

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Inter Partes Review of:

Trial Number: To Be Assigned

U.S. Patent No. 6,482,228

Filed: November 14, 2000

Issued: March 25, 2003

Attorney Docket No.: 058888-0000014

Inventor(s): Norred, Troy R.

Assignee: Norred, Troy R.

Title: PERCUTANEOUS AORTIC VALVE
REPLACEMENT

Panel: To Be Assigned

Mail Stop Patent Board
Patent Trial and Appeal Board
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF THOMAS VASSILIADES, JR., M.D.

I, Thomas Vassiliades, Jr., M.D., declare as follows:

1. I am over 18 years of age. I make this declaration based on my own personal knowledge, personal experience, and belief. If called upon, I can competently testify to the facts stated in this declaration.

2. I am currently the Vice President of Medical Affairs for the Structural Heart Division of Medtronic, Inc. A copy of my curriculum vitae is attached as Exhibit 1.

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3. I earned a Bachelor of Arts degree (AB) from Duke University in Durham, North Carolina. I earned a Doctor of Medicine degree (MD) from the University of North Carolina School of Medicine at Chapel Hill, North Carolina. Lastly, I earned a Master of Business Administration degree (MBA) from Emory University's Goizueta Business School in Atlanta, Georgia.

4. I completed my general surgery residency at Emory University Affiliate Hospitals in Atlanta, Georgia. Additionally, I completed my fellowship training in cardiothoracic surgery at the University of Michigan Hospitals in Ann Arbor, Michigan.

5. From 1992 to 2003 I worked as a cardiac surgeon, first at Holmes Regional Medical Center in Melbourne, Florida and then at Cardiothoracic Surgical Associates of Northwest Florida in Pensacola, Florida.

6. From 1993 to 2003 I also worked as the Founder/Director of Cardiac Surgery at Cardiology Consultants in Pensacola, Florida; the Founder/Director of Cardiac Surgery at Baptist Hospital in Pensacola, Florida; and the Director of Cardiothoracic Surgery at Sacred Heart Hospital in Pensacola, Florida.

7. From 2003 to 2005, I served as an Assistant Professor in the Department of Surgery, Division of Cardiothoracic Surgery, at Emory University's School of Medicine. From 2005 to 2010, I served as an Associate Professor in the Department of Surgery, Division of Cardiothoracic Surgery, at Emory University's

School of Medicine.

8. I have extensive experience in treating heart valve disease. During my clinical practice career, I performed and participated in approximately 5,000 heart procedures of which approximately 1,000 of these were heart valve operations, consisting of valve repair and replacement of all four heart valves.

9. I am a member of the American Board of Surgery and the American Board of Thoracic Surgery.

10. From 1995 to 2001 I served as the Executive Councilor of the Florida Society of Thoracic and Cardiovascular Surgeons.

11. In 2003 I joined the American Society for Thoracic Surgery and the Society of Thoracic Surgeons (“AATS/STS”) joint Work Force on the Evaluation of New Technology. From 2004 to 2005 I served as the Co-Chair of the AATS/STS Joint Task Force on Percutaneous Valve Technology. In 2008 I joined the AATS/STS Tech-Con Workforce, which focuses on novel therapies in cardiac and general thoracic surgery. In 2009 I joined the Society of Thoracic Surgeons’ Program Committee and began serving as the Tech-Con Co-Director.

12. From 2005-2007 I was a member of the Heart Valve Society of America’s Therapeutic Interventions Council.

13. In 2005 I was appointed to the Circulatory Devices Panel of the Medical Devices Advisory Committee of the Center for Device and Radiological

Health of the Food and Drug Administration in Washington, DC.

14. In 2007 I joined the Executive Committee and Board of Directors for the International Society for Minimally Invasive Cardiothoracic Surgery.

15. My research includes heart valves and replacement heart valves, including serving as an investigator on the following: “The Partner Trial: Placement of Aortic Transcatheter Valves: Edwards SAPIEN Transcatheter Heart Valve” (co-investigator); “Development of a Set of Devices and Techniques for the Minimally Invasive Treatment of Aortic Stenosis” (co-principle investigator); and “EVEREST Percutaneous Mitral Valve Repair” (local principle investigator).

16. I have participated in lectures, seminars, and visiting professorships concerning heart valves and replacement heart valves, including speaking on “Percutaneous Heart Valve Technology” at the 21st Annual Cardiovascular Conference in Hawaii on February 16, 2008 in Kona, Hawaii and “Valve Replacement” at the American Heart Association, Local Chapter Meeting on January 26, 1994 in Pensacola, Florida.

17. I have authored articles and book chapters on heart valve and replacement heart valves, including: “Percutaneous Pulmonary Valve Replacement: 3-Month Evaluation of Self-Expanding Valved Stents” (Invited Commentary, *Ann Thorac Surg* 2006; 82:708-713); “The Clinical Development of Percutaneous Heart Valve Technology: a Position Statement of the Society of

Thoracic Surgeons (STS), the American Association for Thoracic Surgery (AATS), and the Society of Cardiovascular Angiography and Intervention (SCAI)” (J. Thoracic Cardiovascular Surgery 2005; 129(5):970-6; J. Am. Coll. Cardiol. 2005; 45(9):1554-60; Ann. Thorac. Surg. 2005; 79(5):1812-8; and Catheter Cardiovasc. Interv. 2005; 65(1):73-79); “Fixing broken heart valves percutaneously: the shape of things to come?” (Expert Review of Cardiovascular Therapy 2006; 4(1):1-3); “Percutaneous Heart Valve Technology: As I See It.” (Cardiothoracic Surgery Network, October, 2005); and “Percutaneous valve technologies for aortic valve replacement” (Advances and Controversies in Adult Heart Valve Surgery, Termedia, 2007).

18. This declaration is submitted in support of the petition for inter partes review to be filed by Medtronic, Inc. in respect to U.S. Patent No. 6,482,228 to Norred, issued November 19, 2002 and titled “Percutaneous aortic valve replacement.” (“the ‘228 Patent”).

19. In preparing this statement, I studied the ‘228 Patent and six references, namely: a German article titled “A Foldable, Artificial Heart Valve,” published by Spiegel Online (“Spiegel”); German Patent Application No. 195 46 692 (“Figulla”); German Patent Application No. 198 57 887 A1 (“Fraunhofer”); U.S. Patent No. 6,454,799 (“Schreck”); U.S. Patent No. 6,425,916 (“Garrison”); and U.S. Patent No. 3,657,744 (“Ersek”) (collectively, the “Prior Art References”).

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