

Munich, 23 June 2016

Our ref. (please always state): EDWLI.0056

The facts and arguments (point VII) for the

OPPOSITION

filed in the name and on behalf of **Edwards Lifesciences LLC**, 1 Edwards Way Irvine, CA 92614, against the European patent EP 2 926 766 B1 entitled “Repositionable heart valve” (European patent application No. 15 167 832.3) of Boston Scientific Scimed, Inc., One Scimed Place, Maple Grove, MN 55311-1566 / US are presented in the following:

The opposition fee is to be debited from our account 28002046.

A.

Requests

- I. It is requested to revoke the patent in its entirety, based on the grounds that:
 1. its subject-matter is not patentable within the terms of Arts. 52 to 57 EPC (Art. 100(a) EPC), since it is neither novel nor based on an inventive step;
 2. the opposed patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC, Art. 83 EPC); and
 3. the subject-matter of the opposed patent extends beyond the content of the application as filed (Art. 100(c) EPC, Art. 76, 123(2) EPC).

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References

- BB1 Feature analysis of claim 1
- BB2 WO 2005/062980 A2 (PCT application of opposed patent)
- BB3 EP 1 702 247 (parent application)
- BB4 WO 02/36048 A1 (“Seguin I”)
- BB4A AU 2002212418 B2 (certified translation of BB4)
- BB5 WO 03/003949 A2 (“Seguin II”)
- BB6 US 5,957,949 (“Leonhardt”)
- BB7 US 2001/0027338 A1 (“Greenberg”)
- BB8 US 6,015,431 (“Thornton”)
- BB9 WO 03/037222 (“Lawrence Brown”)
- BB10 US 10/746,280 (priority application of opposed patent)
- BB11 US 6,729,356 B1 (“Baker”)
- BB12 US 2004/082989 A1 (“Cook”)
- BB13 US 5,693,088 (“Lazarus”)

2. Below is a feature analysis of independent claim 1:

Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

1. an expandable cylindrical anchor (30)
 - 1.a) supporting a replacement valve (20),
 - 1.b) the anchor (30) having a delivery configuration and a deployed configuration,
 2. at least one sac (200)
 - 2.a) disposed about the exterior of the anchor (30)
 - 2.b) to provide a seal.
3. The above feature analysis is enclosed as a separate document (Exhibit BB1).

D.

Added subject-matter (Art. 100(c), 76(1) and 123(2) EPC)

4. The opposed patent (EP 2 926 766 B1) had been filed as a divisional of EP 1 702 247, which is based on the PCT application WO 2005/062980 A2 (hereafter: "WO '980", Exhibit BB2). The relevant description and the figures of the opposed patent as filed are identical to the description and figures of WO '980. Therefore, in the following reference will be only made to the disclosure of WO '980 and Art. 76(1) EPC. However, the exact same arguments and reasoning also applies for the opposed patent as originally filed and Art. 123(2) EPC.
5. In accordance with G 1/05 (OJ EPO 2008, 271) and G 1/06 (OJ EPO 2008, 307), it is a condition that anything disclosed in the granted patent must be directly and

6. In T 219/09 the board of appeal of the EPO held that, according to established case law, it will normally not be allowable to base an amended claim on the extraction of isolated features from a set of features originally disclosed only in combination, e.g. a specific embodiment in the description (intermediate generalization).
7. Omitting features that are originally disclosed in context is only exceptionally permissible in the absence of any clearly recognizable functional or structural relationship among the features of the specific combination originally disclosed (cf. decision T 1067/97) and if the omitted feature is not inextricably linked with those features (cf. decision T 714/00).

I.

General Remarks

8. In WO '980 a heart valve prosthesis is disclosed e.g. in Figs. 5A – I and in particular in Fig. 5F, which shows sacs (200). This figure is pictured below:

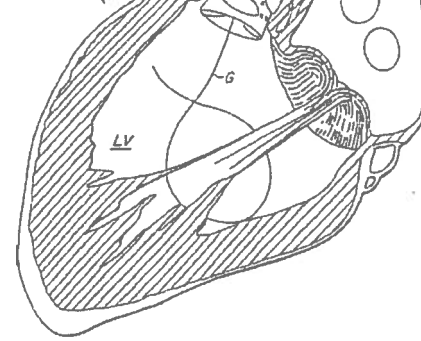


FIG. 5F

9. The device is further shown e.g. in Fig. 15A:

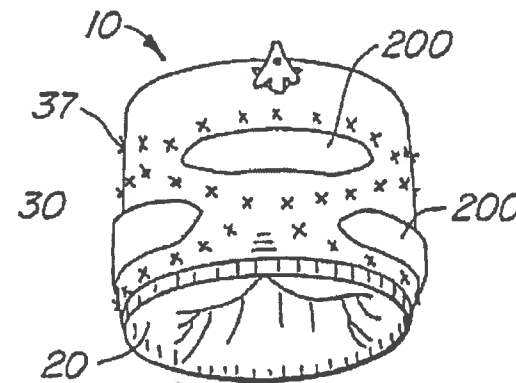


FIG. 15A

10. However, the patentee left out numerous essential features disclosed in the description of WO '980 which stand in clear functional and/or structural context with the features specified in claim 1 as granted, resulting in an inadmissible intermediate generalization.

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