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Patent No. 2749254 (Patent Application No. 14161991.6)
Owner: Boston Scientific Scimed, Inc.
Opponent: Lang & Tomerius Patentanwaltspartnerschaft mbB

NOTICE OF OPPOSITION

I. AN OPPOSITION IS FILED AGAINST

Patent No.: 2749254
Application No.: 14161991.6
Date of grant: 22 December 2004
Title: Repositionable heart valve

Zur Kasse
775 €

II. PATENT OWNER

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III. OPPONENT

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IV. REQUESTS

1. It is requested to revoke the patent in its entirety, based on the grounds that

- its subject-matter extends beyond the content of the application as filed (Art. 100(c) EPC and Art. 123(2)/Art 76(1) EPC);

- its subject-matter is not novel (Art. 100(a) EPC and Art. 54 EPC);

- its subject-matter does not involve an inventive step (Art. 100(a) EPC and Art. 56 EPC).

2. Oral proceedings are requested in the event that the patent cannot be revoked on the basis of the written proceedings.

V. PRIOR ART

The opposition is based on the following prior art:

D1   WO 98/29057 A1 (D1); published on 09 July 1998,

D2   FR 2 826 863 A1 (D2); published on 10 January 2003,

D3   US 5,957,949 A (D3); published on 28 September 1999,

D4   US 4,084,268 A (D4); published on 18 April 1978,

D5   WO 01/76510 A2 (D5); published on 18 October 2001,

D6   US 2002/0032481 A1 (D6); published on 14 March, 2002,

D7   Extract from online Macmillan dictionary for the term "bunch up" ("www.macmillandictionary.com/dictionary/british/bunch_2").

VI. REASONS

1. The opposed patent EP 2 749 254 B1

1.1 Subject matter

The opposed patent (hereinafter the "patent in suit") relates to an apparatus for endovascularly replacing a heart valve comprising a seal (claim 1).

The patent in suit shows a heart valve which comprises a seal. The seal comprises a fabric seal which extends from the distal end of valve 20 proximally over anchor during delivery ([0121]). During deployment, as illustrated in Figure 23, 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 ([0121]). The bunched up fabric or pleats may oc-

cur, when the pockets are filled with blood in response to backflow blood pressure ([0121]). Figure 24 illustrates anchor 30, surrounded by fabric seal 380 in between native valve leaflets 382 ([0121]). 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 fully deployed ([0121], [0326]).
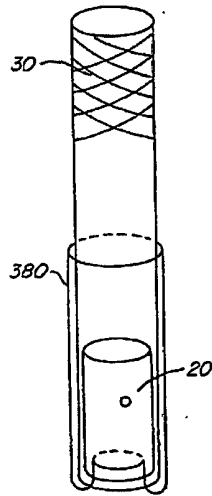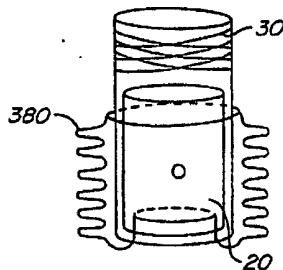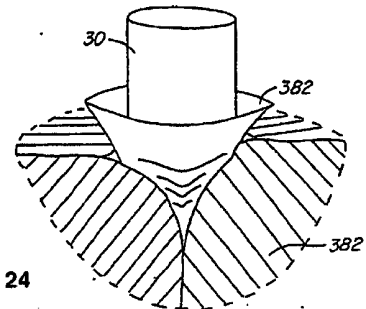

FIG. 22   **FIG. 23**   **FIG. 24**

1.2 Claim 1

The patent in suit comprises one independent claim with the following features of the preamble:

(P1) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

(P2) an expandable anchor (30),

(P3) supporting a replacement valve,

(P4) the anchor (20) having a delivery configuration and a deployed configuration, the object is allegedly solved with the following features of the characterizing portion:

(C1) a fabric seal,

(C2) extending from the distal end of the valve (20) proximally over the anchor in the delivery configuration,

(C3) wherein the seal is bunched up,

(C4) in the deployed configuration.

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

The application to the patent in suit was filed as a divisional application of EP 1 702 247 (parent application), originally published as international application WO 2005/062980 A2.

Hereinafter, references to the text of the parent application as filed are made with respect to WO 2005/062980 A2 as published.

2.1   Inadmissible extraction of an isolated feature as compared to WO 2005/062980 A2

Features C1-C3 of claim 1 as granted are not based on a claim as filed in the parent application but solely on the description on page 24, lines 1–7, and page 60, lines 9-20, and figures 32-34 of the original application (according to the Examiner - see annex to the Communication of June 18, 2014).

Claim 1 as granted contains inadmissibly extracted isolated features of the apparatus for endovascularly replacing a heart valve described in the original application WO 2005/062980 A2 (published July 14, 2005). Thus, claim 1 contains intermediate generalizations concerning the features fabric flaps and pockets that extend into spaces formed by the native leaflets and foreshortening:

a)   Fabric flaps and pockets that extend into spaces formed by the native leaflets

The parent application reads on 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 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve".

The features missing in claim 1 of the patent in suit (underlined above) are:

-    creating fabric flaps and pockets
-    that extend into spaces formed by the native valve leaflets.

These features are not to be omitted since they are presented as essential features in combination with the features C3 and C4 incorporated into claim 1 whenever originally mentioned:

"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" – see page 86, lines 26-27 of the parent application.

Omitting these individual features is an unallowable extension of the subject matter as initially filed in the parent application. The desired sealing effect is **only** possible due to the fabric flaps and pockets which extend into spaces formed by the native valve leaflets. Only thereby a sealing effect is reached, which is acknowledged by the proprietor. A mere bunching up is obviously insufficient.

Referring to D7, the term "bunch" or "bunch up" also has a very general meaning which does not inherently result in the creation of flaps and pockets extending into spaces formed by native valve leaflets. The term "bunch up" generally means to form into a tight round shape, and the term "bunch" for cloth means to come together in small folds. Just referring to "bunching up" therefore covers (i) even a small amount of folding or bending not necessarily sufficient to form flaps and pockets that will extend into spaces formed by native valve leaflets; and (ii) forming a rounded shape without necessarily forming flaps and pockets; and (iii) bunching of the fabric at a different position not even in contact with the native valve leaflets (e.g. internally of the anchor).

Therefore, the granted claim has been significantly broadened compared to the disclosure of the original WO 2005/062980 A1.

The unallowable generalization or omission becomes even more apparent in view of the fact that both omitted features are clearly related to each other:

In the present case, a skilled reader cannot be assumed to have any doubts as to whether missing features are in a structural or functional relationship with claimed features C3 and C4 (T 1067/97). This follows from the conjunctions "to" and "that" and from the fact that there is no disclosure indicating that the above features may be selected separately. The conjunction "to" emphasizes the specific functional purpose of the bunching up (i.e. creating fabric flaps and pockets) and the conjunction "that" describes structural features (i.e. extending into spaces formed by the native valve leaflets) of the bunching up.

Moreover the patent language clearly distinguishing between single facultative features (see e.g. the end of the same sentence, p. 34, l. 30-31; "*particularly* when the pockets are filled with blood") appears to be consistent in this respect.

Therefore, the isolation of features C3/C4 without the structurally and/or functionally related features "creating fabric flaps and pockets" and "that extend into spaces formed by the native valve leaflets" leads to an inadmissible intermediate generalization.

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