

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.*

**PATENT OWNER'S REPLY IN SUPPORT OF ITS  
MOTION TO EXCLUDE EVIDENCE PURSUANT TO 37 C.F.R. § 42.64**

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

In its opposition to Patent Owner’s motion to exclude the declarations of its expert, Dr. Buller, Petitioner does not dispute Patent Owner’s showing that:

- In forming his opinion that U.S. Patent No. 8,992,608 (the “‘608 patent”) is obvious, Dr. Buller never considered evidence of objective indicia of nonobviousness even in connection with his reply declaration, which was submitted *after* Patent Owner placed such evidence into the record through its Response (Paper 22 at 47-72);
- “There is no authority suggesting that attorney argument or *another* witness’ consideration of evidence of objective indicia of nonobviousness—such as that of Mr. Wood—can compensate for the failure of the obviousness expert to consider such evidence”<sup>1</sup> (Paper 41 at 8); and
- “[W]hen secondary considerations are present ... it is error not to consider them” and “[t]he objective indicia ... play an important role as a guard against the statutorily proscribed hindsight reasoning in the obviousness analysis”<sup>2</sup>

---

<sup>1</sup> Petitioner notes in passing that its Corporate Vice President, Larry Wood, addresses the objective indicia that Dr. Buller failed to address (Paper 45 at 2-3, 15 n.8), but Mr. Wood is not a person of skill in the art and does not opine that the ‘608 patent is obvious. (See Ex. 2096 at 3-4; Ex. 1046 ¶ 9.)

<sup>2</sup> Petitioner’s observation that *Patent Owner’s* experts do not discuss secondary considerations (Paper 45 at 2, 8 n.5) misses the point; its experts’ opinion—that the

(Paper 41 at 2-3 (quoting Federal Circuit cases)).

Petitioner also incorrectly contends that “[o]nce Dr. Buller determined that there was no nexus between [its product] and the Challenged Claims, there was no need for him to further address specific evidence of secondary considerations.”

(Paper 45 at 6.) Because Dr. Buller’s analysis of nexus is incorrect, he is not relieved of the need to consider the objective evidence of nonobviousness.

## **I. PATENT OWNER HAS DEMONSTRATED NEXUS**

Petitioner wrongly argues that Patent Owner’s position regarding nexus—that the two fabric skirts of Sapien 3, which are sutured together to form the fabric seal of the ‘608 patent—depends on a belated claim construction argument.

(Paper 45 at 11.) In fact, Patent Owner relies on the plain and ordinary meaning—not a specialized construction—of “attached,” which includes both direct and indirect attachment. (*See* Paper 41 at 5-7 (citing cases).) Thus, the claimed fabric seal may be directly attached to the replacement valve leaflets or, as in Sapien 3, indirectly attached by means of a second piece of fabric. (*See* Ex. 2080 at 103-10.)

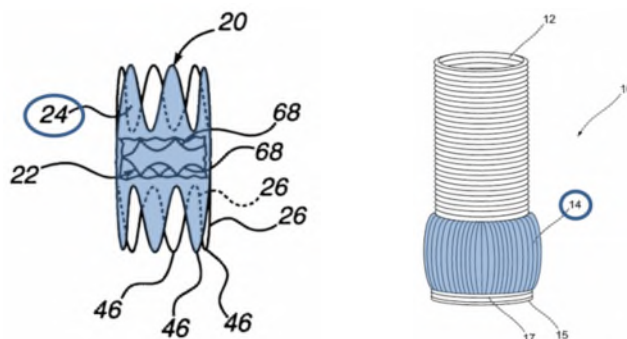
It is Petitioner that relies on an improper claim construction that it failed to plead; Dr. Buller assumes that the fabric seal must be made from a single piece of fabric and cannot be constructed from two or more pieces sewn together, despite the absence of support for this narrow construction of the ‘608 patent’s claims.

---


‘608 patent is *not* obvious—is not susceptible to hindsight bias.

