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**Datasheet for the decision
of 4 June 2019**

Case Number: T 0463/16 - 3.2.08

Application Number: 10164361.7

Publication Number: 2241287

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

Minimally-invasive heart valve with cups positioners

Patent Proprietor:

Edwards Lifesciences Corporation

Opponents:

Isarpatent
LUDWIG, Gabriele
Stolmár, Matthias
Negendanck, Matthias

Headword:

Relevant legal provisions:

EPC Art. 56, 76(1), 100(c), 123(2), 84

Keyword:

Inventive step - (yes)

Amendments - extension beyond the content of the application
as filed or earlier application as filed (no)

Decisions cited:

G 0003/14

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0463/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 4 June 2019

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
14 December 2015 concerning maintenance of the
European Patent No. 2241287 in amended form.**

Composition of the Board:

Chairwoman P. Acton
Members: C. Herberhold
Y. Podbielski

Summary of Facts and Submissions

I. By decision posted on 14 December 2015 the Opposition Division decided that European patent No. 2241287 as per the first auxiliary request then on file, and the invention to which it related, met the requirements of the EPC.

II. The patent proprietor (appellant 1) as well as opponent 1 (appellant 2) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

Further parties to the appeal proceedings are opponent 2 (respondent 1), opponent 3 (respondent 2) and opponent 5 (respondent 3).

By withdrawing their oppositions during the appeal proceedings, opponent 4 ceased to be party to the appeal proceedings.

III. Oral proceedings before the Board were held on 4 June 2019.

As announced by letter dated 22 May 2019 respondent 2 (opponent 3) did not attend. Respondent 1 (opponent 2), although duly summoned, was also not represented.

In accordance with the provisions of Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without them.

At the end of the oral proceedings the requests of the parties were as follows:

Appellant 1 requested that the decision under appeal be set aside and a patent be granted on the basis of claims 1-10 of the main request filed as auxiliary request 1 during the oral proceedings before the Board, columns 1-16 of the description filed during the oral proceedings before the Board and Figures 1-17B of the patent specification.

Appellant 2 requested that the decision under appeal be set aside and the patent be revoked.

Respondent 2 requested that the appeal of appellant 1 be dismissed and that the patent be revoked or "at least" be maintained as held allowable by the opposition division.

Respondent 3 made no requests in the written proceedings. It requested during oral proceedings, when the later withdrawn main request was discussed, that the definitions presented by appellant 1 of the terms "at the outflow end" and "at the inflow end" as well as "midway between" be included in the minutes of the oral proceedings.

IV. Independent claim 1 of the main request (filed as auxiliary request 1 during oral proceedings before the Board) reads as follows:

"A prosthetic heart valve (22) configured to be delivered in a minimally invasive manner to a native aortic valve annulus, comprising:
a collapsible, self-expanding, Nitinol leaflet frame (72) having three upstanding and generally axially-

oriented U-shaped commissure regions (32), the three commissure regions being positioned at an outflow end of the leaflet frame and circumferentially about a flow axis,

characterized by

the three commissure regions alternating with and intermediate three U-shaped cusp regions (30) being positioned at an inflow end of the leaflet frame, the three commissure regions and three cusp regions defining a continuous, undulating shape;

three flexible leaflets (52) attached to the leaflet frame, each leaflet having an arcuate cusp edge (102) opposite a free edge and a pair of commissure edges therebetween, the leaflets being attached around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions of the leaflet frame; and

three U-shaped cusp positioners (42) made of Nitinol and rigidly fixed to the leaflet frame and disposed circumferentially about the flow axis and located at the outflow end of the leaflet frame, each cusp positioner having two legs (92) and an apex (90) with the apex of the U-shape pointing toward the outflow end of the leaflet frame and the two legs of the U-shape pointing toward the inflow end of the leaflet frame, each apex being located midway between two of the commissure regions of the leaflet frame, wherein each of the U-shaped cusp positioners extends further radially outward than the commissure regions of the leaflet frame for providing three points of contact with surrounding tissue to help stabilize and anchor

the prosthetic heart valve within the native aortic valve annulus."

The further requests have no bearing on the present decision.

V. The following documents played a role in the present decision:

D1: WO-A-2004/082527 (parent application);

D7: US-A-6,425,916;

D20: WO-A-01/76510.

