IPR2017-00060

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*.

PETITIONERS' UPDATED EXHIBIT LIST

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PETITIONERS' UPDATED EXHIBIT LIST

| EXHIBIT 1001 | U.S. Patent No. 8,992,608 to Haug et al. |
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| EXHIBIT 1002 | File History of U.S. Application No. 12/492,512 |
| EXHIBIT 1003 | WO 98/29057 to Cribier <i>et al</i> . |
| EXHIBIT 1004 | WO 03/047468 to Spenser <i>et al</i> . |
| EXHIBIT 1005 | U.S. Patent App. Pub. No. 2003/0236567 to Elliot |
| EXHIBIT 1006 | U.S. Patent App. Pub. No. 2004/0082989 to Cook et al. |
| EXHIBIT 1007 | Declaration of Dr. Nigel Buller |
| EXHIBIT 1008 | Alain Cribier <i>et al.</i> , "Early experience with percutaneous transcatheter implantation of heart valve prosthesis for the treatment of end-stage inoperable patients with calcific aortic stenosis," J. Am. Coll. Cardiol., 43(4): 698-703 (2004). |
| EXHIBIT 1009 | U.S. Patent App. Pub. No. 2001/0039450 to Pavcnik et al. |
| EXHIBIT 1010 | U.S. Patent App. Pub. No. 2004/0033364 to Spiridigliozzi et al. |
| EXHIBIT 1011 | U.S. Patent No. 3,365,728 to Edwards |
| EXHIBIT 1012 | Charles T. Dotter, "Transluminally-Placed Coilspring Endarterial Tube Grafts," Investigative Radiology, 329-32 (1969). |
| EXHIBIT 1013 | Frank Ing, "Stents: What's Available to the Pediatric Interventional Cardiologist?" Catheterization and Cardiovascular Interventions 57:274-386 (2002). |
| EXHIBIT 1014 | U.S. Patent No. 6,206,911 to Milo |
| EXHIBIT 1015 | Excerpts from Vossoughi et al., Stent Graft Update (2000) |
| EXHIBIT 1016 | Excerpts from Dolmatch et al., Stent Grafts: Current Clinical Practice (1999) |
| EXHIBIT 1017 | Andersen et al., "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs," European Heart Journal, 13:704-08 (1992). |
| EXHIBIT 1018 | U.S. Patent No. 5,411,552 to Andersen <i>et al.</i> |
| EXHIBIT 1019 | U.S. Patent No. 6,015,431 to Thornton <i>et al</i> . |
| EXHIBIT 1020 | U.S. Patent App. Pub. No. 2001/0021872 to Bailey et al. |
| EXHIBIT 1021 | U.S. Patent No. 6,352,554 to De Paulis |
| | |

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| EXHIBIT 1022 | European Patent 2 749 254 B1 to Salahieh et al. |
|--------------|--|
| EXHIBIT 1023 | American Heritage College Dictionary, 4th Ed. 2002 (definition of "flaps") |
| EXHIBIT 1024 | Merriam-Webster's Collegiate Dictionary, 10th ed. (2001) (definitions of "flaps" and "pleats") |
| EXHIBIT 1025 | Charles S. Thompson <i>et al.</i> , "Endoluminal stent grafting of the thoracic aorta: Initial experience with the Gore Excluder," Journal of Vascular Surgery, 1163-70 (June 2002). |
| EXHIBIT 1026 | Gore Excluder Instructions for Use (2002) |
| EXHIBIT 1027 | U.S. Patent No. 5,957,949 to Leonhardt et al. |
| EXHIBIT 1028 | Assignment record for U.S. Patent App. Pub. No. 2003/0236567 to Elliot |
| EXHIBIT 1029 | Lawrence <i>et al.</i> , "Percutaneous Endovascular Graft: Experimental Evaluation," Radiology, 163(2): 357-60 (May 1987). |
| Exhibit 1030 | European Patent 2 926 766 B1 to Salahieh et al. |
| Exhibit 1031 | Boston Scientific's August 24, 2016 Response in Opposition Proceedings of EP 2 749 254 B1 |
| Exhibit 1032 | Boston Scientific's August 24, 2016 Reply in German Infringement Proceeding 4a O 137/15 |
| Exhibit 1033 | U.S. Patent No. 5,855,601 to Bessler <i>et al</i> . |
| Exhibit 1034 | U.S. Patent No. 5,476,506 to Lunn |
| Exhibit 1035 | Supplemental Declaration of Nigel. P. Buller, M.D. |
| Exhibit 1036 | Approved Judgment, <i>Edwards Lifesciences, Inc. v. Boston</i> <i>Scientific Scimed, Inc.</i> , HC-2015-004574 dated March 3, 2017 |
| Exhibit 1037 | Judgment, <i>CoreValve Inc. v. Edwards Lifesciences AG et al.</i> , HC 07 C01243 dated January 9, 2009 |
| Exhibit 1038 | Approved Judgment, <i>Edwards Lifesciences AG v. Cook Biotech</i> <i>Inc.</i> , HC08 C 00934 dated June 12, 2009 |
| Exhibit 1039 | Memorandum, <i>Edwards Lifesciences AG et al. v. CoreValve,</i> <i>Inc. et al.</i> , C.A. No. 08-91 (GMS) dated February 1, 2011 |
| Exhibit 1040 | Plaintiffs' Opening Brief in Support of Their Motion for Enhanced Damages Pursuant to 35 U.S.C. § 284, <i>Edwards</i> <i>Lifesciences LLC, et al. v. Medtronic CoreValve LLC, et al.</i> C.A. 12-023 (GMS) dated March 24, 2014 |
| Exhibit 1041 | Vossoughi et al. (Eds.), <u>Stent Graft Update</u> , Medical and Engineering Publishers Inc. (2000) |

