

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

3 MEDTRONIC, INC., and
4 MEDTRONIC VASCULAR, INC.,

5 Petitioners,

6 vs.

Case No. IPR2020-00126

U.S. Patent No. 8,048,032

7 TELEFLEX INNOVATIONS

8 S.A.R.L.,

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)

IPR2020-00135 (Patent RE45,776 E)

IPR2020-00136 (Patent RE45,776 E)

IPR2020-00137 (Patent RE47,379 E)

IPR2020-00138 (Patent RE47,379 E)

15 VIDEOCONFERENCE VIDEOTAPED

16 DEPOSITION OF

17 LORENZO AZZALINI, M.D.

18 DATE: December 7, 2020

19 TIME: 1:02 p.m.

20 PLACE: Richmond, Virginia

21 (via videoconference)

22 JOB NO.: MW 4338343

23 REPORTED BY: Dawn Workman Bounds, CSR
24
25

Veritext Legal Solutions

Page 2

1 A P P E A R A N C E S
 2 (ALL APPEARANCES VIA VIDEOCONFERENCE)
 3 ON BEHALF OF PETITIONERS:
 4 CYRUS A. MORTON, ESQ.
 WILL MANSKE, ESQ.
 5 ROBINS KAPLAN LLP
 2800 LaSalle Plaza
 6 800 LaSalle Ave
 Minneapolis, MN 55401
 7 612.349.8500
 camorton@rkmc.com
 8 wmanske@RobinsKaplan.com
 9

10 ON BEHALF OF PATENT OWNER:
 11 ALEX S. RINN, ESQ.
 DEREK VANDENBURGH, ESQ.
 12 JOSEPH W. WINKELS, ESQ.
 CARLSON CASPERS VANDENBURGH & LINDQUIST, PA.
 13 Capella Tower, Suite 4200
 225 South Sixth Street
 14 Minneapolis, MN 55402
 612.436.9623
 15 arinn@carlsoncaspers.com
 dvandenburg@carlsoncaspers.com
 16 jwinkels@carlsoncaspers.com
 17

ALSO PRESENT:
 18 Greg Smock, Teleflex
 19 Adam Wallin, Videographer
 20
 21
 22
 23
 24
 25

Page 3

1 I N D E X
 2 WITNESS: LORENZO AZZALINI, M.D. PAGE
 3 EXAMINATION BY MR. MORTON..... 5
 4 EXAMINATION BY MR. RINN..... 36
 5 EXHIBITS PREVIOUSLY MARKED/REFERRED TO
 6 No. 2151: Declaration of Dr. Lorenzo Azzalini..... 20
 7
 8
 9
 10
 11
 12
 13
 14
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24
 25

Page 4

1 P R O C E E D I N G S
 2 THE VIDEOGRAPHER: We are going on the
 3 record at 1:02 p.m. on December 7, 2020. This is media
 4 unit 1 of the video-recorded deposition of Dr. Lorenzo
 5 Azzalini being taken via Zoom, and taken by counsel for
 6 the Petitioner in the matter of Medtronic, Incorporated
 7 and Medtronic Vascular, Incorporated versus Teleflex
 8 Innovations S.A.R.L., in the United States Patent and
 9 Trademark Office before the Patent Trial and Appeal
 10 Board. Case Number IPR2020-00126.
 11 My name is Adam Wallin from the firm
 12 Veritext, and I am the videographer. The court reporter
 13 is Dawn Bounds from the firm Veritext.
 14 Will counsel please identify themselves
 15 for the record.
 16 MR. MORTON: This is Cyrus Morton of
 17 Robins Kaplan on behalf of Petitioner Medtronic. Also
 18 with me on the deposition is William Manske.
 19 MR. RINN: This is Alex Rinn on behalf of
 20 patent owner with the Carlson Caspers firm. Also with me
 21 today from Carlson Caspers are Derek Vandenburg and Joe
 22 Winkels, and Greg Smock is on the line from Teleflex.
 23 THE VIDEOGRAPHER: Will the court reporter
 24 please swear in the witness, and we can proceed.
 25 THE REPORTER: Due to the need for this

