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

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
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)

REMOTE VIDEOTAPED DEPOSITION OF
STEPHEN BRECKER, M.D.

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

PAGES: 1 to 180
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REPORTED BY: Merilee Johnson, RDR, CRR, CRC, RSA

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(All appearing remotely via videoconference)

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EXHIBITS

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EXHIBITS
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E X H I B I T S
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(PROCEEDINGS, 01/19/2021, 5:03 a.m.)

THE VIDEOGRAPHER: Good morning. Today is January 19, 2021. The time is 5:03 a.m., and we are on the record.

Today we'll take the videotaped deposition in Case No. IPR2020-00138. This deposition is being held remotely.

Counsel, please state your appearance and affiliation for the record.

MR. LEVITT: Good morning. I'm Ken Levitt with Dorsey and Whitney appearing on behalf of Teleflex. With me today is Derek Vandenburgh of the Carlson Caspers firm, Pete Keith and Greg Smock of Teleflex.

I would just note for the record that I believe this is being done in connection with a number of IPRs, but I believe the court reporter already has the caption for it.

MS. ROBERG-PEREZ: On behalf of petitioner, Medtronic, Sharon Roberg-Perez from Robins Kaplan. With me are my colleagues Cy Morton and Ryan Dornberger.

MR. LEVITT: Good morning, Dr. Brecker.

THE WITNESS: Good morning.

MR. LEVITT: I'm Ken Levitt. I

appreciate you've been deposed before a number of times, so I won't go through the preliminaries. I would only say that if you get to a point where you need a break, and I appreciate the time difference as well, just let me know. It won't be a problem.

STEPHEN BRECKER, M.D.,
duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. LEVITT:

Q. Dr. Brecker, is there a difference between a lesion in a saphenous graft and a lesion that's not in a saphenous graft?

A. So there can be a difference. They're all atheromatous lesions; that's what we're talking about. Lesions in vein grafts traditionally have been viewed as having more embolic potential.

Q. What do you mean they having more embolic protection?

A. No, I said they have more embolic potential.

Q. Potential. I'm sorry.

And why do they have more embolic potential?

A. Well, it's not a rule. All I'm saying is that lesions in vein grafts can have a higher

burden of friable material and also thrombus. That's not to say that you couldn't get that type of lesion in a native vessel.

Q. Is there a difference in the nature of the friable material from a lesion in a vein versus a normal vessel?

A. Well, again, you're -- it's not a hard-and-fast division. It's simply that lesions in vein grafts can be, and are recognized as having, a higher potential for friability and embolization. That is not to say that you couldn't have the most straightforward lesion in a vein graft and an incredibly friable thrombotic lesion in a native vessel.

Part of it might relate to the caliber of the vessel, but also the atheromatous process. But it's not that lesions in native vessels are like this and lesions in vein grafts are like that. It's not that they are different. It's not a different disease.

Q. Can you explain what a saphenous vein graft is, just at a high level of generality?

A. So a saphenous vein graft is the term used to describe removing a segment of a patient's leg vein and using it as -- in the context that we're

discussing -- a coronary artery bypass graft, where you take a length of normal vein from a patient's leg and use it as a graft, suturing the top end to the aorta and the bottom end to the coronary vessel. The structure is a vein. And there are differences between the wall of an artery and the wall of a vein.

You can also use vein grafts for other indications. You can use segments of vein grafts just as a -- sorry, segments of vein just as a patch, and you can use it in treating other parts of the vascular system.

Q. So generally speaking, a segment of vein is moved from the leg to the coronary context in order to go around some lesion that, for whatever reason, isn't being treated directly?

A. You're correct. It's used to bypass a lesion, but it's the alternative form of -- this is coronary artery bypass surgery, so that's the treatment that's being given.

Q. How does thrombus differ from embolic material?

MS. ROBERG-PEREZ: Objection. Form.

A. Well, thrombus is a blood clot, in its simplest term. Embolic material is a term used to

describe material that moves from one portion of the body to another. And in a general term, there are a large number of different types of things that can embolize that doesn't necessarily have to be thrombus.

Q. One of which is a lesion?

A. No, not -- I wasn't thinking of that. I think your question was what -- how does it differ from embolic material.

So embolic material can be many different things: blood clots in orthopedic surgery; you can have fat embolism, the fat can embolize as the bones are being manipulated; if air is introduced into the circulation in an angiographic procedure, you can get air embolism.

So when you say "lesion material," I'm not completely sure -- if you mean in a coronary artery do you get embolization of more than just blood clots, the answer is yes. In a coronary lesion, whether it's in a native vessel or a vein graft, you could get embolization of blood clots, of some plaque material, some cholesterol, fibrin.

Many -- there's components to the lesion, and some of that could embolize. I would think that the largest component of an embolus in a

coronary vessel is blood clot.

Q. Would it be fair to say that embolic material released during a stenting procedure is typically more particulate in nature than thrombus?

MS. ROBERG-PEREZ: Objection. Form.

A. Not necessarily. It could be. Might not be.

Q. Is it fair to say that embolic material that's released during a stenting procedure is typically carried into the bloodstream?

A. Well, it's carried downstream.

Q. Let's talk about suction catheters for a few minutes. Dr. Brecker, have you ever put a stent catheter through a suction catheter?

A. So I've been asked this several times in previous depositions, and my answer is the same: I have not.

Q. So let's say, hypothetically, that you wanted to put a stent catheter through a suction catheter such as Itou. If you were to put the suction catheter in and suction, and then advance the stent catheter through the suction catheter, is it fair to say you would push residual embolic material downstream into the bloodstream?

A. So could you just repeat the sequence to me

again?

Q. Sure. If you were to insert a suction catheter and then use it to suction material, and then leaving the suction catheter in, insert a stent catheter into the guide catheter and the suction catheter, would you then push residual material downstream into the bloodstream?

A. Well, my answer is: Not necessarily. There had been teaching of the use of suction and aspiration catheters to deliver stents, and specific teaching that would have advocated the process you described. I think it would depend a lot on the nature of the vessel, the nature of what you were treating.

I can envisage a situation where you put the suction catheter, get complete clearance of whatever you're wanting to clear, got the good backflush. You wouldn't necessarily, then, embolize anything. It's certainly a theoretical possibility, but you wouldn't -- it wouldn't be a definite, by any means.

Q. How would you backflush the suction catheter?

A. Suction.

Q. Is there still a risk, though, that without

removing the suction catheter and flushing it, there's going to be residual embolic material in the catheter?

A. It's a possibility. But there had -- there was -- there were descriptions of this in literature that specifically said not to remove the aspiration catheter.

So it wasn't -- it wasn't that you would -- that it couldn't be done; it certainly could. And you would want to, to remove procedural steps.

There would be disadvantages to potentially removing the aspiration catheter at that point because any catheter change brings with it a prolongation of the procedure, which itself can lead to blood clot or the introduction of air. And I've seen both of those happen during catheter exchange procedures.

So during an interventional procedure, it's a balance as to the order in which you do things. And you certainly wouldn't not simply leave the aspiration catheter there to advance a stent if that was the appropriate thing to do in the procedure.

Q. Is it fair to say that if you leave the aspiration catheter in after aspirating out

thrombotic material, there is a risk that there's going to be residual thrombotic material in the suction catheter that is then pushed downstream when you advance the stent catheter through the suction catheter?

MS. ROBERG-PEREZ: Objection. Asked and answered.

A. I think I've said that, that it's a potential risk. But if you've cleared the thrombus, you've got good backflush by suction, you've got precedent in literature and practice. It would not be an absolute contraindication.

It's a potential risk. You're balancing that against the risk of the catheter exchange, prolonging the procedure, that itself, as I said, can produce thrombus and introducing air.

Q. Dr. Brecker, if you were to insert a suction catheter and then, before suctioning, advance a stent catheter into the suction catheter, is it accurate to say that if you were then to apply suction to the suction catheter, the presence of the stent and stent catheter would inhibit the suction?

A. So that's an interesting question. It's dealt with explicitly in prior art, where it says

that the aspirational suction catheter can be sized such that you can suction with a stent in place.

So, again, it depends on the relative sizes of the catheters that we're talking about. But as a general rule, I would not agree that it means you couldn't then suction. It had been specifically taught that you could.

Q. Is it fair to say that having the stent catheter in the suction catheter while performing the suction would restrict the suction?

A. Well, I've answered, I think. It would depend on the size of the stent, size of the catheter, the nature of what you were sucking.

It's a possible theoretical point, yes. But as I've said, that specific procedure that you're describing had been taught in prior art.

Q. Is there a typical size stent catheter that you advance through a 6 French guide catheter in a coronary intervention procedure?

MS. ROBERG-PEREZ: Objection. Form.

A. Well, there's a large range of stents. And their crossing profiles are documented.

Q. So if you're using a 6 French guide catheter and you have a suction catheter inserted through that, and a stent with an .056 crossing

profile, is that a workable combination?

A. I don't know. I haven't -- I haven't considered that specifically. If it relates to an opinion I've given in a declaration, I'd be happy to go to it. I don't think I have considered that specific scenario that you're setting out.

Q. Have you considered the -- are there stent catheter and suction catheter combinations where inserting stent catheter through the suction catheter, and then applying suction to the suction catheter, would have reduced suction flow because of the presence of a stent catheter inside the suction catheter?

A. So I haven't given an opinion on that specific point.

Q. Sitting here today, you don't have an opinion on that?

A. I haven't considered it. I hadn't -- I don't think I've given an opinion in any of the declarations that are the subject of today. So I haven't done that experimentation. I haven't done that exercise of assessing that.

Q. Okay. So let me ask a different question. Dr. Brecker, if you were to put a suction catheter in and then advance the stent catheter through the

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