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

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

DECLARATION OF LARRY WOOD

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List of Materials Cited

Petitioner's Exhibits:

Exhibit 1048, Shuren, *Life-Saving, Smart Regulation on Behalf of Patients with Aortic Stenosis*, FDA Voice dated June 16, 2014
Exhibit 1049, Edwards Endovascular HVT – Patriot Technical Design Review Proof of Concept & Selection of 1st Generation Valve dated June 11, 2003
Exhibit 1050, History of Sapien and the Future of THV
Exhibit 1051, Boston Scientific's 2016 Annual Report
Exhibit 1052, Freeman et al., *First-in-Man Transfemoral Transcatheter Aortic Valve Replacement with the 29 mm Edwards SAPIEN XT Valve*, Catheterization and Cardiovascular Interventions, 82:664-70 (2013)
Exhibit 1053, Wiegerinck et al., *An Up-to-date Overview of the Most Recent Transcatheter Implantable Aortic Valve Prostheses*, Expert Review of Medical Devices, 31-45 (2016)
Exhibit 1054, Zaman et al., *Incidence and Predictors of Permanent Pacemaker Implantation Following Treatment with the Repositionable Lotus™ Transcatheter Aortic Valve*, Catheterization and Cardiovascular Interventions (2016)
Exhibit 1055, August 18, 2016 Letter from B. Zuckerman to J. Mazzarella re: P130009/S057
Exhibit 1056, Medtronic CoreValve™ Evolut™ R System First TAVI to Receive CE Mark for Intermediate Risk Aortic Stenosis Patients, Medtronic Press Release (August 1, 2016)
Exhibit 1057, Medtronic Expands TAVR Access to More Patients With Symptomatic, Severe Aortic Stenosis Upon Intermediate Risk FDA Approval, Medtronic Press Release (July 10, 2017)
Exhibit 1058, Boston Scientific Receives CE Mark for Lotus™ Valve System, Boston Scientific Press Release (October 28, 2013)
Exhibit 1073, "Centera: Novel Transcatheter Heart Valve Shows Promise in Aortic Stenosis," EuroPCR Meeting News (May 26, 2017)
Exhibit 1074, Edwards Lifesciences Press Release: "Edwards' Novel Self-Expanding Transcatheter Heart Valve Demonstrates Excellent Early Patient Outcomes" (May 17, 2017)
Exhibit 1075, "Edwards' Self-Expanding Transcatheter Heart Valve Demonstrates Excellent Early Patient Outcomes," DAIC (May 24, 2017)

Patent Owner Exhibits:

Exhibit 2002, Press Release: FDA approves expanded indication for two transcatheter heart valves for patients at intermediate risk for death or complications associated with open-heart surgery, FDA 8/18/2016
Exhibit 2003, Thourani, V. H., et al., Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients : a propensity score analysis, The Lancet, Apr. 3, 2016

Exhibit 2015, Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve, Edwards Lifesciences (Sept. 5, 2007)
Exhibit 2017, SAPIEN XT Valve Product Overview, Edwards Lifesciences
Exhibit 2018, Ramin S. Hastings & Isaac George, The Sapien 3 Valve, Cardiac Interventions Today, Mar./Apr. 2016
Exhibit 2020, Press Release: Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S., Edwards Lifesciences (Nov. 2, 2011)
Exhibit 2021, Press Release: Edwards Lifesciences Launching Sapien XT Valve In The U.S., Edwards Lifesciences (June 16, 2014)
Exhibit 2031, Slide Deck titled "SAPIEN 3 26mm CDR Nov 2010" (EDWARDS 01933840-939)
Exhibit 2047, "FACT SHEET: Cribier-Edwards Percutaneous Aortic Heart Valve," Edwards Lifesciences
Exhibit 2051, Martin B. Leon slide deck titled "A Randomized Evaluation of the SAPIEN XT Transcatheter Valve System in Patients with Aortic Stenosis Who Are Not Candidates for Surgery: PARTNER II, Inoperable Cohort," dated March 10, 2013
Exhibit 2059, Tae-Hyun Yang et al., Incidence and Severity of Paravalvular Aortic Regurgitation With Multidetector Computed Tomography Nominal Area Oversizing or Undersizing After Transcatheter Heart Valve Replacement With the Sapien 3, 8 JACC: Cardiovascular Interventions 462 (2015)
Exhibit 2062, Freek Nijhoff et al., Transcatheter Aortic Valve Implantation With the New Balloon-Expandable Sapien 3 Versus Sapien XT Valve System, Circulation: Cardiovascular Interventions, June 1, 2015
Exhibit 2063, Document titled "Journey to S3," dated May 8, 2016 (EDWARDS 02399064-68)
Exhibit 2072, Matthew J. Czarny & Jon R. Resar, Diagnosis and Management of Valvular Aortic Stenosis, Clinical Medicine Insights: Cardiology 2014:8(S1), 15-24

I, Larry Wood, declare as follows:

1. I am over the age of eighteen (18) and otherwise competent to make this Declaration.

2. I understand that this Declaration is being submitted in connection with Edwards'[1] reply in support of *inter partes* review ("IPR") of U.S. Patent No. 8,992,608 (the "'608 Patent").

3. As I explain in detail below, I am an employee of Edwards. I have not been compensated separately for my efforts in connection with the preparation of this Declaration, but have instead continued to receive my usual salary, including with respect to periods of time during which I worked on this Declaration. My regular Edwards compensation is in no way contingent on the results of these or any other proceedings.

4. I am making this Declaration based upon my own personal knowledge (except where otherwise indicated), and I am competent and prepared to testify regarding the contents of this Declaration.

I. INTRODUCTION AND QUALIFICATIONS

5. I am currently the Corporate Vice President, Transcatheter Heart Valves, at Edwards Lifesciences, a position I have held since 2007. In that capacity, I

[1] "Edwards" refers collectively to Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG.

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