Page 5

1 deposition to take place remotely because of the
 2 government's order for physical distancing, the parties
 3 will stipulate that the court reporter may swear in the
 4 witness over the videoconference and that the witness has
 5 verified that he is in fact Lorenzo Azzalini.
 6 Agreed, counsel?
 7 MR. RINN: Agreed.
 8 MR. MORTON: Agreed.
 9 LORENZO AZZALINI, M.D.,
 10 duly sworn via videoconference as stipulated by counsel
 11 was examined and testified as follows:
 12 EXAMINATION
 13 BY MR. MORTON:
 14 Q. Good afternoon, Dr. Azzalini.
 15 Have you had your deposition taken
 16 before?
 17 A. This is the first time I have my deposition
 18 here with me, yeah.
 19 Q. Okay. You've never had your deposition taken
 20 before in any other matter?
 21 A. No, no. That's the first time.
 22 Q. Okay. Did you have time to prepare for this
 23 deposition with counsel?
 24 A. Yes, I reviewed my declaration.
 25 Q. Okay. But were you prepared for the deposition

<p style="text-align: right;">Page 6</p> <p>1 with counsel; either Mr. Rinn, Mr. Winkels, did you spend 2 time with them to prepare for your deposition? 3 A. Yeah, I spent -- I spent a few hours with them. 4 Q. Okay. So as you can see, it's a deposition. I 5 ask the questions. You give the answers. 6 I want to make sure, since it's a Zoom 7 deposition, can you hear my questions appropriately? 8 A. Yes, I can. 9 Q. And as you sit there, can you think of any 10 reason why you would not be able to give truthful and 11 accurate responses to my questions this afternoon? 12 A. No. 13 Q. When did you begin practicing? 14 A. So I finished training in 2013 as a 15 cardiologist, and then I started an interventional 16 cardiology fellowship between '13 and '15. And then I 17 spent the last five years as a practicing interventional 18 cardiologist. 19 Q. Okay. So since you've been training and 20 practicing, there have always been GuideLiners; is that 21 fair? 22 A. That's correct, yes. 23 Q. Always been some form of a rapid exchange 24 version of a guide extension catheter, right? 25 A. Yes, I've mainly been exposed to GuideLiner.</p>	<p style="text-align: right;">Page 8</p> <p>1 experience with GuideLiner, so usually one tries to use 2 what he or she is more used to. 3 But other than that, since I've used the 4 other two devices so few times, I cannot really make a 5 scientific opinion whether one is better than the other 6 or vice versa. 7 Q. All right. And have you -- have you used all 8 three versions of GuideLiner? 9 A. No. I think I just used the V3, the latest 10 one. 11 Q. Okay. You never had a chance to - even in your 12 studies or training - work with or use GuideLiner 13 versions 1 or 2? 14 A. I don't think so. 15 It might be that GuideLiner Version 1 16 never made it to Europe for sure when I started using it. 17 I think that -- I'm pretty sure I just used V3. 18 Q. So these products all have what we call a "side 19 opening" in this case, a proximal opening, into the 20 distal tubular structure. 21 You're familiar with that? 22 A. Yeah. So are you referring to the half-pipe or 23 collar or the end? 24 Q. Yes; no, that's the end where you kind of go 25 from a pushrod or a push wire, you have some kind of a</p>
<p style="text-align: right;">Page 7</p> <p>1 Q. Okay. And have you ever used Guidezilla or 2 Telescope? 3 A. Yes. Guidezilla probably around 10 times or a 4 dozen times, and Telescope just, I think, once. 5 Q. Okay. So obviously you've used GuideLiner more 6 often. 7 But now that you've looked at the other 8 two, do you have -- do you have a favorite or any reason 9 why you'd use one versus the other? 10 A. So I think mainly in most places I've worked, 11 the main guide catheter extension was a -- was 12 GuideLiner. So part of the reason why I use more -- 13 actually, most of the reason why I use more GuideLiner is 14 because the cath lab where I worked had that on the 15 shelf. 16 And I also think that Telescope came quite 17 later than the other two products on the market. 18 Q. Sure. And I'm just asking -- you know, assume 19 that on the shelf is a -- is GuideLiner, Guidezilla, and 20 Telescope, they're all on the shelf. 21 Other than just kind of your familiarity 22 with GuideLiner, do you have any reason why you'd pick 23 one over the other in terms of their structure or 24 function? 25 A. Well, as you mentioned, I have much more</p>	<p style="text-align: right;">Page 9</p> <p>1 half-pipe -- whatever you've got -- opening into the 2 tube, that section there. From a patent standpoint, 3 we've been calling that a side opening. 4 A. Okay. 5 Q. But it's just the proximal opening into the 6 distal tube. So that section, okay? 7 A. Okay. 8 Q. In the time that you have spent with Version 3 9 and Guidezilla - and I think you said you used Telescope 10 once - do you have any preference, any clinical 11 difference in terms of that part of the device, between 12 one device and another? 13 A. So my understanding is that both Telescope and 14 GuideLiner, that half-pipe is made of -- so it's like a 15 plastic like material, where Guidezilla is made of a 16 metallic compound. 17 So as mentioned, since I haven't used the 18 other two devices much and I 99.9 percent have used the 19 GuideLiner, I cannot make a -- like a recommendation or 20 like an opinion whether polymer or metal is better. 21 Q. Okay. Do you have any other differentiating 22 factor, from just a clinical standpoint, between the 23 different materials used, polymer and metal, that you 24 think about? 25 A. So I'm not an engineer, so this is the only one</p>

3 (Pages 6 - 9)

Veritext Legal Solutions

www.veritext.com

888-391-3376



Find authenticated court documents without watermarks at docketalarm.com.

