

BIRD & BIRD LLP · Maximiliansplatz 22 · D-80333 München

Via facsimile in advance: +49 89 2399 4465 (without exhibits)

European Patent Office
Bob-van-Benthem-Platz 1
80469 München

Dr. Daniela Kinkeldey
Ext: +49 (0) 89 3581 6229
daniela.kinkeldey@twobirds.com

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Our ref. (please always state): EDWLI.0054

The facts and arguments (point VII) for the

OPPOSITION

filed in the name and on behalf of **Edwards Lifesciences Corporation**, 1 Edwards Way Irvine, CA 92614, USA, against the European patent EP 2 749 254 B1 entitled "Repositionable heart valve" (European patent application No. 14 161 991.6) of Boston Scientific Scimed, Inc., One Scimed Place, Maple Grove, MN 55311-1566, USA 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 Articles 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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- II. In accordance with the Guidelines for Examination, Part E, Section VII, Point_4 accelerated processing is requested since an infringement action in respect of the European patent is pending before the regional court of Düsseldorf, Germany (case number 4aO 137/15).
- III. Oral proceedings pursuant to Art. 116 EPC are requested.

B.

Relevant References

- 1. The opposition is based on the following prior art:

BB1	Feature analysis of claim 1 of opposed patent
BB2	WO 2005/062980 A2 (PCT application of opposed patent)
BB3	WO 98/29057 A1
BB4	US 4,084,268 A
BB5	US 5,855,601 A
BB6	WO 03/047468 A1
BB7	EP 1 702 247 A0 (parent application of opposed patent)
BB8	US 10/971,535 (priority application of opposed patent)
BB9	Assignments filed with the US Patent Office for priority document of opposed patent
BB10	WO 2005/102015 A2
BB10A	US 60/565,118 (priority application of BB10)
BB11	WO 98/55047 A1
BB12	US 6,015,431 A
BB13	WO 03/037222 A2
BB14	US 6,729,356 B1
BB15	US 2001/0027338 A1
BB16	US 2004/0082989 A1
BB17	US 2003/0236567 A1
BB18	US 5,411,552 A

C.

Feature analysis of claim 1 and the alleged invention

2. The opposed patent comprises 13 claims including independent claim 1. All claims of the opposed patent relate to an apparatus for endovascularly replacing a patient's heart valve.

I.

3. Below is a feature analysis of independent claim 1 which provides the following features:

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

1. an expandable anchor (30)
 - 1.a) supporting a replacement valve (20),
 - 1.b) the anchor having a delivery configuration and a deployed configuration, characterized by
 2. a fabric seal (380)
 - 2.a) extending from the distal end of the valve (20) proximally over the anchor in the delivery configuration,
 - 2.b) wherein the seal is bunched up in the deployed configuration.
4. The above feature analysis is enclosed as a separate document (Exhibit BB1).

II.

5. In general, the alleged invention relates to an apparatus for endovascularly replacing a heart valve. The apparatus claimed by independent claim 1 of the opposed patent includes an expandable anchor (feature group 1) and a fabric seal (feature group 2).
6. According to feature 2.a) of claim 1, the seal extends from the distal end of the valve (20) proximally over the anchor in the delivery configuration.

7. Feature 2.a) is interpreted to the effect that the seal extends proximally from the distal end of the valve, i.e. the valve being the reference for the extension of the seal.

D.

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

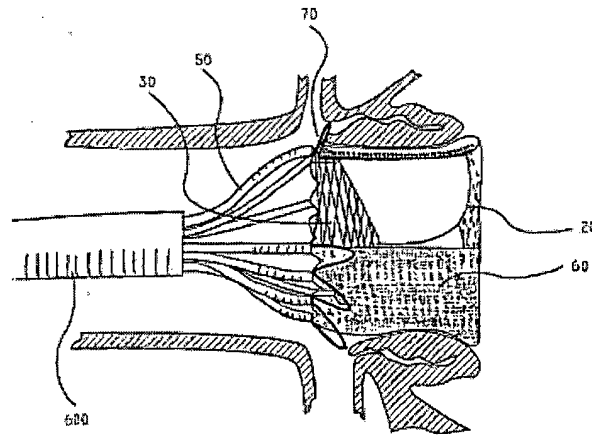
8. The opposed patent (EP 2 749 254 B1) was filed as a divisional of EP 1 702 247, which is based on the PCT application WO 2005/062 980 A2 (hereafter: "WO'980", Exhibit BB2). The relevant description and the figures of the opposed patent as filed are identical to the description and figures of WO '980. 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.
9. 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 unambiguously derivable not only from the original application on which the patent has been granted, but also from what was disclosed in each of the preceding applications as filed. Accordingly, the subject matter claimed in the granted claims of the opposed patent must also be disclosed in WO'980 (Art 76(1) EPC).
10. 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).
11. 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). This is not the case here and the claims as granted are an intermediate generalisation of the disclosure of WO'980.

I.

General Remarks

12. In WO'980 a heart valve prosthesis is disclosed e.g. in Fig 107C, where the fabric seal is disclosed to bunch up in the deployed configuration (page 85, ll. 28-29). This Fig 107C is pictured below:



13. The heart valve prosthesis shown above is substantially similar to the prosthesis marketed by the patentee as the so-called Lotus Valve. This valve looks as follows as may be taken from the homepage of Boston Scientific (<http://www.bostonscientific.com/en-US/products/transcatheter-heart-valve/lotus-valve-system.html>):

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