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Paper No. 8
Filed: October 25, 2017

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 IPR2017-01304
Patent 6,203,558 B1

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, 2, 9, 14, and 20–22 ("the challenged claims") of U.S. Patent No. 6,203,558 B1 (Ex. 1001, "the '558 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 '558 patent is at issue in *Boston Scientific Corp. & Boston Scientific SciMed Inc. v. Edwards Lifesciences Corp.*, No. 16-cv-730 (C.D. Cal.). Pet. 64; Paper 4, 2.

C. The '558 Patent

The '558 patent, titled "Stent Delivery System Having Stent Securement Apparatus," issued March 20, 2001, from U.S. Patent Application No. 09/418,277, which was filed October 14, 1999. Ex. 1001, [45], [54], [21], [22].

Figure 1 of the ’558 patent is reproduced below.

Fig. 1

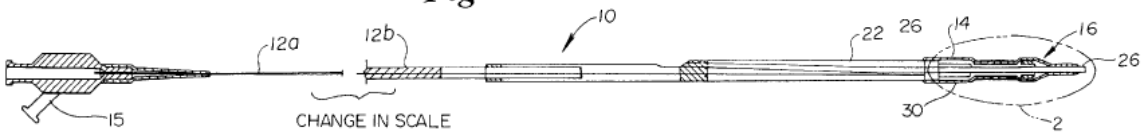

Figure 1 depicts an isometric view of a balloon catheter. Ex. 1001, 5:59–61. As shown in Figure 1, catheter 12 includes balloon 14 at distal end 16, to which stent 18 is fixed. *Id.* at 8:21–24, 8:32–33. In use, catheter 12 is advanced through a patient’s vasculature to a desired location and, once reached, balloon 14 and stent 18 are expanded. *Id.* at 8:58–64. 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 8:64–66.

Figure 4 of the ’558 patent is reproduced below.

Fig. 4

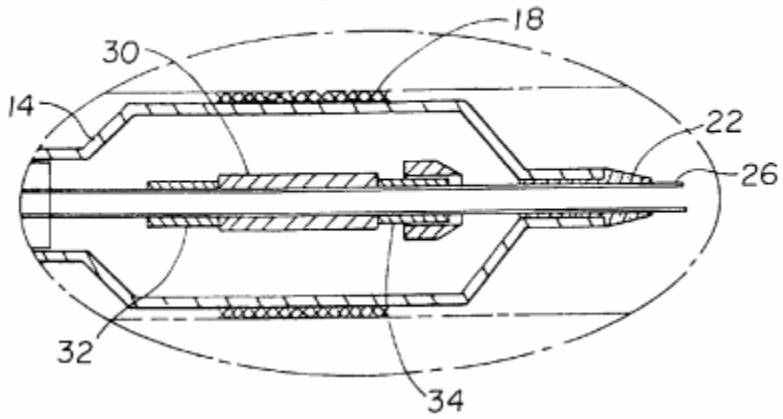

Figure 4 depicts an enlarged cross-sectional view of the distal end of catheter 12, with balloon 14 and stent 18 in expanded states. *Id.* at 6:1–4. As shown in Figure 4, “mounting body 30 . . . is included inside balloon 14 to provide a cushion and/or substrate of enlarged diameter relative to the

stent to support and hold the stent and secure it during crimping and the delivery procedure." *Id.* at 9:36–40. In Figure 4, mounting body 30 is a cylindrical sleeve carried on inner lumen 26 of the catheter. *Id.* at 9:43–47. However, the '558 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 10:8–11:50.

D. Illustrative Claim

Of the challenged claims, claim 1 is the sole independent claim and is reproduced below:

> 1. A system/assembly for delivery and deployment of an inflation expandable stent within a vessel, comprising:
>
> a catheter having proximal and distal ends;
>
> a stent, inflation expandable from a delivery diameter to a deployment diameter, such that the delivery diameter is reduced from the deployment diameter for conforming the stent to the catheter, such that the stent, in its delivery diameter, is coaxially mounted on the catheter near the catheter distal end;
>
> *an expandable inflation means coaxially mounted on the catheter within the stent, for expansion of the stent* from the delivery diameter to the deployment diameter upon application of deployment pressure to the expandable inflation means; and
>
> *a mounting and retaining means coaxially mounted on the catheter within the expandable inflation means, the*

> *mounting and retaining means designed and adapted to provide a securement for the stent* in the delivery diameter to maintain the stent in position on the catheter during delivery to the deployment site,
>
> the catheter having a shaft and the expandable inflation means being positioned at a distal part of the shaft, the mounting and retaining means being positioned for receiving the stent on the expandable inflation means for radial expansion of the stent upon expansion of the expandable inflation means, the mounting and retaining means including at least one mounting body carried by the shaft inside the expandable inflation means whereby the diameter of the shaft and expandable inflation means are increased at the distal part for facilitating the mounting and retaining of the sent, the mounting body including at least one separation, whereby the flexibility of the body and catheter is increased.

Ex. 1001, 25:63–26:28 (emphasis added).

E. Prior Art Relied Upon

Petitioner relies upon the following prior art references, as well as the Declaration of Thomas Trotta (Ex. 1003). Pet. 23.

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

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