

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**

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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”¹ (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”²

¹ 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.)

² 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.

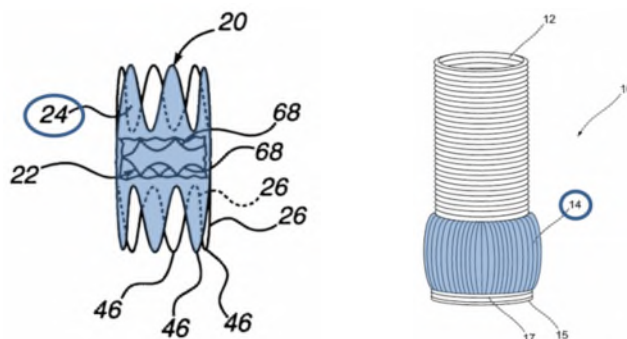
(Paper 45 at 11.) In fact, Patent Owner relies on the plain and ordinary meaning—not a specialized construction—of “attached,” which includes both direct and indirect attachment. (*See* Paper 41 at 5-7 (citing cases).) Thus, the claimed fabric seal may be directly attached to the replacement valve leaflets 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 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(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

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