

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 IPR2017-01296
Patent 6,007,543

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

WIEKER, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Edwards Lifesciences Corporation (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–3, 6–12, 19–21, and 24–29 (“the challenged claims”) of U.S. Patent No. 6,007,543 (Ex. 1001, “the ’543 patent”). Paper 2 (“Pet”). Boston Scientific Scimed, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 7 (“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.” *See also* 37 C.F.R § 42.4(a) (delegating authority to the Board). After considering the Petition and Preliminary Response, for the reasons discussed below, we do not institute an *inter partes* review.

B. Related Proceeding

The parties represent that the ’543 patent is at issue in *Boston Scientific Corp. & Boston Scientific SciMed Inc. v. Edwards Lifesciences Corp.*, No. 16-cv-730 (C.D. Cal.). Pet. 85; Paper 4, 2.

C. The ’543 Patent

The ’543 patent, titled “Stent Delivery System with Stent Securement Means,” issued December 28, 1999, from U.S. Patent Application No. 08/702,150, which was filed August 23, 1996. Ex. 1001, [45], [54], [21], [22].

Figure 1 of the '543 patent is reproduced below.

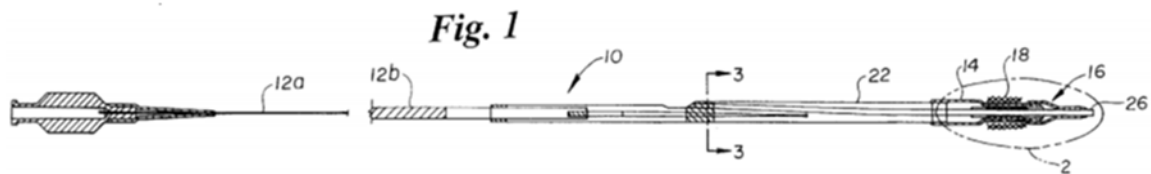


Figure 1 depicts an isometric view of a balloon catheter and stent. Ex. 1001, 2:12–15. As shown in Figure 1, catheter 12 includes balloon 14 at distal end 12b, to which stent 18 is fixed. *Id.* at 2:40–42, 50–51. In use, catheter 12 is advanced through a patient’s vasculature to a desired location and, once reached, balloon 14 and stent 18 are expanded. *Id.* at 2:51–55. 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 1:10–15, 2:55–58.

Figure 3 of the '543 patent is reproduced below.

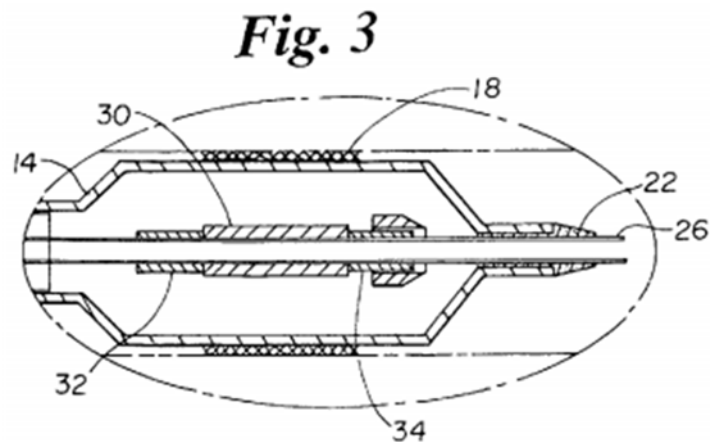


Figure 3 depicts an enlarged cross-sectional view of the distal end of catheter 12, with balloon 14 and stent 18 in expanded states. *Id.* at 2:20–23. As shown in Figure 3, “a mounting body 30 . . . is included inside balloon 14 to provide a cushion and/or substrate of enlarged diameter relative to the stent shaft to support and hold the stent and secure it during crimping and

the delivery procedure.” *Id.* at 3:26–30. In Figure 3, mounting body 30 is a cylindrical sleeve carried on inner lumen 26 of the catheter. *Id.* at 3:35–37. However, the ’543 patent also discloses alternate mounting bodies, including a spiral cut mounting body (*id.* at Fig. 4), a cylindrical body comprising separate, adjacent rings 30a (*id.* at Fig. 5), a two-piece interlocked body 30a, 30b (*id.* at Fig. 6), or a body comprising a plurality of separate, spaced bodies 30a, 30b, 30c (*id.* at Fig. 8). *See id.* at 3:66–4:38.

D. Illustrative Claim

Of the challenged claims, claims 1 and 19 are independent. Independent claim 1 is illustrative, and is reproduced below:

1. A stent delivery system comprising:
 - a radially expandable stent of generally cylindrical configuration, having a first end and a second end and a contracted state and an expanded state, and
 - a catheter having a shaft having a diameter and *expandable inflatable means* associated therewith at a distal part of the shaft, wherein the inflatable means comprises a balloon, and including *mounting and retaining means for receiving the stent on the expandable inflatable means* for radial expansion of the stent upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means, the at least one mounting body being substantially the same length as the stent and being positioned on the shaft such that when the stent is loaded onto the inflatable means and the shaft in the stent's contracted state at least a portion of the at least one mounting body is under the stent and between the first and second ends of the stent, whereby the diameter of the shaft and inflatable portion are increased at the distal part for facilitating the mounting and retaining of the stent.

Ex. 1001, 4:49–5:4 (emphasis added). Independent claim 19 recites a “balloon catheter” comprising, *inter alia*, “means for inflating the balloon.” *Id.* at 6:13, 6:17–18.

E. Prior Art Relied Upon

Petitioner relies upon the following prior art references, as well as the Declaration of Thomas Trotta (Ex. 1003). Pet. 20–21.

Reference	Patent No.	Relevant Dates	Exhibit No.
Sugiyama '032	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
Olympus	JP 1992-64367	Filed July 3, 1990 Published Feb. 28, 1992	Ex. 1015 ¹
Jendersee	US 5,836,965	Filed June 7, 1995 Issued Nov. 17, 1998	Ex. 1016
Pathak	US 5,741,323	Filed June 7, 1995 Issued Apr. 21, 1998	Ex. 1026
Williams	US 5,437,083	Filed May 24, 1993 Issued Aug. 1, 1995	Ex. 1027

¹ Exhibit 1015 includes a Japanese-language version of the reference, at exhibit pages 1–15, an English translation of the reference, at exhibit pages 16–35, and a notarized Certificate of Translation, at exhibit pages 36–37.

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