# 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 IPR2017-0060 Patent 8,992,608

\_\_\_\_\_

#### **DECLARATION OF GREGORY S. CORDREY**

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board

U.S. Patent and Trademark Office P.O. Box 1450

Alexandria, VA 22313-1450



- I, Gregory S. Cordrey, declare as follows:
- I am a partner at the law firm of Jeffer Mangels Butler & Mitchell,
   LLP, counsel to Petitioners Edwards Lifesciences Corporation, Edwards
   Lifesciences LLC and Edwards Lifesciences AG (collectively "Petitioners") in the
   above-captioned matter.
- 2. I have provided this declaration as evidence in support of Petitioners' Reply In Support of *Inter Partes* Review of U.S. Patent No. 8,922,608.
- 3. Exhibit 1015 is a true and correct copy of excerpts from Vossoughi et al., Stent Graft Update (2000).
- 4. Exhibit 1016 is a true and correct copy of excerpts from Dolmatch et al., Stent Grafts: Current Clinical Practice (1999).
- 5. Exhibit 1026 is a true and correct copy of the Gore Excluder

  Instructions for Use (2002) available at the Federal Drug Administration website at

  <a href="https://www.fda.gov/ohrms/dockets/ac/02/briefing/3893b1\_AAA.DEVICE.PMA.I">https://www.fda.gov/ohrms/dockets/ac/02/briefing/3893b1\_AAA.DEVICE.PMA.I</a>

  FU.pre02.pdf.
- 6. Exhibit 1028 is a true and correct copy of Assignment record for U.S. Patent App. Pub. No. 2003/0236567 to Elliot obtained from the USPTO online records at <a href="http://portal.uspto.gov/pair/PAIRPrintServlet">http://portal.uspto.gov/pair/PAIRPrintServlet</a> on July 23, 2016.
- 7. Exhibit 1035 is a true and correct copy of the Supplemental Declaration of Niguel P. Buller, M.D.



- 8. Exhibit 1036 is a true and correct copy of Approved Judgment, Edwards Lifesciences, Inc. v. Boston Scientific Scimed, Inc., HC-2015-004574 dated March 3, 2017.
- 9. Exhibit 1037 is a true and correct copy of Judgment, *CoreValve Inc. v. Edwards Lifesciences AG et al.*, HC 07 C01243 dated January 9, 2009.
- 10. Exhibit 1038 is a true and correct copy of Approved Judgment, Edwards Lifesciences AG v. Cook Biotech Inc., HC08 C 00934 dated June 12, 2009.
- 11. Exhibit 1039 is a true and correct copy of Memorandum, *Edwards Lifesciences AG et al. v. CoreValve, Inc. et al.*, C.A. No. 08-91 (GMS) dated February 1, 2011.
- 12. Exhibit 1040 is a true and correct copy of Plaintiffs' Opening Brief in Support of Their Motion for Enhanced Damages Pursuant to 35 U.S.C. § 284, *Edwards Lifesciences LLC*, et al. v. Medtronic CoreValve LLC, et al. C.A. 12-023 (GMS) dated March 24, 2014.
- 13. Exhibit 1041 is a true and correct copy of Vossoughi et al. (Eds.), Stent Graft Update, Medical and Engineering Publishers Inc. (2000).
- 14. Exhibit 1042 is a true and correct copy of Dolmatch et al. (Eds.), Stent-Grafts Current Clinical Practice, Thieme (2000).



- 15. Exhibit 1043 is a true and correct copy of the Deposition Transcript of Stephen J.D. Brecker, M.D. (Sept. 1, 2017).
- 16. Exhibit 1044 is a true and correct copy of the Deposition Transcript of Andrew J. Manganaro, M.D. (Sept. 15, 2017).
- 17. Exhibit 1047 is a true and correct copy of the Curriculum Vitae of Larry Lee Wood.
- 18. Exhibit 1048 is a true and correct copy of Shuren, *Life-Saving*, *Smart Regulation on Behalf of Patients with Aortic Stenosis*, FDA Voice (June 16, 2014).
- 19. Exhibit 1049 is a true and correct copy of Edwards Endovascular
   HVT Patriot Technical Design Review Proof of Concept & Selection of 1<sup>st</sup>
   Generation Valve dated June 11, 2003.
- 20. Exhibit 1050 is a true and correct copy of Presentation of Stanton Rowe, "History of Sapien and the Future of THV," bearing Bates numbers [EDWARDS 02433143-211].
- 21. Exhibit 1051 is a true and correct copy of Boston Scientific's 2016 Annual Report.
- 22. Exhibit 1052 is a true and correct copy of 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).

- 23. Exhibit 1053 is a true and correct copy of 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).
- 24. Exhibit 1054 is a true and correct copy of Zaman et al., *Incidence* and *Predictors of Permanent Pacemaker Implantation Following Treatment* with the Repositionable Lotus<sup>TM</sup> Transcatheter Aortic Valve, Catheterization and Cardiovascular Interventions (2016).
- 25. Exhibit 1055 is a true and correct copy of August 18, 2016 Letter from B. Zuckerman to J. Mazzarella re: P130009/S057.
- 26. Exhibit 1056 is a true and correct copy of Medtronic CoreValve™ Evolut™ R System First TAVI to Receive CE Mark for Intermediate Risk Aortic Stenosis Patients, Medtronic Press Release (August 1, 2016).
- 27. Exhibit 1057 is a true and correct copy of Medtronic Expands
  TAVR Access to More Patients With Symptomatic, Severe Aortic Stenosis
  Upon Intermediate Risk FDA Approval, Medtronic Press Release (July 10, 2017).



## DOCKET

### Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

#### **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

#### **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

#### **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

#### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### **LAW FIRMS**

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### **FINANCIAL INSTITUTIONS**

Litigation and bankruptcy checks for companies and debtors.

#### **E-DISCOVERY AND LEGAL VENDORS**

Sync your system to PACER to automate legal marketing.

