

**Internal distribution code:**

- (A) [ - ] Publication in OJ
- (B) [ - ] To Chairmen and Members
- (C) [ - ] To Chairmen
- (D) [ X ] No distribution

**Datasheet for the decision  
of 12 April 2024**

**Case Number:** T 1650/21 - 3.2.01

**Application Number:** 14186568.3

**Publication Number:** 2870946

**IPC:** A61F2/24

**Language of the proceedings:** EN

**Title of invention:**

Paravalvular leak sealing mechanism

**Patent Proprietor:**

St. Jude Medical, Cardiology Division, Inc.

**Opponent:**

Boston Scientific Corporation

**Headword:**

**Relevant legal provisions:**

EPC Art. 123(2), 54, 56

RPBA 2020 Art. 12(4)

**Keyword:**

Amendments - allowable (no)

Novelty - auxiliary request (yes)

Inventive step - improvement not credible - obvious solution -  
auxiliary request (yes)

Amendment to case - admissibly raised and maintained (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

**Case Number: T 1650/21 - 3.2.01**

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.01**  
**of 12 April 2024**

**Appellant:** St. Jude Medical, Cardiology Division, Inc.  
(Patent Proprietor) 177 E. County Road B  
St. Paul MN 55117 (US)

**Representative:** Valea AB  
Box 1098  
405 23 Göteborg (SE)

**Appellant:** Boston Scientific Corporation  
(Opponent) 300 Boston Scientific Way  
Marlborough, MA 01752-1234 (US)

**Representative:** Peterreins Schley  
Patent- und Rechtsanwälte PartG mbB  
Hermann-Sack-Straße 3  
80331 München (DE)

**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
16 July 2021 concerning maintenance of the  
European Patent No. 2870946 in amended form.**

**Composition of the Board:**

**Chairman** G. Pricolo  
**Members:** M. Geisenhofer  
P. Guntz

## Summary of Facts and Submissions

I. The appeals were filed by the patent proprietor and the opponent against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 1, the patent in suit met the requirements of the EPC.

II. The opposition division held that the subject-matter of this request was novel over documents

D2 WO 2012/177942 A2,  
D3 US 2013/0274873 A1 and  
D4 WO 2010/008548 A2, respectively,

and inventive when starting from *inter alia* document D2 as closest prior art.

They further decided that the patent according to auxiliary request 1 disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

With regard to the main request, the opposition division decided that claim 1 contained subject-matter that extended beyond the content of the application as originally filed.

III. Oral proceedings were held before the Board.

(a) The appellant-patent proprietor requested that the decision under appeal be set aside and the patent be maintained in amended form based on the main request, in the alternative on one of auxiliary requests 1-11 or 13-22, all requests being filed

with the appellant-patent proprietor's grounds of appeal.

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

IV. Independent claim 1 of the **main request** reads as follows:

*"A prosthetic heart valve (300; 400), comprising:  
a stent body (302; 402) including a generally tubular annulus section (340; 440) defining a first circumferential row of cells (312a; 412a);  
one or more prosthetic valve elements mounted to the stent body and operative to allow flow in an antegrade direction but to substantially block flow in a retrograde direction through the annulus section;  
a cuff (306; 406) attached to the stent body and positioned on a luminal surface of the stent body; and  
a plurality of sealing members (320; 420a, 420b) attached to the cuff and having an open side (321; 421a, 421b) facing in a first axial direction and a closed side facing in a second axial direction opposite to the first axial direction so that a flow of blood in the second axial direction will tend to force blood into the sealing members and cause the sealing members to billow outwardly relative to the stent body,  
wherein each of the sealing members has a shape chosen from the group consisting of generally triangular, generally trapezoidal, and generally semicircular, characterized in that each of the plurality of sealing members is individually attached to the cuff."*

Claim 1 of **auxiliary request 1** differs from the main request in that the wording "a plurality of sealing

members (320; 420a, 420b) attached to the cuff and having an open side (321; 421a, 421b)" is replaced by "*a plurality of sealing members (320; 420a, 420b) attached to the cuff, each sealing member of the plurality of sealing members having an open side (321; 421a, 421b)*".

Claim 1 of **auxiliary request 2** requires in addition to auxiliary request 1 that

*"each one of the sealing members is not directly attached to the stent body"*

whereas claim 1 of the **auxiliary request 3** requires the following additional feature:

*"each one of the sealing members is attached to both the cuff and the stent body"*.

