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**Datasheet for the decision
of 17 December 2024**

Case Number: T 0830/22 - 3.2.01

Application Number: 12825480.2

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A61L27/14, A61L27/54

Language of the proceedings: EN

Title of invention:
IMPROVEMENTS FOR PROSTHETIC VALVES AND RELATED INVENTIONS

Patent Proprietor:
Tendyne Holdings, Inc.

Opponent:
Reininger, Jan

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(2), 84

Keyword:

Grounds for opposition - subject-matter extends beyond content of earlier application (yes)

Amendments - intermediate generalisation - extension beyond the content of the application as filed (yes)

Claims - clarity - auxiliary request (no)

Decisions cited:

Catchword:



Beschwerdekammern
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Case Number: T 0830/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 17 December 2024

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 27 January 2022
revoking European patent No. 2741711 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeal was filed by the appellant (patent proprietor) against the decision of the opposition division to revoke the patent EP 2 741 711.
- II. During the opposition proceedings, the opponent had raised the grounds of opposition under Articles 100(a), (b) and (c) EPC.
- III. The opposition division decided that the subject-matter of the claims as granted extended beyond the content of the application as filed.

They further admitted auxiliary request 1, but held that it lacked clarity. Auxiliary requests 2 - 11 also contained added subject-matter.

- IV. Oral proceedings were held before the Board.
 - (a) 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 according to one of the auxiliary requests 1-12 filed with the statement of grounds of appeal.
 - (b) The respondent (opponent) requested that the appeal be dismissed.

- V. Claim 1 of the **main request** reads as follows:

"A prosthetic valve (110) for implantation in a native valve annulus between an atrium and a ventricle of a heart comprising:
a self-expanding tubular stent (112) having a proximal, atrial end and an opposite, distal, ventricular end;
a leaflet assembly (118) disposed within the stent (112) and supporting set of valve leaflets (120);
a collar (116) attached to and encircling the tubular stent (112) to form a V-shape in cross-section, the collar (116) originating at the distal, ventricular end of the stent (112) and expanding in diameter away from the distal, ventricular end of the stent (112) towards the proximal, atrial end of the stent (112)."

In claim 1 of **auxiliary request 1** the collar is specified to be "an annular collar (116)".

Claim 1 of **auxiliary request 2** specifies again that the collar is annular, but also recites the additional feature

"wherein the annular collar is configured to be deployed into a mitral or tricuspid valve annulus".

Claim 1 of **auxiliary request 3** claims in addition to claim 1 of the main request the feature

"wherein the collar guides the prosthetic valve into place at the mitral or tricuspid valve annulus during deployment and keeps the valve in place once it is deployed".

Claim 1 of **auxiliary request 4** differs from claim 1 of the main request in that the collar is specified to be "a stiff-yet-flexible collar (116)".

Claim 1 of **auxiliary request 5** is based on claim 1 of auxiliary request 5 but additionally requires the feature

"wherein the annular collar is configured to be deployed into a mitral or tricuspid valve annulus".

Claim 1 of **auxiliary request 6** claims in addition to claim 1 of the main request the feature

"wherein the annular collar strengthens the leaflet assembly/stent combination by providing additional structure"

whereas claim 1 of **auxiliary request 7** requires the feature

"wherein the valve collar is adapted to inhibit perivalvular leak by flexing and sealing across the irregular contours fo the annulus and atrium".

Claim 1 of **auxiliary request 8** is based on claim 1 of auxiliary request 7 but additionally recites that the collar is *"a stiff-yet-flexible collar (116)"*.

Claim 1 of **auxiliary request 9** combines the amendments of auxiliary requests 6 and 7.

Claim 1 of **auxiliary request 10** requires the collar to be *"an annular collar (116)"* and additionally recites the feature

"the annular collar providing, when the prosthetic valve is deployed into an annulus of a native valve, a lateral compressive force against the native valve annulus and a seal between the atrium and the ventricle".

Claim 1 of **auxiliary request 11** is based on claim 1 of the main request but recites the additional feature

"wherein the prosthetic valve (110) can be seated within the native valve annulus through the use of tines or barbs, wherein the tines or barbs are used in conjunction with, or in place of one or more tethers".

Claim 1 of **auxiliary request 12** differs from claim 1 of the main request in that it requires additionally *"tines or barbs providing attachment to adjacent native tissue, when the prosthetic valve is deployed into an annulus of a native valve"*.

VI. The appellant's arguments relevant for the present decision can be summarised as follows:

- (a) Claim 1 of the main request did not contain added subject-matter.
- (b) The same applied to auxiliary requests 1 - 10.
- (c) Auxiliary request 11 was admitted by the opposition division (as then auxiliary request 1A) whereby they exercised their discretion correctly.
- (d) Claim 1 of auxiliary request 11 was clear.
- (e) Auxiliary request 12 should be admitted by the Board.
- (f) Auxiliary request 12 does not contain added subject-matter.

