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AND MEDTRONIC VASCULAR, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

MEDTRONIC, INC., a Minnesota corporation, MEDTRONIC USA, INC., a Minnesota corporation, and MEDTRONIC VASCULAR, INC., a Delaware corporation,

Plaintiff,

v.

AGA MEDICAL CORPORATION, a Minnesota corporation,

Defendant.

Case No. C07 00567 MMC

DECLARATION OF DR. CHRISTOPHER K. ZARINS, M.D. IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Date: April 3, 2009
Time: 9:00 AM
Place: Courtroom 7, 19th Floor
Judge: Hon. Maxine M. Chesney

I, Dr. Christopher K. Zarins, declare:

1. I make the following statements in this declaration based on my personal knowledge of the facts stated herein, and if called upon to testify, I could testify competently as to such matters.

2. I have been retained by Medtronic, Inc. as an expert in the above-captioned matter.

3. I am a vascular surgeon at Stanford University Medical Center as well as a Professor at the Stanford University School of Medicine, Department of Surgery. I was the Chief of Vascular Surgery at Stanford from 1993-2005. Prior to Stanford University, I was the Chief of Vascular Surgery at the University of Chicago, Medical Center from 1976 to 1993. My employment and educational history are detailed in my CV, attached at Exhibit 1.

4. A list of publications on endovascular procedures and research and editorial boards I have sat on are listed at Exhibit 1.

5. I am a named inventor on six patents related to intravascular procedures. The list of my issued patents is attached at Exhibit 2.

6. I have been performing endovascular procedures since 1978, which includes implanting self-expanding medical devices for the treatment of aneurysms. I also have performed open surgical procedures for repair of aortic aneurysms. I am currently a practicing cardiovascular surgeon.

7. I am personally familiar with and have personally implanted into patients a variety of self-expanding medical devices made from shape memory alloys, including Medtronic's AneuRx and TALENT devices. I have also implanted Gore's EXCLUDER, TAG and VIABAHN devices as well as AGA's Vascular Plug devices.

8. In the course of my professional activities, I have become familiar with medical devices used for treating cardiovascular disease, and am aware of evolving and current best practices used in endovascular procedures to implant self-expanding medical devices.

A. RETENTION IN CASE

9. I am being compensated at a rate of $3,500 per full 8-hour day (partial days to be pro-rated) for my work on this case.

B. SCOPE OF OPINIONS

10. In this declaration, I address the need for, and commercial success of self-expanding shape memory devices used in endovascular procedures used in lieu of open surgical techniques.

C. MATERIALS CONSIDERED

11. In forming the opinions set forth in this declaration, I have relied upon my personal education, training, background and extensive professional experience performing endovascular procedures.

12. I am familiar with the Instructions for Use ("IFU") for the AneuRx, Talent, EXCLUDER, TAG, VIABAHN, VIABIL, VIATORR, HELEX products. I am also familiar with the IFU for AGA's Vascular Plug products. See, http://www.goremedical.com and http://www.amplatzer.com/.

13. In forming my opinions, I have also reviewed the Jervis Patents being asserted against AGA Medical Corporation ("AGA"), U.S. Patent Nos. 5,067,957 ("'957 Patent"), 5,190,546 ("'546 Patent"), and 6,304,141 ("'141 Patent") (collectively, the "patents-in-suit").

14. In the event of a trial in this matter, in connection with my testimony, I may also rely upon Exhibit 3, as well as demonstrative exhibits, Medtronic and AGA's expert reports, and the trial testimony and trial exhibits of Medtronic and/or AGA's witnesses.

D. SECONDARY INDICIA OF NON-OBVIOUSNESS

15. I understand that the patent law regarding secondary considerations or indicia of non-obviousness can include, among other things, factors such as (1) a long felt need for the solution provided by the claimed invention; (2) the commercial success of a product covered by the patent; and (3) acceptance by others of the claimed invention in the industry.