Page 10

1 that I can think of, honestly.
2 Q. Okay. Okay. Thanks.
3 So in the time you've been performing
4 procedures, have you experienced a situation where you're
5 just using a guide catheter, and it backs out of the
6 coronary ostium?
7 A. Yes. It's pretty common, unfortunately.
8 THE REPORTER: I'm sorry, Doctor. Repeat
9 what you're saying.
10 A. Yes, unfortunately it is a pretty common
11 occurrence.
12 BY MR. MORTON:
13 Q. Okay. And when that has happened, you need
14 to -- obviously you need to do something to address that
15 situation, right?
16 A. Uh-huh.
17 Q. Have you ever responded to that by trying to
18 deep-seat just the guide catheter further into the
19 coronary artery?
20 A. Yes, that's a -- one possibility. It's
21 actually probably the first thing you can think of.
22 Q. Okay. And can you give me an idea of how often
23 you've tried that and how successful it's been?
24 A. So on probably every time that you have back --
25 back-up support issues, you try to push the guide back

Page 11

1 in. Then you can go further than that and actually try
2 to deep-seat the guide catheter inside the coronary
3 artery.
4 So are you referring to that?
5 Q. Yes.
6 A. So these maneuvers, I tried it in the past, and
7 I still sometimes try it. It's quite laborious, I would
8 say. It can -- I usually use it only on the right
9 coronary artery because it's -- there are no major
10 branches, as opposed to the left coronary artery.
11 You have to be very delicate because the
12 guide catheter is pretty big and can be also stiff. So
13 you can create some damage on the -- on the artery walls.
14 So usually you cannot advance a lot inside a coronary
15 artery.
16 Having said that, it's successful
17 sometimes; but I would say in the minority of cases.
18 Q. Okay. So it's something you would commonly
19 try, but in a minority of cases, it would -- it's
20 successful; is that right?
21 A. Exact -- in the minority of cases, it would be
22 successful. I do not try very often, first of all, as I
23 mentioned, because on the left coronary, it's dangerous.
24 So already more than 50 percent of the cases I do not do
25 it because that left coronary is more than 50 percent of

Page 12

1 the cases.
2 On the right, every now and then. I would
3 not say frequently.
4 Q. Okay. How about -- another thing that I've
5 heard that you can do is swap out and use a completely
6 different guide catheter. It may have different
7 materials, different bend to it.
8 Is that something that you've done in your
9 practice?
10 A. Yes. So that's a feasible option if you
11 realize from the very beginning that you're having
12 trouble and you think that there is a better catheter --
13 when I say better, I mean a different shape -- that
14 better fits into that coronary.
15 Once you started with procedure and you
16 started wiring and ballooning and stenting, it's really
17 not an option; because you would have to sacrifice your
18 wire position, and that is -- comes with consequences and
19 risks.
20 So if the vessel is dissected, it's not
21 wise and safer for the patient to change the guide
22 because this would imply removing everything.
23 Q. Got it.
24 So can you just focus your answer just on
25 when it is a feasible option and tell me what that is?

Page 13

1 A. It would be feasible, I would say only -- for
2 example, you take the diagnostic picture and -- with the
3 guide catheter, and you immediately realize that there's
4 no way you can accomplish that procedure because you've
5 made a poor guide catheter choice, and that must happen
6 very early in the procedure.
7 If you start wiring and ballooning,
8 usually it's not a safe thing to do.
9 Q. Got it.
10 How about another thing that I've heard
11 you can do is -- it may be in your declaration -- is to
12 use a buddy wire.
13 Are you familiar with that?
14 A. Yes. I am familiar with that, yes.
15 Q. And is that something that you've done in your
16 career to address a problem of a guide catheter backing
17 up?
18 A. Yes. It's something that I try, for example,
19 more often than deep-seating, even nowadays.
20 Actually, many times I might go to tech --
21 first line technique when I have back-up support issues.
22 Because maybe you already have another wire on the table,
23 and you can just insert it. It -- it creates a rail onto
24 which the other device - the balloon or stent - can go,
25 and it's sometimes successful, yes.

