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**Datasheet for the decision
of 3 March 2023**

Case Number: T 1507/18 - 3.2.08

Application Number: 07827132.7

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Title of invention:
FIXATION MEMBER FOR VALVE

Patent Proprietor:
Medtronic Ventor Technologies Ltd.

Opponent:
Jenavalve Technology, Inc.

Relevant legal provisions:
EPC Art. 54(2)

Keyword:
Novelty - main request (yes)



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Case Number: T 1507/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 3 March 2023

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
16 April 2018 concerning maintenance of the
European Patent No. 2068767 in amended form.**

Composition of the Board:

Chairwoman Y. Podbielski
Members: G. Buchmann
A. Björklund

Summary of Facts and Submissions

- I. The opposition division had decided that European patent No. 2 068 767 in amended form fulfilled the requirements of the EPC.
- II. Both parties filed an appeal against that decision.
- III. Oral proceedings took place before the Board on 3 March 2023.
- IV. The main request of Appellant 1 (patent proprietor) was that the decision under appeal be set aside and the patent be maintained as granted.
- V. Appellant 2 (opponent) requested that the decision under appeal be set aside and the patent be revoked.
- VI. In the present decision, reference is made to the following documents:
- D1 US 2003/0036791 A1
D2 WO 2004/082527 A2
D5 WO 2004/019825 A1
D8 US 2005/0137691 A1
- VII. Claim 1 of the current **main request** reads as follows (the numbering of the features has been added by the Board).

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"A prosthesis (10) for implantation at a native semilunar valve of a native valve complex of a subject, the native valve complex having three semilunar sinuses and three native commissures, the prosthesis comprising

a valve prosthesis support, for supporting a prosthetic valve, characterised by

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the support comprising: a support structure (14) comprising exactly three engagement arms (22) that meet one another at three respective junctures, wherein the engagement arms are shaped so as to define three peak complexes at the three respective junctures, and three trough complexes, each of which is between two of the peak complexes,

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wherein each of the peak complexes includes m local peaks and $m-1$ local troughs, where m is greater than or equal to 1;

4

wherein each of the trough complexes includes n local troughs and $n-1$ local peaks, where n is greater than or equal to 1; and

5

wherein, upon implantation of the prosthesis, each of the engagement arms is at least partially disposed within a respective one of the semilunar sinuses, such that each of the peak complexes is disposed distal to and in rotational alignment with a respective one of the native commissures, and each of the trough complexes is disposed at least partially within the respective one of the semilunar sinuses."

VIII. The arguments of appellant 1 can be summarised as follows:

Main request - amendments

Claim 1 as granted was mainly based on claim 189 as originally filed which disclosed a prosthesis comprising a single support structure. It was allowable

under Article 123(2) EPC to add Features 3 and 4 from the description.

Main Request - Novelty

Novelty over D1

Figure 5 of D1 showed a support structure having (proximal) trough complexes 31 consisting of one local trough (not indicated correctly in the figure). The reference number 30 was located even more proximal and represented a local trough between two local peaks of the peak complexes.

In order to fulfill Feature 5 of claim 1, the peak complexes must be disposed distal to the trough complexes by a certain distance which is sufficient to bridge the distance between the commissures and the semilunar sinuses. This was not disclosed by D1.

Novelty over D5

D5 did not show the relationship of the commissures and the peak complexes of the support structure as specified in Feature 5. The valve prosthesis of D5 could be correctly implanted while the peak complexes of the support structure were disposed proximal of the native commissures.

Novelty over D2

D2 did at least not disclose Feature 5 of claim 1.

Novelty over D8

D8 did at least not disclose Feature 5 of claim 1.

- IX. The arguments of appellant 2 can be summarised as follows:

Main request - amendments

Claim 1 as granted defined a prosthesis having one support structure, whereas the application as originally filed disclosed a prosthesis having an inner and an outer support structure. Furthermore, it was not allowable under Article 123(2) EPC to add Features 3 and 4 of the (outer) support structure to the claim, from an embodiment which comprised two support structures.

Main Request - Novelty

Lack of Novelty over D1

Figure 5 of D1 showed a support structure having (proximal) trough complexes 31 consisting of four local troughs and three local peaks. The reference number 30 designated the (distal) peak complexes consisting of a single peak.

A proper implantation of the prosthesis was only possible if the peak complexes were disposed distal of the native commissures.

Lack of Novelty over D5

D5 disclosed a valve prosthesis including a support structure 1. The support structure comprised three

support hoops forming engagement arms (Stützbügel 2), each forming a trough complex to be disposed within a semilunar sinus. The support hoops also formed peak complexes at the juncture there between. The correct implantation of the valve prosthesis was only possible if the peaks were located distal of the native commissures.

Lack of Novelty over D2

D2 disclosed all features of claim 1, in particular each apex of the cusp positioners 42 of the support structure of D2 could be regarded as a juncture in the sense of claim 1 (Figures 2 and 3).

Lack of Novelty over D8

Figure 3 of D8 disclosed a support structure (620) including three engagement arms connected at junctions forming peak complexes. Three trough complexes were present between the peak complexes.

Reasons for the Decision

1. Main request - amendments - Article 123(2) EPC
- 1.1 According to the objection of appellant 2, claim 1 as granted defined a prosthesis having one support structure, whereas the application as originally filed disclosed a prosthesis having an inner and an outer support structure. Throughout the description, the prosthesis comprised both an inner and an outer support structure. A prosthesis with only one support structure was not disclosed.

1.2 Claim 1 as granted is mainly based on claim 189 as originally filed. This claim specifies an "apparatus comprising a prosthesis... comprising a valve prosthesis support...". This definition explicitly includes an apparatus comprising a prosthesis which has only one prosthesis support. Furthermore, a prosthesis alone can already represent an "apparatus comprising a prosthesis". Therefore, claim 189 as originally filed discloses a prosthesis comprising a single support structure. This general disclosure is present in the application as filed even if all described embodiments refer to prostheses which have two support structures.

1.3 Appellant 2 further argued that Features F3 and F4 which were added to claim 189 before grant, had been unallowably isolated from an embodiment that included an inner and an outer support structure (page 78, line 22 - page 79, line 3 and Figure 3E).

However, the inserted features of the (outer) support structure in the claim are completely independent from the existence or function of the inner support structure. Furthermore, Figures 3A-E are particularly intended to illustrate configurations of the outer support structure only (page 77, lines 30-31).

Therefore, the outer support structure of claim 189 as originally filed may be specified by the features described in view of Figure 3E without violating Article 123(2) EPC.

1.4 Therefore, the ground of opposition under Article 100(c) EPC does not stand against the maintenance of the patent as granted.

2. Main request - novelty - Article 54(2) EPC

2.1 Novelty over D1

2.1.1 D1 discloses a valve prosthesis comprising a valve prosthesis support. The support comprises a support structure (20, 30, 31) comprising exactly three engagement arms (feeler elements 30, 31) that meet one another at three respective junctures (they are connected to an undulated ring, Figure 5), wherein the engagement arms are shaped so as to define three peak complexes at the three respective junctures, and three trough complexes, each of which is between two of the peak complexes.

The parties agreed that the term "distal" meant "away from the heart" and corresponded to the relative location of the "peaks" whereas "proximal" meant "close to the heart" and corresponded to the relative location of the "troughs".

2.1.2 In order to assess novelty of claim 1 with respect to D1, it had to be clarified whether the feelers 30 or the feelers 31 were oriented proximally or distally, respectively.

a)

According to appellant 2, Figure 5 of D1 showed a support structure having (proximal) trough complexes 31 consisting of four local troughs and three local peaks. The reference number 30 designated the (distal) peak complexes, each consisting of a single peak.

The Board notes that this interpretation of Figure 5 is consistent with Figure 3 where the reference numeral 30 is located more distally than reference number 31. It

is, however, inconsistent with Figures 1 and 2 where the reference number 30 is located more proximally than the reference number 31. It is also not in accordance with Figure 6 which shows one single loop forming the trough complex 31 whereas Figure 5 allows - in the interpretation of appellant 2 - only four or two local troughs forming the trough complex.

b)

According to appellant 1, Figure 5 of D1 showed a support structure having (proximal) trough complexes 31 consisting of one local trough (not indicated correctly in the figure). The reference number 30 was located even more proximally and represented a local trough between two local peaks of the peak complexes. Appellant 1 based this interpretation on the fact that Figure 2 showed a portion of the prosthesis which was not surrounded by the support structure. This portion was located at the distal end of the prosthesis.

