

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of:

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

Filed: May 3, 2006

Issued:

Trial Number: To Be Assigned

Attorney Docket No.:

Inventors: Howard Root, Greg Sutton,
Jeffrey M. Welch, Jason M. Garrity

Assignee: Vascular Solutions, Inc.

Title: Coaxial Guide Catheter For
Interventional Cardiology Procedures

**DECLARATION BY RONALD SOLAR, PH.D. REGARDING U.S.
PATENT NO. 8,048,032 UNDER 37 C.F.R. § 42.63(a)**

I, Ronald Jay Solar, Ph.D., do declare and state as follows:

I. Background and Experience

1. I received my B.S. in Metallurgy and Materials Science from Pennsylvania State University in 1972, and my Ph.D. in Metallurgy, Materials Science and Biomaterials from University of Pennsylvania in 1976. My studies focused on surgical implants.

2. Since graduation, virtually all of my experience has involved working with various companies on the design, development, and testing of medical devices, the vast majority of which have been in the field of interventional cardiology.

3. Combined, I have over thirty-seven years of academic and industry experience in all aspects of design, research, development, clinical testing, regulation, patenting, manufacture, production, quality control and assurance, marketing, and sales of medical devices. The predominant focus of my work in the medical device industry has been in the design and development of interventional cardiology devices within the peripheral and coronary vascular marketplace. I am a named inventor of fifty U.S. patents on diagnostic and therapeutic catheters, guidewires, vascular stents, and stent delivery systems, and I have extensive experience with the design and functionality of such devices.

4. Attached to this declaration is a copy of my curriculum vitae at Appendix A.

5. I am presently the President and Founder of Renaissance Biomedical, Inc., which is a consulting firm focusing on all aspects of the medical device

industry, including research, design, technical, marketing, patent, clinical, and regulatory issues.

6. I am not employed by, nor receiving grant support from, Boston Scientific Corporation or its subsidiary, Boston Scientific Scimed, Inc. I am receiving compensation for my involvement in this matter based on my standard hourly consulting fees. I have no financial interest in the outcome of this case. A listing of testimony that I have provided in prior proceedings and my compensation is attached hereto as Appendix B.

7. I am competent to make this declaration based upon my personal knowledge and technical expertise in the area of interventional cardiology devices and procedures. In preparing my opinions, I have considered the following materials:

- U.S. Patent No. 8,048,032 to Root, et al. (Exh. 1001)
- File History for U.S. Patent No. 8,048,032 (Exh. 1002)
- U.S. Patent No. 8,292,850 to Root, et al. (Exh. 1004)
- U.S. Patent No. 8,142,413 to Root, et al. (Exh. 1005)
- File History for U.S. Patent No. 8,292,850 (Exh. 1006)
- File History for U.S. Patent No. 8,142,413 (Exh. 1007)
- U.S. Publication No. 2004/0236215 A1 to Mihara et al. (Exh. 1009)
- Translation of Japanese Patent Application No. 2003-070808 (Exh. 1010)
- U.S. Patent No. 5,527,292 to Adams et al. (Exh. 1011)
- U.S. Publication No. 2003/0195546 A1 to Solar, et al. (Exh. 1012)

- U.S. Patent No. 6,638,268 to Niazi (Exh. 1013)
- U.S. Publication No. 2005/0004523 A1 to Osborne, et al. (Exh. 1014)
- U.S. Publication No. 2004/0127927 to Adams (Exh. 1015)
- U.S. Patent No. 6,338,725 B1 to Hermann et al. (Exh. 1016)
- U.S. Patent No. 5,776,141 to Klein et al. (Exh. 1017)
- U.S. Patent No. 7,232,452 to Adams et al. (Exh. 1018)
- U.S. Patent No. 5,328,472 to Steinke et al. (Exh. 1019)
- Takahashi et al., “New Method to Increase a Backup Support of a 6

French Guiding Coronary Catheter,” Catherization and Cardiovascular Interventions 63:452-456 (2004) (Exh. 1020)

- U.S. Patent No. 5,690,613 to Verbeek (Exh. 1021)
- U.S. Patent No. 5,156,594 to Keith (Exh. 1022)
- U.S. Patent No. 5,102,403 to Alt (Exh. 1023)
- Kucklick, Theodore R., The Medical Device R&D Handbook (2006)

(Exh. 1024)

- Non-confidential publicly available versions of the following filings and decisions in the ongoing litigation:

- a. Amended Complaint filed by Vascular Solutions, Inc. in Vascular Solutions, Inc. v. Boston Scientific Corporation, No. 13-cv-1172 (JRT-SER) (D. Minn). (May 28, 2013) (Exh. 1025)
- b. Memorandum In Support of Motion for Preliminary Injunction filed by Vascular Solutions, Inc. in Vascular Solutions, Inc. v. Boston

Scientific Corporation, No. 13-cv-1172 (JRT-SER) (D. Minn).
(June 10, 2013) (Exh. 1026)

- c. Declaration of Howard Root In Support of Vascular Solution, Inc.'s Motion for Preliminary Injunction with Non-Confidential Exhibits filed in Vascular Solutions, Inc. v. Boston Scientific Corporation, No. 13-cv-1172 (JRT-SER) (D. Minn). (June 10, 2013) (Exh. 1027)
- d. Boston Scientific Corporation Opposition to Vascular Solutions, Inc.'s Motion for Preliminary Injunction filed in Vascular Solutions, Inc. v. Boston Scientific Corporation, No. 13-cv-1172 (JRT-SER) (D. Minn). (July 28, 2013) (Exh. 1028)
- e. Non-Confidential Memorandum Opinion and Order Granting In Part Plaintiff's Motion for Preliminary Injunction filed in Vascular Solutions, Inc. v. Boston Scientific Corporation, No. 13-cv-1172 (JRT-SER) (D. Minn). (December 19, 2013) (Exh. 1029)
- f. Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir). filed December 27, 2013 (Exh. 1030)
- g. Vascular Solutions, Inc.'s Opposition to Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir). filed January 3, 2014 (Exh. 1031)
- h. Boston Scientific Corporation's Non-Confidential Opening Brief, No. 2014-1185 (Fed. Cir). filed January 7, 2014 (Exh. 1032)

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