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PATENT- UND RECHTSANWÄLTE

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Opposition against	**EP 2 749 254 B1 (14 161 991.6)**
Proprietor:	Boston Scientific Scimed, Inc.
Opponent 1:	Lang & Tomerius
Opponent 2:	Edwards Lifesciences Corp.
Opponent 3:	Medtronic CV Luxembourg S.à.r.l.

In the name and on behalf of the Proprietor, it is requested

1. to reject the oppositions and to maintain the patent as granted;
2. to summon for oral proceedings.

A. Original Disclosure

A.I Original Disclosure of Granted Claim 1

The subject-matter of granted claim 1 is originally disclosed.

1. The features of the preamble of granted claim 1 are – inter alia – disclosed in the PCT application WO 2005/0652980 (BB2) on page 1, lines 3/4, on page 17, lines 23 to 33, on page 21, lines 25/26, and on page 22, lines 4 to 8. Original claim 1 of the PCT application WO'980

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also provides a suitable disclosure for the preamble of granted claim 1, wherein it is clarified in the PCT application that using a braid is only an optional feature, see PCT application WO'980, page 5, lines 4/5:

> *"The anchor includes an expandable anchor such as a braid."*

and page 22, lines 21-25:

> *„Anchor 30 preferably is fabricated by using self-expanding patterns (laser cut or chemically milled), braids, and materials, such as stainless steel, nickel-titanium ("Nitinol") or cobalt chromium, but alternatively may be fabricated using balloon-expandable patterns where the anchor is designed to plastically deform to its final shape by means of balloon expansion."*).

And finally, also original claims 89 and 340 provide a basis for the preamble of granted claim 1.

2. The characterizing feature of granted claim 1 is disclosed in context with Figures 32-34, see PCT application WO'980, page 34, lines 26-31:

> *"Figures 32-34 show another way to seal the replacement valve against leakage. A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. When deployed, as shown in Figures 33 and 34, fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 30 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve."*

and PCT application WO'980, page 86, lines 22-32:

> *"Figures 32-34 illustrate the process of forming a pleated seal around a replacement valve to prevent leakage. Figure 32 illustrates a fabric seal 380 prior to deployment and foreshortening of the anchor/valve apparatus. In Figure 32, the fabric seal 380 extends from the distal end of valve 20 proximally over anchor 30 during delivery. During deployment, as illustrated in Figure 33, anchor 30 foreshortens and the fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382. The bunched up fabric or pleats occur, in particular, when the pockets are filled with blood in response to backflow blood pressure. The pleating can create a seal around the replacement 30 valve. Figure 34 illustrates anchor 30, surrounded by fabric seal 380 in between native valve leaflets 382. In preferred embodiments, at least a portion of a seal is captured between the leaflets and the wall of the heart when the anchor is folly deployed."*

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3. The Opponents argue that several features have allegedly been described as being essential features, and that these features are missing in granted claim 1. However, none of these features are essential for achieving the sealing effect as explained in the application documents. Accordingly, none of these features is contained e.g. in claims 1, 89 and 340 of the PCT application WO'980. Indeed, many of the objections raised are not truly objections under Article 123(2) EPC, but are in fact inadmissible objections relating to Article 84 EPC with respect to essential features allegedly missing.

A.II Active Foreshortening is no Essential Feature

The aspect of an "active foreshortening" is no essential feature as alleged by the Opponents.

1. First of all, an active foreshortening is not even mentioned in any of independent claims 1, 67, 101, 122, 142, 151, 182, 184, 255, 268, 340, 350, 367, 368, 387, 403 and 428 of the PCT application WO'980. In view of these independent claims as originally disclosed, it is not understandable why the aspect of an active foreshortening should allegedly be essential.

2. The aspect of an active foreshortening relates to a specific delivery catheter – disclosed e.g. in context with Figures 3A to 3F – which axially compresses the anchor (without applying any radial forces) to achieve a radial expansion. However, the original application documents also clarify that other types of delivery catheters may be used to deploy heart valve implants of the present invention, in particular by balloon inflation:

- PCT application WO'980, page 8, lines 15/16:

  "Expansion of the anchor and replacement valve may be by balloon-expansion, self-expansion, and combinations thereof."

