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**Datasheet for the decision  
of 29 June 2023**

**Case Number:** T 1192/22 - 3.2.01

**Application Number:** 11718197.4

**Publication Number:** 2560580

**IPC:** A61F2/24

**Language of the proceedings:** EN

**Title of invention:**

PROSTHETIC VALVE WITH SEALING MEMBERS

**Patent Proprietor:**

Medtronic Inc.

**Opponents:**

Abbott Cardiovascular Systems, Inc.  
Neovasc Tiara Inc.  
Boston Scientific Corporation

**Headword:**

**Relevant legal provisions:**

EPC Art. 108, 54  
EPC R. 99  
RPBA 2020 Art. 12(3), 12(5), 13(2)

**Keyword:**

Admissibility of appeal - notice of appeal - (yes)  
Novelty - main request (no) - auxiliary requests 1, 1b, 1c (no)  
Discretion not to admit submission - submission admitted (no)  
Amendment after summons - cogent reasons (no)

**Decisions cited:**

T 0319/18

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 1192/22 - 3.2.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.01**  
**of 29 June 2023**

**Appellant:** Medtronic Inc.  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
10 March 2022 concerning maintenance of the  
European Patent No. 2560580 in amended form.

**Composition of the Board:**

**Chairman** G. Pricolo  
**Members:** S. Mangin  
A. Jimenez

## Summary of Facts and Submissions

- I. The appeals were filed by the appellant (patent proprietor) and appellants 1-3 (respectively opponents 1-3) against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request 1, the patent in suit (hereinafter "the patent") met the requirements of the EPC.
- II. The opposition division held that:
- (i) the main request extended beyond the content of the application as filed (Article 100(c) EPC),
  - (ii) the first auxiliary request fulfilled the requirements of Articles 84 EPC and 123(2) EPC,
  - (iii) the first auxiliary request was novel over:
    - D1/D6 (US 2005/137695 / WO 2005/062980 A2),
    - D3 (US 2004/186563 A1),
    - D7 (WO 2010/008548 A9),
    - D9/D27 (WO 2007/071436 A2 / EP 2 074 964 A1)
    - D10 (WO 2009/024859 A2),
    - D18 (WO 2006/009690 A1),
    - D19 (WO 2010/008549 A1),
    - D20/D25 ( US 2005/0075719 A / WO 2005/046529 A1)and
    - D26 (WO 2009/0421 96 A2)
  - (iv) the first auxiliary request involved an inventive step:
    - starting from D3 in combination with common general knowledge, D20/D25, D26 or D28 (WO 2008/035337 A2),
    - starting from D6 in combination with D3,
    - starting from D19 in combination with D3 and
    - starting from D25 in combination with common general knowledge or D7
  - (v) the invention according to auxiliary request 1 was disclosed in a manner sufficiently clear and complete

for it to be carried out by a person skilled in the art (Article 100(b) EPC).

III. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted or, alternatively, that the patent be maintained on the basis of auxiliary requests 1/1b/1c, 2, 3/3b/3c, 4, 5/5b/5c, 6, 7/7b/7c, 8, 9/9b/9c, 10/10b/10c, and 11/11b/11c filed with the statement of grounds of appeal, corresponding to the requests filed in opposition proceedings on 13 December 2021.

The appellants (opponents 1-3) requested that the decision under appeal be set aside and that the European patent be revoked.

IV. Oral proceedings were held on 29 June 2023 before the Board.

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

F1 A prosthetic heart valve assembly comprising:  
F2 a prosthetic valve (200) including  
F2.1 a circumferential wall having an inner surface and an outer surface,  
F2.2 wherein the prosthetic valve (200) is radially contractible and expandable for transcatheter delivery to a native annulus (304); and comprises  
F3 three commissural posts (214) and  
F4 three sealing members (402)  
F4.1 mounted on the prosthetic valve (200) and substantially evenly placed around the prosthetic valve (200),

**characterized in that**

F4.2 each of said three sealing members (402) being longitudinally aligned with a commissural post (214) of the prosthetic valve (200),

F4.3 wherein the sealing members (402) are configured to engage gaps (302) between the implanted prosthesis and the native valve to prevent paravalvular leakage.

VI. Independent claim 1 of auxiliary request 1 corresponds to claim 1 of the main request with feature F4 being amended as follows:

F4: "three independent sealing members (402)".

VII. Independent claim 1 of auxiliary request 1b corresponds to claim 1 of the main request with feature F4.1 being amended as follows:

F4.1: "mounted on the prosthetic valve (200) and substantially evenly spaced around the prosthetic valve (200)".