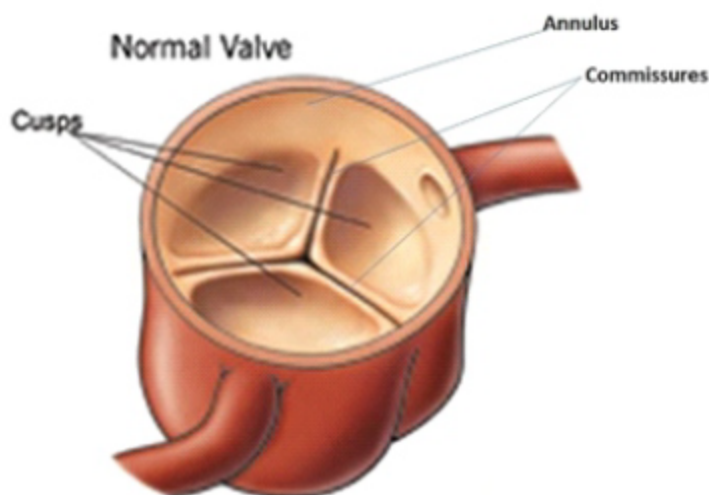
The Board notes that this interpretation is partially consistent with Figure 4 which shows the loop 30 at the most proximal end of the prosthesis and the portion without support at the distal end. This interpretation is, however, not consistent with the fact that in Figure 4, the loop 31 then appears to be oriented distally. It is also not consistent with Figure 3 where the reference number 30 is located distal of the loops 31.

c)

From the above, it results that the disclosure of D1 is not unambiguous with respect to the proximal/distal orientation of the loops of the wavy support structure shown in Figure 5. Moreover, it is not unambiguously disclosed to which extent the peak complexes are

located distal to the trough complexes in the expanded state of the support. This property is, however, important to fulfill Feature 5 of claim 1 which requires that "each of the peak complexes is disposed distal to ... the native commissures" while "each of the trough complexes is disposed at least partially within the respective one of the semilunar sinuses."

2.1.3 The native commissures are anatomically located at the top end of the attachment of the valve leaflets to the aortic wall, at the point where the valve leaflets meet. The upper edges of the leaflets extend in a curved shape between the commissures. Behind the valve leaflets, towards the aortic wall, the semilunar sinuses (or cusps) extend radially outward beyond the diameter of the tubular shape of the aorta. This anatomy is shown in an exemplary manner in the following figure which was submitted by appellant 2.



Therefore, in order to fulfill Feature 5, the peak complexes must be disposed distally of the trough complexes by a certain distance which is sufficient to bridge the distance between the commissures and the

semilunar sinuses.

Such a distance is neither implicitly nor explicitly disclosed in D1. In particular, D1 does not disclose the location of the commissures relative to the implanted prosthesis. On the contrary, Figures 2 and 3 show the openings of the coronary arteries 52 which are anatomically located proximally of the commissures, at a location close to the distal end of the prosthesis. Both the feelers 30 and the feelers 31 are shown as located proximally of the coronary arteries. Therefore, it is not unambiguously shown whether the peak complexes of the support structure of D1, i.e. the most distal loops of the waveform of the support structure shown in Figure 5, are disposed distally of the commissures, or not.

- 2.1.4 According to appellant 2, the Figures 1 and 2 should not be taken into account in view of the question whether the peak complexes were located distally of the native commissures, because they did not show the implanted state of the prosthesis, but the crimped state. However, Figure 2 shows the anatomy in relation to the already expanded support structure. Only the carrier element 20 is shown in the crimped state.

Appellant 2 argued that the definition of Feature 5 only referred to the anatomy of "a subject" (see Feature 1). This included subjects which have anatomically differing sizes and geometries. Hence, for the support structure disclosed by D1, a subject could always be found so that the support structure fulfilled the requirements of Feature 5.

The Board is not convinced. Even if the dimensions of the anatomy vary to a certain extent, the proportions

of e.g. the diameter of the heart valve and the longitudinal location of the commissures are anatomically well defined. Therefore, a prosthesis adapted to a certain diameter must have longitudinal dimensions adapted thereto in order to be regarded as suitable as a valve prosthesis for implantation at a semilunar valve.

Appellant 2 further argued that the claim only refers to a "semilunar valve", not to the aortic valve. However, the patent refers also to the pulmonary valve (paragraphs [0046]-[0047]) which is the second semilunar valve of the heart and has a well defined anatomy. The claim is valid for both semilunar valves. The prosthesis of D1 does not fulfil the requirements of feature 5 with regard to either of these valves.

2.1.5 For the reasons given above, the subject-matter of claim 1 as granted is not unambiguously disclosed in D1, and is therefore novel over D1.

2.2 Novelty over D5

D5 discloses a prosthesis for implantation at a native semilunar valve including a support structure (1). The support structure comprises three support hoops forming engagement arms (Stützbügel 2), each forming a trough complex to be disposed within a semilunar sinus (page 5, lines 1-13 and Figure 3c). The support hoops also form peak complexes at the juncture there between (Figure 6).