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| Exhibit 1042 | Dolmatch et al. (Eds.), Stent-Grafts Current Clinical Practice, Thieme (2000) |
| Exhibit 1043 | Deposition Transcript of Stephen J.D. Brecker, M.D. (Sept. 1, 2017) |
| Exhibit 1044 | Deposition Transcript of Andrew J. Manganaro, M.D. (Sept. 15, 2017) |
| Exhibit 1045 | Reply Declaration of Nigel P. Buller, M.D. |
| Exhibit 1046 | Declaration of Larry Lee Wood |
| Exhibit 1047 | Curriculum Vitae of Larry Lee Wood |
| Exhibit 1048 | Shuren, Life-Saving, Smart Regulation on Behalf of Patients with Aortic Stenosis, FDA Voice (June 16, 2014) |
| Exhibit 1049 | Edwards Endovascular HVT – Patriot Technical Design Review Proof of Concept & Selection of 1 st Generation Valve dated June 11, 2003 |
| Exhibit 1049 [Redacted] | [REDACTED] Edwards Endovascular HVT – Patriot Technical Design Review Proof of Concept & Selection of 1 st Generation Valve dated June 11, 2003 |
| Exhibit 1050 | Rowe, Stanton, "History of Sapien and the Future of THV" [EDWARDS 02433143-211] |
| Exhibit 1050 [Redacted] | [REDACTED] Rowe, Stanton, "History of Sapien and the Future of THV" [EDWARDS 02433143-211] |
| Exhibit 1051 | Boston Scientific's 2016 Annual Report |
| Exhibit 1052 | Freeman et al., <i>First-in-Man Transfemoral Transcatheter Aortic Valve Replacement with the 29 mm Edwards SAPIEN XT Valve</i> , 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., <i>Incidence and Predictors of Permanent Pacemaker</i> <i>Implantation Following Treatment with the Repositionable</i> <i>Lotus</i> TM <i>Transcatheter Aortic Valve</i> , 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 |
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| EXHIBIT 1057 | Symptomatic, Severe Aortic Stenosis Upon Intermediate Risk |
| | FDA Approval, Medtronic Press Release (July 10, 2017) |
| Exhibit 1059 | |
| Exhibit 1058 | Boston Scientific Receives CE Mark for Lotus TM Valve System, |
| | Boston Scientific Press Release (October 28, 2013) |
| Exhibit 1059 | WO 2005/102015 to Bergheim <i>et al.</i> |
| Exhibit 1060 | Jayalath, R.W. et al., "Aortic Calcification," Eur. J. Vasc. |
| | Endovasc. Surg., Vol. 30, 476-488 (2005) |
| Exhibit 1061 | Compilation of Pictures of PVT Prototype Designs |
| Exhibit 1062 | Engineering Drawings, S3 External Skirt |
| Exhibit 1062 | [REDACTED] Engineering Drawings, S3 External Skirt |
| [Redacted] | |
| Exhibit 1063 | Engineering Drawings, S3 Internal Skirt |
| Exhibit 1063 | [REDACTED] Engineering Drawings, S3 Internal Skirt |
| [Redacted] | |
| Exhibit 1064 | Brecker Deposition Exhibit 1, Excerpts from Textbook of |
| Lamon 1001 | Interventional Cardiology, 2d Ed. (1994) |
| Exhibit 1065 | U.S. Patent App. No. 13/290,369 Prosecution History, |
| | Examiner's Answering Brief to Appeal (Mar. 12, 2015) |
| Exhibit 1066 | U.S. Patent App. No. 13/290,369 Prosecution History, PTAB |
| | Appeal Decision (June 2, 2017) |
| Exhibit 1067 | Declaration of Professor Stephen J.D. Brecker in Support of |
| | Boston Scientific's Reply Claim Construction Brief (D.I. 109 in |
| | Boston Scientific Corp. v. Edwards Lifesciences Corp., C.A. No. |
| | 16-275 (SLR) (SRF) (D. Del.)) |
| Exhibit 1068 | Lotus Valve FDA Recall Notice |
| Exhibit 1069 | Edwards Lifesciences LLC's and Edwards Lifesciences PVT, |
| | Inc.'s Reply Claim Construction Brief Regarding U.S. Patent |
| | Nos. 7,510,575, 9,168,133, and 9,339,383 (D.I. 106 in <i>Boston</i> |
| | Scientific Corp. v. Edwards Lifesciences Corp., C.A. No. 16-275 |
| | (SLR) (SRF) (D. Del.)) |
| Exhibit 1070 | Roy, David et al., "Transcatheter Aortic Valve Implantation for |
| | Pure Severe Native Aortic Valve Regurgitation," JACC, Vol. |
| | 16(15), 1577-84 (2013) |
| Exhibit 1071 | J.A. Southard, M.D., TAVR: It's a Career, Not Just a Procedure! |
| | (May 5, 2012) available at |
| | www.ucdmc.ucdavis.edu/internalmedicine/cardio/pdf/Symposiu |

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