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**Datasheet for the decision  
of 15 February 2023**

**Case Number:** T 2627/18 - 3.2.01

**Application Number:** 15167832.3

**Publication Number:** 2926766

**IPC:** A61F2/01, A61F2/24

**Language of the proceedings:** EN

**Title of invention:**  
REPOSITIONABLE HEART VALVE

**Patent Proprietor:**  
Boston Scientific Scimed, Inc.

**Opponents:**  
(3) St Jude Med, Inc/ Abbott Med GmbH/ St Jude Med UK Ltd/ SJM  
Int, Inc./ SJM Coord Center BVBA/ St Jude Med SC Inc  
(4) BIOTRONIK AG

**Headword:**

**Relevant legal provisions:**  
EPC Art. 76(1)

**Keyword:**

Divisional application - subject-matter extends beyond content of earlier application (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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**Case Number: T 2627/18 - 3.2.01**

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.01**  
**of 15 February 2023**

**Appellant:** Boston Scientific Scimed, Inc.  
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**Decision under appeal:** **Interlocutory decision of the Opposition**  
**Division of the European Patent Office posted on**

26 September 2018 concerning maintenance of the  
European Patent No. 2926766 in amended form.

**Composition of the Board:**

**Chairman**            G. Pricolo

**Members:**            A. Wagner  
                             P. Guntz

## **Summary of Facts and Submissions**

- I. The appeals of the patent proprietor and of opponent 3 lie against the decision of the opposition division to maintain the European Patent No. 2926766 in amended form on the basis of auxiliary request 3 filed at 15:10h as auxiliary request 1C during the oral proceedings.
- II. In its decision, the opposition division held among others that claim 1 of the patent as granted did not incorporate inadmissible amendments (Articles 100(c), 76(1), 123(2) EPC) but that its subject-matter was not new over US 5,957,949 (D6). Furthermore auxiliary request 1 filed on 11 April 2018 and auxiliary request 2 filed as auxiliary request 1B during oral proceedings were found to contravene the requirement of Article 76(1) EPC.
- III. Oral proceedings were held before the Board on 15 February 2023 in the presence of the two appellants. As announced with letter dated 21 November 2022 the other party (opponent 4) who withdrew its appeal on 7 December 2018 did not attend the oral proceedings. Opponent 4 did not submit any arguments on the merits in these appeal proceedings. Opponents 2 and 1 did not participate in the appeal proceedings; their oppositions had been withdrawn on 17 May 2017 and 17 January 2019, respectively.

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted or that it be maintained in amended form on the basis of one of auxiliary requests 1 to 6, auxiliary requests 1, 3, 5 and 6 having been

submitted as auxiliary requests 1, 2, 4 and 5 with the statement of grounds of appeal, auxiliary request 2 having been submitted with the reply to the opponent 3's statement of grounds of appeal and auxiliary request 4 (a correction of auxiliary request 3 as submitted with the statement of grounds of appeal) having been submitted with letter of 12 January 2023.

The appellant (opponent 3) requested that the decision under appeal be set aside and that the European patent be revoked.

IV. Claim 1 of the **main request** (patent as granted) reads as follows:

Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:  
an expandable cylindrical anchor (30) supporting a replacement valve (20),  
the anchor (30) having a delivery configuration and a deployed configuration, and  
at least one sac (200) disposed about the exterior of the anchor (30) to provide a seal.

In claim 1 of **auxiliary request 1** the following feature is added:

wherein the at least one sac (200) is adapted to be filled with blood.

Claim 1 of **auxiliary request 2** is based on the main request and reads as follows:

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

an expandable cylindrical anchor (30) supporting a replacement valve (20),  
the anchor (30) having a delivery configuration and a deployed configuration, and  
sacs (200) for reducing leakage of blood through gaps in the irregular interface between native leaflets and the anchor, wherein the sacs (200) are disposed about the exterior of the anchor (30), wherein the sacs are adapted to fill with blood when the apparatus is implanted in order to provide a seal.

