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**Datasheet for the decision
of 30 July 2019**

Case Number: T 0158/16 - 3.2.08

Application Number: 10184036.1

Publication Number: 2260798

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

Cardiac valve prosthesis having internal cover for preventing regurgitation

Patent Proprietor:

Edwards Lifesciences PVT, Inc.

Opponents / Former Opponents:

Medtronic, Inc./US/Medtronic Vascular Galway
Boston Scientific Corporation
Symetis SA
St Jude Med, Inc./Abbott Med GmbH/St Jude Med UK Ltd
/SJM Int, Inc./SJM Coord Center BVBA/St Jude Med S
C Inc

Headword:

Relevant legal provisions:

EPC Art. 123(2), 123(3)

Keyword:

Amendments - extension beyond the content of the earlier application as filed (yes) - extension of protection conferred (yes)

Decisions cited:

J 0011/80, J 0001/87, T 0600/00, T 2514/11

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0158/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 30 July 2019

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 December 2015 concerning maintenance of the
European Patent No. 2260798 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 21 December 2015 the Opposition Division decided that European patent No. 2260798 as per the 3d auxiliary request then on file, and the invention to which it related, met the requirements of the EPC.
- II. The patent proprietor (appellant 1) and opponents 2, 3 and 4 (appellants 2, 3 and 4) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. In a communication dated 14 November 2018 the Board informed the parties that the term of the patent had expired and requested the appellants to declare, in accordance with Rule 84(1) EPC, whether they intended to further proceed with the appeal. The Board noted that if the appeal was withdrawn within that period, 50% of the appeal fee was to be reimbursed.
- IV. Appellant 2 declared in its letter dated 9 January 2019 that they intended to further proceed with the appeal. Appellant 1 declared in its letter dated 24 January 2019 that they did not intend to further proceed with the appeal. Following the Board's communication pursuant to Articles 15(1) and 17(2) of the Rules of Procedure of the Boards of Appeal appellant 1 submitted arguments and new claim requests with letter dated 17 June 2019. At the beginning of the oral proceedings appellant 2 requested that the submissions of appellant 1 dated 24 January 2019 be interpreted as a withdrawal of the appeal.
- V. Appellants 2 (opponent 2) and 3 (opponent 3) withdrew their oppositions during the appeal proceedings and

thereby ceased to be party to the appeal proceedings. Opponent 1 had withdrawn its opposition already during opposition proceedings.

VI. Oral proceedings before the Board were held on 30 July 2019.

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

Appellant 1 (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted, or, in the alternative, that the patent be maintained on the basis of one of the following requests: auxiliary request 1 or 2 (hereinafter "AR1" and "AR2") filed during the oral proceedings before the Board; auxiliary request 1 or 1a filed with the grounds of appeal dated 29 April 2016; auxiliary request 2a or 3 filed during the oral proceedings before the opposition division; auxiliary requests 3a, 3b, 3c or 3d filed with letter dated 17 June 2019; or auxiliary requests 4, 5, 6, 7, or 8 filed with letter dated 20 September 2016 (originally filed on 20 August 2014).

Appellant 2 (opponent 4) requested that the decision under appeal be set aside and the patent be revoked.

VII. Claim 1 of the main request (corresponding to claim 1 as granted) reads as follows (feature assignment as in the impugned decision):

"1. A prosthetic valve assembly for replacing a stenotic native aortic valve, comprising:

2. a metallic frame (10)

(a) having upper and lower extremities,
(b) said frame being collapsible to a compressed position for advancement through a patient's femoral artery using a catheterization technique,
(c) said frame being expandable to an expanded position for implantation within said stenotic native aortic valve;

characterized in that it further comprises:

3. a collapsible valvular structure (14)

(a) sutured to said frame between said upper and lower extremities,
(b) said valvular structure formed of pericardium,
(c) for occluding blood flow in one direction; and

4. an internal cover (19)

(a) made with the same tissue as said valvular structure,
(b) said internal cover coupled to said valvular structure
(c) and having a lower end attached to said lower extremity of said frame,
(d) said internal cover sutured to a wall of said frame and extending along an internal surface of said wall of said frame,

(4e) said internal cover extending only along a lower part of said frame for preventing regurgitation of blood through said wall of said frame below said valvular structure,

(4f) an upper extremity of the internal cover sutured to the frame along a zig-zag line above a coupling line of the valvular structure,

(g) said internal cover suitable for allowing passage of blood from an aorta towards the coronary ostia."

