Paper No. 10 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 IPR2017-01294 Patent 6,371,962 B1

Before JAMES T. MOORE, JAMES A. TARTAL, and AMANDA F.WIEKER, *Administrative Patent Judges*.

MOORE, 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 corrected Petition requesting an *inter partes* review of claims 1–3, 6–13, 20–22, 25–30, 35, and 36 ("the challenged claims") of U.S. Patent No. 6,371,962 B1 (Ex. 1001, "the '962 patent"). Paper 8 ("Pet"), 1. Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response. Paper 9 ("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 '962 patent is at issue in *Boston* Scientific Corp. & Boston Scientific SciMed Inc. v. Edwards Lifesciences Corp., No. 16-cv-730 (C.D. Cal.). Pet. 88; Paper 4, 2.

C. The '962 Patent

The '962 patent, titled "Stent Delivery System With Stent Securement Means," issued April 16, 2002, from U.S. Patent Application No. 09/420,294, which was filed October 19, 1999. Ex. 1001, [45], [54], [21], [22].



Figure 1 of the '962 patent is reproduced below.

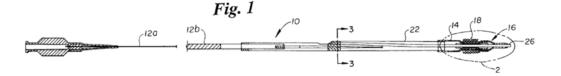


Figure 1 depicts an isometric view of a balloon catheter. Ex. 1001, 2:19–22. As shown in Figure 1, catheter 12 includes balloon 14 at distal end 16, to which stent 18 is fixed. *Id.* at 2:47–50. In use, catheter 12 is advanced through a patient's vasculature to a desired location and, once reached, balloon 14 and stent 18 are expanded. *Id.* at 3:65–4:7. 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.*

Figure 3 of the '962 patent is reproduced below.

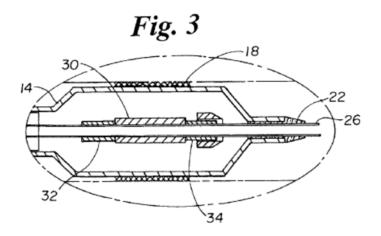


Figure 3 depicts an enlarged cross-sectional view of the distal end of catheter 12, with balloon 14 and stent 18 in expanded states. *Id.* at 2:27–30. As shown in Figure 3, "mounting body 30 . . . is included inside balloon 14 to provide a cushion and/or substrate of enlarged diameter relative to the stent shaft to support and hold the stent and secure it during crimping and



the delivery procedure." *Id.* at 3:33–38. In Figure 3, mounting body 30 is a cylindrical sleeve carried on inner lumen 26 of the catheter. *Id.* at 3:42–47. However, the '962 patent also discloses alternate mounting bodies including, for example, 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 4:6–4:45.

D. Illustrative Claim

Of the challenged claims, claims 1, 20, and 35 are independent. Claims 1 and 20 are reproduced below:

1. A stent delivery system for carrying and delivering a stent having a first end and a second end and a contracted state and an expanded state, the system comprising:

a catheter having a shaft having a diameter and expandable inflation means associated therewith at a distal part of the shaft and including mounting and retaining means for receiving the stent on the expandable inflatable means whereby the stent is radially expanded upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body, the at least one mounting body having a length and an outer surface diameter and being carried on and surrounding the shaft inside the inflatable means whereby the diameter of the shaft is increased at the distal part for facilitating the mounting and retaining of the stent and wherein, when the stent is mounted on the catheter, the at least one mounting body is between the stent and the shaft, the outer surface diameter of the at least one mounting body being substantially constant along its length.

Ex. 1001, 4:56–5:8. (Emphasis added).



20. A balloon catheter for intraluminal delivery of a stent, the catheter comprising a shaft having a diameter, a balloon associated with a distal portion of the shaft for receiving a stent, the stent having a first end and a second end and a contracted state and an expanded state, and *means for inflating the balloon*, the shaft including at least one mounting body radially carried on the shaft inside the balloon, whereby the diameter of the shaft is increased inside the balloon to facilitate mounting and retaining of a stent to the catheter over the balloon, the at least one mounting body 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, the at least one mounting body having a length and an outer surface diameter, wherein the outer surface diameter is substantially constant along the length.

Id. at 6:14–30. (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. 26.

| Reference | Patent No. | Relevant Dates | Exhibit No. |
|---------------|---------------|---|-----------------------|
| 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 | Ex. 1013 |
| | | Issued June 17, 1997 | |
| 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 |

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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