VI. The essential arguments of appellant 2 can be summarised as follows:

Extension of the claimed subject-matter beyond the original disclosure

While D1 disclosed e.g. in paragraphs [0064] or [0016] that the leaflet frame and the cusp positioners may be made of Nitinol, this disclosure was always in the context of a manufacture of the frame from a two-dimensional blank. Omitting in the claimed subject-matter the manufacture from a two-dimensional blank thus resulted in an unallowable intermediate generalization.

Furthermore, there was no basis in the earlier application as filed for each apex of the U-shaped cusp positioners being located midway between two of the commissure regions of the leaflet frame. Appellant 1 had referred to paragraphs [0059] and [0062] in this respect. However, paragraph [0059] only disclosed the points of contact with the surrounding tissue to be midway between the three commissures, not the apexes.

Paragraph [0062], while speaking about ensuring good contact between the apex of the cusp positioners and the surrounding walls of the aortic valve AV sinus cavities, did not disclose this contact to be midway. There was thus no disclosure for these features claimed in combination.

Inventive step

Document D7 formed the closest prior art. It disclosed all features of claim 1 apart from the cusp regions being U-shaped and the cusp edge of each leaflet extending along one of the cusp regions. In particular, D7 disclosed in column 4, lines 52-54, an embodiment with the valve displacer and the cardiac valve being integrated into a single structure, which implied the possibility of the cusp positioners being rigidly fixed to the leaflet frame as claimed. It was further evident from figures 5, 9 and 11 that the apex of the U-shaped cusp positioner was located midway between two of the commissure regions.

As already mentioned in the impugned patent, paragraph [0004], such U-shaped cusp regions with the cusp edge of each leaflet extending along one of the cusp regions were, however, well known in the art and provided a support structure for optimum functionality of the prosthetic leaflets, see paragraph [0039].

The problem to be solved was thus to provide continuous support for the valve leaflets, or, more generally, to improve the functionality of the valve.

When looking for a solution to said problem, the person skilled in the art would consider the teaching of document D20. In order to provide optimal valve

performance - i.e. to solve the problem posed - said document taught a construction with a leaflet sub-assembly in which each of the leaflets was supported substantially entirely around an undulating wireform, see D20, page 19, penultimate paragraph, with the cusp edge following the (U-shaped) wireform, see page 12, lines 28-30 and page 13, lines 23, 24.

Thus prompted to employ the leaflet sub-assembly of D20 for the valve system of D7, Figure 9, the person skilled in the art would come to a heart valve as claimed. Indeed replacing the cardiac valve shown in D7, Figure 10 with the cardiac valve disclosed in D20, Figures 6 and 7 was a straight forward procedure, which only required known means of connecting implant elements, such means being routinely employed in the art.

The subject-matter of claim 1 did thus not involve an inventive step.

Adaptation of the description to the claims

Contrary to the requirements of Article 84, the amended description did not support the amended claims for the following reasons. Although claim 1 defined the cusp regions to be U-shaped, paragraph [0038] of the description referred to arcuate or U-shaped cusp regions. Furthermore, although claim 1 defined the U-shaped cusp positioners to have two legs pointing toward the inflow end of the leaflet frame, the description in paragraph [0047] still referred to these two legs as extending generally toward the inflow end.

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

No extension of the claimed subject-matter beyond the original disclosure

D1, Paragraph [0016] clearly and unambiguously disclosed that the leaflet frame and the cusp positioners may be made of Nitinol. This sentence was independent of the two foregoing sentences, which disclosed a "desirable" and thus facultative manufacturing process of the support frame from a two-dimensional blank. Furthermore, claim 4 as filed disclosed the leaflet frame and the cusp positioners to be made of Nitinol.

With respect to the position of the U-shaped cusp positioners, paragraph [0062] disclosed that the cusp positioners were flaring outwards from the remainder of the support frame and that this outward flaring helped to ensure good contact between the apex of the cusp positioners and the surrounding walls of the aortic valve AV sinus cavities. It was thus the apex of the respective cusp positioner which made contact with the surrounding tissue and which thus formed the point of contact. There were three such apexes, which was fully consistent with the existence of three points of contact being provided by the three U-shaped cusp positioners as referred to in paragraph [0059]. As disclosed in said paragraph, the three points of contact, i.e. the apexes, were midway between the three commissures. Nothing more was claimed, such that there was no unallowable intermediate generalisation present.

The subject-matter of present claim 1 therefore did not extend beyond the disclosure of the earlier application or of the application as filed.

Inventive step

As correctly analysed by appellant 2, document D7 did not disclose U-shaped cusp regions and the leaflets being attached around the leaflet frame with the cusp edge of each leaflet extending along one of these cusp regions.

Even if the skilled person for some reason considered providing the prosthetic heart valve as shown in Figures 9 and 10 of D7 with a leaflet frame as disclosed in Figures 6 and 7 of D20, it was fully unclear how such a combination could be effectuated. The two heart valve prostheses were of fundamentally different design, such that the person skilled in the art would not even consider combining them. In more detail, the combination suggested as obvious by appellant 2 required to connect a connecting coil element **36** - as shown in D7, Figures 9, 10 - to somewhere on the arcuate cusp regions or on the tissue engaging base **104** of D20, Figure 6. This either resulted in giving up the concept of the arcuate cusp regions, or was impossible as the tissue engaging base was fully covered by a fabric skirt and furthermore carried elements such as posts **146** and **148** which impeded the connection of such a coil element. Additionally, a connection using a coil element such as shown in Figure 9 of D7 did not result in a rigid attachment of the cusp positioners to the leaflet frame. The combination suggested by appellant 2 thus had to be considered a complete re-engineering of the valve which exceeded by far the capabilities of the

skilled person and which could only be envisaged, if at all, by hindsight.

The subject-matter of claim 1 thus involved an inventive step.

Adaptation of the description to the claims

Contrary to appellant 2's opinion, there was no discrepancy between the claims and the description according to the main request objectionable under Article 84 EPC. The word "arcuate" in paragraph [0038] was nothing more than a synonym of "U-shaped". As to the legs of the U-shaped cusp positioners extending generally toward the inflow end, this wording was justified as in all embodiments represented in the drawings, these did not extend in a fully straight and direct way to the inflow end, but were indeed slightly angled.

Reasons for the Decision

1. Articles 100(c), 76(1) and 123(2) EPC

The patent was granted on a divisional application. The parent is WO-A-2004/082527 which entered the European phase under the application number EP2004757521.2.

The description of the divisional application is identical to the description of the parent, with the originally filed claims of the parent being incorporated therein as "clauses". For examination whether the claimed subject-matter extends beyond the disclosure of the earlier application as filed or the application as filed (be it under Article 76(1), 100(c)

or 123(2) EPC), it is thus sufficient to verify that the claimed subject-matter can be clearly and unambiguously derived from the disclosure of the parent application (D1). This was common ground between the parties. In the following reference is thus made to the respective passages of the parent application only.

- 1.1 Claim 1 of the present main request defines that the leaflet frame is a "Nitinol leaflet frame" and that the "U-shaped cusp positioners [are] made of Nitinol". Appellant 2 was of the opinion that D1 only disclosed said features in the context of the support frame being made from a two-dimensional blank.

However, paragraph [0016] presents the manufacture from a two-dimensional blank as "desirable", i.e. as a preferred yet facultative feature. This is in accordance with the structure and disclosure of the originally filed claims. Dependent claim 4 (which is directly dependent on claim 1) defines that the leaflet frame and the cusp positioners are made of Nitinol. Claim 3 as originally filed (dependent on claims 1 and 2) defines the support frame to be formed by a process which comprises providing a two-dimensional blank of the support frame. Thus the claimed manufacture from Nitinol is not structurally or functionally linked with the manufacture from a two-dimensional blank. In other words, omission of the manufacture from a two-dimensional blank does not result in an unallowable generalisation.

- 1.2 Appellant 2 has further objected to the feature of each apex of the U-shaped cusp positioners being "located midway between two of the commissure regions of the leaflet frame" as not being originally disclosed.

However, D1, paragraph [0059], lines 11 *et seq.* discloses that "in whatever form, the cusp positioners **42** provide the valve **22** with three points of contact with the surrounding tissue that is **midway** between the three commissures **32**". As this disclosure relates to "whatever form", it also relates to the claimed "U-shaped cusp positioners...having two legs and an apex with the apex of the U-shape pointing toward the outflow end of the leaflet frame and the two legs of the U-shape pointing toward the inflow end of the leaflet frame", "wherein each of the U-shaped cusp positioners extends further radially outward than the commissure regions of the leaflet frame for providing three points of contact with surrounding tissue."

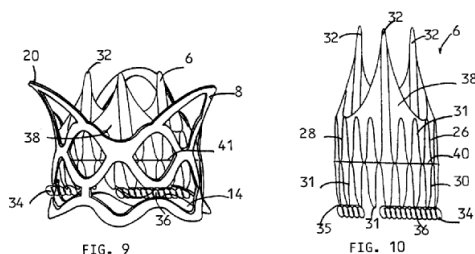
Paragraph [0062] further talks about "good contact between the apex of the cusp positioners and the surrounding walls of the aortic valve AV sinus cavities." It is thus clear that the three points of contact mentioned in paragraph [0059] (and in claim 1 of the main request) are the three apexes which in paragraph [0062] are explicitly disclosed to make good contact to the surrounding wall. As the three points of contact are disclosed to be midway between the three commissures, the person skilled in the art clearly and unambiguously derives from the disclosure that each apex is located midway between the commissure regions. The feature under debate does thus not extend beyond the content of the earlier application or application as filed.

2. Inventive step

Appellant 2 argued that starting from document D7 as closest prior art and combining it with the teaching of

document D20, the person skilled in the art would in an obvious manner come to the subject-matter claimed.

The valve according to D7 is essentially a two part construction (possibly integrated into a single structure and delivered together rather than separately, see column 4, lines 52-54) with the protrusion **34** of support structure **26** locking into opening **14** of the valve displacer **8** (the valve displacer displacing the stenotic leaflets of the diseased native valve):

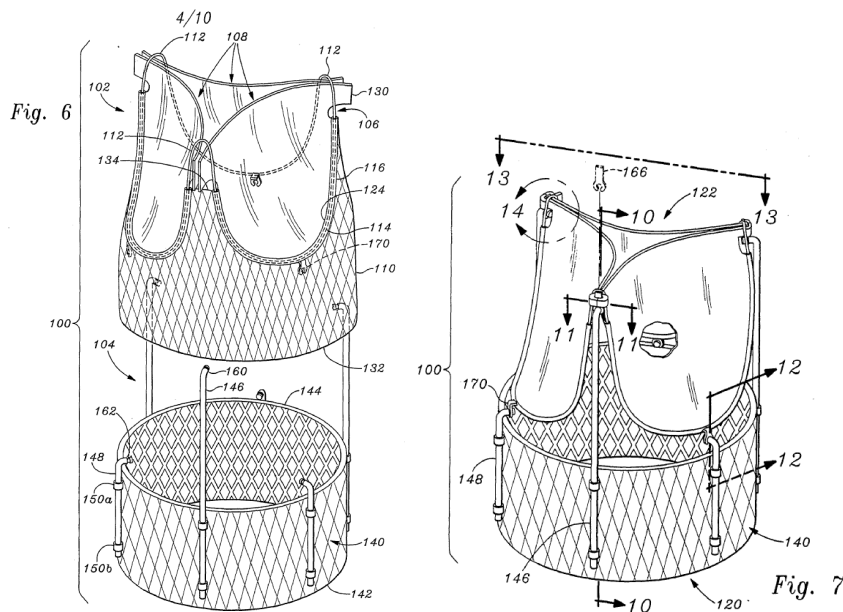


According to appellant 2, extensions **20** qualify as the U-shaped cusp positioners as claimed.

The parties agree that D7 does at least not show that the cusp regions of the leaflet frame (corresponding to "support structure **26**" in Figure 10 represented above) are U-shaped and the cusp edge of each leaflet extends along one of the cusp regions.

Leaving aside - for the sake of the argument - the further differing features identified by appellant 1, appellant 2 argued that the person skilled in the art would learn from D20, page 19, penultimate paragraph, that optimal valve performance was to be reached by each of the leaflets being supported substantially entirely around an undulating wireform. He would thus solve the problem to optimize valve performance by

employing a leaflet frame as shown in D20, Figures 6 and 7 (reproduced below):



However, contrary to the view of appellant 2, the Board is not convinced that this is a straight forward procedure leading directly to a heart valve as claimed.

To begin, D7 uses a tri-leaflet valve with a base (Figure 11, **41** and column 5, lines 46-60). While the leaflet frame shown in D7, Figure 10 is well suitable to hold within its windings **31** such a base, it is not clear how and where it could support the elastic wireform **106** employed in D20 (D20, Figure 6, **106**) with the three individual leaflets supported therein (page 12, lines 27 *et seq.*). According to appellant 2, the person skilled in the art would simply exchange the support structure shown in D7, Figure 10 with the complete support structure shown in D20, Figure 7 (thus including both, the leaflet sub-assembly **102** and the tissue engaging base **104** as shown in Figure 6). While it was true that in this way the interconnecting coil structure of prior art D7 would be lost, the person skilled in the art would have no difficulty to provide

such a structure on the support structure **104** of D20 (Figure 6 or 7) or even to employ alternative connection means in order to connect the valve assembly to the valve displacer **8**.

However, the D20 leaflet sub-assembly not only comprises an elastic wireform **106**, but also a fabric skirt **110** (see D20, page 12, lines 27, 28, Figure 6, **110**). Said skirt has been removed in Figure 7 for clarity reasons to illustrate the details of the connecting system between the base and the leaflet sub-assembly (page 13, lines 9-12 and page 6, lines 30-32). The individual leaflets are stitched to the skirt (see Figure 12) which then continues toward the inflow end of the valve (Figure 7, **120**), the fabric skirt being captured between and in direct contact with the tubular member **140** and the surrounding tissue (page 18, lines 27, 28). Therefore, the person skilled in the art learns from D20 that there is no need for a further element (such as the valve displacer of D7) in-between the valve and the host annulus. Furthermore, even if the person skilled in the art were to use such a further element, it would not be possible to attach a coil like element in the way disclosed in D7, Figure 10 because the skirt would be in the way. The person skilled in the art would also not simply dispense of the skirt as this is disclosed to have important functions in the attachment of the cusps **108** (see D20, Figure 12) and in providing - by virtue of the continuous connection between the cusp edges of the leaflet and the skirt - a flow channel for blood entering at the inflow end (page 18, lines 29-31). It thus cannot be considered obvious to simply use the valve **100** as disclosed in D20 instead of valve **6** disclosed in D7.

Designing an alternative connection while keeping the functions of the skirt exceeds the routine adaptations made by the person skilled in the art without use of inventive skills.

Therefore, the Board comes to the conclusion that even by combining the teachings of D7 and D20 the person skilled in the art would not in an obvious manner have arrived at a valve falling under the scope of independent claim 1.

The subject-matter of claim 1 thus involves an inventive step.

3. Adaptation of the description, Article 84 EPC

3.1 Paragraph [0038]

As explained during oral proceedings, claim 1 as granted defined the cusp regions to be U-shaped. Thus any inconsistency between the definition in the claim (which defined only U-shaped) and the wording in paragraph [0038] (which speaks about "arcuate or U-shaped") was present in the patent as granted. Consequently, even if this difference in wording were considered an inconsistency, it could not be objected to under Article 84 EPC in opposition appeal proceedings (see G 3/14, OJ EPO 2015, 102).

3.2 Paragraph [0047]

The term "extending generally toward the inflow end" used in the description is appropriate for the legs of the U-shaped cusp positioners as they are described throughout the patent, which are slightly angled with respect to the flow axis, with the commissures being

slightly taller than the cusp positioners (paragraph [0049]). Indeed, in view of the disclosed embodiments, also the respective claim feature "extending towards the inflow end" has to be interpreted as "extending generally toward the inflow end", such that there is no violation of the requirements of Article 84 EPC in this respect.

3.3 Appellant 2 did not have further objections against the description as amended during oral proceedings before the Board.

4. Further requests by respondents 2 and 3

4.1 The request by respondent 2 to revoke the patent

The Board notes that respondent 2 has not filed an appeal. Thus, as a party to the proceedings as of right under Article 107, second sentence, EPC, they cannot challenge the maintenance of the patent as amended in accordance with the interlocutory decision (G 2/92, OJ EPO 1994, 875). Some of their requests are thus inadmissible. However, with respondent 2 not being represented at the oral proceedings and with appellant 1 pursuing requests of overlapping scope, this issue did not have an impact on the course of the proceedings.

4.2 The request by respondent 3 to include into the minutes the definitions of "at the outflow end" and "midway between" presented by appellant 1 during the oral proceedings.

Respondent 3 gave as the reason for its request that such an inclusion in the minutes would be of importance for further (national) proceedings.

According to established case law, it is not the function of the minutes to record statements which a party considers will be of use to it in any subsequent proceedings in national courts, for example in infringement proceedings as to the extent of protection conferred by the patent in suit. This is because such statements are not "relevant" to the decision which the board has to take, within the meaning of R. 124(1) EPC. Such matters are within the exclusive jurisdiction of the national courts (Case Law of the Boards of Appeal, 8th edition 2016, III.C.4.9.2). This is even more so in the present case, where the Board did not use the definitions submitted by appellant 1, since the definition of these features was not relevant for the present decision.

Order

For these reasons it is decided that:

1. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:
 - Claims 1-10 of the main request filed as auxiliary request 1 during the oral proceedings before the Board,
 - Columns 1-16 of the description filed during the oral proceedings before the Board,
 - Figures 1-17B of the patent specification.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated