

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 11 August 2022**

Case Number: T 0633/19 - 3.2.08

Application Number: 13701096.3

Publication Number: 2806829

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

AN ARRANGEMENT, A LOOP-SHAPED SUPPORT, A PROSTHETIC HEART VALVE AND A METHOD OF REPAIRING OR REPLACING A NATIVE HEART VALVE

Patent Proprietor:

Medtentia International Ltd Oy

Opponent:

Edwards Lifesciences Corporation

Relevant legal provisions:

EPC Art. 83

Keyword:

Sufficiency of disclosure - (no)



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0633/19 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 11 August 2022

Appellant: Edwards Lifesciences Corporation
(Opponent) One Edwards Way
Irvine, CA 92614 (US)

Representative: Somerville, Andrew Edward
Somerville Associates
Dunston Innovation Centre
Dunston Road
Chesterfield S41 8NG (GB)

Respondent: Medtentia International Ltd Oy
(Patent Proprietor) Upseerinkatu 1-3, Tower 1
02600 Espoo (FI)

Representative: Betten & Resch
Patent- und Rechtsanwälte PartGmbH
Maximiliansplatz 14
80333 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 December 2018 concerning maintenance of the
European Patent No. 2806829 in amended form.**

Composition of the Board:

Chairman M. Foulger
Members: G. Buchmann
C. Schmidt

Summary of Facts and Submissions

I. With the decision posted on 21 December 2018 the opposition division decided to maintain the European patent No. 2 806 829 in amended form.

The opposition division found that the subject-matter of claim 1 according to the then valid auxiliary request 1 fulfilled the requirements of Articles 123(2), 83, 54(2) and 56 EPC.

II. The opponent filed an appeal against this decision.

III. Oral proceedings took place before the Board on 11 August 2022.

IV. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

V. The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained in the form held allowable by the opposition division.

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

D7

US 2009/0299471 A1

VP

Demonstration video from the Advanced Materials Research Group of the University of Nottingham,
<https://www.youtube.com/watch?v=1rrPv5AlVXg>

VII. Claim 1 of the (only) **main request** reads (numbering added):

1

"An arrangement for replacement or repair of a native heart valve, comprising:

2

a loop-shaped support (41) being an annuloplasty ring;

3

and a radially expandable stented prosthetic heart valve (70); and

4

wherein an outer segment (32) of said loop-shaped support (41) is positionable towards surrounding valve tissue of a native heart valve and

5

wherein an outer surface (74) of said prosthetic heart valve (70) is positionable towards an inner segment (34) of said loop-shaped support (41) so as to prevent paravalvular leakage or regurgitation between said prosthetic heart valve (70) and said surrounding valve tissue of said native heart valve and

6

wherein a circumference of said loop-shaped support (41) is substantially larger than a circumference of said prosthetic heart valve (70) and

7

wherein said loop-shaped support (41) is radially downsizeable to fit tightly around said prosthetic heart valve (70) so as to seal the area between said prosthetic heart valve (70) and said loop-shaped support (41),

8

wherein said inner segment (34) is adapted for

receiving said radially expandable prosthetic heart valve (70), and

9

wherein said loop-shaped support (41) is radially rigid for preventing an expansion of said prosthetic heart valve (70) beyond said inner segment (34),

10

characterized in that said loop-shaped support (41) is helically shaped and/or screwable into said annulus (20) for improved stability."

(Feature numbering added by the Board)

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

Sufficiency of disclosure - Article 83 EPC

All features of claim 1 were sufficiently described in paragraphs [0058] and [0064].

During the implantation of the loop-shaped support (41), the speed of the deformation of the support upon contact with blood could be easily controlled by a skilled person. Hence, a helically coiled support could be formed inside the patient's body before the diameter thereof was reduced by the shape memory effect.

An example was given in document D7.

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

Sufficiency of disclosure - Article 83 EPC

The patent did not disclose an arrangement comprising

the combination of features specified by claim 1. The support (41) assumed its final reduced diameter immediately upon implantation without previously forming a helically coiled shape having a larger diameter than the prosthetic heart valve.

Reasons for the Decision

1. Sufficiency of disclosure - Article 83 EPC

1.1 The appellant objected under Article 83 EPC because the patent did not disclose an arrangement comprising the combination of features specified by claim 1. The description did not provide the skilled person with sufficient information to carry out the claimed invention.

1.2 As explained by the respondent, paragraph [0058] of the description describes an arrangement comprising the Features 1-5 and 8-10. It comprises a helically shaped support to be positionable towards surrounding valve tissue, and a radially expandable stented heart valve positionable towards the inner segment of the loop-shaped support, the support receiving the expandable heart valve and being rigid to prevent further expansion of the heart valve.

An arrangement comprising Features 6 and 7 was described in paragraph [0064] in which it was explained that the loop-shaped support may be larger than the circumference of the prosthetic heart valve and may be downsizeable by using a shape memory material. The downsizing led to a tight fit around the prosthetic

heart valve.

1.3 The description further discloses how the loop-shaped support is inserted into the patient. This is done, according to paragraph [0050] and according to the respondent, by using a shape memory material which is straightened for delivery through a catheter, and which assumes its programmed helical shape when leaving the catheter at the heart valve. The blood heats the material above the transition temperature which causes the support to assume its programmed helical loop shape.

1.4 The Board notes that the claimed subject-matter represents an intermediate state of the loop shaped support. For implantation, the support has a straight shape and at the end of the procedure it has a helical shape fitting tightly on the prosthetic heart valve. The claimed helical support having a size larger than the prosthetic heart valve possibly exists as an intermediate state during implantation. This is however not explicitly described in the patent.

Since the blood is the heat source for providing for the phase transition of the shape memory material, the support starts to deform to its final programmed shape as soon as it comes into contact with the blood.

1.5 The respondent argued that the support could be prevented from immediately assuming its final curvature by using a thermal insulation or by cooling the support. Thereby, it was possible to firstly form a complete coil having a larger diameter, and subsequently downsizing this coil.

However, the patent is silent about any means which

would delay the complete deformation of the support in reaching its final shape. Not even the necessity of such means is mentioned in the description.

Furthermore, such means cannot be regarded as common general knowledge which the skilled person could rely on.

- 1.6 The respondent referred to a video presentation (VP) published on the internet which showed that the transition to the programmed shape could easily be controlled.

However, in the examples involving water as a heat source, said video only shows rapid deformations which are completed within a fraction of a second. Such examples cannot demonstrate the timely control over the transition process.

- 1.7 The respondent also referred to document D7 which disclosed a helical annuloplasty ring which was deformed from a straight state to a first activated coiled state by using the body temperature, and which was then deformed to a second activated coiled state by further using body temperature (paragraph [0099]).

However, D7 also describes that a restraining member was necessary to prevent immediate deformation of the annuloplasty ring to the final (second) state (e.g. paragraph [0102]).

Therefore, D7 does not support the argument that the skilled person was aware of how to put the subject-matter of claim 1 into practice. On the contrary, D7 indicates that it would be a further invention to provide means which prevent the shape memory material from deforming completely, directly after contact with

blood.

- 1.8 In summary, claim 1 specifies an arrangement including a loop-shaped support in an intermediate state in which the support is helically loop shaped and has not yet reached its final memorised shape having a smaller diameter. The patent does not disclose the means necessary to achieve this intermediate state nor are these means part of the common general knowledge of the skilled person.

Therefore, the subject-matter of claim 1 of the main request is not disclosed in a manner sufficiently clear and complete to be carried out by a person skilled in the art (Article 83 EPC).

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:



C. Moser

M. Foulger

Decision electronically authenticated