Claim 1 of the **auxiliary request 4** is based on claim 1 of auxiliary request 1 but additionally requires in the characterizing portion that each of the plurality of sealing members is individually attached to the cuff

*"such that one sealing member is positioned substantially within each cell in the first circumferential row of cells"*.

V. The appellant-patent proprietor's arguments (as far as they were relevant for the decision) can be summarised as follows:

(a) Claim 1 of the **main request** defined a plurality of sealing members whereby each of the sealing members had an open side, the amendments hence not going beyond the disclosure of the application as originally filed.

(b) The subject-matter of claim 1 of the **auxiliary request 1** was novel over D2 (taking into

consideration the embodiments of figure 2F, 2F1 and 2F2), D3 and D4, respectively. None of these documents disclosed a plurality of sealing members attached to the cuff on the luminal side of the stent body.

- (c) Attaching the sealing members individually to the cuff was also inventive when starting from document D2 since the skilled person would not consider attaching the sealing members to the inner cuff.
- (d) **Auxiliary requests 2 and 3** should be admitted since they were based on similar requests filed during opposition proceedings. Furthermore, reasons were given in the appellant-patent proprietor's reply to the statement of ground why the claimed subject-matter was novel and inventive.
- (e) The subject-matter of claim 1 according to auxiliary requests 2 and 3 was inventive since the skilled person had no incentive to attach the sealing members shown in the embodiment of figure 2F or 2F2 of D2 to either the inner cuff alone or to both the inner cuff and the stent body.
- (f) **Auxiliary request 4** should be admitted for the same reasons as set out with regard to auxiliary requests 2 and 3.
- (g) The subject-matter according to auxiliary request 4 was novel over D3 since the pockets of figure 13 were not formed by a plurality of individual sealing members attached to the inner cuff but by portions of inner and outer cuff.

VI. The appellant-opponent's arguments (as far as they were relevant for the decision) can be summarised as follows:

- (a) Independent claim 1 of the **main request** defined a plurality of sealing members forming pockets that were filled through one single open side. The originally filed application provided only disclosure for sealing members having each an open side, claim 1 hence defining subject-matter that extended beyond the disclosure of the application as filed.
- (b) The subject-matter of claim 1 according to the **auxiliary request 1** was not novel over D2 (taking into consideration the embodiments of figure 2F, 2F1 and 2F2), D3 and D4, respectively. At least it was not inventive when starting from D2, D4 or D5 as closest prior art.
- (c) The **auxiliary requests 2 and 3** should not be admitted since they lacked substantiation in appeal proceedings.
- (d) The subject-matter of claim 1 according to the auxiliary requests 2 and 3 was not inventive when starting from D2 as closest prior art.
- (e) The **auxiliary request 4** was not sufficiently substantiated in appeal proceedings and hence should not be admitted.
- (f) The subject-matter of auxiliary request 4 was not novel over D3.

## Reasons for the Decision

### Main request

#### Amendments

1. Claim 1 according to the main request corresponds to granted claim 1. It was amended in such a way that it contains subject-matter which extends beyond the content of the application as originally filed (Article 100(c) and 123(2) EPC).
- 1.1 Claim 1 defines "*a plurality of sealing members attached to the cuff and having an open side ... and a closed side*".
- 1.2 Since the term "*having an open side*" is used in singular, claim 1 defines a plurality of sealing members sharing one single open side.
  - 1.2.1 The appellant-patent proprietor argued that it could be deduced from the wording of the claim that each of the sealing members was provided with its own open side. This was the only technically reasonable interpretation of claim 1.
  - 1.2.2 The Board considers the expression "*having an open side*" to refer to the group of sealing members and not to each of the sealing members taken individually.
    - (a) The wording of the claim distinguishes between "*each of the sealing members*" and the "*plurality of sealing members*":

When defining the geometry of the sealing members (triangular, trapezoidal or semicircular) the claim refers *expressis verbis* to "*each of the sealing members*" to require that each of the plurality of sealing members shall have the mentioned geometry.

The term "*plurality of sealing members*" differs from the term "*each of the sealing members*" and must be understood in the present context as referring to the group of sealing members as a whole, i. e. the plurality of sealing members is combined with one single open side.

- (b) This understanding is not excluded by technical considerations, contrary to the appellant-patent proprietor's argument:

The wording of the claim does not give any details of how the plurality of sealing members is arranged. It is hence not excluded that the pockets formed by the sealing members are connected by a connecting structure such that blood entering a first pocket through an open side is transferred via this connecting structure to adjacent pockets that are not provided with open sides.

- 1.3 The application as originally filed does not provide disclosure for a combination of a plurality of sealing members with only one open side. It only provides disclosure for a plurality of sealing members whereby each sealing member has its own individual open side.

This was not disputed by the appellant-patent proprietor.

2. The Board hence confirms the opposition division's decision with regard to the main request.
3. The appellant-patent proprietor's appeal is therefore to be dismissed.

### **Auxiliary request 1**

#### Novelty

4. The subject-matter of claim 1 according to the auxiliary request 1 is novel (Article 56 EPC).
- 4.1 The appellant-opponent argued that claim 1 lacked novelty over the embodiments of figures 2F, 2F1 and 2F2 of D2, over D3 and over D4, respectively.
- 4.2 The embodiments shown in **figures 2F and 2F1 of D2** disclose a prosthetic heart valve according to the preamble of claim 1. The prosthetic heart valve comprises a stent body ("support" 110) and one or more prosthetic valve elements which allow flow in an antegrade direction but block flow in a retrograde direction.

The stent body can be covered by a cuff ("cover" 151) either on its inner side, on its outer side or on both sides (see paragraph [00206]). D2 hence discloses an embodiment where the cuff is positioned on a luminal surface of the stent body only.

Two sealing members 160 are arranged on opposing sides of the support and extend in radial direction to inhibit paravalvular leakage. They comprise tent-like conical or pyramidal tubes (hence a generally

triangular shape) with an open side such that a flow of blood in retrograde direction will force blood into the sealing members and cause them to billow outwardly relative to the stent body.

This was not disputed by the appellants.

- 4.2.1 The appellant-opponent argued that the sealing members in figures 2F and 2F1 were individually attached to the cuff, referring to paragraph [00208]. They considered this the unique technically possible way.

The appellant-patent proprietor countered that the sealing members in figures 2F and 2F1 were attached to the stent body but not to the cuff.

- 4.2.2 The Board notes that paragraph [00208] describes that "*the pair of sealing members 160A, 160B may be coupled to opposing sides of the support 110*". In the Board's understanding, this does not imply that the sealing members are attached to the stent body but only provides information on the location where the sealing members are arranged.

D2 in fact does not provide any information on how the sealing members are connected to the other valve parts, be it either the cuff or the stent body. The relevant paragraphs [00206] - [00208] do not describe any technique how the sealing members are attached and where.

- 4.2.3 In the Board's view, it is technically possible to attach the sealing members of D2 by sewing to the cuff, but it is also possible to tie them to the longitudinal struts of the stent body. There is hence no implicit

disclosure that the sealing members must necessarily be attached to the cuff.

4.2.4 The subject-matter of claim 1 hence differs from the prosthetic heart valve disclosed in figures 2F and 2F1 of D2 in that each of the plurality of sealing members is individually attached to the cuff.

4.3 The embodiment shown in **figure 2F2 of D2** comprises a bell-shaped skirt 163 extending around the lower extremity of the stent body instead of the plurality of sealing members.

The skirt is sewn to a cuff ("cover" 166) on the luminal surface of the stent body. The skirt can include plaits or internal partitions dividing the skirt into a series of vertical tubular sections around the circumference of the support (see paragraph [00209]).

4.3.1 The appellant-opponent argued that the plaits or internal partitions divided the skirt into a plurality of sealing members that were individually attached.

4.3.2 In the present context, the Board does not follow this interpretation of claim 1.

The wording of the claim requires a plurality of sealing members whereby

- each of the sealing members has a triangular, trapezoidal or semicircular shape, and
- each of the plurality of sealing members is individually attached to the cuff.

It is hence implicit to claim 1 that the sealing members are individual elements.

4.3.3 The subject-matter of claim 1 hence differs from the prosthetic heart valve disclosed in figure 2F2 of D2 in that

- the prosthetic heart valve comprises a plurality of (individual) sealing members;
- each of the sealing members has a triangular, trapezoidal or semicircular shape; and
- each of the plurality of sealing members is individually attached to the cuff.

4.4 **Document D3** discloses in figure 13 a prosthetic heart valve with a stent body and a cuff ("skirt"). The valve includes a series of pockets each with an open side and a closed side. The pockets are formed by a portion of the outer skirt and a portion of the inner skirt of the cuff (see paragraph [0078]).

Following a similar reasoning as set out above with regard to the embodiment of Figure 2F2 of D2, the subject-matter of claim 1 differs from D3 in that

- the prosthetic heart valve comprises a plurality of (individual) sealing members;
- each of the sealing members has a triangular, trapezoidal or semicircular shape; and
- each of the plurality of sealing members is individually attached to the cuff.