II. BACKGROUND FOR THE JERVIS PATENTS' TECHNOLOGY

16. Before self-expanding stent devices were available, open surgery and its attendant risks were used to treat aneurysms. Open surgery involves greater risks to the patient of infection due to the larger incisions made into the body, and the trauma and invasiveness of open surgery. Open surgical techniques involve longer periods of sedation for the patient, and longer recovery periods than endovascular procedures.

A. HISTORY OF THE TREATMENT OF ANEURYSMS

17. One example of the tremendous benefit of self-expanding shape memory alloy medical devices is found in the history of the treatment of aneurysms. An aneurysm is a weakening in the wall of a blood vessel, such as the aorta, where the walls enlarge and thin to the point where a rupture of the blood vessel can occur. If the aorta ruptures, within just a couple of heartbeats, the rapid blood loss can cause the death of the patient.

18. Aneurysms are becoming more prevalent – over the last 30 or 40 years, there has been about a 300 percent increase in the prevalence of aneurysms.

19. The first successful aneurysm repair using surgical graft replacement was performed in San Francisco by Dr. Norman Freeman in 1951. Within a month, Charles Dubost in Europe also accomplished this feat.

20. In 1953, Michael DeBakey performed the first prosthetic graft repair of an aortic aneurysm using his wife's sewing machine to make graft to treat the aneurysm.

21. Dr. Julio Palmaz in the 1980s began working on the concept of an intravascular stent or a strut type of a structure that would provide a scaffold to hold the artery open and prevent it from re-collapsing. Such stents are still used today to treat arterial narrowing or stenoses.

22. The FDA approved the use of such endovascular stents in 1991 in the United States for use in peripheral arteries and in 1994 for use in coronary arteries.

23. Dr. Juan Parodi used a stent to fix a graft fabric to the aortic neck; thus, combining the concepts together to perform the first successful endovascular repair in a human in 1991.

24. Using the concept of endovascular repair with a stent graft, one could treat an aneurysm through small groin incisions by placing the device through the femoral artery. This had a dramatic impact on morbidity and mortality, and a great benefit to patients.

25. Dr. Michael Dake also worked on developing homemade Z-stents to which he sewed a Dacron graft material. Dr. Dake first used his homemade Z-stents in 1992. Dr. Dake and I began using these devices to treat aortic aneurysms in 1993.

26. There was an explosion of interest in the intravascular field which led to the commercial development of a number of different devices which quickly were adopted for the treatment of vascular disease.

B. USE OF SELF-EXPANDING MEDICAL DEVICES

27. Generally, self-expanding medical devices made from shape memory alloys are delivered into patients using their own specially designed delivery catheter systems.

28. Because of the self-expansion aspect of the devices, the device must be constrained into a deformed shape having a smaller diameter to fit within a delivery system; otherwise a physician could not deliver the device through the patient's vasculature.

29. The general steps of implanting an endovascular device are as follows: first a small incision is made, so as to gain access to a vein or artery which leads to the site of the defect. A constrained device, which is attached to a delivery catheter system, is advanced through the vasculature of the patient to the site of the defect to be treated. When the device is located at the correct position, the physician removes the restraint so that the constrained device may self-expand into its fully opened shape.

30. Physicians typically are specifically trained to use a particular device before implanting that type of device into patients. In some cases, absent appropriate training, a medical device company will not allow a physician to order their devices without having first completed such training. Directions for implantation procedures are provided with each device, in the form of Instructions for Use. The IFUs contain step-by-step instructions on how to implant the device into patients.

C. DEVELOPMENT OF INTRAVASCULAR STENTS

31. As examples of successful medical devices made from shape memory alloys, there are currently several self-expanding devices sold by several different companies that have been approved by the FDA for use in the United States. For example, Medtronic currently sells the AneuRx and Talent endograft products in the United States. W.L. Gore & Associates sells the EXCLUDER, TAG, VIABAHN, VIABIL and VIATORR products in the United States and elsewhere. AGA Medical sells the AMPLATZER® Septal Occluder, Multi-Fenestrated Septal

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