(See Ex. 1045 ¶¶ 11-13); *Baby Trend, Inc. v. Wonderland Nurserygoods Co.*, IPR2015-00841, Paper 77 at 18 (PTAB June 27, 2016) (finding “a fabric member” to mean either “a single piece of fabric or multiple pieces of fabric” because there is “no clear intent to limit ‘a fabric member’ to just a unitary construction”). Indeed, this construction would lead to the absurd result that an infringer may avoid liability simply by manufacturing any claim element as two or more subcomponents to be combined upon final assembly.

Petitioner’s argument that Patent Owner distinguished the ‘608 patent over the prior art during prosecution based on a single-piece construction of the claimed fabric seal (Paper 45 at 11-13) is also wrong. The amendment on which Petitioner relies added the requirement that the “fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor” in response to a rejection over Leonhardt in view of De Paulis. (Ex. 1002 at 7/9/14 Amendment.) This amendment, however, pertains to the location and orientation of the fabric seal—not whether it is constructed from one or more pieces of material. Indeed, the alleged seals of Leonhardt and De Paulis were single-piece constructions:



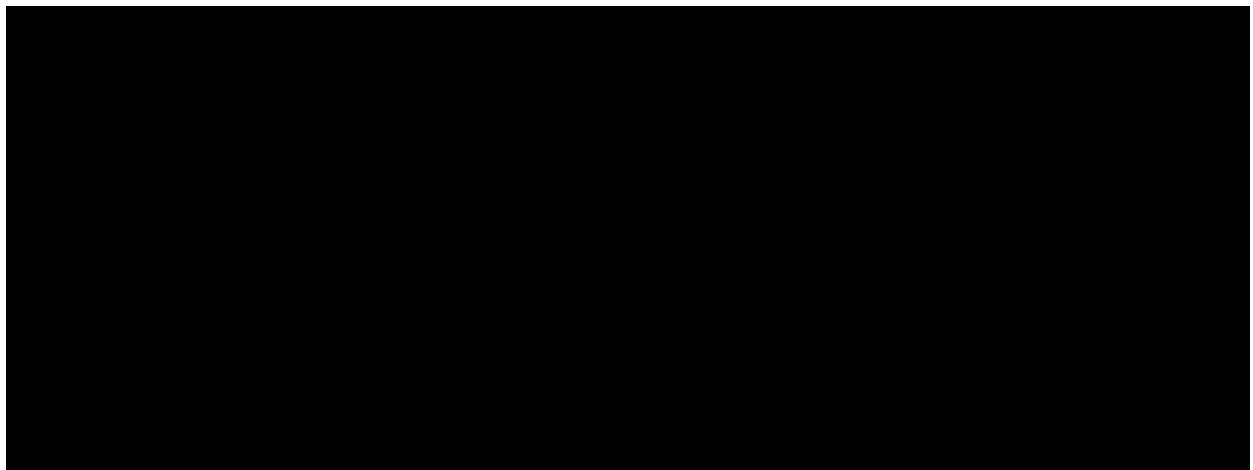
(Ex. 1027 at FIG. 4; Ex. 1021 at FIG. 2.) In the case of Sapien 3, its fabric seal, formed by two pieces of fabric sutured together, extends from the replacement valve and back proximally over the expandable anchor as claimed in the '608 patent. (Ex. 2080 at 103-110.)

Petitioner's arguments regarding the "commissure support element" are equally unavailing. In its Motion (Paper 41 at 7), Patent Owner made clear that the claimed commissure support element is Sapien 3's 









(Ex. 2077 at 11; Ex. 2046 at 28.) Petitioner ignores this showing.

Even if the commissure support element were Sapien 3's "windows," as Petitioner contends (Paper 45 at 14), that element is "attached" to the anchor, as the claims require. Petitioner's argument that the windows are not attached to the frame because they are "an integral part of the frame" (*id.*) improperly fails to

# 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.