4.5 **Document D4** discloses in figure 13 a prosthetic heart valve with a stent body and a cuff. A series of pockets is provided around the circumference of the valve using fabric material 220.

It is, however, not directly and unambiguously derivable from figure 10 that the pockets are formed from individual sealing members. It cannot be excluded

that the pockets were formed by a band of fabric extending around the entire circumference of the stent body which then is sewn to the cuff along lines such that the pockets are formed.

The subject-matter of claim 1 hence differs from D4 in that

- the prosthetic heart valve comprises a plurality of (individual) sealing members;
- each of the sealing members has a triangular, trapezoidal or semicircular shape; and
- each of the plurality of sealing members is individually attached to the cuff.

4.6 The subject-matter of claim 1 according to the auxiliary request 1 is hence novel, as the opposition division correctly decided.

Inventive step

5. The subject-matter of claim 1 according to the auxiliary request 1 is not based on inventive activity (Article 56 EPC).

5.1 The embodiments of figures 2F and 2F1 of D2 represent in the Board's view the closest prior art. As stated above (point 4.2.4), the subject-matter of claim 1 differs from this embodiment in that each of the plurality of sealing members is individually attached to the cuff.

5.2 D2 is silent with regard to how the pair of sealing members 160 is attached and where they are attached. The skilled person when reducing D2 into practice must therefore choose a suitable position where to attach the sealing members to the valve.

There are only three options for attaching the sealing members:

- (a) to the stent body;
- (b) to the cuff; or
- (c) to both the stent body and the cuff.

5.2.1 In this context, the Board does not agree with the formulation of the objective technical problem as identified by the opposition division (reasons 20, decision on page 13, penultimate paragraph).

The opposition division formulated this problem based on the assumption that the effect of the distinguishing feature is "providing individual seals than can be provided where needed and that are individually attached to an inner cuff".

Individual seals that can be provided where needed are however already disclosed by D2. As set out in paragraph [00208] of D2, the sealing members "*are configured to fit adjacent or within commissures between the posterior and anterior leaflets, to effectively seal the outer surfaces of the sealing members 160A, 160B to the native valve tissue*".

5.2.2 The Board hence considers the problem formulated by the appellant-opponent, namely to implement a heart valve based on the teaching of D2 regarding the embodiment in figures 2F and 2F1, to be correct. The skilled person indeed, irrespective of any other technical effects, has to find a way for attaching the sealing members of figure 2F and 2F1 to the valve.

5.3 Taking a choice between option (a) - (c) cannot be considered to be based on an inventive activity but is

merely an obvious choice from only three options, contrary to the opposition division's decision.

- 5.4 Choosing either option (b) or (c) results in each sealing member being individually attached to the cuff, claim 1 of the auxiliary request 1 hence not being inventive.

### **Auxiliary requests 2**

6. Auxiliary request 2 differs from the auxiliary request 1 in that claim 1 additionally requires that the sealing members are not directly attached to the stent body.

Inventive step

7. The subject-matter of claim 1 according to the auxiliary request 2 is not based on an inventive activity (Article 56 EPC).
- 7.1 The additional feature added to claim 1 restricts the possible choices where to attach the sealing members in the embodiments of figures 2F and 2F1 to option (b).
- 7.2 Choosing one way of attaching the sealing members within the three available options (a) - (c) is, however, not inventive.
- 7.2.1 The appellant-patent proprietor alleged that attaching the sealing members only to the cuff allows for reducing the overall bulkiness and/or profile of the prosthetic valve (cf. the patent proprietor's statement of grounds of appeal, page 11, third paragraph of chapter 4.2).

7.2.2 Irrespective of this additional advantage, the above explained reasoning with regard to inventive step of the auxiliary request 1 also applies to auxiliary request 2. The skilled person has to find a way for attaching the sealing members of figure 2F and 2F1 to the valve whereby choosing one of the three available options (a) - (c) does not involve an inventive step.

A reduced bulkiness is, assuming that the effect indeed can be achieved, at the best a bonus effect.

Admissibility (Article 12 RPBA)

8. Since the subject-matter of claim 1 according to auxiliary request 2 is not patentable, it can remain undecided whether it can be admitted into the appeal procedure and/or whether it was already admissibly raised during opposition proceedings.

### **Auxiliary request 3**

9. Auxiliary request 3 differs from the auxiliary request 1 in that claim 1 additionally requires that the sealing members are each attached to both the cuff and the stent body.

Inventive step

10. The subject-matter of claim 1 according to the auxiliary request 3 is not based on an inventive activity (Article 56 EPC).

