

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

---

**PETITIONERS' OBJECTIONS UNDER 37 C.F.R. § 42.64(b)(1)  
TO EVIDENCE SUBMITTED WITH PATENT OWNER RESPONSE**

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

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioners Edwards Lifesciences Corporation, *et al.* (Petitioners) hereby serve these objections to evidence submitted by Patent Owner Boston Scientific Scimed, Inc. (“Patent Owner”) with Patent Owner’s Preliminary Response in the above noted case. This notice is being timely filed within 10 business days of institution of the Trial, which occurred on March 29, 2017.

**1. Exhibit 2001**

Petitioners object to the admissibility of Exhibit 2001 under FRE 401/402, 403, and 901. Specifically:

- **FRE 401/402, Lack of Relevance:** The exhibit was purportedly published in 2016, long after the priority date of U.S. Patent 8,992,608 (“patent-at-issue”). Additionally, Exhibit 2001 is a brochure regarding Petitioners’ product, which is not at issue in or relevant to this IPR. For these reasons, it is not relevant to the issues in the Trial.
- **FRE 403, Prejudicial, Confusing, Misleading:** The exhibit was purportedly published after the priority date of the patent-at-issue. Additionally, Exhibit 2001 is a brochure regarding Petitioners’ product, which is not at issue in or relevant to this IPR. Therefore, it is likely to cause confusion regarding the state of the art at the time of the alleged invention and also is misleading and potentially prejudicial.

- **FRE 901, Lack of Authenticity:** Patent Owner has not provided any evidence sufficient to authenticate this exhibit. Therefore, the exhibit is inadmissible under FRE 901.

## 2. Exhibit 2002

Petitioners object to the admissibility of Exhibit 2002 under FRE 401/402, 403, 801/802 and 901. Specifically:

- **FRE 401/402, Lack of Relevance:** The exhibit was purportedly published on August 18, 2016, long after the priority date of the patent-at-issue. Additionally, Exhibit 2002 is a news release regarding Petitioners' product, which is not at issue in or relevant to this IPR. For these reasons, it is not relevant to the issues in the Trial.
- **FRE 403, Prejudicial, Confusing, Misleading:** The exhibit was purportedly published after the priority date of the patent-at-issue. Additionally, Exhibit 2002 is a news release regarding Petitioners' product, which is not at issue in or relevant to this IPR, and is cited only for the proposition that open heart surgery is traumatic. Therefore, it is likely to cause confusion regarding the state of the art at the time of the alleged invention and also is misleading and potentially prejudicial.
- **FRE 801/802, Hearsay:** The exhibit and publications cited therein are inadmissible hearsay because Patent Owner offers it to prove the truth of

the matter asserted, and this exhibit does not fall within any hearsay exception.

- **FRE 901, Lack of Authenticity:** Patent Owner has not provided evidence sufficient to authenticate this exhibit. “When offering a printout of a webpage into evidence to prove the website’s contents, the proponent of the evidence must authenticate the information from the website itself, not merely the printout.” *Neste Oil Oyj v. REG Synthetic Fuels, LLC*, IPR2013-00578, Paper 53 at 4 (P.T.A.B. March 12, 2015). Patent Owner has not proffered testimony of a witness with personal knowledge of the website to authenticate the exhibit. Therefore, the exhibit is inadmissible under FRE 901.

### 3. Exhibit 2003

Petitioners object to the admissibility of Exhibit 2003 under FRE 401/402, 403, and 901. Specifically:

- **FRE 401/402, Lack of Relevance:** The exhibit was purportedly published on April 3, 2016, long after the priority date of the patent-at-issue. Additionally, Exhibit 2003 is a clinical study regarding Petitioners’ product, which is not at issue in or relevant to this IPR. For these reasons, it is not relevant to the issues in the Trial.

- **FRE 403, Prejudicial, Confusing, Misleading:** The exhibit was purportedly published after the priority date of the patent-at-issue. Additionally, Exhibit 2003 is a clinical study regarding Petitioners' product, which is not at issue in or relevant to this IPR, and is cited only as background regarding the transcatheter aortic valve replacement procedure. Therefore, it is likely to cause confusion regarding the state of the art at the time of the alleged invention and also is misleading and potentially prejudicial.
- **FRE 901, Lack of Authenticity:** Patent Owner has not provided any evidence sufficient to authenticate this exhibit.

#### 4. Exhibit 2004

Petitioners object to the admissibility of Exhibit 2004 under FRE 401/402, 403, 801/802 and 901. Specifically:

- **FRE 401/402, Lack of Relevance:** The exhibit was purportedly published in 2013, long after the priority date of the patent-at-issue. As such, it is not relevant to the issues in the Trial.
- **FRE 403, Prejudicial, Confusing, Misleading:** The exhibit was purportedly published after the priority date of the patent-at-issue. Therefore, it is likely to cause confusion regarding the state of the art at

# 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.