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Paper No. 64
March 23, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES AG,
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*.

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed below, claims 1–4 of U.S. Patent No. 8,992,608 B2 (Ex. 1001, "the '608 patent") were shown to be unpatentable by a preponderance of the evidence.

A. PROCEDURAL HISTORY

Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of *inter partes* review of claims 1–4 of the '608 patent. Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

Pursuant to 35 U.S.C. § 314(a), we determined the Petition showed a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of claims 1–4 and instituted *inter partes* review of the '608 patent. Paper 7 ("Inst. Dec."). After institution, Patent Owner filed a Patent Owner Response. Paper 21; Paper 22 (publicly available redacted version of the Patent Owner Response) ("PO Resp."). Petitioner filed a Reply to Patent Owner's Response. Paper 33; Paper 34 (publicly available redacted version of Petitioner's Reply to Patent Owner's Response) ("Pet. Reply").

Patent Owner also filed a Motion to Exclude expert testimony (Paper 41, "PO Mot."), to which Petitioner provided a Response in opposition (Paper 45, "Pet. Resp."), further to which Patent Owner provided a reply in support (Paper 49 (publicly available redacted version of Patent Owner's Reply to Petitioner's Response); Paper 50 ("PO Reply"); and further to which Petitioner provided a Surreply (Paper 51, "Pet. Surreply").

Oral argument was held before the Board on December 19, 2017. Paper 55 ("Tr.").[1] We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Having considered the record before us, we determine Petitioner has shown by a preponderance of the evidence that claims 1–4 of the '608 patent are unpatentable. *See* 35 U.S.C. § 316(e). We also deny Patent Owner's Motion to Exclude.

B. Related Matters

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.

C. 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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[1] Prior to the oral argument, Patent Owner filed Objections (Paper 53) to the demonstratives filed by Petitioner and Petitioner filed Objections (Paper 52; *see also* Paper 58 (corrected objections)) to the demonstratives filed by Patent Owner. The objections of the Parties generally relate to allegations that a demonstrative slide misstates the record or is improper new evidence or argument. *See id.* Demonstrative exhibits are not evidence. In this Final Written Decision, we rely directly on the arguments presented properly in the briefs of the Parties and the evidence of record, not on demonstrative slides; therefore, the objections of the Parties are overruled.

II. BACKGROUND

The '608 patent, titled "Everting Heart Valve," issued March 31, 2015, from U.S. Application No. 12/492,512, filed June 26, 2009. Ex. 1001, (21), (22), (45), (54). As background information, below we provide a summary of the '608 patent, along with an illustrative claim from the '608 patent, and we identify the instituted grounds of unpatentability and the proffered expert testimony. We also address our reasons for denying the Motion to Exclude.

A. SUMMARY OF THE '608 PATENT

The '608 patent generally relates to "methods and apparatus for endovascularly replacing a patient's heart valve." Ex. 1001, Abstract. "Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates." *Id.* at 1:29–31. Petitioner further explains that the '608 patent "is directed to a collapsible and expandable prosthetic heart valve delivered via a catheter ('transcatheter heart valve' or 'THV')." Pet. 1.

Figures 3A and 3B of the '608 patent are reproduced below.

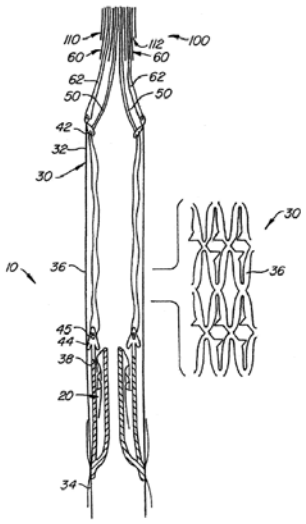

FIG. 3A

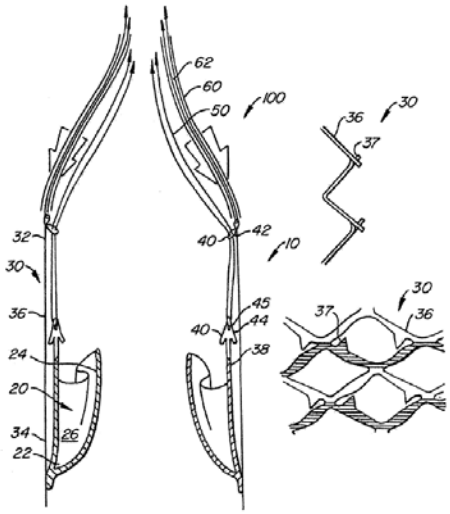

FIG. 3B

Illustrated in Figure 3A is the delivery and in Figure 3B the deployment of a replacement heart valve and anchor. Ex. 1001, 3:36–38. Apparatus 10 may be deployed from lumen 112 by retracting sheath 110, which causes anchor 30 to dynamically self-expand to a partially deployed configuration. *Id.* at 7:30–39. "Control wires 50 then are retracted relative to apparatus 10 and tubes 60 to impose foreshortening upon anchor 30." *Id.* at 7:39–41.

The '608 patent also states that "[a]nnular 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." *Id.* at 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.

According to the '608 patent, one of the obstacles to replacing a patient's heart valve is the risk of paravalvular leakage ("PVL") around the replacement valve, as illustrated in Figure 13, reproduced below.[2]

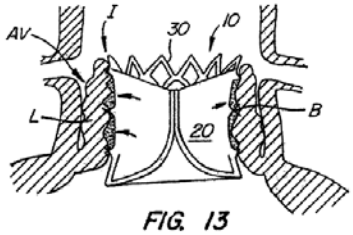

FIG. 13

[2] Paravalvular leakage is also referred to as paravalvular aortic regurgitation ("PAR"). PO Resp. 7 (further describing PVL / PAR as "the tendency for blood to leak around the outside of the prosthetic frame during diastole, the phase of the cardiac cycle when the aortic valve must prevent blood from reentering the heart through the aorta") (citing Ex. 2004, 307). Additionally, the Parties do not distinguish "perivalvular" leakage from "paravalvular" leakage, therefore, our understanding is that the two terms are used in the art interchangeably. *See, e.g.*, Ex. 1059, 12 (describing the use of a cuff to prevent "perivalvular leak around the valve").

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