- 10.1 The feature added to claim 1 restricts the possible choices where to attach the sealing members in the embodiments of figures 2F and 2F1 to option (c).
- 10.2 Choosing option (c) among the above-mentioned three options (a) - (c) does not involve an inventive step.
  - 10.2.1 The appellant-patent proprietor alleged that attaching the sealing members to both the cuff and the stent body allows for reducing the risk of tearing the cuff at the points of attachment (cf. patent proprietor's statement of grounds of appeal, page 11, fourth paragraph of chapter 4.2).
  - 10.2.2 Choosing one way of attaching the sealing members from the three available options (a) - (c) is a non-inventive choice as explained above.
  - 10.2.3 The reduced risk of tearing - which effect is neither mentioned in, nor derivable from the patent in suit - constitutes, if any, a bonus effect when the skilled person takes the non-inventive choice to attach the sealing members to both the cuff and the stent body.

Admissibility (Article 12 RPBA)

- 11. Since the subject-matter of claim 1 according to auxiliary request 3 is not patentable, it can remain undecided whether it can be admitted into the appeal procedure and/or whether it was already admissibly raised during opposition proceedings.

#### **Auxiliary request 4**

##### Admissibility

12. Auxiliary request 4 filed with the statement of grounds of appeal corresponds to auxiliary request 4 filed in opposition proceedings with letter dated 14 May 2021.

12.1 The appellant-opponent requested in writing not to admit this request into the proceedings, because it was late filed, was never been discussed in first instance proceedings and the Opposition Division never admitted it. During oral proceedings admittance was also discussed in view of substantiation.

12.2 The Board notes that auxiliary request 4 filed in opposition proceedings with letter dated 14 May 2021 essentially corresponds to the auxiliary request 4 previously filed with letter dated 9 September 2020 in reaction to the summons issued by the opposition division. Compared thereto, the wording of the characterizing portion of claim 1 is solely amended to excise the clearly redundant text "*and in that the plurality of sealing members includes a plurality of sealing members (320a; 420a)*", whereby the claimed subject-matter remains the same. Under these circumstances the Board takes the view that auxiliary request 4, even if filed few days before the date (17 May 2021) of oral proceedings before the opposition division, was admissibly filed in opposition proceedings (Article 12(4) RPBA 2020).

12.2.1 As regards substantiation, in their statement of grounds the patent proprietor submitted that "*by positioning one sealing member substantially within each cell (as recited in the Fourth, Ninth to Eleventh*

*and Twentieth to Twenty second Auxiliary Requests), the overall bulkiness and/or profile of the prosthetic valve may be minimized".* The reference to the effect obtained by means of the added feature constitutes in the Board's view an indication that the added feature is meant to support inventiveness.

- 12.2.2 Under these circumstances, the Board sees no reason that would justify not admitting auxiliary request 4 in the appeal proceedings (Article 12(3) and (5) RPBA).

#### Novelty

13. The subject-matter of claim 1 according to the auxiliary request 4 is novel (Article 54 EPC).
- 13.1 The appellant-opponent argued that the subject-matter of claim 1 was not novel over D3.
- 13.2 As set out above with regard to novelty of the subject-matter of auxiliary request 1, document D3 lacks a plurality of individual sealing members. For this reason alone, the subject-matter of claim 1 is already novel.

#### Inventive step

14. The subject-matter of claim 1 according to the auxiliary request 4 is also inventive (Article 56 EPC).
- 14.1 None of the prior art documents cited in the appeal procedure suggests arranging individual sealing members such that they are positioned substantially within each cell in the first circumferential row of cells of a stent body.

- 14.2 The subject-matter of claim 1 hence is not rendered obvious by the prior art.
- 14.3 The appellant-opponent did not raise objections with regard to inventive step under Article 56 EPC and the Board sees no reason for questioning the validity of the claims. Accordingly, the claims according to auxiliary request 4 form a suitable basis for maintaining the patent in amended form.

#### Adaptation of the description

15. It was undisputed between the parties that the description contains several passages that need to be adapted to the wording of the independent claim of auxiliary request 4. Both the appellant-patent proprietor and the appellant-opponent agreed that the adaptation of the description could be done upon remittal of the case to the opposition division.

Under these circumstances, the Board considered it as appropriate to remit the case with the order to maintain the patent with the claims of auxiliary request 4 and a description to be adapted.

#### **Order**

#### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of the claims of auxiliary request 4 as submitted with the statement of grounds of appeal of the

appellant-patent proprietor and a description and figures to be adapted.

The Registrar:

The Chairman:



M. Schalow

G. Pricolo

Decision electronically authenticated