VII. The respondent's arguments relevant for the present decision can be summarised as follows:

- (a) Claim 1 of the main request was an unallowable intermediate generalization of what was disclosed in the application as originally filed.
- (b) The same applied to claim 1 of auxiliary requests 1 - 10.
- (c) Auxiliary request 11 should not have been admitted by the opposition division.
- (d) Claim 1 of auxiliary request 11 lacked clarity.
- (e) Auxiliary request 12 should have been filed in opposition proceedings and hence should not be admitted in appeal proceedings.
- (f) The subject-matter of claim 1 of auxiliary request 12 lacked disclosure in the application as originally filed.

Reasons for the Decision

Main request

Amendments (Article 100(c) EPC)

- 1. The subject-matter of claim 1 according to the main request lacks disclosure in the application as originally filed.
- 1.1 The opposition division held that claim 1 of the main request is an unallowable intermediate generalization of the embodiment shown in figure 12 of the application as originally filed (paragraph 18.1.1 of reasons). They

decided that the subject-matter of claim 1 lacks tethers.

1.2 It is undisputed that the originally filed claims do not provide disclosure for a V-shaped collar but that the embodiment of figure 12 (further described in the originally filed description in paragraphs [00404]-[00409]) is the only suitable basis for the combination of features according to claim 1 of the main request.

1.2.1 The appellant referred to paragraph [00406] and argued that tethers were optional in figure 12 due to the expression "*may include*" and "*may be connected*" used in this passage.

1.2.2 The Board disagrees. Paragraph [00406] describes that the stent "*may include a plurality of tether attachments (not pictured) to which a plurality of tethers 138 may be connected*". This does not constitute a clear and unambiguous disclosure that tethers 138 are optional. In fact, the sentence refers to tether attachments which are not pictured and that may be understood as particular features of the stent intended for attaching the tethers thereto. Such particular attachments for the tether may be optional but not the tethers as such. In fact, in Figure 12 tethers 138 are indeed pictured and paragraph [00404] also clearly requires tethers (138).

The second part of the expression "*to which a plurality of tethers 138 may be connected*" is the linguistic consequence of the first expression referring to an optional feature. Only if tether attachments are included, the tethers may be connected to these attachments.

- 1.3 Omitting these tethers amounts to an unallowable intermediate generalization.
 - 1.3.1 These tethers are intrinsically linked to the concept of pulling the stent with V-shaped collar into the annulus of the native valve as described in paragraph [00300]. Only the combination of both the collar and tethers can provide a tight fit of the prosthetic heart valve in the annulus such that collar and tethers are functionally and structurally interacting.
 - 1.3.2 The appellant argues that paragraph [00369] is a general statement that is applicable to any embodiment mentioned in the application, this paragraph explaining that the tethers are optional. The skilled person would hence consider omitting the tethers of the valve shown in figure 12.
 - 1.3.3 The Board disagrees.
 - (a) Firstly, paragraph [00369] refers to the use of either tines or barbs, or to a combination of tines or barbs with tethers. Using neither tines or barbs, nor tethers but using no fixing means at all is not disclosed in this passage such that the skilled person would not understand paragraph [00369] as a suggestion to omit all tethers shown in figure 12.
 - (b) Secondly, the expression "*may be used in conjunction with, or in place of one or more tethers*" does not provide a direct and unambiguous disclosure for replacing all tethers by tines or barbs. The expression is ambiguous and can be understood in the sense of "*may be used in place of the one or more tethers*". However, it could also be

understood as "*may be used in place of one or more of the existing tethers*", i. e. that one or more, but not necessarily all tethers are replaced by tines and barbs.

- (c) Thirdly, paragraph [00369] does not contain a general statement that is applicable to any embodiment disclosed in the application as originally filed. On the contrary, paragraph [00369] describes an embodiment of the valve ("*In another embodiment...*") which is not necessarily the same embodiment as that shown in figure 12. As set out in paragraph [00404], the valve shown in figure 12 is only "*one embodiment of a prosthetic heart valve according to the present invention*", hence one of a plurality of embodiments disclosed in the application as originally filed. Paragraph [00369] therefore cannot be read in conjunction with the description of the embodiment of figure 12 but it is not excluded that it concerns a different embodiment.

1.4 The appellant's arguments with regard to further passages providing a disclosure for the subject-matter of claim 1 (i. e. valve with collar but without tethers) cannot convince for the following reasons:

1.4.1 Paragraphs [00034] and [00035] refer to two independent embodiments since both paragraphs start with "*In another embodiment*".

(a) Paragraph [00034] does not mention a collar and hence cannot provide a suitable basis for claim 1.

(b) Paragraph [00035] mentions a collar, however only in combination with a particular material (web of

polyester or polyester-like fabric or metal mesh) and a particular shape.

Both passages hence do not provide a suitable basis for the combination of features as claimed in claim 1 of the main request.

- 1.4.2 Paragraphs [00208] and [00209] are part of the brief description of the drawings. Paragraph [00208] refers to the view of a collared stent that is "*tethered to tissue within the left ventricle*" as shown in figure 12.

Paragraph [00209] then refers to "*how the collar can originate*" as illustrated in figures 13a and 13b.

Figures 13a and 13b thus concern a detail of the embodiment of figure 12 but - contrary to the appellant's allegation - do not show independent, self-contained embodiments of the replacement valve.

- 1.4.3 Paragraphs [00294] and [00295] refer to the general function of the collar. These passages deal in the Board's view with one of the details of the valve, here the collar. Furthermore, the sentence "*Tether-based compliance may be used alone, or in combination with the collar-based compliance*" in this paragraph provides disclosure for tethers alone or the combination of tethers and collar - however not for a collar alone.

- 1.5 The Board hence shares the opposition division's decision that the application as originally filed only provides disclosure for a prosthetic heart valve with V-shaped collar and tethers. Claim 1 of the main request does not claim tethers and hence is an unallowable intermediate generalization.

Auxiliary requests 1 - 10

Amendments (Article 123(2) EPC)

2. The subject-matter of claim 1 according to any of auxiliary requests 1 - 10 lacks disclosure in the application as originally filed.
- 2.1 Auxiliary requests 1 - 10 correspond to auxiliary requests 2 - 11 filed during opposition proceedings and formed the basis for the opposition division's decision.
- 2.2 The opposition division held (paragraph 20 of reasons) that, for the same reasons as set out with regard to the main request, none of auxiliary requests 1 - 10 is allowable since none of these requests contains the missing feature "tethers".
- 2.3 The Board fully agrees.

Auxiliary request 11

Clarity (Article 84 EPC)

3. Claim 1 of auxiliary request 11 lacks clarity.
- 3.1 The opposition division admitted this request (then auxiliary request 1) during oral proceedings but held (reasons 19.2 of their decision) that the expression "*tines or barbs are used in conjunction with, or in place of one or more tethers*" does not allow to clearly

determine whether the claimed prosthetic heart valve comprises tethers and even if, how many.

3.2 The Board agrees that claim 1 is not clear.

The expression "*used in place of one or more tethers*" in product claim 1 is ambiguous because it is at least unclear whether it is meant to indicate that tines or barbs are ideally provided in place of tethers (such tethers never being provided), or that existing tines or barbs are used instead of tethers that were provided at a first stage but were then replaced by such tines or barbs at a later stage.

This ambiguity in the expression results in an ambiguity in the scope of protection attached to claim 1, because depending on how the expression is read, the claimed prosthetic valve would have a different structure.

3.3 Furthermore, as set out above with regard to the corresponding expression used in paragraph [00369], the term "*in place of one or more tethers*" is also ambiguous because it is unclear whether it is meant to exclude the presence of any tethers (i. e. all tethers being replaced), or whether it is meant to imply the presence of at least one tether (i. e. one or more of the tethers being replaced, but not all of them). In this respect, the Board agrees with the findings of the opposition division in the contested decision (page 10, 2nd paragraph).

(a) The appellant argued with their letter dated 17 October 2024 and during oral proceedings that the term "*one or more tethers*" refers to all tether(s), independently on whether there is just

one tether present or several tethers. The term "one or more tethers" shall be understood as a standard expression used to express that the number of tethers is not restricted.

(b) The Board does not follow this understanding. Since the expression is ambiguous (as set out above in 1.3.3 (b)) the skilled reader is not able to determine without doubts whether the scope of the claim encompasses embodiments without tethers.

3.4 Claim 1 of auxiliary request 11 is therefore unclear as correctly decided by the opposition division.

4. It hence can be left undecided whether the opposition division exercised their discretion correctly when admitting auxiliary request 11.

Auxiliary request 12

Amendments (Article 123(2) EPC)

5. The subject-matter of claim 1 according to auxiliary request 12 lacks disclosure in the application as originally filed.

5.1 Claim 1 of auxiliary request 12 requires a combination of a V-shaped collar with a plurality of tines or barbs. Tethers are no longer required.

5.2 The appellant alleges that support for the combination according to claim 1 can be found in the embodiment of figure 12 taken in combination with paragraph [00369].

5.3 As set out above in 1.3.2 (b) and (c), the teaching of paragraph [00369] is ambiguous, and it concerns a different embodiment than the embodiment shown in figure 12. The application as originally filed hence lacks a direct and unambiguous disclosure of the features required by claim 1 of auxiliary request 12.

6. It thus can be left undecided whether auxiliary request 12 filed with the grounds of appeal still can be admitted into the proceedings (Article 12 RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

G. Pricolo

Decision electronically authenticated