

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORP.,

Petitioner,

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.*

**PATENT OWNER BOSTON SCIENTIFIC SCIMED, INC.'S
FIRST SET OF OBJECTIONS TO
PETITIONER EDWARDS LIFESCIENCES CORP.'S EXHIBITS**

Pursuant to 37 C.F.R. § 42.64(b)(1), the undersigned, on behalf of and acting in a representative capacity for Boston Scientific Scimed, Inc. (“Patent Owner”), hereby submits the following objections to Petitioner Edwards Lifesciences Corp.’s (“Petitioner”) Exhibits 1003, 1007-10, 1012-13, 1015-16, 1018, 1021-22, 1026, 1028-29, 1031-32, and any reference to and/or reliance on the foregoing. Patent Owner’s objections below apply the Federal Rules of Evidence (“F.R.E.”) as required by 37 C.F.R. § 42.62.

I. OBJECTIONS TO EXHIBITS 1003, 1008-10, 1018, 1021-22, 1026, 1031-32, AND ANY REFERENCE TO AND/OR RELIANCE THEREON

Evidence objected to: Exhibits 1003 (WO 98/29057 to Cribier *et al.*), 1008 (Alain Cribier *et al.*, “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)), 1009 (U.S. Patent App. Pub. No. 2001/0039450 to Pavcnik *et al.*), 1010 (U.S. Patent App. Pub. No. 2004/0033364 to Spiridigliozzi *et al.*), 1018 (U.S. Patent No. 5,411,552 to Andersen *et al.*), 1021 (U.S. Patent No. 6,352,554 to De Paulis), 1022 (European Patent 2 749 254 B1 to Salahieh *et al.*), 1026 (Gore Excluder Instructions for Use (2002)), 1031 (Boston Scientific’s August 24, 2016 Response in Opposition Proceedings of EP 2 749 254 B1), 1032 (Boston

Scientific's August 24, 2016 Reply in German Infringement Proceeding 4a O 137/15), and any reference to and/or reliance thereon.

Grounds for objection: F.R.E. 401 (“Test for Relevant Evidence”); F.R.E. 402 (“General Admissibility of Relevant Evidence”); F.R.E. 403 (“Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons”).

A. Exhibits 1003, 1008-10, 1018, 1021-22, 1026, and 1031-32 are Irrelevant

Exhibits 1003, 1008-10, 1018, 1021-22, 1026, and 1031-32 are not relevant to any ground on which this IPR was instituted and, if admitted, their minimal probative value would be substantially outweighed by the unfair prejudice they would cause, the confusing and misleading nature of the materials, the undue delay upon these proceedings, and the waste of time that would ensue, in violation of F.R.E. 401-403.

II. OBJECTIONS TO EXHIBIT 1007 AND ANY REFERENCE TO AND/OR RELIANCE THEREON

Evidence objected to: Exhibit 1007 (Declaration of Dr. Nigel Buller) and any reference to and/or reliance thereon.

Grounds for objection: F.R.E. 401 (“Test for Relevant Evidence”); F.R.E. 402 (“General Admissibility of Relevant Evidence”); F.R.E. 403 (“Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons”);

37 C.F.R. § 42.61 (“Admissibility”); F.R.E. 601 (“Competency to Testify in General”); F.R.E. 602 (“Need for Personal Knowledge”); F.R.E. 701 (“Opinion Testimony by Lay Witness”); F.R.E. 702 (“Testimony by Expert Witness”); F.R.E. 703 (“Bases of an Expert’s Opinion Testimony”); F.R.E. 704 (“Opinion on an Ultimate Issue”); F.R.E. 705 (“Disclosing the Facts or Data Underlying an Expert’s Opinion”); 37 C.F.R. § 42.65 (“Expert Testimony; Tests and Data”).

A. Ground 1: Dr. Buller is Not a Qualified Expert

There has been no showing that Dr. Buller is qualified to provide expert testimony on any technical matter relevant to transcatheter aortic heart valves, including engineering devices for sealing spaces formed by native valve leaflets and fluid dynamics associated with paravalvular leakage of transcatheter aortic heart valves (*see, e.g.*, Ex. 1007 Sections IV.E and V-IX), rendering his testimony on these matters improper and inadmissible pursuant to at least F.R.E. 702-705 and 37 C.F.R. § 42.65. There has further been no showing that Dr. Buller is qualified to provide expert testimony on whether the claims of U.S. Patent No. 8,992,608 (the “‘608 patent”) are valid and whether a person of ordinary skill would have been motivated to combine prior art references to disclose the inventions claimed in the ‘608 patent (*see, e.g., id.* Sections V-IX), rendering his testimony on these matters improper and inadmissible pursuant to at least F.R.E. 702-705 and 37 C.F.R. § 42.65. There has further been no showing that Dr. Buller is qualified to

provide expert testimony on claim construction or the application of claim terms from the '608 patent, (*see, e.g., id.* Sections VIII-IX), rendering his testimony on these matters improper and inadmissible pursuant to at least F.R.E. 702-705 and 37 C.F.R. § 42.65. Further, Dr. Buller has not demonstrated that he possesses first-hand knowledge, experience, or perceptions regarding the testimony identified above, rendering any lay testimony or lay opinions on these matters improper and inadmissible pursuant to at least F.R.E. 601-602 and 701.

Accordingly, Dr. Buller's testimony regarding the matters identified above, and any reference thereto and/or reliance thereon in Petitioner's submissions, would be misleading and unfairly prejudicial to Patent Owner, in violation of F.R.E. 403.

B. Dr. Buller's Testimony is Not Based on Sufficient Facts, Data, or Scientific Evidence

Dr. Buller's testimony regarding the validity of the '608 patent claims and a person of ordinary skill's motivation to combine prior art references to disclose the inventions claimed in the '608 patent, including how prior art devices could be combined, why prior art devices would be combined, and the function of combined prior art devices (*see, e.g., id.* Sections IV-IX (in particular, paragraphs 60-63, 67-69, 87, 98, 100-106, 142-144, 148-150, 158-159, 163, 168-169, 174, 180-83, 187, 191, and 194-96)), is not based on sufficient facts, data, or scientific evidence,

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