UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

TELEFLEX INNOVATIONS S.À.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)

Declaration of Dr. Lorenzo Azzalini

I, Dr. Lorenzo Azzalini, hereby declare as follows:

1. I am currently the Director of Complex Coronary Interventions at VCU Health Pauley Heart Center in Richmond, Virginia, where I am a practicing interventional cardiologist as well as an associate professor of medicine at Virginia

Commonwealth University. I received my medical degree from the University of Padua in Padua, Italy in 2006. I went on to conduct my Cardiology residency at Hospital de la Santa Creu i Sant Pau in Barcelona, Spain, which I completed in 2013. After my residency I conducted two Interventional Cardiology fellowships, one in 2013-2015 at the Montreal Heart Institute in Montreal, Quebec, Canada and a second in 2019-2020 at The Mount Sinai Hospital in New York. Between 2015 and 2019 I was Co-Director of the Chronic Total Occlusion Program at San Raffaele Hospital, in Milan, Italy. A copy of my CV is attached to this declaration as Exhibit A.

2. Since at least 2013, a major part of my practice has included performing percutaneous coronary intervention ("PCI") procedures, which includes among other things performing balloon angioplasties and placing stents. In the course of my career, I have performed thousands of such procedures, and I closely keep up with new developments and techniques for PCI procedures.

3. Guide extension catheters, like GuideLiner, have become an indispensable device for interventional cardiologists, particularly those that practice in the area of complex percutaneous coronary interventions (known as "complex PCI").

4. Insufficient guide catheter backup support has been a problem for interventional cardiology procedures since at least the early 1990's, when

cardiologists began to perform PCI procedures with some regularity. This was particularly true for what we refer to as "complex" cases where the patient's anatomy is difficult to navigate and/or the location and type of lesion being treated is particularly difficult.

5. Long before the invention of the GuideLiner, there were various techniques that interventional cardiologists attempted to use to deal with the problem of guide catheter backout (or poor guide catheter support), but these techniques were often not successful and posed greater risk to the patient. These techniques included use of larger (than otherwise needed) guide catheters for increased rigidity, deep seating of a guide catheter's distal end within a coronary artery, and/or use of a second guidewire as part of a "buddy wire" technique. Not only did each of these techniques increase procedural risks to the patient's health, they each took additional procedure time which can add further risks to the patient. As procedure time is lengthened, the patient's anatomy is more likely to constrict, a dissection of vessels becomes more likely, plaque on vessel walls is more likely to break off and potentially cause a stroke or distal embolization (which can lead to acute myocardial infarction), the patient may be subjected to excessive amounts of contrast media (which are deleterious for the kidneys), and the patient is subjected to more radiation in connection with fluoroscopic imaging (which exposes the patient to higher risk for skin injury and potentially cancer). For at least these

reasons, pre-GuideLiner techniques for dealing with the long-existing problem of poor guide catheter support were not desirable solutions.

6. Another technique that was employed to try to deal with the problem of poor guide support was to use a longer, full-length over-the-wire catheter inside a guide catheter and two hemostasis valves in what is referred to as a "mother-and-child" configuration. This approach was not a desirable solution and was never widely adopted. Among other reasons, in the vast majority of cases the cardiologist does not determine that a guide extension catheter is needed until the middle of the procedure. Given the overall length of the mother-and-child configuration, a 270-400 cm guidewire is necessary to employ this technique, but such a guidewire length is not what interventional cardiologists typically start a procedure with due to the need for a dedicated second operator helping with balloon and stent exchange. Rather, a shorter 180-190 cm "rapid exchange length" guidewire is commonly used as this is compatible with the rapid exchange balloons and stents used to treat coronary lesions and can be manipulated by a single operator. Accordingly, to attempt the mother-and-child technique, the cardiologist would have to pull out the already positioned rapid exchange length guidewire and replace it with a longer guidewire. This is highly undesirable because once a guidewire is in place across a lesion to be treated the interventional cardiologist does not want to lose that position. It is often difficult, and sometimes impossible,

to regain that guidewire position a second time with the longer wire. Even if the guidewire position can be regained, it will be a considerable loss of time, further subjecting the patient to the risks discussed above.

7. The mother-and-child approach also needs two operators. This need for two operators is highly undesirable because needing two operators means there are two sets of hands being controlled by two people where coordination is important. Inevitably there are miscommunications and misleading tactile feedback, both of which can inhibit successful performance of an interventional procedure. Requiring two operators also adds significant costs to the procedure.

8. For all of these reasons, the mother-and-child technique did not solve the long-existing problem of insufficient backup support.

9. When the GuideLiner product launched in 2009, it changed the field of interventional cardiology for the better. It gave cardiologists a completely new type of device that finally solved the long-existing guide catheter backout problem. Back in that period, I remember senior interventional cardiologists hailing the introduction of this new device as a major breakthrough in our specialty, greatly simplifying and improving balloon and particularly stent delivery through tortuous and calcified coronary arteries.

10. I have used GuideLiner devices over 400 times. In my opinion, GuideLiner provided cardiologists, for the first time, with a rapid exchange device

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