Emphasis added by the Board to mark the two features most relevant for the present decision.

VIII. Claim 1 of AR1 differs from claim 1 of the main request in that features 4e and 4f have been amended as follows:

(e) said internal cover extending only along a lower part of said frame for preventing regurgitation of blood through said wall of said frame below said valvular structure, wherein the internal cover (19) additionally covers the internal side of the frame (10) partially 3 to 5 mm above the coupling line (18) of the valvular structure and wherein

(f) an upper extremity of the internal cover is sutured to the frame along a zig-zag line above a the coupling line of the valvular structure,....

IX. Claim 1 of AR2 is as claim 1 of AR1 apart from the word "only" being removed in feature 4e.

(e) said internal cover extending ~~only~~ along a lower part of said frame for preventing regurgitation of blood through said wall of said frame below said valvular structure, wherein the internal cover (19) additionally covers the internal side of the frame (10) partially 3 to 5 mm above the coupling line (18) of the valvular structure and wherein,

(f) an upper extremity of the internal cover is sutured to the frame along a zigzag line above a the coupling line of the valvular structure,....

X. The wording of the remaining auxiliary requests as far as it is of relevance for the present invention can be summarized as follows:

- (a) Claim 1 of auxiliary requests 1, 2a, 3, 3a, 3b, 3c and 3d comprises the following amendment of feature 4f:

"...(4f) an upper extremity of the internal cover sutured to the frame along a zig-zag line of the intercrossing bars above a coupling line of the valvular structure, ..."

Feature 4e is as in the main request.

- (b) The remaining auxiliary requests (auxiliary requests 1a and 4-8) all comprise features 4e and 4f as in the main request.

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

Submissions of appellant 1 dated 24 January 2019 - to be interpreted as a withdrawal of the appeal.

In reply to the Board's communication asking the appellants to indicate, pursuant to Rule 84(1) EPC, whether they intended to further proceed with the appeal, appellant 1 had submitted in its letter dated 24 January 2019 that the patentee "does not intend to further proceed with the appeal". By expressing its clear intention not to continue with the proceedings appellant 1 had in effect taken the procedural step of withdrawing the appeal.

This assessment was further supported by the fact that the legal effect of no continuation of the appeal under Rule 84 EPC on the one hand and a withdrawal of the appeal on the other hand was the same, namely that the appeal ended without a decision.

Main request - Article 100(c) EPC

During examination proceedings, feature 4e had been added to claim 1 as granted essentially from the passage on page 21, second paragraph of the earliest application as originally filed. The meaning of feature 4e, and in particular the meaning of the term "a lower part", had thus to be identical to the meaning in that paragraph, which comprised a clear definition of "the upper part" as being the part defined above the coupling line of the valvular structure. Consequently, the lower part was defined as the part below the coupling line. Feature 4e thus had to be understood in analogy to the embodiment of Figure 6b, thereby at the same time excluding the embodiment of Figure 6c. Hence, there was no disclosure - nor could there be any for logical reasons - of a prosthetic valve having an inner cover extending only along a lower part of the frame and at the same time having an upper extremity of the internal cover sutured to the frame above a coupling line of the valvular structure.

The subject-matter of claim 1 as granted which simultaneously comprised features 4e and 4f thus extended beyond the disclosure of the earliest application as originally filed.

Admission of AR1 and AR2 into the proceedings

The new auxiliary requests aimed at overcoming objections which had been raised already in the grounds of appeal. Filing them now was not an appropriate reaction to the proceedings. Hence, these requests should not be admitted.