VIII. Independent claim 1 of auxiliary request 1c corresponds to claim 1 of the main request with feature F4 of auxiliary request 1 and feature F4.1 of auxiliary request 1b.

## **Reasons for the Decision**

1. Admissibility of the appeal of the appellant 2 (opponent 2) - Article 108 and Rule 99 EPC

The appeal of appellant 2 (opponent 2) is admissible.

1.1 The appellant (proprietor) noted that in the notice of appeal dated 19 May 2022, appellant 2 (opponent 2) neither indicated the correct parties of the present proceedings (but "Neovasc Tiara Inc. ./ . St. Jude

Medical") nor the correct patent number of the presently opposed patent (but "EP 2 866742 BJ").

1.2 The notice of appeal of appellant 2 was filed electronically and as such included a cover sheet "Letter accompanying subsequently filed items" and a document attached thereto designated in the cover sheet as "Notice of appeal" and which is the document referred to above including the erroneous indications. The cover sheet however, identifies the correct application number (11718197.4) and gives the representative's reference (272.00360P) used in first instance proceedings by opponent 2. It is thus evident from the overall circumstances that opponent 2's intention was to indicate the correct case specified on the cover sheet also in the document attached to said cover sheet. Since the impugned decision was readily identifiable, the error is immaterial to the admissibility of the appeal.

2. Main request - Novelty over D3 - Article 54 EPC

The subject-matter of claim 1 is not novel over D3.

2.1 The appellant (proprietor) argued that D3 did not anticipate the subject-matter of claim 1 for the following reasons:

2.1.1 The commissure regions 76 depicted in figures 5 and 8 could not be considered as commissural posts.

The skilled person in the present technical field would not consider an artificially isolated portion of the continuous undulating wire of the frame of figure 5 as a post. Posts as used in the present technical field



were rather vertical elements having a straight shape and not an undulating profile.

- 2.1.2 The panels of tissue 54 depicted in figure 6B could not be considered as sealing members mounted on the prosthetic valve as they were part of the functioning valve.

The panels of tissue 54 spanning the frame of the stent enabled the prosthetic valve to function. Without the panels of tissues 54 the valve could not be functioning, as blood would flow through the stent structure. Therefore, the panels of tissue could not be considered as "mounted on the prosthetic valve" but were part of the valve.

- 2.1.3 The panels of tissue 54 were not configured to engage gaps between the implanted prosthesis and the native valve to prevent paravalvular leakage.

The "panel of fabric or other material 54" was configured to exclusively extend between legs of the stent structure of the prosthesis and stayed within the margin defined by said legs of stent structure, but did not extend to any gap that existed further radially outwardly therefrom, between the prosthesis of reference D3 and the native valve.

A paravalvular leakage, that typically occurred around the outer circumference of a prosthesis, could not occur at the sites where the panels 54 were positioned in the device of reference D3. In the top view of figure 2B the panels could not be identified because they were located beneath the structures to which reference sign "C" pointed to in this figure. Any leakage that might occur at these circumferential

positions around the prosthesis, e.g. through gaps between the prosthesis and the native tissue, could thus not be prevented by said panels 54.

The panels 54 prevented blood leakage through cusps in the closed state of the prosthesis from the interior of the device (D3, paragraphs [0066] and [0080]). This was however not a paravalvular leakage.

- 2.1.4 D3 did not disclose three sealing members being evenly placed around the prosthetic valve and each sealing member being longitudinally aligned with a commissural posts of the prosthetic valve.

Paragraph [0066] of D3 did not refer to the panels of fabric 54 per se, but only to just "some of this panel of fabric 54" i.e. an undefined portion thereof, not the entire panel per se. From the teaching of reference D3, it could not be derived whether these portions of the fabric 54 were "longitudinally aligned with a commissural post" or "evenly spaced around the prosthetic valve", as required by granted claim 1. Moreover, the only position of the "panel of fabric 54" that was explicitly described in reference D3 was that it covered the area "between the inflow or lower edge of each cusp connector 40 and the corresponding commissures 32" (D3, paragraph [0066]), which did not include any space at or on the stent material. Granted claim 1, however, first defined the frame with its posts, before then requiring that the sealing members were "mounted on the prosthetic valve and substantially evenly placed around the prosthetic valve". It remained unclear where this portion of the material was actually positioned and whether it was positioned such as to realize the specific alignments required by granted claim 1 for the sealing members.

2.2 The Board does not agree. D3 discloses all the features of claim 1.

2.2.1 Figures 5 and 8 of D3 disclose three commissural posts.

The three commissure regions 76 longitudinally extending comprising assembly holes for suturing the leaflets are commissural posts. The commissural posts of figures 4 and 6 of the patent are similar to the commissural regions 76 of figure 5 of D3. In both the patent and D3, the commissural posts are an integral part of the stent, are longitudinally extending and comprise holes to suture the leaflets. As noted by the appellants 1-3 (opponents 1-3), the geometry and the structural aspects of the commissural posts are not further specified in claim 1 and cannot be distinguished from the commissural regions of D3.

2.2.2 Figures 3A and 6B disclose sealing members (panels of tissue 54) mounted on the prosthetic valve.

The Board does not agree with the interpretation of claim 1 made by the appellant (proprietor). Claim 1 defines "a prosthetic valve assembly comprising a prosthetic valve (200) (...), and comprises three commissural posts and three sealing members mounted on the prosthetic valve (200) and substantially evenly placed around the prosthetic valve (200)". Although claim 1 describes the commissural posts and the sealing members as being mounted on the prosthetic valve it is clear that both the commissural posts and the sealing members are part of the prosthetic valve. The interpretation of the expression "mounted on the prosthetic valve" made by the appellant (proprietor), considering that the prosthetic valve should be

functioning before the sealing members are added to distinguish claim 1 from D3 is rather artificial. Claim 1 is directed to a prosthetic valve assembly and it is the novelty of this end product with all its features which is to be assessed.

- 2.2.3 The panels of tissue 54 in figures 3A and 6B are configured to engage gaps between the implanted prosthesis and the native valve to prevent paravalvular leakage.

Figures 3A and 6B disclose panels of tissue 54 mounted on the valve. The panels of tissue 54 are attached to the frame of the valve. The Board notes that claim 1 neither specifies how the sealing members should be mounted on the valve, nor the size and the shape of the sealing members. Claim 1 only specifies that *"the sealing members are configured to engage gaps between the implanted prosthesis and the native valve to prevent paravalvular leakage"*, which is the case in D3. Paragraph [0066]:

*"A panel of fabric or other material 54 covers an area between the inflow or lower edge of each cusp connector 40 and the commissures 32. Some of this panel fabric 54 desirably contacts the lumen wall of the aortic valve AV annulus to help prevent leakage around the valve"* and paragraph [0080]:

*"The covers 54 help prevent leakage of blood around the implanted valve 22, and especially in the areas between each pair of cusps 30"*

both disclose directly and unambiguously that the covers 54 prevent paravalvular leakage (leakage around the implanted valve). Therefore, these covers must engage gaps between the implanted prosthesis and the native valve otherwise they could not prevent leakage.

2.2.4 D3 discloses three sealing members being evenly spaced around the prosthetic valve and being longitudinally aligned with a commissural posts of the prosthetic valve.

As can be seen in figures 4 and 5, the commissural posts are evenly placed and spaced around the support frame. According to paragraph [0066] of D3, the panel of fabric covers an area between the lower edge of each cusps connector 40 and the corresponding commissures 32. Therefore, the panels of fabric 54 are longitudinally aligned with the commissure posts and are, similarly to the commissural posts, evenly placed around the valve. The panels of fabric in D3 also extend circumferentially around the prosthetic valve and radially. This is however not excluded by claim 1 and is certainly comparable to the sealing members of figures 4 and 6 of the patent, which have a certain width and thickness. Finally the entire panel cloth should be considered and not just a part of it for the longitudinal alignment with the commissural posts. Indeed claim 1 requires the sealing members to be longitudinally aligned with the commissural posts and not just the portion engaging the gaps between the implanted prosthesis and the native valve.

3. Auxiliary request 1 - Novelty over D3

The subject-matter of claim 1 of auxiliary request 1 specifies that the three sealing members are independent. The addition of this feature does not confer novelty to the subject-matter of claim 1 over D3.

3.1 The appellant (proprietor) argued that the panels of fabric in D3 were not independent from each other. The

term "independent" should be understood as structurally separate, that meant, each sealing member being a separate entity.

3.2 The Board does not follow the arguments of the appellant (proprietor). The panels of cloth 54 are separate panels covering an area between the lower edge of each cusp connector and the commissures 32. While the panels of cloth may be indirectly connected via the cusps 30, they are still independent, i.e distinct panels of cloth and assuring their sealing function independently from each other. The three panels of cloth 54 can therefore be considered as independent.

4. Auxiliary request 1b - Novelty over D3

The subject-matter of claim 1 of auxiliary request 1b differs from claim 1 of the main request in that the term "placed" has been replaced by "spaced". This amendment does not confer novelty to the subject-matter of claim 1 over D3.

4.1.1 The appellant (proprietor) relied on their arguments provided for the main request.

4.1.2 In the context of the invention the Board considers that the terms "placed" and "spaced" have the same meaning. The three commissural posts and the three sealing members (panels of fabric 54) are evenly positioned around the prosthetic valve as can be seen in figures 5, 3A and 6B in combination with paragraphs [0066] and [0080] and therefore anticipates feature F4.1.

5. Auxiliary request 1c - Novelty over D3

The subject-matter of claim 1 of auxiliary request 1c is a combination of the subject-matter of claim 1 of auxiliary requests 1 and 1b, i.e. comprising the term "independent" and the term "spaced" instead of the term "placed". For the same reason as for auxiliary requests 1 and 1b, the Board judges that the subject-matter of claim 1 of auxiliary request 1c is not novel over D3.

6. Auxiliary requests 2-11c - Admissibility

Auxiliary requests 2-11c are not admitted in the proceedings pursuant to Article 12(3) RPBA 2020 in conjunction with Article 12(5) RPBA 2020.

6.1 Auxiliary requests 2-11c were submitted by the appellant (proprietor) with their letter of 31 December 2021 in opposition proceedings. After identifying the amendments and providing the basis, the appellant (proprietor) added

- for auxiliary requests 2, 4, 6 and 8:

*"With this request, patentee addresses, for example, the objection raised under Art. 100(a) EPC against claim 1 (see also item 8.7 of the preliminary opinion). Accordingly, this request complies with Rule 80 EPC".*

- for auxiliary requests 3, 3b, 3c, 5, 5b, 5c, 7, 7b, 7c, 9, 9b, 9c, 10, 10b, 10c, 11, 11b, 11c:

*"With these requests, patentee addresses, for example, the objection raised under Art. 100(a) and (c) EPC against claim 1 (see also items 6.3 and 8.7 of the preliminary opinion). Accordingly, these requests comply with Rule 80 EPC".*

With their statement of grounds of appeal, the appellant submitted auxiliary requests 2-11c and copied and pasted the above mentioned submissions related to

auxiliary requests 2-11c made in opposition proceedings.

- 6.2 With their statement of grounds of appeal the appellants 1-3 (opponents 1-3) raised novelty and inventive step objections against claim 1 of the main request and/or auxiliary request 1.

Appellant 1 (opponent 1) raised lack of novelty objections against claim 1 of auxiliary request 1 in view of D1/D6, D3, D7, D9, D20 and D26 and inventive step objections in view of D7 alone. Appellant 1 (opponent 1) further raised objections against the granted dependent claims.

Appellant 2 (opponent 2) raised lack of novelty objections against the subject-matter of claim 1 of the main request in view of D1/D6, D3, D7, D18, D19 and inventive step objections in view of D7 alone or D17 in combination with D7. Appellant 2 (opponent 2) further raised lack of novelty objections against the subject-matter of claim 1 of auxiliary request 1 in view of D1, D3, D7, D18 and D19 and lack of inventive step objections over D19 in combination with common general knowledge/D2/D3/D17.

Appellant 3 (opponent 3) raised lack of novelty objections against the subject-matter of claim 1 of the main request in view of D1/D6, D3, D7, D19 and inventive step objections in view of D7 alone or starting from any stent-valve with commissural posts in combination with D6. Appellant 3 (opponent 3) further raised lack of novelty objections against the subject-matter of claim 1 of auxiliary request 1 in view of D1/D6, D3, D7 and D19 and lack of inventive step objections starting from D3 in combination with D20,



D26, D28 and starting from D19. Finally Appellant 3 (opponent 3) raised objections against the auxiliary requests 1b-11c.

6.3 With the reply to the statement of grounds of appeal of the appellants-opponents the appellant-proprietor did not make any submission regarding the auxiliary requests 2-11c.

6.4 With their reply, appellant 1 (opponent 1) argued that in the appellant's (proprietor's) statement of grounds of appeal, there were no discussion as to which of the several specific objections raised by the appellants 1-3 (opponents) was intended to be addressed by the amendments made in the auxiliary requests. In their view it was not self-explanatory at first glance how the auxiliary requests 1b-11c should overcome the objections raised by the appellants 1-3 (opponents 1-3 respectively) for lack of novelty and inventive step. Appellant 1 (opponent 1) requested the rejections of the auxiliary requests, apart from auxiliary request 1, as being not substantiated.

With their reply, appellant 2 (opponent 2) argued that for auxiliary requests 2-11c the proprietor did not state which objections were addressed by the amendments under Article 100(a) EPC and failed to provide a substantiation. Appellant 2 (opponent 2) further noted that it was unclear how the amendments could restore novelty in view of the prior art.

6.5 The Board indicated under point 10 of the communication under Article 15(1) RPBA 2020 that at this stage the patentability of the auxiliary requests 2-11c had not been substantiated.

6.6 With letter of 13 April 2023, the appellant (proprietor) contested the lack of substantiation of the auxiliary requests as according to them, it was the natural assumption that the addition of features addressing objections under Art. 100(a) EPC was to overcome said objections by the presence of the added feature. They further stated that none of the features added to auxiliary requests 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11 were disclosed in D3 and D19.

6.7 The appellant (proprietor) further argued that all the auxiliary requests 1-11c were already submitted and substantiated in opposition and that their admissibility was never contested by the opponents. At the stage of the first-instance opposition proceedings, the requests were thus admissibly filed. The same requests were filed with the statement of grounds of appeal. Their admissibility could therefore not be put into question.

Furthermore, with the statement of grounds of appeal, the requests were substantiated. The amendments made were highlighted and the basis for the amendments was provided. Furthermore adding a limitation to a claim that had been attacked under lack of novelty (or inventive step) in view of several cited references naturally addressed these objections by attempting to distinguish the claim and thus at least rendering it novel over the references by said very additional limitation.

6.8 The Board does not agree.

6.8.1 In accordance with the principles underlying Article 12(3) RPBA 2020, the statement of grounds of appeal and any reply to it must contain the party's complete case. Accordingly, they shall set out clearly and concisely

the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should specify expressly all the requests, facts, objections, arguments and evidence relied on. Furthermore, taken as a whole, the Rules of Procedures of the Board of appeal make it clear that appeal proceedings are primarily written in nature. The purpose of these provisions is to ensure fair proceedings for all parties and to enable the Board to start working on the case on the basis of each party's complete submissions. In inter partes proceedings, both rights and obligations should be divided equally among the parties so that the Board can perform its independent judicial function. Under Article 12(5) RPBA 2020, a Board has discretion not to admit any part of a submission on appeal which does not meet the requirements in Article 12(3) RPBA 2020.

Reference is made to the 10th edition of the case Law V.A.4.3.5 "Incomplete case in grounds of appeal or reply - Article 12(3) RPBA 2020 in conjunction with Article 12(5) RPBA 2020".

6.8.2 While the auxiliary requests 2-11c filed with the statement of grounds of appeal correspond to the auxiliary requests 2-11c filed in opposition, these requests were not substantiated neither with the statement of grounds of appeal nor with the reply. The appellant (proprietor) merely stated that these requests addressed, for example, the objections raised under Article 100(a) EPC or the objections raised under Article 100(a) and (c) against claim 1. The appellant (proprietor) did not explain how the amendments concretely addressed the specific lack of novelty and inventive step objections that were raised for the main request by the appellants 1-3 (opponents 1-3). Reasons for the amendments made to restore novelty over the

documents cited against novelty were not addressed. Furthermore, reasons for the amendments made to address the inventive step objections were not submitted. Without any indication of how the added features render the subject-matter of claim 1 novel and/or inventive over the cited prior art, the appellant (patent proprietor) put the onus on the Board and the appellants 1-3 (opponents 1-3) to deduce the case being made themselves and come up with suitable responses, which is at odds with the requirements of Article 12(3) RPBA 2020.

- 6.8.3 With letter of 13 April 2023, the appellant (proprietor) stated that none of the added features to claim 1 of the auxiliary requests were disclosed in either document D3 or D19 and thereby addressed the novelty objections. The Board notes that these submissions only addressed the novelty objection raised in view of D3 and D19 and did not address the other novelty objections nor the inventive step objections. In any case the substantiation of the auxiliary requests 2-11c comes after the summons to oral proceedings and after the Board's communication under Article 15(1) RPBA 2020. Pursuant to Article 13(2) RPBA 2020 the Board shall not take into account such late filings unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned. In the present case there was no reason to delay the substantiation of the requests (reference is made to decision T 319/18).

**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