2.2.1 Feature 5 was the only disputed feature in view of novelty over D5. D5 does not explicitly disclose that "each of the peak complexes is disposed distal to and in rotational alignment with a respective one of the

native commissures" while "each of the trough complexes is disposed at least partially within the respective one of the semilunar sinuses", as required by Feature 5.

2.2.2 Appellant 2 argued that the support structure of D5 further comprised commissure hoops (Kommissurenbügel 3, Figure 6). The support hoops 2 and the commissure hoops 3 clamped the native valve leaflets like a paper clamp (page 6, lines 23-30). This was only possible if the common connection point of the support hoops and the commissure hoops (i.e. the peak complex) was located distally of the commissures.

However, the Board notes that due to the flexibility of the valve leaflets and the curved shape of the upper edges of the valve leaflets (as explained above in point 2.1.3), it is possible to arrange the peak complex proximally of the commissures. This is normally associated with impinging on the commissures or folding over of the leaflets, and it is avoided by the geometry as defined by Feature 5, see e.g. paragraphs [0302] or [0353] of the patent.

2.2.3 In addition to the above, the figures of D5 do not show the relationship of the commissures and the support hoops as specified in Feature 5. Figures 3c and 3d show the native aortic valve including a cross section of the leaflets, and the coronary openings (black circles close to the tips of arrows 2). In Figure 3d which shows the support in an expanded state, it is assumed that the bold black lines represent the support hoops 2, in analogy to Figure 3c. These are, however, completely depicted proximally of the coronary openings and consequently of the native commissures. This is in

contrast to Feature 5.

2.2.4 The parties also discussed the passage on page 16, line 29 - page 17, line 3 of D5. This passage describes that the prosthetic valve is located in the support structure at the same level as the junctures of the three support hoops 2. Given that there is no further information about the type of the valve, this description does not allow the conclusion that these junctures are to be disposed distally of the native commissures.

2.2.5 Therefore, document D5 does not unambiguously disclose the subject-matter of claim 1 as granted.

2.3 Novelty over D2

2.3.1 Document D2 discloses an aortic valve prosthesis which has "cusp positioners" which press the native leaflets outwardly towards the semilunar sinuses. No part of the valve is intended to be positioned inside the semilunar sinus, as it is required by the claim.

2.3.2 The main argument of appellant 2 was that each apex of the cusp positioners 42 of the support structure of D2 can be regarded as a juncture in the sense of claim 1 (see Figures 2 and 3). However, this implies that in order to fulfil the claim features, the valve of D2 must be implanted by inserting the cusp connectors 40 into the semilunar sinuses. This would result in a position of the prosthesis which is contrary to the teaching of D2 (rotated by 60°) which describes that the cusp connectors 40 and the commissures 32 of the prosthesis are to be aligned with the native commissures (paragraph [0054]-[0055]). Only in this wrong rotational position do they fulfil the definition

of Feature 5 according to which the peak complexes (allegedly formed by the junctures or cusp positioners 42) are in rotational alignment with the native commissures. A reader skilled in the art would not interpret D2 in this way.

2.3.3 Furthermore, appellant 2 did not demonstrate how that part of Feature 5 according to which "each of the peak complexes is disposed distal to ... the native commissures" while "each of the trough complexes is disposed at least partially within the respective one of the semilunar sinuses", would be fulfilled by the prosthesis shown in D2.

2.3.4 Therefore, document D2 does not disclose the subject-matter of claim 1 as granted.

2.4 Novelty over D8

2.4.1 According to appellant 2, Figure 3A-3D of D8 disclosed a support structure 620 including three engagement arms connected at junctions forming peak complexes. Three trough complexes were present between the peak complexes, so that Features 1-4 were disclosed by D8.

However, the description of "Figure 3" (paragraphs [0041]-[0043]) does not match with Figures 3A-3D. Also paragraph [0054] which appellant 2 referred to, does match to Figures 7A-7I as alleged by appellant 2. Appellant 2 did not explain whether any parts of the description of D8 referred to Figures 3A-D and would describe the components and the function of the structures depicted in these figures.

2.4.2 The figures alone do not provide sufficient information as to any technical features which would correspond to

the features of claim 1.

- 2.4.3 Therefore, it was not demonstrated that D8 discloses the subject-matter of claim 1 as granted.
- 2.5 For the above reasons, the ground of opposition under Article 100(a) EPC (novelty) does not stand against the maintenance of the patent as granted.
3. No further grounds of opposition were raised against the main request.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is maintained as granted.

The Registrar:

The Chairwoman:



C. Moser

Y. Podbielski

Decision electronically authenticated