AR1 - Article 100(c) and 123(2) EPC

The amendment in feature 4f did not change the fact that this feature was incompatible with feature 4e and that the combination of feature 4e and amended feature 4f in a single claim had no basis in the earlier application as originally filed. Claim 1 of AR1 was thus likewise not allowable for the reasons already discussed.

AR2 - Article 123(3) EPC

Because features 4e and 4f contradict each other, claim 1 as granted comprised no subject-matter and conferred no protection at all. Even assuming that the contradiction was removed, the protection conferred could thus only be extended. Furthermore, the removal of a limiting feature enlarged the scope of protection already for logical reasons. Even if the person skilled in the art realized that claim 1 was inconsistent and consulted the description looking for a meaningful claim interpretation, it would still remain unclear whether the claim aimed at defining the embodiment of Figure 6b or 6c.

Remaining requests - Article 100(c) EPC

The above arguments with respect to the main request applied mutatis mutandis to all further auxiliary requests.

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

Submissions of appellant 1 dated 24 January 2019 - not to be interpreted as a withdrawal of the appeal.

The withdrawal of an appeal had to be requested explicitly. The procedure foreseen under Rule 84(1) EPC in a case where the patent had lapsed in all Contracting States had to be distinguished from this. During the oral proceedings appellant 1 explained that it had declared its intention not to proceed further with the appeal on the assumption that no other appellant wished to continue either.

Main request - Article 100(c) EPC

Features 4e and 4f were based essentially on page 21, second paragraph of the description. Even if there was a slight inconsistency between these features, when reading this passage in its context, the person skilled in the art would realize that the claim was unambiguously directed to the embodiment of Figure 6c in which the inner cover extended only along a lower part of the frame but additionally partially covered an upper part in that its upper extremity was sutured to the frame above the coupling line. Claim 1 was drafted exactly with the features disclosed in combination in said paragraph, its subject-matter thus being originally disclosed.

Admission of AR1 and AR2 into the proceedings

The filing of AR1 and AR2 was in response to the discussion during the oral proceedings before the Board. Consequently, they could not have been filed earlier and should be admitted into the proceedings.

AR1 - Article 100(c) and 123(2) EPC

Claim 1 of AR1 now corresponded even more to the verbatim disclosure on page 21, second paragraph. The word "or" in this passage actually meant that both features were present together, i.e. with the internal cover extending along a lower part of the frame and additionally partly along an upper part thereof. In this respect, the term "additionally" clarified that the word "only" was not exclusive and that further coverage of the frame outside the lower part was disclosed, as consistently shown in the embodiment of Figure 6c.

AR2 - Article 123(3) EPC

In accordance with Articles 123(3) and 69 EPC, the drawings and the description had to be used to determine the protection conferred. As demonstrated above, consultation of the description and the drawings resulted in the protection conferred covering a prosthetic valve with an internal cover extending along a lower part of the frame but also partly along the upper part. The omission of the word "only" thus removed nothing more than a slight unclarity in granted claim 1 without any extension of the protection conferred. Indeed the scope of protection covered and had always covered the embodiment of Figure 6c and not the one of Figure 6b. The protection conferred by claim 1 of AR2 was thus exactly the same as the one conferred by claim 1 as granted.

Hence, the requirements of Article 123(3) were fulfilled.

Remaining requests - Article 100(c) EPC

For the reasons discussed with respect to the main request, the subject-matter of claim 1 of the remaining auxiliary requests did likewise not extend beyond the disclosure as originally filed.

Reasons for the Decision

1. Submissions of appellant 1 dated 24 January 2019 - not a withdrawal of the appeal

The case law of the Boards of Appeal concerning the withdrawal of an appeal has established several principles. One is that for a withdrawal to be effective it is not necessary that a declaration is made which includes the word "withdrawal" expressly (J 7/87, OJ 1988/422).

