

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 IPR2017-01295
Patent 8,709,062 B2

Before JAMES A. TARTAL, ROBERT L. KINDER, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Edwards Lifesciences Corporation (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–26 (“the challenged claims”) of U.S. Patent No. 8,709,062 B2 (Ex. 1001, “the ’062 patent”). Paper 2 (“Pet.”). Boston Scientific Scimed, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”). We instituted an *inter partes* review of challenged claims 1–7, 9–15, 17–21, and 23–26 on one ground of unpatentability, pursuant to 35 U.S.C. § 314. Paper 9, 33–34 (“Dec. on Inst.”).

After institution, Patent Owner filed a Response (Paper 15, “PO Resp.”) to the Petition. Before the due date for Petitioner’s Reply, however, the U.S. Supreme Court issued its decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *See* Paper 17. Pursuant to *SAS Institute*, a decision to institute an *inter partes* review under 35 U.S.C. § 314 may not institute trial on fewer than all claims challenged in the petition. *SAS Institute*, 138 S. Ct. at 1355–56, 1358. In this proceeding, however, we had denied institution with respect to challenged claims 8, 16, and 22, on two grounds of unpatentability. *See* Dec. on Inst. 9–21. Accordingly, we modified our Decision on Institution to include review of challenged claims 8, 16, and 22, and all grounds presented in the Petition. Paper 17, 2.

Pursuant to Patent Owner’s request, we allowed Patent Owner to incorporate into its Patent Owner Response (Paper 15) the arguments presented in its Preliminary Response (Paper 8). Paper 18, 3–4. Additionally, we modified the due date for Petitioner’s Reply and authorized Petitioner to respond to both the Decision on Institution and Patent Owner’s

Preliminary Response, in its Reply. *Id.* at 4. Consistent with our Order, Petitioner filed a Reply to the Patent Owner Response (Paper 20, “Reply”).

An oral hearing was held on August 7, 2018, and a transcript of the hearing is included in the record. Paper 27 (“Tr.”).

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has shown by a preponderance of the evidence that challenged claims 1–7, 9–15, 17–21, and 23–26 of the ’062 patent are unpatentable, but has not met its burden with respect to claims 8, 16, and 22.

B. Related Proceedings

The parties represent that the ’062 patent is at issue in *Boston Scientific Corp. & Boston Scientific SciMed Inc. v. Edwards Lifesciences Corp.*, No. 8:16-cv-00730 (C.D. Cal.). Pet. 101; Paper 4, 2.

C. The ’062 Patent

The ’062 patent, titled “Stent Delivery System Having Stent Securement Apparatus,” issued April 29, 2014, from U.S. Patent Application No. 13/619,231, which was filed September 14, 2012. Ex. 1001, (45), (54), (21), (22).

Figure 1 of the ’062 patent is reproduced below.

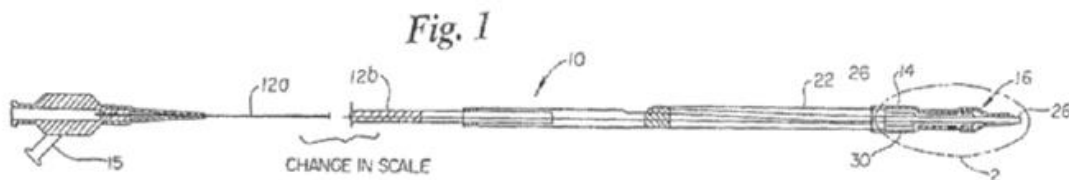


Figure 1 depicts an isometric view of a balloon catheter. Ex. 1001, 5:53–65. As shown in Figure 1, catheter 12 includes balloon 14 at distal end 16, to which stent 18 is fixed. *Id.* at 8:15–18, 26–27 (stent not shown in Figure 1).

In use, catheter 12 is advanced through a patient's vasculature to a desired location and, once reached, balloon 14 and stent 18 are expanded. *Id.* at 8:49–55. After expansion, the balloon is deflated and the catheter and balloon are withdrawn, while the stent remains in place to maintain the vessel in an expanded state. *Id.* at 8:55–57.

Figure 4 of the '062 patent is reproduced below.

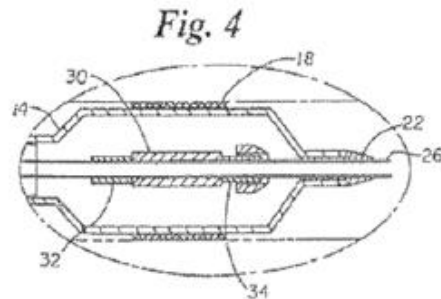


Figure 4 depicts an enlarged cross-sectional view of the distal end of catheter 12, with balloon 14 and stent 18 in expanded states. *Id.* at 6:3–6.

As shown in Figure 4, “mounting body 30 . . . is included inside balloon 14 to provide a cushion and/or substrate of enlarged diameter relative to the stent to support and hold the stent and secure it during crimping and the delivery procedure.” *Id.* at 9:28–32. In Figure 4, mounting body 30 is a cylindrical sleeve carried on inner lumen 26 of the catheter. *Id.* at 9:35–37. However, the '062 patent also discloses alternate mounting bodies including, for example, a spiral cut mounting body (*id.* at Fig. 5), a cylindrical body comprising separate, adjacent rings 30a (*id.* at Fig. 6), a two-piece interlocked body 30a, 30b (*id.* at Fig. 7), a body comprising a plurality of separate, spaced bodies 30a, 30b, 30c (*id.* at Fig. 9), a rigid coil mounting body (*id.* at Fig. 10), or an enlargeable and collapsible mounting body (*id.* at Figs. 11–12, 17–21). *See id.* at 9:66–11:17.

D. Illustrative Claim

Challenged claims 1, 13, 21, and 26 are independent. Claim 1 is illustrative, and is reproduced below.

1. A medical device, comprising:
 - an elongate shaft including a first tubular member and a second tubular member;
 - a balloon coupled to the shaft;
 - a first member coupled to the first tubular member and positioned within the balloon, the first member including a distal stop with a tapered distal portion;
 - wherein the distal stop includes a proximal end face extending substantially perpendicular to a longitudinal axis of the elongate shaft;
 - a second member coupled to the first tubular member and positioned within the balloon, the second member having a distal end disposed proximal of the distal stop; and
 - a medical implant coupled to the shaft and positioned adjacent to the balloon.

Ex. 1001, 25:30–44.

E. Applied References

Petitioner relies upon the following references, and the Declaration of Thomas Trotta (“the Trotta Declaration,” Ex. 1003). Pet. 20–21; *see also* Ex. 1026 (correction to the Trotta Declaration).

Reference	Patent No.	Relevant Dates	Exhibit No.
Sugiyama	US 4,994,032	Filed Nov. 29, 1988 Issued Feb. 19, 1991	Ex. 1009
Fischell '507	US 4,768,507	Filed Aug. 31, 1987 Issued Sept. 6, 1988	Ex. 1010
Fischell '274	US 5,639,274	Filed June 2, 1995 Issued June 17, 1997	Ex. 1013
Burton	US 5,026,377	Filed Aug. 17, 1990 Issued June 25, 1991	Ex. 1014

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