Claim 1 of **auxiliary request 3** is based on the main request, wherein the following feature is added:

wherein the at least one sac (200) comprises slots (202) that can be used to back-fill the at least one sac with ambient blood passing through the replacement valve (20).

Claim 1 of **auxiliary request 4** is based on auxiliary request 3, wherein the additional feature of auxiliary request 3 is amended as follows:

wherein the at least one sac (200) comprises 'fish-scale' slots (202) that can be used to back-fill the at least one sac with ambient blood passing through the replacement valve (20).

Claim 1 of **auxiliary request 5** is based on the main request, wherein the following feature is added:

wherein the at least one sac (200) is adapted to be filled by blood washing past the at least one sac (200).

Claim 1 of **auxiliary request 6** is based on the main request, wherein the expression "at least one" sac is amended to "sacs" and the the following feature is added:

wherein the sacs (200) can be back-filled with ambient blood passing through the replacement valve (20).

V. The appellant's (opponent 3's) arguments relevant to the present decision may be summarized as follows:

The subject-matter of the claims of the patent as granted was taken out of the context of the parent application as a whole and also out of the specific embodiments of the apparatus for which the sacs were described. None of the auxiliary requests overcame this objection. Additionally, auxiliary request 2, filed with the reply to the opponent 3's statement of grounds of appeal, should be rejected on the grounds of late filing.

In particular, the opposition division was wrong in concluding that the claim wording "at least one sac" could find a basis in the disclosure of page 32, line 30 "*Compliant sacs 200 may be disposed...*". It was impossible that an element explicitly mentioned in the plural form could be considered as providing a direct disclosure for an element in singular form. Figure 15C and figure 15E may show a single sac but only with the additional requirement that the sac was provided with a cylindrical or spiral shape spanning multiple heights. Actually all embodiments of figures 15A to 15E disclosed a distribution of the sacs along the height of the anchor.

The opposition division's opinion with regard to the



feature "one or more slots" e.g. in dependent claim 3 of auxiliary requests 1 and 2 or in claim 1 of auxiliary request 3, had to be confirmed (impugned decision, point 19.4). If slots 202 were provided, they were only disclosed as fish-scale slots. Furthermore it was not derivable from the original disclosure that the slots could "be used to back-fill the at least one sac". According to page 33, line 9, the "*sacs 200 comprise 'fish-scale' slots 202 that may be back-filled*".

The auxiliary requests 2 to 6 included the idea that the sacs were adapted to fill or to be filled at the treatment site with blood washing past the sacs or passing through the replacement valve. The only disclosure about the filling when the apparatus was implanted could be found on page 33, second paragraph, referring to the three embodiments shown in figures 16A to 16C. In all these figures the sacs were open to the lumen 31 of the anchor. A filling at the treatment site with sacs not being open to the lumen 31 was originally not disclosed.

VI. The appellant's (patent proprietor's) arguments relevant to the present decision may be summarised as follows:

Page 32, line 30 ("*Compliant sacs 200 may be disposed...*") provided a general disclosure of "at least one sac" without any structural or functional link to other features of the apparatus or the anchor, or to specific arrangements of the sacs at the exterior of the anchor. As could be seen e.g. from figure 15C, the general disclosure comprised the provision of just one sac.

From figure 15B seen together with page 33, lines 6, 7,

wherein it was stated that "*alternative sac configurations will be apparent to those of skill in the art*" it was clear that also just one sac could be provided, e.g. as a continuous, cylindrical sac, without the requirement of spanning multiple heights. A single sac as e.g shown in figure 15D would not fall under the claim as it would not have the required sealing function.

Contrary to the opposition division's opinion (decision, point 19.4) the exact shape of the slots 202 was not intrinsically linked to the ability of the sacs to be back-filled with ambient blood. Any other slot shape would be appropriate. Therefore the omission of the feature "fish-scale" was an allowable intermediate generalisation.

According to page 32, lines 31, 32, the "*sacs 200 may be filled with an appropriate material, for example, water, blood, foam or a hydrogel*". A filling with blood as specified in the auxiliary requests intrinsically required a filling at the treatment side and the presence of openings, as else the blood could not enter the sac. Thus the concept of sacs adapted to fill or to be filled at the treatment site with ambient blood found a basis in the parent application.

The filling of the sacs as shown in figure 16C occurred via the openings of the sac to the lumen 31. However these openings were just one specific embodiment. For the embodiment shown in figure 16B it was explicitly stated on page 33, line 11, that the "*pores 204 may be used to fill the sacs*". Also the embodiment with the slots may be back-filled by using the slots. Back-filling meant that the blood that passed through the valve seeped back and filled the sacs through the slots

from the exterior of the anchor. The openings of the sacs to the lumen of the anchor were only mentioned with reference to figure 16C and not functionally linked to the filling at the treatment site as such.

### **Reasons for the Decision**

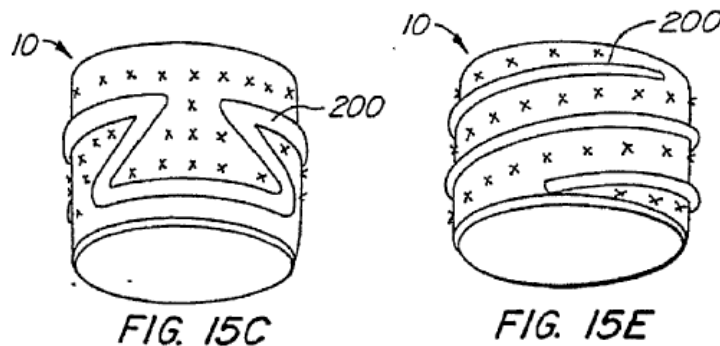
1. None of the requests on file meet the requirements of Article 76(1) EPC. The following reasoning is based on the parent application of the patent in suit, being published under the international publication number WO 2005/062980 A2.
2. All requests refer to at least one sac or sacs disposed about the exterior of the anchor (3) to provide a seal. In the parent application WO 2005/062980 A2 the only disclosure concerning the sac or sacs can be found on page 32, line 23 to page 33, line 13 with reference to figures 13 to 16.
3. The appellant (opponent 3) raised numerous objections under Article 76(1) EPC with regard to all requests on file. The board agrees with at least three of the objections. The main request and auxiliary requests 1 to 6 contravene Article 76(1) EPC because at least one of these objections applies, as will be explained in the following.
4. As none of the requests of the appellant (patent proprietor) meets the requirements of the EPC the question of admission of auxiliary request 2 into appeal proceedings under Article 12(4), (6) RPBA 2020 raised by the appellant (opponent 3) can thus remain unanswered.

**5. "At least one sac"**

5.1 Claim 1 of the main request and of auxiliary requests 1, 3, 4 and 5 includes the feature "at least one sac". The appellant (patent proprietor) was of the opinion that the general statement "*compliant sacs 200 may be disposed...*" on page 32, line 30, provided sufficient basis for the option of disposing just one sac about the exterior of the anchor.

5.2 The board does not agree. The term "sacs" clearly refers to the plural, which is usually understood as "at least two". Thus page 32, line 30, does not provide a suitable basis for the disputed feature.

5.3 It is acknowledged that in the embodiments shown in figure 15C and figure 15E (reproduced below) a single sac (200) is provided.



However such a single sac only is disclosed in a specific configuration, i.e. with a "*cylindrical shape that spans multiple heights*" or as "*a spiral sac*" (page 33, lines 4 to 6).

5.4 Even if the board would follow the argument of the appellant (patent proprietor) that from figure 15B (reproduced below), wherein two sacs are provided as continuous cylinders at various heights, it would be

directly clear that only one of the sacs 200 might be provided to perform the sealing function without spanning multiple heights, still, the sac is only disclosed in a specific configuration, i.e. as a continuous cylinder covering the entire circumference of the anchor (see figure 15B with page 33, line 3).