Another established principle is that a request for a withdrawal of an appeal can only be accepted without question if it is completely unqualified and unambiguous (J 11/80, OJ 1981/141, Reasons 5). Where there is any doubt as to the actual intent of a party, a declaration may be construed as a withdrawal only if the related facts confirm that such was the party's true intent (applying J 11/87, OJ 1988/367 to a withdrawal of an appeal).

Appellant 1 had declared in its letter dated 24 January 2019 that the patent proprietor "does not intend to further proceed with the appeal". An intention not to proceed is open to several interpretations. It can mean that the party does not wish to take an active role in the appeal anymore while maintaining the party status of an appellant. It can also mean that the appellant

intends to withdraw the appeal at a later date without indicating when this might be the case. The wording used by appellant 1 is as such not unambiguous and does thus not amount to a withdrawal of an appeal, see also T 60/00 (Reasons 2.3 and 2.4) and T 2514/11 (Reasons 2.1) where similar declarations were held not to amount to a withdrawal of an appeal.

Appellant 2 emphasised that the declaration of appellant 1 was made in reply to a communication of the Board asking the appellants, pursuant to Rule 84(1) EPC, to declare within a period of two months whether they intended to further proceed with the appeal ("Rule 84(1) EPC communication"). The Board notes that in the case where there is more than one appellant, such as in the present one, the legal consequence that proceedings are terminated only ensues if none of the appellants requests that the proceedings be continued. The answer of one appellant as to whether to continue the proceedings will often depend on that of the other. Appellant 2 had declared already on 9 January 2019 that it intended to further proceed with the appeal. For the other appellant then to withdraw the appeal would be a rather unusual behaviour of a party. This factual context does therefore not lend support to the suggestion that it was the true intent of appellant 1 to withdraw the appeal.

To summarise, a reply to a Rule 84(1) EPC communication is taken with a view to the legal consequences that are foreseen in that rule. In the case where there is more than one appellant, a declaration made by one of several appellants stating that it no longer intends to further proceed with the appeal is aimed at this legal consequence, which only ensues if none of the appellants requests that the proceedings be continued.

The only clear and unambiguous information that the Board can derive from such a declaration is the appellant's agreement that the proceedings are terminated if no other appellant requests that they be continued. This, however, is far removed from a withdrawal of an appeal, which is a procedural act entirely independent of the behaviour of the other parties.

To conclude, with letter dated 24 January 2019 appellant 1 did not withdraw the appeal.

2. Main request - Article 100(c) EPC

2.1 The patent is based on a 4th generation divisional application. The parent applications are WO 98/29057 (EP 0967939, AN 97953935.0), EP 1 621 162 (AN 05024006.8) and EP 2 000 115 (appeal case T 565/14, AN 08016624.2).

The description and drawings of all parent applications are identical to the description and drawings of the application. However, the claims of the original WO application have not remained in the respective divisionals. As discussed in T 565/14, point 1.1 of the reasons (the case concerns the direct parent application of the present one), it is thus sufficient to verify whether the claimed subject-matter is directly and unambiguously derivable, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the description and drawings of the earliest application WO-A-98/29057 (referred to as BB1 in the following) as filed.

2.2 The invention is directed to a prosthetic valve assembly for replacing a stenotic native aortic valve,

the prosthesis comprising an internal cover for preventing regurgitation of blood through the wall of the prosthesis frame below the valvular structure, while being suitable for allowing passage of blood from an aorta towards the coronary ostia.

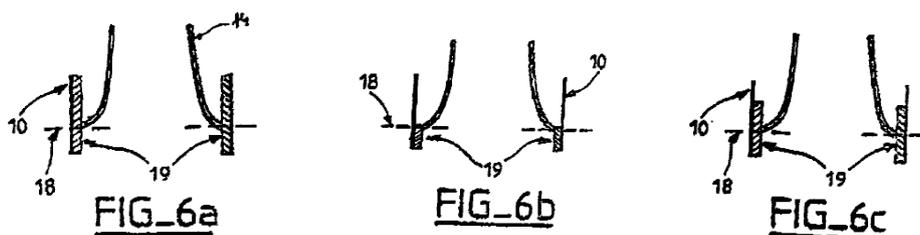
The parties agree that features 4e and 4f - being the most relevant features of the internal cover for the present decision - are in essence based on BB1, page 21, second paragraph. This passage reads as follows:

"In the different sectional views of the different examples of IV [read: "implantable valves"] according to the invention, as illustrated at Figures 6a to 6c, the internal cover 19 covers the totality of the internal side of the frame 10 (Figure 6a), **only** the lower part of the frame 10 (figure 6b), **or** it can additionally cover partially 3 to 5 mm as shown in the passage of blood from aorta to the coronary ostia Figure 6c, **the upper part defined above the coupling line 18 of the valvular structure.**"

(emphasis added by the Board)

From this passage, the skilled person derives that the frame has an upper part and a lower part. The upper part is defined as being above the coupling line. Consequently, the lower part *per definition* lies below the coupling line.

The embodiments described in this paragraph are reproduced below:



The paragraph describes an embodiment wherein only the lower part of the frame is covered (Figure 6b). Figure 6b is consistent with the definition of the "upper part" in the same paragraph in that the internal cover only extends below coupling line 18 and thus exclusively along a lower part of said frame.

As can be derived from the word "**or**" (represented in bold in the citation above) after the embodiment of Figure 6b, an alternative embodiment is described, in which the internal cover additionally covers a part in the passage of blood from the aorta to the coronary ostia as shown in Figure 6c. While also in this embodiment the lower part is covered, it is not only the lower part which is covered but the lower part and additionally a part of the upper part. Indeed, the feature that only the lower part is covered excludes the embodiment of Figure 6c. There is thus no disclosure of only the lower part being covered (as defined in feature 4e) and a portion of the upper part being additionally covered (as required by feature 4f).

Thus, the subject-matter of claim 1 as granted which comprises features 4e and 4f in combination, i.e. connected by an "and" and not by an "or" (as originally disclosed), extends beyond the disclosure of Bb1 as originally filed.

- 2.3 The opposition division argued that the wording "a lower part" was not to be understood as being restricted to the part below the coupling line as otherwise it should have been formulated as "the" lower part of the frame. Thus, "a lower part" could be any part below the upper extremity of the frame.

However, in this interpretation the respective upper part would not be defined as being "above the coupling line of the valvular structure", contrary to what is explicitly defined on page 21, lines 9, 10 of BB1. The interpretation by the opposition division thus ignores the explicit definition of the terms in the application as filed. In this context, the use of the indefinite article should not be given too much weight. As the "lower part of the frame" mentioned in feature 4e has no antecedent, the use of the indefinite article is entirely in line with the definition of the terms in BB1, page 21, second paragraph.

- 2.4 Appellant 1 further argued that the word "only" on page 21, second paragraph, when read in context, would not be understood by the skilled person as strictly exclusive. In view of the term "additionally" in the consecutive part of the sentence, it was clear that "only along a lower part of the frame" did indeed not exclude some coverage of the upper part.

However, the word "only" has a clear meaning: it requires the internal cover to extend along the lower part and nowhere else. The second part of the phrase (connected by "or") discloses an embodiment with the internal cover extending along the lower part and additionally partly along the upper part. Reading the passage in context, the skilled person's understanding is not that the word "only" would need to be given a larger meaning, but that for that embodiment - because of the "or" - the word "only" simply does not apply. As argued above, there is thus no disclosure of an internal cover extending only along a lower part of the frame and additionally along a part of the upper part.

3. Admission of AR1 and AR2 into the proceedings

Although late filed, AR1 and AR2 are considered a bona fide attempt to respond to the course of the proceedings. They are of low complexity and can be dealt with by the Board and the other party without adjournment of the proceedings. They were thus admitted.

4. AR1 - Article 100(c) and 123(2) EPC

The further definition in claim 1 of AR1 according to which the "internal cover (19) additionally covers the internal side of the frame (10) partially 3 to 5 mm above the coupling line (18) of the valvular structure" cannot change the above analysis that feature 4f has not been disclosed as being combined with feature 4e - even if amended - in a single embodiment. As discussed above, the respective original disclosures are connected by an "or" not by an "and". Combining the features into a single embodiment thus results in new technical information for the person skilled in the art.

Consequently, the subject-matter of claim 1 of AR1 likewise extends beyond the disclosure of the earliest application as originally filed.

5. AR2 - Article 123(3) EPC

In claim 1 of AR2 the word "only" in feature 4e has been removed. The claim is now in essence directed to the alternative disclosed after the "or" on p. 21, second paragraph, i.e. to the embodiment of Figure 6c.

In accordance with Article 123(3) EPC it has to be ascertained that the amendment does not extend the protection conferred by the European patent. According to Article 69(1) EPC the extent of the protection conferred by a European patent shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

Both parties essentially agree that there is a discrepancy between features 4e and 4f in claim 1 as granted. Assuming (as appellant 2 does) that for that reason alone claim 1 as granted did not confer any protection at all is too formalistic. Instead, the person skilled in the art would have used the description and the drawings to interpret the claim and to determine the protection conferred.

Appellant 1 argued that by this approach the person skilled in the art inevitably came to the conclusion that the claim as granted was directed to the embodiment shown in Figure 6c. This was exactly the embodiment now defined in claim 1 of AR2, such that no extension of the protection had been introduced.

However, as discussed during the oral proceedings, if two features are contradictive the contradiction can be caused by either of the two. In the present case, it might be that feature 4e was intended to be drafted without the "only" ('first approach'). It might, however, likewise be that it is feature 4f which had been intended in a way consistent with feature 4e such that indeed only the lower part of the frame was covered (thus covering the embodiment of Figure 6b and not the one of Figure 6c; 'second approach'), e.g. by defining the upper extremity as being sutured to the frame along a zig-zag line at the coupling line of the

valvular structure (see e.g. Figure 7). When using - in accordance with Article 69 EPC - the description and the drawings to interpret the claims, both approaches are equally meaningful, because both result in one of the alternative embodiments of Figure 6b and 6c being protected.

However, the second approach results in the protection conferred being extended because following this approach claim 1 as granted did not cover the embodiment of Figure 6c, whereas claim 1 of AR2 does. The amendment thus extends the protection conferred and is not allowable in view of the requirements of Article 123(3) EPC.

In this context, it cannot play a role whether using the first approach would not have resulted in an extension of the protection conferred. It is the proprietor who is responsible for the drafting of the claims. An inconsistency and the ambiguity in scope resulting therefrom cannot be to the proprietor's benefit and to the detriment of third parties.

To put it differently, a third party had good reasons (cf. the 'second approach') to assume that claim 1 as granted covered essentially the embodiment of Figure 6b, and not the one of Figure 6c. It would now be surprised by the protection conferred by claim 1 shifting after grant towards the embodiment of Figure 6c. Such shift of the protection conferred is exactly what Article 123(3) EPC is meant to prevent.

The amendment in AR2 is thus not allowable in view of the requirements of Article 123(3) EPC.

6. Remaining requests - Article 100(c) EPC

The remaining requests either have features 4e and 4f as in claim 1 as granted, such that the reasoning in point 2.2 above applies. Or, they comprise amended feature 4f in which the term "along a zig-zag line" has been replaced by "along a zig-zag line of the intercrossing bars". However, even amendmended feature 4f defines the upper extremity to be sutured to the frame ... above a coupling line of the valvular structure, i.e. somewhere in the upper part, which is in contradiction to the cover extending only along a lower part of the frame.

Thus, also for the remaining requests, the reasoning in point 2.2 applies and their respective subject-matter extends beyond the disclosure of the earliest application as originally filed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated