

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

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

**DECLARATION OF HOWARD ROOT SUBMITTED IN CONNECTION
WITH PATENT OWNER'S RESPONSES**

I, Howard Root, hereby declare and state as follows:

1. I make this Declaration in connection with Patent Owner's Responses to Petitions filed in response to the following IPR Petitions:

IPR No.	Patent No.
IPR2020-01341	8,142,413
IPR2020-01342	8,142,413
IPR2020-01343	RE 46,116
IPR2020-01344	RE 46,116

I refer to the patents in this table collectively as "the GuideLiner patents," as they are the patents that were obtained for and protect the GuideLiner® guide extension catheter, which was the most successful product introduced by Vascular Solutions, Inc. ("VSI"), a company that I founded and was the Chief Executive Officer of for 20 years. I am also a named inventor on the GuideLiner patents.

2. I was originally trained as a lawyer and worked in private practice from 1985-1990. In 1990, I left private practice to serve as General Counsel at ATS Medical, Inc., a medical device company, which has since been acquired by Medtronic, Inc. I left ATS Medical in 1996 and founded VSI in 1997. I acted as the CEO of VSI from 1997 until 2017. In 2017, VSI was acquired by Teleflex Incorporated, the current owner of the GuideLiner patents (through a subsidiary entity).

3. I am aware that Teleflex has filed suit against Medtronic, Inc. and Medtronic Vascular, Inc. (“Medtronic”) for infringement of the GuideLiner patents. I have been retained as a consultant on behalf of Teleflex in connection with that lawsuit and the present IPR Petitions. However, I have no ongoing involvement in the Teleflex business and I have no financial interest in the outcome of the litigation.

4. Throughout my time at VSI, I was personally active in, among other things, product conception and development, legal and marketing efforts, and sales. I was actively involved with the GuideLiner project and product embodiments at the time the inventions of the GuideLiner patents were conceived and reduced to practice, and at the time the applications that ultimately resulted in the patents-in-suit were filed. GuideLiner created the market for rapid exchange guide extension catheters, but that success was not due to VSI’s size or its pre-existing market position. At the time of the GuideLiner launch, VSI was a relatively small medical device company that had developed, among other products, a number of specialty catheters used in interventional cardiology procedures—but it had no market dominating products. I and others have said numerous times that GuideLiner is what put VSI on the map. GuideLiner was launched at the end of 2009, and by 2013, GuideLiner had become the company’s top-selling product. By the first quarter of 2014, GuideLiner had been used in

virtually all of the over 2,000 interventional cardiac catheterization labs across the United States. GuideLiner's tremendous success and its ubiquity in the market led many customers to refer to VSI as "the GuideLiner company."

Conception of GuideLiner

5. I attended the annual Transcatheter Cardiovascular Therapeutics ("TCT") conference in 2004, which took place in Washington, D.C. from September 27 to October 1. By that time I had recognized issues physicians were experiencing with guide catheter backout in complex interventional coronary procedures. I realized that there was a need for a solution in complex interventional coronary procedures that provided better guide positioning, device delivery, and procedural conveniences than what then existed.

6. Around the time of the 2004 TCT conference, I conceived of the idea for a guide extension catheter that would provide improved back-up support with rapid exchange delivery, which would offer far more convenience than other options available at the time. Sometime after the TCT conference, but before 2005, my co-inventors and I met to discuss particular ideas for how to make such a device.

7. At a high level, the device we developed was a guide extension catheter to be used within a one French size larger guide catheter. The guide extension catheter included a substantially rigid proximal portion comprising a

“rail” structure and a tubular portion with a lumen distal of the proximal portion, which together were longer than the overall length of a standard guide catheter. The distal tube portion was reinforced with a braid or coil, and it could have a highly flexible atraumatic “bumper tip.” In use, a standard guide catheter would be inserted first into the vasculature until the distal end of the guide catheter was located in the ostium of a cardiac artery within the heart. Our guide extension catheter would then be inserted through the guide catheter until the tubular portion’s distal end extended past the distal end of the guide catheter and into the cardiac artery. An interventional cardiology device, such as a balloon catheter or a stent, would then be inserted through the guide catheter (running alongside the rail of our guide extension catheter), into the proximal end of the tubular portion of our guide extension catheter, and ultimately out of the distal end of the tubular portion and into the cardiac artery.

8. We also contemplated that the guide extension catheter would optionally be used together with a dilator. The dilator would be inserted into the tubular portion outside the body and would further assist with guiding the extension catheter past the end of the guide catheter and into the cardiac artery. The dilator would then be removed from the body prior to insertion of an interventional cardiology device such as a stent or balloon catheter.

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