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**Datasheet for the decision  
of 6 March 2023**

**Case Number:** T 0877/20 - 3.2.01

**Application Number:** 12795707.4

**Publication Number:** 2787924

**IPC:** A61F2/24

**Language of the proceedings:** EN

**Title of invention:**

TRANSCATHETER VALVE HAVING REDUCED SEAM EXPOSURE

**Patent Proprietor:**

Medtronic Inc.

**Opponents:**

St. Jude Med, LLC/Abbott Med GmbH/St. Jude Med UK  
Ltd/SJM Int. Inc./SJM Coordination Center BVBA/  
St. Jude Med S. C. Inc.

**Headword:**

**Relevant legal provisions:**

EPC R. 116(2)

EPC Art. 84, 123(2), 123(3), 54, 56

**Keyword:**

Auxiliary request 4 - admitted according to the right criteria  
Amendments - added subject-matter (no) - broadening of claim  
(no)  
Clarity (yes)  
Novelty - (yes)  
Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

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**Chambres de recours**

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**Case Number:** T 0877/20 - 3.2.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.01**  
**of 6 March 2023**

**Respondent:**

(Patent Proprietor)

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**Decision under appeal:**

**Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
16 January 2020 concerning maintenance of the  
European Patent No. 2787924 in amended form.**

**Composition of the Board:**

<b>Chairman</b>	G. Pricolo
<b>Members:</b>	S. Mangin
	O. Loizou

## **Summary of Facts and Submissions**

- I. The appeal was filed by the appellant (opponents) against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 4, the patent in suit (hereinafter "the patent") met the requirements of the EPC.
- II. The Opposition Division admitted auxiliary request 4 which was filed during oral proceedings in opposition. The opposition division held that:
- (1) the auxiliary request fulfilled the requirements of Articles 123(2), 123(3) and 84 EPC;
  - (2) the subject-matter of claim 1 was novel over D2 (WO 2011/079803 A1) / D2a EP2520249 A1 equivalent in English, D3 (WO2012/032187) and D4 (US7914569 B2) and involved an inventive step starting from D4 in combination with common general knowledge or with D13 (US 2006/0276813 A1).
- III. Oral proceedings were held before the Board via videoconference on 6 March 2023.
- IV. The appellant (opponents) requested that the decision under appeal be set aside and that the patent be revoked.
- V. The respondent (patent proprietor) requested that the appeal of the opponent be dismissed (main request), or in the alternative, that the patent be maintained on the basis of one of auxiliary requests 5-14 filed with their statement of grounds of appeal or alternatively one of the auxiliary requests 15-53 filed with their reply.
- The respondent as the previous appellant 1 withdrew

their appeal and requested reimbursement of their appeal fee.

VI. Auxiliary request 4

Independent claim 1 with the feature numbering used in the appealed decision reads as follows:

**M1** A valve prosthesis comprising:

**M1.1** a. a self-expandable frame

**M1.2** comprising struts (60) and nodes (61) which define a plurality of cells,

**M1.3** the frame being generally cylindrical with a longitudinal axis and an inflow end;

**M2** b. a valve body (14) supported by the frame and comprising:

**M2.1** i. a plurality of leaflets (22) sewn to a skirt (21) to form joints (27) between each leaflet and the skirt, in which each joint between each leaflet and the skirt is curved to define upper and lower portions of each joint,

**M2.2** ii. adjoining leaflets (22) are sewn together to form commissures (24) which are sewn to the frame downstream of the inflow end, and

**M2.3** iii. a bottom edge sewn to the inflow end of the frame, and

**M2.4'** iv. at least one side seam (43) which extends between a lower portion of one of the joints (27) and the bottom edge

**M2.5** wherein the at least one side seam (43) extends downwardly from a point on a lower half of the one of the joints (27).

VII. In the present decision, reference is made to the following documents:

D5: WO 2011/147849

D6: WO 2012/039753

D7: WO 2009/053497

## **Reasons for the Decision**

### **1. Auxiliary request 4 (main request in appeal) - Admissibility**

With their main request being to dismiss the appeal, the respondent requested that the patent be maintained in the form considered allowable by the opposition division, namely in accordance with auxiliary request 4 filed in opposition proceedings.

The Opposition Division admitted auxiliary request 4 filed during the oral proceedings. Auxiliary request 4 corresponds to auxiliary request 3 filed in advance of the oral proceedings, but with the deletion of all method claims.

The Board considers that the Opposition Division correctly exercised their discretion, using the right criteria, in admitting auxiliary request 4.