- PCT application WO'980, page 13, lines 25-27:

  "The apparatus may also include a deployment tool coupled to the anchor within the catheter and an expandable balloon disposed within the delivery catheter, the balloon being adapted to expand the anchor."

- PCT application WO'980, page 22, lines 21-25:

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> *„Anchor 30 preferably is fabricated by using self-expanding patterns (laser cut or chemically milled), braids, and materials, such as stainless steel, nickel-titanium ("Nitinol") or cobalt chromium, but alternatively may be fabricated using balloon-expandable patterns where the anchor is designed to plastically deform to its final shape by means of balloon expansion."*

As a result, the Opponents' view that the heart valve implant of the present invention can only be deployed by an "active foreshortening" (applying axial compression forces), is incorrect.

3. In addition, the general disclosure on a bunched-up fabric seal in the PCT application WO'980, on page 34, lines 26-31, does not mention any foreshortening:

> *"Figures 32-34 show another way to seal the replacement valve against leakage. A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. When deployed, as shown in Figures 33 and 34, fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 30 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve."*

4. The embodiment of Figures 107A-C on which Opponent 2 is relying its objection, is only "another embodiment" as clarified in the PCT application WO'980 on page 84, line 30. However, pointing to an additional alternative embodiment is no suitable argument for an essential feature, if the general disclosure of the invention does not require an active foreshortening.

But even the embodiment of Figures 107A-C clarifies that achieving a bunched-up shape of the seal in the deployed configuration of the heart valve implant does not require any foreshortening. The PCT application WO'980 only mentions on page 85, line 28, that *"foreshortening can cause seal 60 to bunch up ..."*.

5. Opponent 2 assumes that all problems mentioned in the PCT application must be solved by the apparatus/implant of the opposed patent. This view is, however, based on a misunderstanding of the original disclosure.

Contrary to Opponent 2's allegation, the PCT application WO'980 does not require on page 4, lines 1-3, that all drawbacks mentioned in context with the prior art, must be solved according to the present invention (see Opponent 2's opposition brief, paragraph 31). The words "methods

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and apparatus" are mentioned in plural in this text passage. Therefore, the correct understanding of this passage is that various different solutions are provided in order to solve certain problems of prior art implants. The number and variety of independent claims as originally filed already show that the PCT application discloses various different solutions addressing different drawbacks. However, forcing the Proprietor to include all advantageous aspects in an independent claim would unduly limit the right to get sufficient protection for an invention.

6. And finally, Opponent 2 refers to page 27, lines 3-5 of the PCT application WO'980. However, this passage relates to a different embodiment, namely the embodiment shown in Figures 5A to 5F, which does not even have a bunched-up fabric seal, see in particular Figure 5E. Therefore, also this attempt of Opponent 2 to argue that an active foreshortening is an essential feature, must fail.

A.III Non-Hydraulic/Non-Pneumatic Anchor Actuators are no Essential Features

The non-hydraulic or non-pneumatic anchor actuators are no essential features.

1. First of all, the non-hydraulic or non-pneumatic anchor actuators described in context with some embodiments of the PCT application are features of the delivery/deployment system, i.e. of the catheter, but no features of the heart valve implant. Accordingly, the passage in the PCT application WO'980 on page 21, lines 28-33, only refers to the delivery/deployment system, but not to the heart valve implant. Therefore, it is not logical that the non-hydraulic or non-pneumatic anchor actuators should allegedly be essential features of the heart valve implant.

2. In addition, the original application documents also clarify that other types of delivery catheters may be used to deploy the heart valve implant of the present invention, in particular by balloon inflation:

- PCT application WO'980, page 8, lines 15/16:

  "Expansion of the anchor and replacement valve may be by balloon-expansion, self-expansion, and combinations thereof."

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