4 (Pages 10 - 13)

Veritext Legal Solutions

www.veritext.com

888-391-3376



Find authenticated court documents without watermarks at docketalarm.com.

Page 14

1 Q. Okay. Can you give me any idea sort of what
2 percentage of cases you would attempt a buddy wire, and
3 it would be successful?
4 A. So let's say that in -- in a case that I have
5 support issues, I would try that probably 40, 50 percent
6 of the times and not in all -- in all the times; not
7 always, because there are some cases that, you know,
8 already from the beginning that there is no way the buddy
9 wire technique can work.
10 Also, because sometimes the lesion you're
11 trying to -- to bring balloons to is -- is just so tight,
12 so narrow, that it's almost impossible that you're going
13 to be able to cross with a second wire; and you can run
14 the risk of dissecting, so damaging the vessel.
15 But other than that, yeah, I would say
16 maybe 40 -- maybe 45 percent of the time, I would try
17 that.
18 Q. Okay. And in the cases when you tried it, how
19 often is it successful?
20 A. Of that 40 to 45 percent, it might be
21 successful in 30 percent.
22 So if we make that 45 percent 100 now, it
23 would be successful in 30 percent.
24 Q. Okay. So, ultimately, 30 percent out of 100
25 percent successful with the buddy wire?

Page 15

1 MR. RINN: Objection, form.
2 A. 30 percent of the 45 -- of the 45 percent of
3 the time where I would try the buddy wire, so it's --
4 it's way less than that.
5 BY MR. MORTON:
6 Q. Okay. I was just trying to figure out where
7 it -- where it falls.
8 So 40 to 45 percent of the time, you try
9 the buddy wire, and 30 percent of those times, it's
10 successful?
11 A. Yeah. I would say basically over -- a total
12 absolutely, in absolute terms of 100, I would say 15
13 percent, it's successful.
14 Q. Okay.
15 A. Okay. To make it clear.
16 Q. So how about another option, which would be
17 a -- what I'll call a full-length mother-and-child with a
18 full-length child catheter; is that something that you're
19 familiar with?
20 A. I know pretty well what you're talking about.
21 I've used that technique -- not for
22 interventional purposes, so not to do like a -- with a
23 balloon or a stent; whereas, sometimes -- pretty rarely,
24 though, to -- in -- for diagnostic angiograms, sometimes
25 the catheter would not reach, and I would use a smaller

Page 16

1 catheter inside the main catheter to reach the coronary.
2 But not for interventional purposes,
3 because, as I mentioned before, since I started
4 practicing, the GuideLiner and then the Guidezilla and
5 Telescope were already available.
6 Q. Sure. Understand that.
7 So if we focus again on the time that you
8 did use it, if I understand, you've used a full-length
9 mother-and-child system where you've extended the child
10 catheter further into the coronary vasculature, you just
11 did that only for diagnostic; is that right?
12 A. Yes. Let me specify.
13 So basically sometimes the ostia is very
14 dilated. You need the cath -- you have a catheter that
15 points toward the coronary ostia, but you cannot reach
16 it; so you put a smaller catheter inside.
17 So you're not actually going into the
18 coronary artery with the child, but just onto the
19 beginning of it, so the ostium.
20 Q. All right. Have you ever -- have you ever
21 witnessed what I'll call a full-length mother-and-child
22 being used for the purpose of actually delivering a
23 device, like a balloon or stent?
24 A. So I think I might have seen presentations from
25 the past, but even my teachers and mentors that I had the

Page 17

1 privilege of working with that are pretty reknown in the
2 field, they quickly converted to the guide catheter
3 extension - initially the GuideLiner, then Guidezilla,
4 and Telescope - when I was in practice. So I just know
5 the information from the past.
6 Q. Okay. So basically once there was a rapid
7 exchange version of mother-and-child, everybody used
8 that; is that fair?
9 A. I don't know the exact nomenclature of -- how
10 you want to frame the guide catheter extension; but I
11 would just call it guide catheter extension.
12 Q. So these things that we've discussed, we
13 discussed deep-seating, using a different guide catheter,
14 and the buddy wire.
15 So are these all -- are all three of those
16 things, things that you would potentially try first; and
17 then if they didn't work, then you would try a guide
18 extension catheter?
19 A. Not all the times.
20 So with -- you know, with experience, it
21 comes -- sometimes you get to a point to where from the
22 get-go, you understand a buddy wire would not work.
23 Or you cannot, for example, change to a
24 bigger or different guide catheter if you're going from
25 radial axis because you're already using a big catheter,

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.