

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

TELEFLEX INNOVATIONS S.A.R.L.  
Patent Owner.

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Case IPR2020-01341 (Patent 8,142,413)  
Case IPR2020-01342 (Patent 8,142,413)  
Case IPR2020-01343 (Patent RE 46,116)  
Case IPR2020-01344 (Patent RE 46,116)

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**Declaration of Dr. Lorenzo Azzalini**

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

I previously submitted a declaration in connection with the following IPRs before the Patent Trial and Appeal Board: IPR2020-00126, IPR2020-00127, IPR2020-00128, IPR2020-00129, IPR2020-00130, IPR2020-00132, IPR2020-00134, IPR2020-00135, IPR2020-00136, IPR2020-00137, and IPR2020-00138.


My opinions from my original declaration dated September 21, 2020, attached hereto as Appendix A, remain true and correct, and I hereby adopt and submit

them in connection with the following IPRs before the Patent Trial and Appeal Board: IPR2020-01341, IPR2020-01342, IPR2020-01343, and IPR2020-01344.

For my time spent on this matter, I am being compensated at \$650 per hour, which is my standard rate for this type of consulting. The compensation for my time is not contingent on the results of these or any other legal proceedings.

I declare that all statements made herein of my knowledge are true, and that all statements made on information and believe are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: May 5, 2021

By:   
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Dr. Lorenzo Azzalini

**APPENDIX A**

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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

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