- 1.1 The appellant argued that auxiliary request 4 should not have been admitted for the following reasons:
- Auxiliary request 4 clearly extended beyond the content of the application as originally filed and the subject-matter of claim 1 was not novel.
  - Auxiliary request 4 was filed at a very late stage during the oral proceedings (time stamp of 17:15), while the deletion of the method claims could have been made earlier since claim 9 of auxiliary request 3 prima

facie lacked novelty and extended the subject-matter contrary to Article 123(2) EPC.

- The proprietor filed multiple new requests for the first time during the oral proceedings in opposition, abusing the oral proceedings for their trial-and-error approach in order to find the best possible allowable claim wording while the opponents was constantly faced with a new claim wording at such a late stage of the opposition proceedings.

- 1.2 The Board judges that the Opposition Division exercised correctly their discretion to admit auxiliary request 4, taking the right principles into account. They considered that the deletion of the method claims did not confront the opponents with new subject-matter and that auxiliary request 4 was prima facie allowable. Indeed the Opposition Division noted that auxiliary request 4 complied with Rule 80 EPC and Articles 84, 123(2) and (3) EPC and overcame the novelty objections raised for claim 9 of auxiliary request 3.

2. Auxiliary request 4 - Clarity

The subject-matter of claim 1 is clear pursuant Article 84 EPC.

- 2.1 The appellant argued that claim 1 of auxiliary request 4 did not fulfil the requirements of Article 84 EPC. The new claim wording required "at least one side seam" which indicated the possibility of the presence of multiple side seams. This would mean that multiple side seams could extend downwardly from the same point on the joint. However, it was not clear how multiple side seams could extend downwardly from the same point on the joint while extending between lower portion of the joint and the bottom edge. The absence of further



details in the claim with regard to the orientation of the side seams rendered the claim language unclear.

- 2.2 The Board does not agree and notes that *"at least one side seam (43) which extends between a lower portion of a joint (27) and the bottom edge"* was present in claim 1 as granted. According to G3/14 the claims of the patent may be examined for compliance with the requirements of Article 84 EPC only when, and then only to the extent that the amendment introduces non-compliance with Article 84 EPC.
- Feature M2.4' which has been amended and feature M2.5 which has been added do not introduce non-compliance with Article 84 EPC.
- Feature M2.1 defines a plurality of curved joints (27) and features M2.4' and M2.5 require that *"at least one side seam (43) which extends between a lower portion of one of the joints (27) and the bottom edge, wherein the at least one side seam (43) extends downwardly from a point on a lower half of the one of the joints (27)"*. Claim 1 thus encompasses a valve body comprising other side seams (43) extending between a lower portion of one of the other joints (27) and the bottom edge. The interpretation of features M2.4' and M2.5 made by the appellant that claim 1 encompasses other side seam extending from the same curved joint (27) is not technically meaningful and is not in line with the description (reference is made to the figures and paragraph [0018] of the patent).

3. Auxiliary request 4 - Article 123(2) and (3) EPC

The subject-matter of claim 1 does not extend beyond the content of the application as filed and its scope of protection is not broadened.

3.1 The appellant was of the opinion that paragraph [027] of the application as filed could not be the basis for the amendments made as paragraph [027] did not disclose:

- (i) to select only one side seam to fulfil the requirements of features M2.4' while leaving it open whether the other joints also fulfil the requirements of feature M2.4'.
- (ii) to provide more than one side seam extending from a point on a specific one of the joints;
- (iii) to combine three substantially identical skirt portions with at least one side seam at exactly one joint; and
- (iv) to omit features inextricably linked with the introduced feature M2.5, in particular:
  - *"Side seam 43 extends downwardly towards the inflow portion of the prosthesis until it reaches the lower (or inflow) edge of skirt 21 located within the region indicated by I".*
  - *"(...) skirt 21 is attached to the frame such that the side seam 43 extends only the relatively short distance represented by a single cell of the frame".*

The inadmissible extension of claim 1 of auxiliary request 4 also led to a wording of claim 1 which was broader than the wording of claim 1 as granted such that claim 1 of auxiliary request 3a extended the scope of the patent in violation of Article 123(3) EPC. In particular, it was now possible that a first side seam extended downwardly from a point on a lower half of one joint, whereas there was a second seam extending in a different direction from a point on a lower half of the same or of another joint. The new feature combination therefore broadened the scope of the patent as granted.

3.2 The Board does not agree.

- 3.2.1 Regarding points (i)-(iii), paragraph [027] forms the basis for *"the at least one side seam extending between a lower portion of one of the joints (27) and the bottom edge"*.

The amended feature is not inextricably linked to the number of seams and paragraph [027] discloses *"in any case, the side seam (43) extends from a point on the lower half of the joint 27 (...)"*. The joint 27 has been defined earlier in the description in paragraph [024] and [025] as being the curved seam between each leaflet and the skirt.

The Board notes that the features defining the at least one side seam (43) in M2.4' and M2.5 would also apply if further side seams extended from another joint between another leaflet and the skirt. As mentioned under clarity, considering that the claim encompasses more than one side seam extending from the same joint is not technically sensible.

- 3.2.2 As regard to point (iv), the Board does not admit the new objections raised for the first time in appeal, pursuant to Article 12(6) RPBA 2020.

The appellant argued that the objections were raised in opposition proceedings and referred to in points 4.1.6 and 5.1.2 of the minutes.

The Board does not agree. Point 4.1.6 referred to auxiliary request 2 in opposition proceedings which did not comprise feature M2.5. So the objections related to this feature could not have been raised.

Furthermore, the Board notes that for auxiliary requests 1, 3 and 4 that contained feature M2.5, the opponent did not raise any objection. Reference is made to points 3.1.2 and 5.1.2 of the minutes.

The appellant further argued that the minutes were not correct and that they had raised an objection on Article 123(2) EPC regarding feature M2.5. However this statement is neither supported by the minutes nor by the decision.

The Board notes that it can only base its assessment on the minutes and the appealed decision. Should the minutes have been erroneous, a correction of the minutes should have been requested as soon as possible. The Board thus has no reason to consider that the minutes are not correct and concludes that the objection under point (iv) above should have been raised in opposition proceedings.

- 3.2.3 The scope of protection defined by the wording of claim 1 has not been broadened, but on the contrary has been limited. Compared to feature M2.4 as granted which read *"at least one lower seam (43) which extends between a lower portion of a joint (27) and the bottom edge"*. The undefined article "a" used in front of the term "joint" in granted claim 1 did not specify which joint it referred to. The use of the expression "one of the" in front of the term "joint" in claim 1 of auxiliary request 4 limits the side seam to extend between one of the joints defined in features M2.1.

Furthermore, granted claim 1 encompasses side seams starting below the joint, whereas feature M2.5 specifies the starting point of the side seam, namely *"from a point on the lower half of the joint 27"*. The above limitation cannot therefore extend the scope of protection as argued by the appellant.

4. Auxiliary request 4 - Novelty - Article 54 EPC

The subject-matter of claim 1 is novel over D2-D7.

During oral proceedings, the appellant argued that the subject-matter of claim 1 was not novel over D2/D2a and D3 and referred to their written submissions for the novelty objections in view of D4, D5, D6 and D7.

#### 4.1 Novelty over D2/D2a

D2/D2a does not disclose directly and unambiguously features M1.1, M2.4' and M2.5.

#### 4.2 Firstly the appellant argued that D2a disclosed a self-expanding frame (feature M1.1). In their view, there was no teaching away from using a self-expanding stent in D2a. While paragraph [0010] referred to a particular expandable stent and its drawbacks, paragraph [0009] referred to the drawbacks related to a balloon expandable valve.

Furthermore, the appellant pointed to paragraph [0022] according to which the stent was made of a nickel-titanium alloy material, a shape-memory alloy, typically used in self expanding stents.

In paragraphs [0075] and [0076] of D2a, the balloon was used to expand the host aortic valve and not the valve prosthesis, which was released after reaching the position of the host aortic valve. The use of the term "released" indicated that the valve prosthetic had a self-expanding frame.

Secondly, features M2.4 and M2.5 were disclosed in figure 19 of D2a. Figure 19 clearly showed sutures of the valve and the stent 4, extending downwardly from a point on a lower half of the joint 5. Similar considerations were also to be derived from figures 1, 11, 12, 13 and 20 in combination with the corresponding description in D2a.

4.3 The Board does not agree. Firstly, while the balloon referred to in the implementation methods 2 and 3 in paragraphs [0075] and [0076] respectively is indeed not used to expand the valve prosthesis, but the host valve, there is no direct and unambiguous disclosure that the valve is self-expanding. The use of nickel-titanium alloy for the stent does not exclude the use of a balloon to expand the stent. While the drawbacks of the valves cited as prior art cannot be regarded as a teaching away from the use of self-expanding stents, as rightly explained by the appellant, there is no direct and unambiguous disclosure of a self-expanding stent either explicit or implicit in D2a. Indeed the term "release" is not proper to self-expanding stent but can equally be used for balloon expanding stent.

Secondly, there is no disclosure of features M2.4' and M2.5. In D2, two embodiments are disclosed: embodiment 1 represented on figures 1-12 and embodiment 2 represented on figures 13-20. While in the valve body of embodiment 1, leaflets are sewn to a skirt (see figures 6-10 and paragraph [0058]), in embodiment 2, the leaflet and parts of the skirt are formed integrally (see figures 15-18 and paragraph [0069]). As claim 1 requires the leaflet to be sewn to a skirt to form joints (feature M2.1) and the side seam extends from a point on a lower half of one of the joints (feature M2.5), only embodiment 1 is to be considered. However, neither the description relating to embodiment 1, nor figures 1, 11 and 12 disclose a side seam that extends between a lower portion of one of the joints and the bottom edge, wherein the at least one side seam extends downwardly between a point on a lower half of one of the joints. Figures 1, 11 and 12 do not depict the suture line of the leaflet and the skirt, they only

depict the leaflet edge 5, such that features M2.4' and M2.5 cannot be derived from these figures.

#### 4.4 Novelty over D3

D3 does not disclose directly and unambiguously feature M2.3.

4.4.1 The appellant argued that feature M2.3 required that a bottom edge of the valve body was sewn to the inflow end of the frame. Page 32, lines 29-31 of D3 explicitly disclosed that *"further, the inner skirt 28 is attached to the cells of the lower crown 24 by means of sutures 14"*. As could be clearly seen from figures 5d and 5e, the lower crown 24 constituted the inflow end of the frame to which the valve body 5 was attached. The appellant also referred to figure 6 and pages 33 and 34 of the description. In this embodiment, the bottom edge of the inner skirt 35 was sewn to the inflow extremity.

4.4.2 The Board does not agree. According to figure 5e and the penultimate sentence of page 32, *"the inner skirt 28 is attached to the cells of the lower crown 24 by means of sutures 14"*. There is thus no disclosure of the bottom edge of valve body being sewn to the inflow end of the frame. Indeed the sutures 14 are not located at the bottom edge of the valve, but above, attached to the middle of the lower crown 24. Figure 6 represents a modified arrangement of the stent component and a modified arrangement of the inner skirt 35 and outer skirt 34. Therefore combining the features of the embodiment depicted in figures 5a-5e with the features of the embodiment depicted in figure 6 does not amount to a direct and unambiguous disclosure of a combination of features of claim 1. For the examination

of novelty different embodiments in a document can only be combined if there is a clear teaching to combine them, which is not the case in D3.

In any case, figure 6 of D3 does not disclose that the bottom edge of the inner skirt 35 is sewn to the inflow end of the frame. Indeed the way the inner skirt is attached to the frame is not disclosed and the end of the frame in figure 6 is formed by the free apexes 50 defining an inflow extremity (see second paragraph of page 33).

#### 4.5 Novelty over D4

D4 does not anticipate features M2.4' and M2.5

4.5.1 The appellant considered a part of the joint (27) between the leaflets and the skirt to be the side seam. The appellant argued that the point on the lower half, from which the side seam extended in feature M2.5 needed not be located in the lower portion. The claim did not provide any relation between the lower portion and the lower half of the joint. Furthermore, claim 1 did not require that the joint be a continuous connection between the leaflet and the skirt. The seam could thus extend from a point on the joint and extend to another point on the joint.

4.5.2 The Board does not agree. This interpretation is artificial and considers the side seam as a part of the joint, whereas claim 1 defines two distinct seams:

- the seam between the leaflets and the skirt, forming a joint;
- the side seam extending downwardly from a point on a lower half of one of the joints.

Figure 5 does not disclose any seam that extends downwardly from a point on a lower half of one of the



curved joint 44. The seam 43 starts from the upper point of the joints 44 and the other seams around the lower part of the valve do not extend from a point on the curved joint 44.

4.6 Novelty over D5, D6 (Article 54(3) document) and D7

D5, D6 and D7 do not anticipate the subject-matter of claim 1.

4.6.1 The appellant argued that the side seams disclosed in all of these documents extended from a connection point at one of the joints between the skirt and the leaflets downwardly to the bottom edge of the frame. This was at least recognisable in figure 6a of D5, figure 3 of D6 and figure 12 of D7.

The subject-matter of claim 1 according to auxiliary request 3 was thus not new in view of each of documents D5, D6 and D7.

4.6.2 The Board does not agree. D5 does not anticipate features M2.1, M2.2, M2.4' and M2.5 in particular as the leaflets are not sewn to the skirt. Indeed in D5, the leaflets are integrally formed with the tissue material of the pieces which together form the skirt portion (D5, page 9, lines 1-15 and figure 1, see bendable transition area 104 forming a junction between the leaflets 102 and the skirt portion 103).

Furthermore, as mentioned by the respondent, D6 does not disclose features M2.4' and M2.5. In D6 there is no direct and unambiguous disclosure that the suture at the struts extend downwardly from a point on a lower half of the seam between the leaflets and the skirt. Paragraph [0052] discloses that "a distance y maybe maintained between the attachment line S and the struts

314". Therefore, the sutures do not extend downwardly from a point on a lower half of the attachment line S.

Finally, paragraph [0050] of D7 is very general: *"Most tissue valves are constructed by sewing the leaflets of pig aortic valves to a stent to hold the leaflets in proper position, or by constructing valve leaflets from the pericardial sac of cows or pigs and sewing them to a stent"*. This paragraph does not anticipate the specific arrangement of the leaflets and the skirt defined in features M2.1 and M2.2:

M2.1 *"i. a plurality of leaflets (22) sewn to a skirt (21) to form joints (27) between each leaflet and the skirt, in which each joint between each leaflet and the skirt is curved to define upper and lower portions of each joint"* and

M2.2 *"ii. adjoining leaflets (22) are sewn together to form commissures (24) which are sewn to the frame downstream of the inflow end"*

Furthermore, figure 12 of D7 illustrating *"a placement of a double polyester (PET) fabric skirt relative to a stent component, according to some embodiments of the present disclosure"* is fuzzy and unclear such that no information as to any side seam can be derived.

Therefore, feature M2.4' and M2.5 are not directly and unambiguously disclosed by figure 12.

5. Auxiliary request 4 - Inventive step - Article 56 EPC

The appellant referred to their written submission for their objections of lack of inventive step of the subject-matter of claim 1.

The Board sees no reasons to depart from its preliminary opinion in its communication pursuant Article 15(1) RPBA 2020 dated 17 October 2022 that the

subject-matter of claim 1 is not rendered obvious starting from D4 in combination with common general knowledge or D13.

- 5.1 The Board agrees with the difference between the subject-matter of claim 1 and D4 and the objective technical problem associated defined identified by the appellant:

The subject-matter of claim 1 differs from D4 in that the at least one side seam extends downwardly from a point on a lower half of the one of the joints.

According to the patent, paragraph [0018], *"one advantage of such an embodiment is the reduction in the amount of any biological response to the seams, e.g., coagulation triggered by stitches or tissue folds"*.

The problem to be solved is regarded as how to reduce the amount of any biological response to the seams, e.g., coagulation triggered by stitches or tissue folds.

- 5.2 According to the appellant, the problem constituted a mere optimization problem. Starting from the embodiment of Fig. 5 in D4, the skilled person knew from basic mathematics that a seam with a smaller length would accumulate less biological material. The skilled person in view of the problem to be solved would consider reducing the length of the seam 43 in figure 5 as this was an obvious modification.
- Therefore, the skilled person would readily consider placing the seam 43 to a location where its length is minimal. This would occur by having the seam 43 extend downwardly from a point on the lower half of the curved joint 44 in figure 5.

Additionally, D13, figure 18, which was very similar to figure 1 of the patent, showed a short seam 61 extending downwardly from the apex of the skirt-leaflet joint. From D4 it would therefore be obvious to place the seam at the shortest distance possible as indicated in D13 which gave a direct hint that the seam could indeed be placed at this position. No technical hindrance occurred as this was a simple repositioning of the seam which the skilled person would find based on a mere optimization calculation.

- 5.3 The Board does not agree. The arguments of the appellant are based on hindsight. It may be known that a shorter seam reduces the amount of biological response to the seam. However, the primary function of the seam is to attach the portions of the skirt together which is to be attached to the frame. The appellant does not take these constraints into consideration.
- Furthermore, figure 18 of D13 shows a short seam 61 extending downwardly. But on figure 18 the seam does not start at the lower apex of the leaflets and the description does not disclose it either.
- Therefore, even if the skilled person would combine the teaching of D4 with the teaching of D13, they would not arrive at the subject-matter of claim 1.

6.

Since the the patent proprietor withdrew its appeal before the decision was announced the appeal fee of the patent proprietor is reimbursed at 25% under Rule 103(4) (a) EPC.

**Order**

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

1. The appeal is dismissed.
2. The appeal fee of the patent proprietor is reimbursed at 25%.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated