

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

PATENT OWNER'S UPDATED EXHIBIT LIST

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

PATENT OWNER'S UPDATED EXHIBIT LIST

Exhibit No.	Description
2001	Sapien 3 Brochure, "Transcatheter Aortic Valve Replacement with the Edwards SAPIEN 3 Transcatheter Heart Valve," 2016
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
2003	Thourani, V. H., et al., Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients : a propensity score analysis, <i>The Lancet</i> , Apr. 3, 2016
2004	Lerakis et al., Paravalvular Aortic Leak After Transcatheter Aortic Valve Replacement Current Knowledge, <i>Circulation</i> , Jan. 22, 2013, p. 397-407
2005	Cribier et al., Mid-Term Experience of Percutaneous Heart Valves, <i>JACC</i> 47:1214:23 (2006)
2006	Bentall, H.H., De Bono, A.: A technique for complete replacement of the ascending aorta, <i>Thorax</i> , 23:338-39 (1968)
2007	Order re: Motions for Summary Judgment, <i>Medtronic Inc. v. Edwards Lifesciences Corp., et al.</i> , No. 12-0327, Dkt. 414 (C.D. Cal. Sept. 17, 2013)
2008	Report and Recommendation at 11, n.6, <i>W.L. Gore & Assocs. v. C.R. Bard, Inc.</i> , Civ. A. No. 11-515-LPS-CJB, Dkt. 428 (D. Del. Nov. 9, 2015)
2009	Declaration of Marc A. Cohn in Support of Motion for Pro Hac Vice Admission (May 9, 2017)
2010	Declaration of Matthew M. Wolf in Support of Motion for Pro Hac Vice Admission (May 9, 2017)
2011	Declaration of Edward Han in Support of Motion for Pro Hac Vice Admission (May 9, 2017)
2012	Proposed Stipulated Protective Order (June 20, 2017)
2013	Comparison to Default Protective Order (June 20, 2017)

Exhibit No.	Description
2014	Edwards SAPIEN Transcatheter Heart Valve (THV) - P100041, U.S. Food & Drug Admin. (Sept. 6, 2013), https://wayback.archive-it.org/7993/20161023015438/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm280840.htm
2015	Press Release: Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve, Edwards Lifesciences (Sept. 5, 2007)
2016	Press Release: Edwards Lifesciences Announces First Human Implants With 18 French Transcatheter Valve System, Edwards Lifesciences (May 14, 2009)
2017	SAPIEN XT Valve Product Overview, Edwards Lifesciences, http://www.edwards.com/devices/heart-valves/sapien-xt-valve (last visited June 21, 2017)
2018	Ramin S. Hastings & Isaac George, The Sapien 3 Valve, Cardiac Interventions Today, Mar./Apr. 2016
2019	Susheel Kodali et al., Paravalvular Regurgitation after Transcatheter Aortic Valve Replacement with the Edwards Sapien Valve in the PARTNER trial: characterizing patients and impact on outcomes, Eur. Heart J. (2014)
2020	Press Release: Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S., Edwards Lifesciences (Nov. 2, 2011)
2021	Press Release: Edwards Lifesciences Launching Sapien XT Valve In The U.S., Edwards Lifesciences (June 16, 2014)
2022	TAVR By Edwards: Our Latest Valve, Edwards Lifesciences, https://tavrbyedwards.com/our-latest-heart-valve-sapien-3 (last visited Nov. 14, 2016)
2023	Press Release: Edwards Receives European Approval for Advanced SAPIEN 3 Valve, Edwards Lifesciences (Jan. 27, 2014)
2024	Takahide Arai et al., Comparison of Edwards SAPIEN 3 versus SAPIEN XT in transfemoral transcatheter aortic valve implantation: Difference of valve selection in the real world, J. Cardiology (2016)
2025	Edwards Lifesciences (EW) Michael A. Mussallem on Q1 2015 Results - Earnings Call Transcript
2026	Edwards Lifesciences (EW) Michael A. Mussallem on Q4 2015 Results - Earnings Call Transcript

Exhibit No.	Description
2027	Press Release: Edwards SAPIEN 3 Transcatheter Heart Valve Receives Expanded Indication From FDA, Edwards Lifesciences (Aug. 18, 2016)
2028	Deposition Transcript of Nigel P. Buller, M.D., dated June 15, 2017
2029	Transcript of Proceedings, <i>Cordis Corp. v. Boston Scientific Corp.</i> , No. 10-39-SLR, Dkt. 275 (D. Del. May 11, 2012)
2030	U.S. Patent No. 7,276,078 to Spenser et al.
2031	Slide Deck titled "SAPIEN 3 26mm CDR Nov 2010" (EDWARDS 01933840-939)
2032	<i>Boston Scientific Corp. v. Edwards Lifesciences Corp.</i> , No. 16-275-SLR-SRF, Dkt. 186 (D. Del. June 1, 2017)
2033	Edwards SAPIEN 3 Transcatheter Heart Valve, Edwards Lifesciences, http://www.edwards.com/devices/Heart-Valves/Transcatheter-Sapien-3 (last visited June 21, 2017)
2034	Slide Deck titled "Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander System 23/26/29 mm Sizes Procedural Training Manual" (EDWARDS 01026580-751)
2035	Photograph of Sapien 3 Valve (BSC-EDW0059565)
2036	Permanent PVL Locking Stitch to Skirt, Element ID 220 (EDWARDS 01026527-35)
2037	Press Release: FDA approves SAPIEN 3 THV artificial heart valve, FDA (June 17, 2015)
2038	TAVItalk Designing the Future of TAVI - A Technology-Focused Edition: The SAPIEN 3 Valve, Edwards Lifesciences, Summer 2014
2039	Document titled "Meeting with Physicians: PHV sizing and paravalvular Leak" dated May 23, 2003 (EDWARDS00743914-18)
2040	Patent application (EDWARDS 01032820-88)
2041	Document titled "Summary of Stanley's and Larry's visit July 27-29, 2004" (EDWARDS 01033971-90)

Exhibit No.	Description
2042	Document titled "Visit Summary Stu, Keith, Jan, Mark K., Larry, Stanley & Laksen," dated May 24, 2006 (EDWARDS 01033782-825)
2043	Document titled "Summary of Management Quarterly Visit July 12-14, 2005" (EDWARDS 01033844-86)
2044	Slide Deck titled "THV2 Design Commitment Review," dated May 13, 2007 (EDWARDS00260617-58)
2045	Slide Deck titled "PHV2," dated March 2006 (EDWARDS 02438701-26)
2046	Slide Deck titled "Limited Clinical Feasibility (FIM) Design Review SAPIEN 3 with the NovaFlex 4 Delivery System (DS) and Accessories" (EDWARDS 0174788-849)
2047	Document titled "FACT SHEET: Cribier-Edwards Percutaneous Aortic Heart Valve," Edwards Lifesciences
2048	Ali N. Azadani et al., Energy Loss Due to Paravalvular Leak With Transcatheter Aortic Valve Implantation, 88 Annals Thoracic Surgery 1857 (2009)
2049	Philippe Généreux et al., Paravalvular Leak After Transcatheter Aortic Valve Replacement, 61 J. Am. C. Cardiology 1125 (2013)
2050	Ignacio Cruz-González et al., Paravalvular Leak Closure After Transcatheter Aortic Valve Implantation Simultaneously Using Amplatzer Vascular Plug III and IV Devices, 68 Revista Española Cardiología 1035 (2015)
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, available at http://www.acc.org/~media/Clinical/PDF-Files/Approved-PDFs/2011/04/04/07/06/PARTNER-2-ACC13-Presentation-Slides.pdf
2052	Vinod H. Thourani slide deck titled "SAPIEN 3 Transcatheter Aortic Valve Replacement Compared with Surgery in Intermediate-Risk Patients: A Propensity Score Analysis," dated April 3, 2016, available at https://www.acc.org/~media/Clinical/PDF-Files/Approved-PDFs/2016/03/29/08/33/SUN%201145am%20ACC16%20Slides%20PARTNER%20II%20Sapien%203.ppt

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.