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**Datasheet for the decision
of 9 January 2024**

Case Number: T 0832/21 - 3.2.01

Application Number: 15152340.4

Publication Number: 2886083

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
A collapsible valve prosthesis

Patent Proprietor:
Corcym S.r.l.

Opponent:
MEDTRONIC INC.

Headword:

Relevant legal provisions:
EPC Art. 54

Keyword:
Novelty - main request (no) - auxiliary request (no)

Decisions cited:

Catchword:



Beschwerdekammern

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Case Number: T 0832/21 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 9 January 2024

Appellant: Corcym S.r.l.
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
6 April 2021 concerning maintenance of the
European Patent No. 2886083 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: M. Geisenhofer
M. Millet

Summary of Facts and Submissions

- I. An appeal was filed by the patent proprietor (appellant) against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 2, the European patent EP 2 886 083 met the requirements of the EPC.
- II. The opposition division *inter alia* held with regard to the higher ranked requests that the subject-matter of both the main request and the auxiliary request 1 was not novel over document
- ZP1 US 2011/0224785 A1.
- III. At the oral proceedings held before the Board,
- the appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request), in the alternative that the patent be maintained in amended form based on auxiliary request 1 submitted with letter dated 2 December 2020 during opposition proceedings; and
 - the respondent (opponent) requested that the appeal be dismissed.
- IV. Independent claim 1 of the main request reads as follows:

"A collapsible heart valve prosthesis (1) including an armature (2) and a set of prosthetic valve leaflets (3a, 3b, 3c) supported by the armature (2), the armature (2) expandable from a contracted condition to an expanded condition for anchoring at an annulus of a natural valve site, wherein the armature (2) includes:

- a tubular intra-annular portion (2a) defining a blood flow lumen having an inflow side and an outflow side, the tubular intra-annular portion (2a) supporting (202, 204, 206) the set of prosthetic valve leaflets (3a, 3b, 3c) in the blood flow lumen and being provided with outward formations (200) for coupling with the natural valve site, and
- at least one extra-annular portion (2b, 2c) linked to the intra-annular portion (2a), the at least one extra-annular portion including an over-annular portion (2b) to extend collar-like over the annulus of the natural valve site at the inflow side of the blood flow lumen,

wherein the at least one extra-annular portion (2b, 2c) includes a pattern of radial finger formations, the prosthesis (1) being characterized in that the radial finger formations exhibit differential flexibility by being stiffer at their proximal ends and more flexible at their distal ends."

Independent claim 1 of the auxiliary request 1 requires the following additional feature adjoined at the end of the claim:

"further including a sheet-like member (210) applied onto the intra-annular portion (2a) and the at least one extra-annular portion (2b)."

V. The appellant's arguments (relevant for the present decision) can be summarized as follows:

- (a) The subject-matter of claim 1 of the **main request** was novel over the embodiment shown in figure 7 of ZP1 since the spikes (196) could not be considered as radial finger formations with differential flexibility. Furthermore, the armature of ZP1 was

anchored in the annulus of the native valve by contracting and not be expanding as explained in paragraph [0102].

- (b) **Auxiliary request 1** was novel since apart from the differences identified with regard to the main request, the embodiment of figure 7 of ZP1 did not disclose a sheet-like member on both the intra-annular portion and the extra-annular portion either.

VI. The respondent's arguments (relevant for the present decision) can be summarized as follows:

- (a) Claim 1 of the **main request** lacked novelty over the embodiment of figure 7 of ZP1 since the spikes' orientation had a radial component and a cross-section decreasing along its extension such that it was a finger formation with differential flexibility.
- (b) The argument that the armature of ZP1 would be contracted for anchoring on the annulus was raised too late and should not be admitted. But even if admitted, the argument was not convincing since the armature of ZP1 was introduced in contracted state into the heart and expanded when being located and anchored in the annulus of the native valve.
- (c) Claim 1 of the **auxiliary request 1** was not novel either since figure 7 of ZP1 showed a covering on both the intra-annular and extra-annular portion. This covering was additionally described in paragraphs [0077] and [0078] whereby paragraph [0074] clarified that it was also present in the embodiment of figure 7.

Reasons for the Decision

Main Request

1. The subject-matter of claim 1 of the main request (patent as granted) is not novel over the embodiment shown in figure 7 of ZP1.

1.1 It was undisputed that the valve prosthesis shown in figure 7 of ZP1 is a heart valve prosthesis including an armature and a set of prosthetic valve leaflets supported by the armature. The armature includes a tubular intra-annular portion and an extra-annular portion linked to the intra-annular portion.

The intra-annular portion supports the set of prosthetic valve leaflets in the blood flow lumen and is provided with outward formations for coupling with the natural valve site.

The extra-annular portion includes an over-annular portion to extend collar-like over the annulus of the natural valve site at the inflow side of the blood flow lumen, and a pattern of finger formations ("*spikes*" 196).

1.2 However, it was disputed whether the armature of the valve prosthesis is expandable from a contracted condition to an expanded condition for anchoring at the annulus.

1.2.1 The appellant alleged that the armature of ZP1 was not expandable but that according to paragraph [0102] of ZP1 the armature was contracted when anchoring it on the native annulus.

1.2.2 Paragraph [0102] refers to the "locking step" of the prosthetic valve. For this purpose, the prosthetic valve comprises an upstream portion (190) and a downstream portion (188) with ratchet teeth (192) movable relatively to the upstream portion in axial direction. The ratchet teeth ensure that the downstream portion can be pushed upwards and that it cannot move downwards such that it is "locked" in installed state when the native annulus is grasped.

1.2.3 Prior to this locking step, however, the upstream portion and the downstream portion need to be inserted into the native heart. As set out in paragraph [0076], the prosthetic valve is therefore collapsible in radial direction to allow implantation and delivery to the native valve in a collapsed state, where it is then expanded in radial direction to fit the annulus of the native valve.

Despite the locking step, the armature of the valve prosthesis of ZP1 is hence expandable from a contracted condition to an expanded condition for anchoring at an annulus of a natural valve as required by claim 1.

1.2.4 It hence can be left undecided whether this argument that was only raised during oral proceedings before the Board can be admitted under Article 13(2) RPBA 2020 as objected by the respondent.

1.3 It was further disputed whether the finger formations of ZP1 are radial finger formations that exhibit differential flexibility by being stiffer at their proximal ends and more flexible at their distal ends.

1.3.1 The appellant alleged that the finger formations of ZP1 were neither radial finger formations nor did they exhibit differential flexibility by being stiffer at their proximal ends and more flexible at their distal ends.

1.3.2 In the Board's view, the spikes shown in figure 7 are radial finger formations in the sense of the patent in suit.

(a) As can be seen from the detail of figure 7 of ZP1, the spikes (196) extend in a direction inclined with regard to both the horizontal (corresponding to the radial direction with regard to the axis of the armature) and the vertical (corresponding to the axial direction).

(b) Such an inclined configuration corresponds to the geometry of the finger formations shown in figure 7 of the patent in suit where the prosthetic valve according to the patent in suit is shown in installed state, this figure showing finger formations extending under an acute angle. Since such an inclined configuration is considered by the patent itself to be a "*radial finger formation*" (cf. [0074] "*in accordance with an application of the present invention*"), the spikes of figure 7 of ZP1 must also be considered to be a "*radial finger formation*", contrary to the opposition division's decision (cf. grounds for the decision 5.4, last paragraph on page 9).

(c) The appellant confirmed during oral proceedings that the expression "*radial finger formation*" does not exclude that the finger formation has an axial component.

- (d) The appellant, however, alleged that a figure is only a schematic representation of the invention such that it is not possible - at least not clearly and unambiguously - to derive from figure 7 whether the spikes of ZP1 extend in a direction having indeed a radial component. The shown inclination could also be the result of an error committed by the person producing the drawings.

- (e) In the Board's view, figure 7 clearly shows an inclined orientation of the spike whereby there is no reason apparent why this inclination represented in figure 7 should be based on a drawing error committed by the person producing the figure. The figure is sufficiently detailed and accurate such that it is to be excluded that the inclination of the spikes was made by error. Moreover, as pointed out by the respondent during oral proceedings, a radial inclination of the spikes makes sense as the spikes should aid with anchoring (see ZP1, par. [0102], last line). Spikes with a radial inclination may indeed provide a better anchoring in axial direction than spikes oriented purely axially.

1.3.3 Furthermore, the spikes of figure 7 of ZP1 exhibit differential flexibility by being stiffer at their proximal end and more flexible at their distal ends.

- (a) It is apparent from figure 7 that the diameter of the spikes decreases from its proximal to its distal end, hence the area moment of inertia also decreases along the length of the spike. According to paragraph [0078] armatures are typically made from Nitinol or stainless steel, which both are

elastic materials. The stiffness (being the product of the constant Young's modulus and the area moment of inertia) of the spikes hence also decreases from its proximal end to its distal end. Flexibility is the inversion of stiffness such that the radial finger formations exhibit differential flexibility by being stiffer at their proximal ends and more flexible at their distal ends.

(b) The appellant argued that the spikes are not flexible at all since they are intended to be driven into the native tissue of the annulus which requires them to be stiff. This corresponds to what the opposition division decided (cf. ground for the decision 5.4, last paragraph on page 9 of the decision).

(c) Since the independent claim, however, does not require a particular absolute value for the stiffness and/or flexibility but only uses a comparison criteria, even a generally stiff finger formation still has a certain flexibility that varies along the finger's length.

1.4 The prosthetic valve shown in figure 7 of ZP1 hence is prejudicial to the novelty of the subject-matter of claim 1 of the main request.

Auxiliary request 1

2. Claim 1 of auxiliary request 1 differs from claim 1 according to the main request in that it additionally stipulates that the valve prosthesis includes a sheet-like member applied onto the intra-annular portion and the at least one extra-annular portion.

3. The subject-matter of claim 1 of auxiliary request 1 is also not novel over the embodiment of figure 7 of ZP1.
- 3.1 The appellant alleged that it was not clearly and unambiguously derivable from figure 7 whether there was a sheet-like member applied to the armature.
- 3.2 Paragraph [0078] of ZP1 explains that a covering (22) covers "*at least a portion of the downstream skirt 24, and at least a portion of upstream annular skirt 26, such as the entire annular skirt (as shown in FIG.1)*". Furthermore, paragraph [0074] sets out that the embodiment of figure 7 differs from the embodiment of figure 1 only in the technique used for anchoring the prosthetic valve. It hence can be deduced that the other characteristics of the prosthetic valves of figures 1 and 7 remain identical, i. e. that the prosthetic valve of figure 7 comprises the same covering as the embodiment of figure 1.
- 3.3 Furthermore, figure 7 exhibits the covering albeit there is no reference sign attributed to it. The upper/outer edge of the covering is visible within the opening formed by arms (194) whereas the lower edge of the covering is visible between arms (180). The covering hence is applied both onto the intra-annular portion and the at least one extra-annular portion.
- 3.4 It is to be noted that the claim wording does not require that the sheet-like material is applied in one piece. On the contrary, paragraph [0075] of the patent specification explains that the sheet member may be applied in two pieces separable by a de-coupling member.

3.5 The covering (22) of ZP1 is hence a sheet-like member which is in the embodiment of figure 7 applied onto the intra-annular portion and the at least one extra-annular portion.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



A. Voyé

G. Pricolo

Decision electronically authenticated