

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-00060
Patent 8,992,608 B2

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

TARTAL, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Edwards Lifesciences Corporation (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting institution of *inter partes* review of claims 1–4 of U.S. Patent No. 8,992,608 B2 (Ex. 1001, “the ’608 patent”). Boston Scientific Scimed, Inc. (“Patent Owner”) filed a Preliminary Response (Paper 6, “Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Upon consideration of the Petition and the Preliminary Response, we conclude the information presented shows there is a reasonable likelihood that Petitioner would prevail in showing the unpatentability of challenged claims 1–4. Accordingly, we authorize an *inter partes* review to be instituted as to claims 1–4 of the ’608 patent. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner’s Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record, as fully developed during trial.

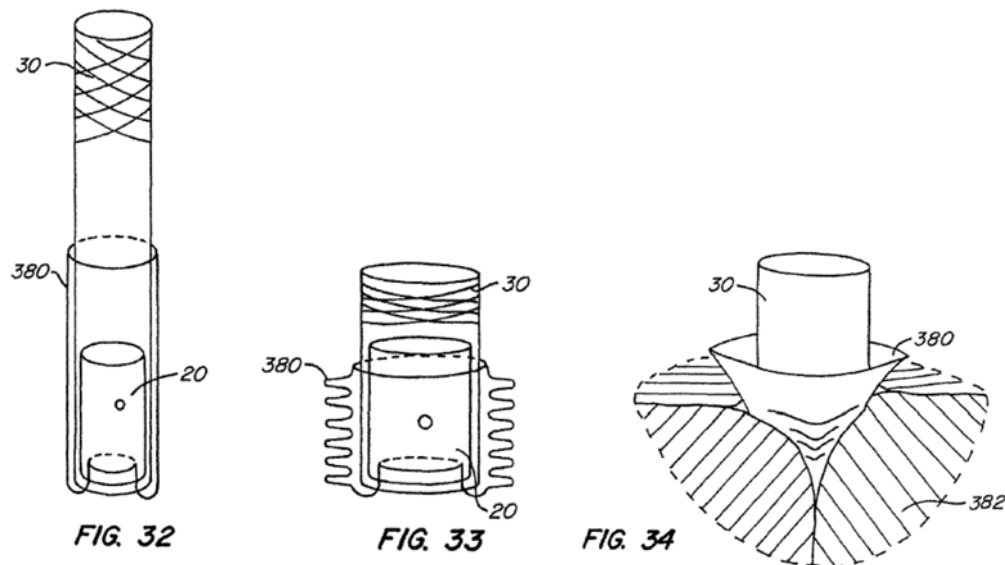
II. BACKGROUND

A. *The ’608 Patent*

The ’608 patent, titled “Everting Heart Valve,” issued March 31, 2015, from U.S. Application No. 12/492,512 (the ’512 application), filed June 26, 2009. Ex. 1001. The ’512 application was a divisional of U.S. Application No. 12/269,213, filed on November 12, 2008 (issued as U.S. Patent No. 8,668,733), which was a continuation of U.S. Application

No. 10/870,340, filed on June 16, 2004 (issued as U.S. Patent No. 7,780,725). *Id.* The '608 patent generally relates to "methods and apparatus for endovascularly replacing a patient's heart valve." Ex. 1001, Abstract.

Figures 32, 33, and 34 of the '608 patent are reproduced below.



An embodiment of the replacement heart valve and anchor is illustrated in Figure 32 in an undeployed configuration, and in Figure 33 in a deployed configuration. Ex. 1001 4:38–42. Figure 34 illustrates the replacement heart valve deployed in a patient's heart valve. *Id.* at 4:43–44. The '608 patent further explains:

FIGS. 32–34 show another way to seal the replacement valve against leakage. A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. When deployed, as shown in FIGS. 33 and 34, fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve.

Id. at 14:21–29.

Figure 3B of the '608 patent is reproduced below.

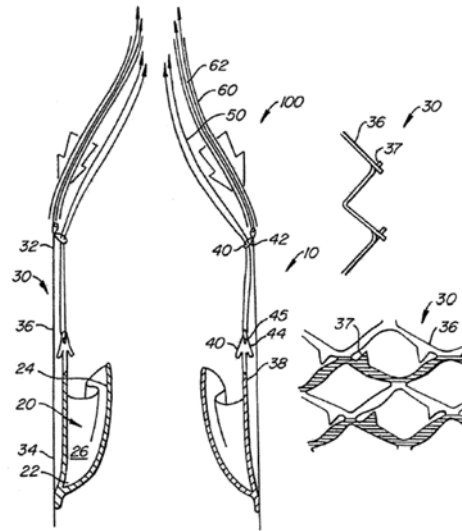


FIG. 3B

Figure 3 B illustrates the deployment of a replacement heart valve. Of particular note for purposes of this Decision, “[a]nnular 60 base 22 of replacement valve 20 preferably is coupled to skirt region 34 of anchor 30, while commissures 24 of replacement valve leaflets 26 are coupled to and supported by posts 38.” Ex. 1001, 5:60–63.

“Replacement valve 20 is preferably made from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues or human cadaver tissue.” *Id.* at 5:51–53.

B. Illustrative Claim

Challenged claim 1 is the sole independent claim challenged, from which challenged claims 2–4 depend. Claim 1 is illustrative of the claimed subject matter and is reproduced below:

1. A system for replacing a heart valve, comprising:
 - an expandable anchor having a collapsed delivery configuration and an expanded configuration, the expandable anchor comprising a distal end;
 - a replacement valve commissure support element attached to the expandable anchor;

a commissure portion of a replacement valve leaflet attached to the commissure support element; and
a fabric seal at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration, the fabric seal having an undeployed state and a deployed state, wherein in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets;
wherein a distal end of the replacement valve leaflet is attached to the fabric seal and when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor, the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue.

Ex. 1001, 22:22–42.

C. Related Proceedings

According to the parties the '608 patent is a subject of a case captioned *Boston Scientific Corp. et al. v. Edwards Lifesciences Corp.*, Case No. 1:16-cv-00275 (D. Del.). Pet. 25; Paper 4, 2. Petitioner also states that “there is at least one pending U.S. patent application, serial number 14/873,462, that claims priority to the '608 patent.” *Id.* at 26.

D. Real Parties in Interest

Petitioner identifies Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG as real parties in interest. Pet. 25. Patent Owner identifies Boston Scientific Scimed, Inc. and Boston Scientific Corp. as real parties in interest. Paper 4, 2.

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