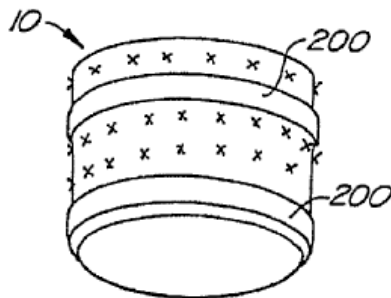


FIG. 15B

5.5 Moreover, the feature "at least one sac" in claim 1 implies that just one of the sacs 200 as e.g. shown in figure 15A or figure 15D (reproduced below), each spanning only a portion of the circumference of the anchor, may be provided. This technical information is not disclosed in the parent application as originally filed.

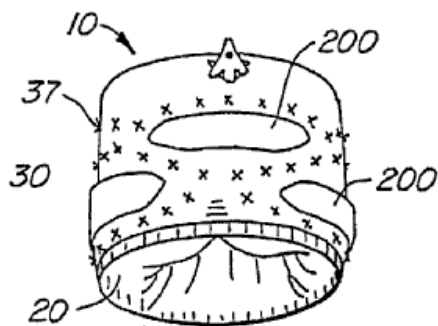


FIG. 15A

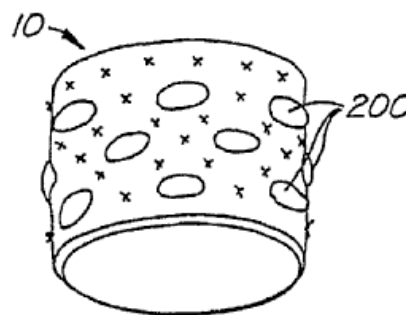


FIG. 15D

Contrary to the appellant's (patent proprietor's) opinion, it cannot be said that the skilled person would exclude from the wording of claim 1 an embodiment

with only one of the sacs shown in figure 15A or figure 15D because in such an embodiment the single sac would not be capable of providing a seal. In fact, the surface of native valve leaflets is irregular and therefore a sac does not necessarily have to extend around the entire circumference of the anchor to perform a sealing function. Moreover, the claim does not specify to what extent the sealing function is achieved (i.e. whether the seal should be along the entire circumference).

5.6 Consequently an apparatus comprising the feature "at least one sac" contains subject-matter which extends beyond the content of the parent application as originally filed.

**6. "Slots that can be used to back-fill the sacs"**

6.1 Claim 1 of auxiliary request 3 (corresponding to auxiliary request 2 underlying the impugned decision) comprises the feature "slots that can be used to back-fill the sacs". The board confirms the decision of the opposition division (impugned decision, point 19.4) that this feature extends the subject-matter beyond the content of the original disclosure.

The disputed feature is also recited in

- dependent claim 4 of the main request,
- dependent claim 3 of auxiliary requests 1 and 2 and
- dependent claim 2 of auxiliary request 5.

6.2 The appellant (patent proprietor) referred to page 33, line 9 ("*sacs 20 comprise 'fish-scale' slots 202 that may be back-filled*") and argued that the exact shape of the slots was not intrinsically linked to the ability of the sacs to be back-filled with ambient blood.

6.3 The board is not convinced. The slots originally were only disclosed as being "fish-scale" slots. Omitting the feature "fish-scale" constitutes an unallowable intermediate generalisation as the skilled person is not taught that any slot shape can guarantee the purpose of the sacs, i.e. to provide a seal and to be back-filled with ambient blood passing through replacement valve 20 (page 33, lines 9, 10).

6.4 Consequently an apparatus comprising sacs provided with the feature "slots" in general contains subject-matter which extends beyond the content of the parent application as originally filed.

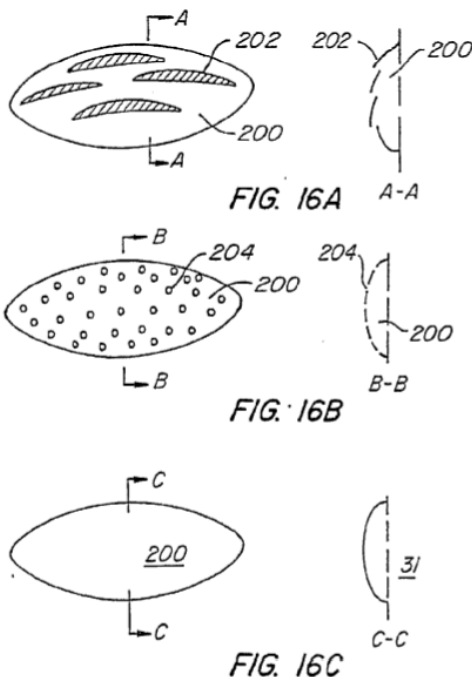
**7. "Sacs (200) can be back-filled with ambient blood passing through the replacement valve (20)"**

7.1 The verbatim feature "*sacs (200) can be back-filled with ambient blood passing through the replacement valve (20)*" is comprised in claim 1 of auxiliary request 6.

The feature that the sacs are adapted to fill or to be filled at the treatment site with blood washing past the sacs or passing through the replacement valve is included in claim 1 of auxiliary requests 2 to 6. Consequently the following reasoning applies mutatis mutandis to claim 1 of all these requests.

7.2 In the parent application, the sacs undisputedly may be filled with blood as one of several appropriate materials (see page 32, lines 31, 32: "*Sacs 200 may be filled with an appropriate material, for example, water, blood, foam or a hydrogel*"). However a disclosure of how the sacs are filled at the treatment

site only can be found on page 33, lines 8 to 13 referring to figures 16A to 16C (reproduced below).



7.3 All embodiments shown in figures 16A to 16C (right hand side) have openings toward the lumen 31 of the anchor. It is undisputed that the embodiment of figure 16C can only be filled through these openings to the lumen 31. The same openings are shown for the embodiments of figure 16A and figure 16B. Thus the skilled person is taught that the sacs are adapted to be filled with blood at the treatment site - but only in combination with openings to the lumen 31 of the anchor. The sacs optionally can be provided with a closed surface, with fish-scale slots 202 or with pores 204.

7.4 The appellant's (patent proprietor's) argument that in the embodiments of figures 16A and 16B the filling of the sacs is intended to occur from the exterior of the apparatus through the slots and pores and therefore the openings to the lumen were optional, is not plausible - neither is the argument that "back-filling" on page 33,



line 9, meant filling from the exterior by blood seeping back to the apparatus after passing through the replacement valve.

- 7.4.1 The original disclosure does not comprise any teaching about the appellant's (patent proprietor's) understanding of back-filling. Page 33, lines 9, 10 describes that the sacs may be back-filled with blood passing through the replacement valve. Thus the blood fills the sacs during passing the valve, not after having passed the valve and subsequently seeping back. The patent teaches that the filling occurs from the back of the sacs when the blood washes past the sacs (page 33, lines 11 to 13).
- 7.4.2 Even if page 33, line 11, discloses that "*pores 204 may be used to fill the sacs*", the corresponding figure 16B only shows pores in combination with openings to lumen 31 - the same openings which are used to fill the sacs of figure 16C.  
The skilled person understands that in all embodiments the sacs are mainly filled with blood from the back, i.e. from the interior of the apparatus.
- 7.4.3 Therefore - contrary to the appellant's (patent proprietor's) view - the only teaching that the skilled person receives from the parent application is to provide sacs that are open to lumen 31 of the anchor to guarantee the filling at the treatment site with blood passing through the replacement valve.
- 7.5 The same reasoning applies to the appellant's (patent proprietor's) argument that based on the disclosure of page 32, lines 31, 32 ("*Sacs 200 may be filled with an appropriate material, for example, water, blood, foam or a hydrogel*") a filling with blood only made sense at

the treatment site and intrinsically required the presence of openings. The parent application does not disclose in general terms how the sacs are filled at the treatment site, but only describes specific configurations and embodiments.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated