)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

15 REMOTE VIDEOTAPED DEPOSITION OF
16 STEPHEN BRECKER, M.D.

17 DATE: January 19, 2021
18 TIME: 5:03 a.m. (Central)
19 PLACE: Veritext Virtual Videoconference

20 PAGES: 1 to 180
21 JOB NO.: MW 4402842
22 REPORTED BY: Merilee Johnson, RDR, CRR, CRC, RSA
23
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<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES (All appearing remotely via videoconference)</p> <p>2</p> <p>3 ON BEHALF OF THE PETITIONERS:</p> <p>4 ROBINS KAPLAN LLP BY: Sharon E. Roberg-Perez, Esq. Cyrus A. Morton, Esq. Ryan E. Dornberger 800 LaSalle Avenue Suite 2800 Minneapolis, Minnesota 55402 Phone: (612) 349-8500 Email: SROberg-Perez@RobinsKaplan.com Email: CMorton@RobinsKaplan.com Email: RDornberger@RobinsKaplan.com</p> <p>9</p> <p>10 ON BEHALF OF THE PATENT OWNERS:</p> <p>11 DORSEY & WHITNEY, LLP 12 BY: Kenneth E. Levitt, Esq. 50 South Sixth Street Suite 1500 Minneapolis, Minnesota 55402 Phone: (612) 340-2600 Email: Levitt.Kenneth@Dorsey.com</p> <p>15</p> <p>16 -and-</p> <p>17 CARLSON, CASPERS, VANDENBURGH, LINDQUIST & SCHUMAN, PA BY: J. Derek Vandenburg, Esq. 225 South Sixth Street Suite 4200 Minneapolis, Minnesota 55402 Phone: (612) 436-9600 Email: DVandenburg@CarlsonCaspers.com</p> <p>21</p> <p>22 ALSO APPEARED:</p> <p>23 Greg Smock (Teleflex) 24 Peter Keith (Teleflex) 25 Justin Bond (Videographer)</p>	<p style="text-align: right;">Page 4</p> <p>1 EXHIBITS (Continued)</p> <p>2</p> <p>3 Exhibit 1026 United States Patent No. 21 4 5,489,278, 5 Date of Patent: February 6, 1996</p> <p>6 Exhibit 1055 Catheterization and 111 7 Cardiovascular Interventions, 8 dated November 2004</p> <p>9 Exhibit 1900 Declaration of Stephen Jon David 19 10 Brecker, MD, FRCP, FESC, FACC 11 Submitted in Support of 12 Petitioner's Opposition to Patent 13 Owner's Motion to Amend, 14 Case Nos. IPR2020-00126, 15 IPR2020-00127, 16 U.S. Patent No. 8,048,032</p> <p>17 Exhibit 1901 Declaration of Stephen Jon David 164 18 Brecker, MD, FRCP, FESC, FACC 19 Submitted in Support of 20 Petitioner's Opposition to Patent 21 Owner's Motion to Amend, 22 Case Nos. IPR2020-00137, 23 IPR2020-00138, U.S. 24 Patent No. RE47,379 25</p>
<p style="text-align: right;">Page 3</p> <p>1 INDEX</p> <p>2</p> <p>3 WITNESS: STEPHEN BRECKER, M.D. PAGE 4 Examination by Mr. Levitt..... 8</p> <p>5</p> <p>6 SPECIAL INSTRUCTIONS: 7 Page 154, Line 19</p> <p>8</p> <p>9 EXHIBITS</p> <p>10</p> <p>11 EXHIBITS MARKED AND FIRST REFERRED TO: PAGE</p> <p>12 Exhibit 1007 United States Patent No. 165 13 7,736,355 B2, 14 Date of Patent: June 15, 2010</p> <p>15 Exhibit 1008 United States Patent No. 22 16 7,604,612 B2, 17 Date of Patent: October 20, 2009</p> <p>18 Exhibit 1009 United States Patent No. 44 19 5,439,445, 20 Date of Patent: August 8, 1995</p> <p>21 Exhibit 1025 United States Patent Application 99 22 No. 2005/0015073 A1, 23 Publication Date: January 20, 24 2005 25</p>	<p style="text-align: right;">Page 5</p> <p>1 EXHIBITS (Continued)</p> <p>2</p> <p>3 Exhibit 1902 Declaration of Stephen Jon David 168 4 Brecker, MD, FRCP, FESC, FACC 5 Submitted in Support of 6 Petitioner's Opposition to Patent 7 Owner's Motion to Amend, 8 Case Nos. IPR2020-00128, 9 IPR2020-00129, 10 IPR2020-00130, 11 U.S. Patent No. RE45,380</p> <p>12 Exhibit 1903 Declaration of Stephen Jon David 169 13 Brecker, MD, FRCP, FESC, FACC 14 Submitted in Support of 15 Petitioner's Opposition to Patent 16 Owner's Motion to Amend, 17 Case Nos. IPR2020-00132, 18 IPR2020-00134, 19 U.S. Patent No. RE45,760 20 21 22 23 24 25</p>

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<p style="text-align: right;">Page 6</p> <p>1 E X H I B I T S 2 (Continued) 3 Exhibit 1904 Declaration of Stephen Jon David 112 4 Breckner, MD, FRCP, FESC, FACC 5 Submitted in Support of 6 Petitioner's Opposition to Patent 7 Owner's Motion to Amend, 8 Case Nos. IPR2020-00135, 9 IPR2020-00136, 10 U.S. Patent No. RE45,776 11 Exhibit 2222 Brochure: Pronto V3 Extraction 150 12 Catheter 13 Exhibit 2230 Ressemann Figure 16J 42 14 Exhibit 2231 Drawing by Dr. Stephen Brecker 155 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 8</p> <p>1 appreciate you've been deposed before a number of 2 times, so I won't go through the preliminaries. I 3 would only say that if you get to a point where you 4 need a break, and I appreciate the time difference 5 as well, just let me know. It won't be a problem. 6 STEPHEN BRECKER, M.D., 7 duly sworn, was examined and testified as follows: 8 EXAMINATION 9 BY MR. LEVITT: 10 Q. Dr. Brecker, is there a difference between 11 a lesion in a saphenous graft and a lesion that's 12 not in a saphenous graft? 13 A. So there can be a difference. They're all 14 atheromatous lesions; that's what we're talking 15 about. Lesions in vein grafts traditionally have 16 been viewed as having more embolic potential. 17 Q. What do you mean they having more embolic 18 protection? 19 A. No, I said they have more embolic 20 potential. 21 Q. Potential. I'm sorry. 22 And why do they have more embolic 23 potential? 24 A. Well, it's not a rule. All I'm saying is 25 that lesions in vein grafts can have a higher</p>
<p style="text-align: right;">Page 7</p> <p>1 (PROCEEDINGS, 01/19/2021, 5:03 a.m.) 2 THE VIDEOGRAPHER: Good morning. Today 3 is January 19, 2021. The time is 5:03 a.m., and we 4 are on the record. 5 Today we'll take the videotaped deposition 6 in Case No. IPR2020-00138. This deposition is 7 being held remotely. 8 Counsel, please state your appearance and 9 affiliation for the record. 10 MR. LEVITT: Good morning. I'm Ken 11 Levitt with Dorsey and Whitney appearing on behalf 12 of Teleflex. With me today is Derek Vandenburg of 13 the Carlson Caspers firm, Pete Keith and Greg Smock 14 of Teleflex. 15 I would just note for the record that I 16 believe this is being done in connection with a 17 number of IPRs, but I believe the court reporter 18 already has the caption for it. 19 MS. ROBERG-PEREZ: On behalf of 20 petitioner, Medtronic, Sharon Roberg-Perez from 21 Robins Kaplan. With me are my colleagues Cy Morton 22 and Ryan Dornberger. 23 MR. LEVITT: Good morning, Dr. Brecker. 24 THE WITNESS: Good morning. 25 MR. LEVITT: I'm Ken Levitt. I</p>	<p style="text-align: right;">Page 9</p> <p>1 burden of friable material and also thrombus. 2 That's not to say that you couldn't get that type 3 of lesion in a native vessel. 4 Q. Is there a difference in the nature of the 5 friable material from a lesion in a vein versus a 6 normal vessel? 7 A. Well, again, you're -- it's not a 8 hard-and-fast division. It's simply that lesions 9 in vein grafts can be, and are recognized as 10 having, a higher potential for friability and 11 embolization. That is not to say that you couldn't 12 have the most straightforward lesion in a vein 13 graft and an incredibly friable thrombotic lesion 14 in a native vessel. 15 Part of it might relate to the caliber of 16 the vessel, but also the atheromatous process. But 17 it's not that lesions in native vessels are like 18 this and lesions in vein grafts are like that. 19 It's not that they are different. It's not a 20 different disease. 21 Q. Can you explain what a saphenous vein graft 22 is, just at a high level of generality? 23 A. So a saphenous vein graft is the term used 24 to describe removing a segment of a patient's leg 25 vein and using it as -- in the context that we're</p>

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<p style="text-align: right;">Page 10</p> <p>1 discussing -- a coronary artery bypass graft, where 2 you take a length of normal vein from a patient's 3 leg and use it as a graft, suturing the top end to 4 the aorta and the bottom end to the coronary 5 vessel. The structure is a vein. And there are 6 differences between the wall of an artery and the 7 wall of a vein.</p> <p>8 You can also use vein grafts for other 9 indications. You can use segments of vein grafts 10 just as a -- sorry, segments of vein just as a 11 patch, and you can use it in treating other parts 12 of the vascular system.</p> <p>13 Q. So generally speaking, a segment of vein is 14 moved from the leg to the coronary context in order 15 to go around some lesion that, for whatever reason, 16 isn't being treated directly?</p> <p>17 A. You're correct. It's used to bypass a 18 lesion, but it's the alternative form of -- this is 19 coronary artery bypass surgery, so that's the 20 treatment that's being given.</p> <p>21 Q. How does thrombus differ from embolic 22 material?</p> <p>23 MS. ROBERG-PEREZ: Objection. Form.</p> <p>24 A. Well, thrombus is a blood clot, in its 25 simplest term. Embolic material is a term used to</p>	<p style="text-align: right;">Page 12</p> <p>1 coronary vessel is blood clot.</p> <p>2 Q. Would it be fair to say that embolic 3 material released during a stenting procedure is 4 typically more particulate in nature than thrombus?</p> <p>5 MS. ROBERG-PEREZ: Objection. Form.</p> <p>6 A. Not necessarily. It could be. Might not 7 be.</p> <p>8 Q. Is it fair to say that embolic material 9 that's released during a stenting procedure is 10 typically carried into the bloodstream?</p> <p>11 A. Well, it's carried downstream.</p> <p>12 Q. Let's talk about suction catheters for a 13 few minutes. Dr. Brecker, have you ever put a 14 stent catheter through a suction catheter?</p> <p>15 A. So I've been asked this several times in 16 previous depositions, and my answer is the same: I 17 have not.</p> <p>18 Q. So let's say, hypothetically, that you 19 wanted to put a stent catheter through a suction 20 catheter such as Itou. If you were to put the 21 suction catheter in and suction, and then advance 22 the stent catheter through the suction catheter, is 23 it fair to say you would push residual embolic 24 material downstream into the bloodstream?</p> <p>25 A. So could you just repeat the sequence to me</p>
<p style="text-align: right;">Page 11</p> <p>1 describe material that moves from one portion of 2 the body to another. And in a general term, there 3 are a large number of different types of things 4 that can embolize that doesn't necessarily have to 5 be thrombus.</p> <p>6 Q. One of which is a lesion?</p> <p>7 A. No, not -- I wasn't thinking of that. I 8 think your question was what -- how does it differ 9 from embolic material.</p> <p>10 So embolic material can be many different 11 things: blood clots in orthopedic surgery; you can 12 have fat embolism, the fat can embolize as the 13 bones are being manipulated; if air is introduced 14 into the circulation in an angiographic procedure, 15 you can get air embolism.</p> <p>16 So when you say "lesion material," I'm not 17 completely sure -- if you mean in a coronary artery 18 do you get embolization of more than just blood 19 clots, the answer is yes. In a coronary lesion, 20 whether it's in a native vessel or a vein graft, 21 you could get embolization of blood clots, of some 22 plaque material, some cholesterol, fibrin.</p> <p>23 Many -- there's components to the lesion, 24 and some of that could embolize. I would think 25 that the largest component of an embolus in a</p>	<p style="text-align: right;">Page 13</p> <p>1 again?</p> <p>2 Q. Sure. If you were to insert a suction 3 catheter and then use it to suction material, and 4 then leaving the suction catheter in, insert a 5 stent catheter into the guide catheter and the 6 suction catheter, would you then push residual 7 material downstream into the bloodstream?</p> <p>8 A. Well, my answer is: Not necessarily. 9 There had been teaching of the use of suction and 10 aspiration catheters to deliver stents, and 11 specific teaching that would have advocated the 12 process you described. I think it would depend a 13 lot on the nature of the vessel, the nature of what 14 you were treating.</p> <p>15 I can envisage a situation where you put 16 the suction catheter, get complete clearance of 17 whatever you're wanting to clear, got the good 18 backflush. You wouldn't necessarily, then, 19 embolize anything. It's certainly a theoretical 20 possibility, but you wouldn't -- it wouldn't be a 21 definite, by any means.</p> <p>22 Q. How would you backflush the suction 23 catheter?</p> <p>24 A. Suction.</p> <p>25 Q. Is there still a risk, though, that without</p>

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<p style="text-align: right;">Page 14</p> <p>1 removing the suction catheter and flushing it, 2 there's going to be residual embolic material in 3 the catheter? 4 A. It's a possibility. But there had -- there 5 was -- there were descriptions of this in 6 literature that specifically said not to remove the 7 aspiration catheter. 8 So it wasn't -- it wasn't that you would -- 9 that it couldn't be done; it certainly could. And 10 you would want to, to remove procedural steps. 11 There would be disadvantages to potentially 12 removing the aspiration catheter at that point 13 because any catheter change brings with it a 14 prolongation of the procedure, which itself can 15 lead to blood clot or the introduction of air. And 16 I've seen both of those happen during catheter 17 exchange procedures. 18 So during an interventional procedure, it's 19 a balance as to the order in which you do things. 20 And you certainly wouldn't not simply leave the 21 aspiration catheter there to advance a stent if 22 that was the appropriate thing to do in the 23 procedure. 24 Q. Is it fair to say that if you leave the 25 aspiration catheter in after aspirating out</p>	<p style="text-align: right;">Page 16</p> <p>1 that the aspirational suction catheter can be sized 2 such that you can suction with a stent in place. 3 So, again, it depends on the relative sizes 4 of the catheters that we're talking about. But as 5 a general rule, I would not agree that it means you 6 couldn't then suction. It had been specifically 7 taught that you could. 8 Q. Is it fair to say that having the stent 9 catheter in the suction catheter while performing 10 the suction would restrict the suction? 11 A. Well, I've answered, I think. It would 12 depend on the size of the stent, size of the 13 catheter, the nature of what you were sucking. 14 It's a possible theoretical point, yes. 15 But as I've said, that specific procedure that 16 you're describing had been taught in prior art. 17 Q. Is there a typical size stent catheter that 18 you advance through a 6 French guide catheter in a 19 coronary intervention procedure? 20 MS. ROBERG-PEREZ: Objection. Form. 21 A. Well, there's a large range of stents. And 22 their crossing profiles are documented. 23 Q. So if you're using a 6 French guide 24 catheter and you have a suction catheter inserted 25 through that, and a stent with an .056 crossing</p>
<p style="text-align: right;">Page 15</p> <p>1 thrombotic material, there is a risk that there's 2 going to be residual thrombotic material in the 3 suction catheter that is then pushed downstream 4 when you advance the stent catheter through the 5 suction catheter? 6 MS. ROBERG-PEREZ: Objection. Asked 7 and answered. 8 A. I think I've said that, that it's a 9 potential risk. But if you've cleared the 10 thrombus, you've got good backflush by suction, 11 you've got precedent in literature and practice. 12 It would not be an absolute contraindication. 13 It's a potential risk. You're balancing 14 that against the risk of the catheter exchange, 15 prolonging the procedure, that itself, as I said, 16 can produce thrombus and introducing air. 17 Q. Dr. Brecker, if you were to insert a 18 suction catheter and then, before suctioning, 19 advance a stent catheter into the suction catheter, 20 is it accurate to say that if you were then to 21 apply suction to the suction catheter, the presence 22 of the stent and stent catheter would inhibit the 23 suction? 24 A. So that's an interesting question. It's 25 dealt with explicitly in prior art, where it says</p>	<p style="text-align: right;">Page 17</p> <p>1 profile, is that a workable combination? 2 A. I don't know. I haven't -- I haven't 3 considered that specifically. If it relates to an 4 opinion I've given in a declaration, I'd be happy 5 to go to it. I don't think I have considered that 6 specific scenario that you're setting out. 7 Q. Have you considered the -- are there stent 8 catheter and suction catheter combinations where 9 inserting stent catheter through the suction 10 catheter, and then applying suction to the suction 11 catheter, would have reduced suction flow because 12 of the presence of a stent catheter inside the 13 suction catheter? 14 A. So I haven't given an opinion on that 15 specific point. 16 Q. Sitting here today, you don't have an 17 opinion on that? 18 A. I haven't considered it. I hadn't -- I 19 don't think I've given an opinion in any of the 20 declarations that are the subject of today. So I 21 haven't done that experimentation. I haven't done 22 that exercise of assessing that. 23 Q. Okay. So let me ask a different question. 24 Dr. Brecker, if you were to put a suction catheter 25 in and then advance the stent catheter through the</p>

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