

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION, EDWARDS
LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES AG,

Petitioners,

v.

BOSTON SCIENTIFIC SCIMED, INC.,

Patent Owner.

Case IPR2017-00060
Patent 8,992,608 B2

Before the Honorable NEIL T. POWELL, JAMES A. TARTAL, and
ROBERT L. KINDER, *Administrative Patent Judges.*

DECLARATION OF STEPHEN J. D. BRECKER

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I, Stephen J. D. Brecker, state and declare as follows:

I. INTRODUCTION

1. I am over the age of 21 and am competent to make this declaration.

2. I am an interventional cardiologist with a special interest in adult structural heart disease and valvular intervention. I have over 25 years of medical experience as a practicing interventional cardiologist. I am the Chief of Cardiology at St. George's University Hospitals in London, U.K. I have performed over eleven hundred transcatheter aortic valve replacement ("TAVR") procedures.

3. I graduated from St. Thomas' Hospital, London in 1984.

Subsequently, I completed senior house officer posts at the Hammersmith Hospital, the Brompton Hospital, and the National Hospital for Nervous Diseases. I then completed registrar training in cardiology at St. Thomas' Hospital and the London Chest Hospital, before taking up a British Heart Foundation Junior Research Fellowship at the Royal Brompton Hospital. I was also a visiting fellow at Johns Hopkins Hospital, Baltimore, before becoming a Consultant Cardiologist and Honorary Senior Lecturer at St. George's in 1996. I am now Professor of Cardiology and Chief of Cardiology Clinical Academic Group at St. George's University Hospitals.

4. My full qualifications are set forth in my CV, attached hereto at Appendix A.

5. I have proctored over 600 TAVR procedures in which I assist and teach other physicians how to perform TAVR. I have been and remain a Global proctor for Medtronic since 2010 at approximately 80 centers worldwide, including over 50 medical centers in the USA for the US Pivotal Trial of the Corevalve product. I have also proctored the TAVR procedure in the UK, Denmark, Belgium, Japan, India, Israel, Holland, Austria, Greece, and South Korea.

6. I have performed TAVR procedures with Medtronic's Corevalve and EvolutR products, as well as Boston Scientific's Lotus product and Edwards' Sapien products.

7. I have been active in the field of TAVR as a clinician, researcher, teacher, and innovator, and I have performed over 1,100 percutaneous TAVR procedures since 2007.

8. I have been a practicing cardiologist since 1996 and I am aware of the technological advances since then.

9. I have experience, since 1996, of looking after cardiology patients with thoracic and abdominal aortic aneurysms and have over more than 20 years, worked closely with our vascular team in their management. St. George's Vascular Surgery are considered international leaders in this field and have carried

out many of the pivotal clinical trials in this area. I refer these patients for assessment and treatment and look after them before and after. On a daily basis I have always interacted with our vascular team and discussed cross-over technologies between our subspecialties. I have implanted covered coronary stents and peripheral stent grafts (probably around 10-15 procedures for management of iliofemoral perforations following TAVR procedures since 2007).

10. I am a named inventor on one patent, describing a specific TAVR guidewire, acquired by Medtronic and two patent applications, one for a trans-catheter mitral valve, another for novel temporary pacing wire.

11. I am a Fellow of the Royal College of Physicians, the European Society of Cardiology, the American College of Cardiology, the British Cardiovascular Society, and the British Cardiovascular Intervention Society.

12. I am the author or co-author of four books, 16 book chapters, and more than 100 peer-reviewed articles.

13. For my time, I am being compensated at \$800 per hour, my standard rate for this type of consulting activity. My compensation is in no way contingent on the results of these or any other legal proceedings.

14. I have reviewed U.S. Patent No. 8,992,608 (the “‘608 patent”), the Petition in this proceeding, the Board’s Institution Decision, the Patent Owner’s Preliminary Response, Dr. Buller’s declaration regarding the ‘608 patent and

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