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**Datasheet for the decision
of 22 February 2022**

Case Number: T 1314/17 - 3.2.08

Application Number: 11156387.0

Publication Number: 2335649

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
Heart valve prothesis

Patent Proprietor:
Medtronic CV Luxembourg S.à.r.l.

Opponent:
BIOTRONIK AG

Relevant legal provisions:
EPC Art. 54(2), 76(1)
RPBA Art. 12(4)

Keyword:
Divisional application - added subject-matter (no) - after
amendment
Novelty - (yes)

Catchword:



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Case Number: T 1314/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 22 February 2022

Appellant: BIOTRONIK AG
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 3 April 2017
rejecting the opposition filed against European
patent No. 2335649 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: G. Buchmann
Y. Podbielski

Summary of Facts and Submissions

- I. With the decision posted on 3 April 2017 the opposition division decided that European patent No. EP 2 335 649 fulfilled the requirements of the EPC.
- II. The opponent filed an appeal against that decision.
- III. Oral proceedings in the form of a videoconference took place before the Board on 22 February 2022. The appellant (opponent) did not attend the oral proceedings.
- IV. At the end of the oral proceedings, the respondent's (patent proprietor's) requests were that the appeal be dismissed, i.e. that the patent be maintained as granted, or that the patent be maintained on the basis of auxiliary request 7 filed on 21 December 2016.
- V. The appellant requested that the decision under appeal be set aside and the patent be revoked. They furthermore requested not to admit auxiliary request 7 into the proceedings.
- VI. In the present decision, reference is made to the following documents:

D2: "Percutaneous Aortic Valve Replacement with a Self-Expanding Stent: The CoreValve ReValving", Cath Lab Digest, Volume 12, Issue 11, November 2004

D3: T. Feldman "Percutaneous Valve Intervention", published on 08.04.2005 at www.tctmd.cpm

D3c: Colour version of D3, page 38

D4: www.corevalve.com as of December 2004
(<https://web.archive.org/web/20041211102847/http://www.corevalve.com/corevalve.htm>)

D4a: Colour version of D4

VII. Claim 1 of the **main request** reads as follows.

The numbering of the features is as proposed by the appellant. The amendments compared to a combination of original claims 1, 9 and 10 are indicated.

"A valve prosthesis (10), comprising:

1

a self-expanding multi-level frame (12)

1.1

having a contracted delivery configuration and an expanded deployed configuration,
~~the multi level frame having in the expanded deployed configuration an enlarged outflow section with a first nominal diameter, a conical inflow section having a second nominal diameter and a constriction region having a third fixed diameter smaller than the first and second nominal diameters;~~

1.2

and a cell pattern that defines contours;

1.3

the cell pattern comprising a plurality of cells having sizes that vary along the length of the prosthesis,

1.4

wherein each cell comprises two zigzag structures having unequal-length struts, wherein the vertices of the zig-zags are coupled together,

2

a valve body (14) affixed to the multi-level frame, the valve body comprising

2.1

a plurality of leaflets affixed to a skirt (21) at joints (24, 27), the joints being affixed to, and supported by, the contours, to evenly distribute forces through the valve body to the multi-level frame, wherein the joints comprise:

2.1.1

commissures (24) between adjoining pairs of the leaflets at lateral ends thereof;

2.1.2

and respective, curved, joints (27) between the base of each leaflet and the skirt following the contours of the multi-level frame so that most of the length of the joint (27) is directly supported by the frame (12)."

VIII. In **auxiliary request 7** the feature omitted from Feature 1.1 was re-introduced into claim 1.

It specifies that

"the multi-level frame has levels (15, 16, 17), in the expanded deployed configuration, of an enlarged outflow section (15) with a first nominal diameter, a conical inflow section (16) having a second nominal diameter and a constriction region (17) having a third fixed diameter smaller than the first and second nominal

diameters".

This feature was also called the "hourglass shape" by the parties.

IX. **The relevant arguments of the respondent can be summarised as follows:**

Main request - added subject-matter - Article 76(1) EPC

Claim 1 as granted could be derived from independent claim 27 of the parent application in combination with claims 32, 33, 35, 36 and 43 which depended therefrom. These claims disclosed a valve prosthesis comprising the features of claim 1 as granted, and without the disputed omitted feature.

Alternatively, claim 1 as granted could be based on claims 1, 9 and 10 and on the description of the parent application. Features 1.3 and 1.4 which referred to the design of the individual cells, were disclosed on page 12, lines 23-29. Their effects as described on page 13, lines 1-3 had no functional link with the omitted feature which related only to the overall shape of the frame. There was a clear distinction between the individual cell design and the overall cell pattern.

Additionally, the omitted feature defining the hourglass shape of the frame was not essential to the invention underlying the divisional application and could, therefore, be omitted.

Admittance of auxiliary request 7

The auxiliary request had been filed during the opposition proceedings and was maintained with the

reply to the grounds of appeal. Therefore, it had to be admitted into the appeal proceedings.

Auxiliary request 7 - novelty - Article 54(2) EPC

D3c did not disclose any "joint" between a leaflet and the skirt of the valve body. A shading of the colours in the picture of D3c could result from a change in the surface structure or from illumination effects. Therefore, a "joint" in the sense of the claim was not directly and unambiguously derivable from D3c.

X. **The relevant arguments of the appellant can be summarised as follows:**

Main request - added subject-matter - Article 76(1) EPC

The features 1.3 and 1.4 which were introduced into claim 1 as granted, defined the cell pattern of the frame. These features were functionally linked with the hourglass shape of the frame. This shape was present in claim 1 of the parent application and could not be omitted from claim 1 as granted.

Admittance of auxiliary request 7

The auxiliary requests filed with the reply to the appeal did not contain convergent subject-matter. They should, therefore, not be admitted.

Auxiliary request 7 - novelty - Article 54(2) EPC

The documents D2, D3, D3c and D4a which showed the "CoreValve" disclosed all features of claim 1.

Regarding the features 1, 1.1, 1.2, 1.3, 2, 2.1 and

2.1.1, a general reference to the opposition proceedings was made.

Reasons for the Decision

1. Main Request - Added Subject-Matter - Article 76 (1) EPC

1.1 The patent in suit is based upon a divisional application of an earlier application (parent application) which had been published as WO 2006/124649 A1.

The description of the divisional application as filed corresponds to that of the parent application as filed. The claims of the parent application were included as "paragraphs" into the divisional application. It follows that when the requirements of Article 76(1) EPC are met, the requirements of Article 123(2) EPC are also met.

1.2 The respondent suggested that claim 1 as granted could be derived from independent claim 27 of the parent application in combination with claims 32, 33, 35, 36 and 43 which depended therefrom. These claims disclosed a valve prosthesis comprising the features of claim 1 as granted, and without the disputed feature.

However, the valve prosthesis of claim 1 as granted comprises a multi-level frame (Feature 1). The combination of features of claims 27, 32, 33, 35, 36 and 43 of the parent application does not comprise a multi-level frame according to Feature 1. Therefore, claim 1 as granted is not derivable from these claims.

- 1.3 Claim 1 as granted is mainly based on claims 1, 9 and 10 of the parent application as well as the description, page 12, lines 23-29 and page 15, lines 21-29.

Claim 1 of the parent application included the feature according to which "the multi-level frame having in the expanded deployed configuration an enlarged outflow section with a first nominal diameter, a conical inflow section having a second nominal diameter and a constriction region having a third fixed diameter smaller than the first and second nominal diameters" (the "hourglass shape").

This feature was omitted from claim 1 as granted.

- 1.4 Features 1.3 and 1.4 are taken from Page 12, lines 24-29. This passage is part of a paragraph which describes an embodiment having multiple levels, corresponding to Feature 1 of claim 1 as granted.

From page 12, line 30 on, the paragraph further explains the effect of these features, namely to permit the cells of each level to meet specific design requirements such as compressibility, expansion characteristics, radial strength and to define a suitable contour for attachment of the valve body.

Contrary to the respondent's arguments, these effects do not only relate to the adaptation of the contours of individual cells to the joints of the valve body. In fact, compressibility, expansion characteristics and radial strength refer to the overall shape of the frame. Therefore, it must be concluded that the Features 1.3 and 1.4 as described in said passage, are functionally linked with the overall shape of the

frame.

In addition, page 13, lines 4-8, describes that the cell pattern (of the embodiment discussed from page 12 on) "enables the frame to expand to the tri-level asymmetric hourglass shape depicted in figure 1A, having conical inflow section, enlarged outflow section and fixed diameter constricted region". This is an explicit link between the cell pattern and the hourglass shape of the frame which was omitted from claim 1 as granted.

The respondent argued that the "cell pattern" was linked with the overall shape of the frame whereas the "cell design" was related to the shape of individual cells. This distinction can, however, not be derived from the description.

- 1.5 The respondent suggested that a cell structure according to Features 1.3 and 1.4 could lead to a cylindrical frame. However, this does not allow the conclusion that such a cylindrical stent is unambiguously disclosed by the parent application. To the contrary, the forming of a cylindrical frame requires a modification of the expansion characteristics, i.e. of the cell pattern of the frame, compared to the disclosed frame.
- 1.6 The respondent also argued that the focus of the invention had shifted with the filing of the divisional application which formed the basis of the patent in suit. The invention was now related to the fixation and support of the leaflet joints to the frame. The overall shape of the frame, which related to the fixation of the prosthesis with respect to the anatomy, was not essential to this aspect of the invention.

It is correct that the hourglass shape itself has a different function than the support of the joints by the frame which is the main aspect of the divisional application. In fact, it is related to the positioning of the prosthesis relative to the anatomy as described on page 14, line 26 - page 15, line 8. It is also correct that for the support of the joints by the frame, the hourglass shape is not required. However, the parent application only discloses frames comprising both aspects and, as discussed above, these aspects are functionally linked by the cell design having an influence on both of them.

In order to allow the omission of a feature from a claim, it is not sufficient that said feature is not essential. Moreover, the subject-matter of the claim as a whole must be unambiguously derivable from the parent application in order to fulfil the requirements of Article 76(1) EPC. This is, however, not the case.

- 1.7 Finally, page 7, lines 16-24 mentions that the objects of the invention are accomplished by a heart valve prosthesis having a self-expanding multi-level frame and an asymmetric hourglass shape in the expanded configuration. The respondent argued that said passage merely described a preferred embodiment, and the compulsory presence of the hourglass shape in claim 1 could not be derived therefrom. However, said passage is the beginning of the general description of the invention which normally describes the invention in its broadest sense. The features mentioned there do not belong to a particular embodiment only, and they may not be omitted from the claim.

1.8 Therefore, the subject-matter of claim 1 of the main request goes beyond the disclosure of the parent application, contrary to Article 76(1) EPC.

2. **Auxiliary request 7**

2.1 **Admittance of auxiliary request 7**

Auxiliary request 7 was filed on 21 December 2016 which was 3 months before the oral proceedings in opposition, and it was maintained by the respondent with the reply to the appeal.

Therefore, auxiliary request 7 forms part of the appeal proceedings according to Article 12(4) RPBA 2007.

The appellant referred to a lack of convergence of the auxiliary requests. However, this argument is moot because only one auxiliary request, which is more limited than the main request, was present at the end of the appeal proceedings.

2.2 **Added Subject-Matter - Article 76 (1) EPC**

In claim 1 of auxiliary request 7, the omitted feature concerning the "hourglass shape" (see main request) has been re-introduced, thereby overcoming the objection under Article 76(1) EPC.

The appellant has not raised any objection against auxiliary request 7 based on Article 76(1) EPC.

2.3 **Novelty - Article 54(2) EPC**

2.3.1 In view of novelty of auxiliary request 7, the appellant referred to documents D2, D3, D3c and D4a

which all treat the same heart valve prosthesis called "CoreValve".

2.3.2 The "CoreValve" is best shown in D3c.

D3c shows a picture of a heart valve prosthesis comprising a self-expanding frame having a cell pattern. A valve body is located inside the frame. It obviously includes three valve leaflets the coaptation edges of which are visible in the picture. The remaining tubular portion (skirt) of the valve body is fixed to the struts of the frame by blue threads.

Claim 1 of auxiliary request 7 requires that the "plurality of leaflets [is] affixed to a skirt (21) at joints (24, 27)" (Feature 2.1).

The term "affixed to", means that there are two separate components which are fixed to each other. This interpretation is supported by the fact that in claim 1 this term is also used for the fixation of the joints to the contours of the cell pattern (second part of Feature 2.1), which are two separate components being fixed to each other. However, such a fixation of leaflets to a skirt is not visible in D3c.

It is possible to make a heart valve from a tubular material and a plurality of separate leaflets affixed to it, as required by Feature 2.1. However, it is also possible to make a heart valve from a tubular material which is folded in a way that a part of it functions as the skirt and the other as valve leaflets. In such a case no fixation of the leaflets to the skirt would be present.

Since it is not possible to discern in D3c which of the

two possible solutions was chosen for the CoreValve, D3c does not unambiguously disclose Feature 2.1 according to which "a plurality of leaflets [is] affixed to a skirt (21) at joints (24, 27)".

2.3.3 Feature 2.1 is also not disclosed in documents D2 or D4:

D2 discloses that the valve body is made from bovine pericardium. However, nothing is said about the structure of the valve body in view of any joints between the valve leaflets and the skirt.

D4 and D4a do not contain any specific information about the structure of the valve body either.

2.3.4 Therefore, the subject-matter of claim 1 of auxiliary request 7 is novel over D2, D3, D3c, D4 and D4a.

2.3.5 The appellant did not raise any further objection against auxiliary request 7.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent with the following claims and drawings, and a description to be adapted thereto:

Claims: No. 1-24 according to auxiliary request 7 filed with the letter of 21 December 2016.

Drawings: Figures 1-6 of the patent specification.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated