

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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EDWARDS LIFESCIENCES CORPORATION, EDWARDS  
LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES AG

*Petitioner,*

v.

BOSTON SCIENTIFIC SCIMED, INC.,

*Patent Owner.*

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Case IPR2017-00060

Patent 8,992,608

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

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

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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 Edwards Lifesciences Corp.’s (“Petitioner”) Exhibits 1035-42, 1045-66, 1068, 1070-76, 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 1035-42 AND ANY REFERENCE TO AND/OR RELIANCE THEREON**

Evidence objected to: Exhibit 1035 (Supplemental Declaration of Nigel. P. Buller, M.D.), Exhibit 1036 (Approved Judgment, *Edwards Lifesciences, Inc. v. Boston Scientific Scimed, Inc.*, HC-2015-004574 dated March 3, 2017), Exhibit 1037 (Judgment, *CoreValve Inc. v. Edwards Lifesciences AG et al.*, HC 07 C01243 dated January 9, 2009), Exhibit 1038 (Approved Judgment, *Edwards Lifesciences AG v. Cook Biotech Inc.*, HC08 C 00934 dated June 12, 2009), Exhibit 1039 (Memorandum, *Edwards Lifesciences AG et al. v. CoreValve, Inc. et al.*, 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, *Edwards Lifesciences LLC, et al. v. Medtronic CoreValve LLC, et al.* C.A. 12-023 (GMS) dated March 24, 2014), Exhibit 1041 (Vossoughi et al. (Eds.), Stent Graft Update, Medical and Engineering Publishers Inc. (2000)), Exhibit 1042 (Dolmatch

et al. (Eds.), *Stent-Grafts Current Clinical Practice*, Thieme (2000)), and any reference to and/or reliance thereon.

Grounds for objection: 37 C.F.R. § 42.23 (“Oppositions and Replies”); 37 C.F.R. § 42.123 (“Filing of Supplemental Information”).

Exhibits 1035-42 were served on April 26, 2017 as supplemental evidence in response to Patent Owner’s first set of objections (*see* Paper 9). Accordingly, Exhibits 1035-42 are to be filed with Petitioner’s opposition to Patent Owner’s motion to exclude, if filed. *See Generico, LLC v. Dr. Falk Pharma GMBH*, IPR2016-00297, Paper 15 at 2-3 (P.T.A.B. July 15, 2016). Exhibits 1035-42, since they were filed with Petitioner’s Reply, constitute improperly filed supplemental information in violation of 37 C.F.R. § 42.123 and new evidence in violation of 37 C.F.R. § 42.23. *See Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,767 (U.S. Patent & Trademark Office Aug. 14, 2012).

## **II. OBJECTIONS TO EXHIBIT 1035 AND ANY REFERENCE TO AND/OR RELIANCE THEREON**

Evidence objected to: Exhibit 1035 (Supplemental Declaration of Nigel. P. Buller, M.D.) 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”).

Exhibit 1035, Dr. Buller's supplemental declaration in response to Patent Owner's first set of objections (*see* Paper 9), fails to address Patent Owner's objections and, therefore, is insufficient to cure the deficiencies of Dr. Buller's first declaration (*see* Ex. 1007). Accordingly, it is not relevant to any ground on which this IPR was instituted and, if admitted, its minimal probative value would be substantially outweighed by the unfair prejudice it 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.

### **III. OBJECTIONS TO EXHIBITS 1036-40 AND ANY REFERENCE TO AND/OR RELIANCE THEREON**

Evidence objected to: Exhibit 1036 (Approved Judgment, *Edwards Lifesciences, Inc. v. Boston Scientific Scimed, Inc.*, HC-2015-004574 dated March 3, 2017), Exhibit 1037 (Judgment, *CoreValve Inc. v. Edwards Lifesciences AG et al.*, HC 07 C01243 dated January 9, 2009), Exhibit 1038 (Approved Judgment, *Edwards Lifesciences AG v. Cook Biotech Inc.*, HC08 C 00934 dated June 12, 2009), Exhibit 1039 (Memorandum, *Edwards Lifesciences AG et al. v. CoreValve, Inc. et al.*, 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, *Edwards Lifesciences LLC, et al. v. Medtronic CoreValve LLC, et al.* C.A. 12-023 (GMS) dated March 24, 2014), 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”); F.R.E. 801 (“Definitions That Apply to This Article; Exclusions From Hearsay”); F.R.E. 802 (“The Rule Against Hearsay”).

**A. Exhibits 1036-40 are Irrelevant**

Exhibits 1036-40 are not relevant to Dr. Buller’s qualifications as an expert in this proceeding 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.

**B. Exhibits 1036-40 are Hearsay**

Exhibits 1036-40 are out-of-court statements offered into evidence by Petitioner to prove the truth of the matters asserted in Exhibits 1036-40. Petitioner has not identified any hearsay exception that applies to Exhibits 1036-40.

Accordingly, Exhibits 1036-40 are in violation of F.R.E. 801-802.

**IV. OBJECTIONS TO EXHIBITS 1041-42, 1052-54, 1059-60, 1070, AND 1072 AND ANY REFERENCE TO AND/OR RELIANCE THERON**

Evidence objected to: Exhibit 1041 (Vossoughi et al. (Eds.), Stent Graft Update, Medical and Engineering Publishers Inc. (2000)), Exhibit 1042 (Dolmatch et al. (Eds.), Stent-Grafts Current Clinical Practice, Thieme (2000)), Exhibit 1052

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