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D E C I S I O N
of 30 August 2000

Case Number: T 0835/97 - 3.2.2

Application Number: 91916465.7

Publication Number: 0547135

IPC: A61F 2/24

Language of the proceedings: EN

Title of invention:
Stentless heart valve and holder

Applicant:
BAXTER INTERNATIONAL INC.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
"Essential features omitted from claim 2 - after amendment
(no)"

Decisions cited:
-

Catchword:
-



Case Number: T 0835/97 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 30 August 2000

Appellant: BAXTER INTERNATIONAL INC.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 10 March 1997
refusing European patent application
No. 91 916 465.7 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
J. C. M. De Preter

Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division dated 10 March 1997 to refuse European patent application No. 91 916 465.7 on the ground that claim 1 did not meet the requirement of Article 123(2) EPC.

The grounds of refusal were that the features (a) to (f), that were defined in claim 32 of the application as originally filed, were omitted from new claim 1 which was based on that claim. According to the decision of the examining division, whereas the features (a), (e), and (f) were not essential for solving the technical problem, the other features (b), (c), and (d) were "essential features" and may, therefore, not be omitted.

- II. On 23 April 1997 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee. On 30 June 1997 a statement of grounds of appeal was filed, with an alternative set of claims of an auxiliary request. A request for oral proceedings was also filed.

- III. Oral proceedings before the Board were held on 30 August 2000. At the oral proceedings the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claim 1 according to the main request submitted by letter of 27 June 1997, or on the basis of the first auxiliary request submitted at the oral proceedings of 30 August 2000, or on the basis of the second auxiliary request submitted by letter of 14 July 2000.

IV. Claim 1 of the main request reads as follows:

"A stentless aortic animal heart valve prosthesis, which is reversible and comprises a segment (4) of an aortic root (9) tanned at low pressure and retaining the natural shape and flexibility and having an intact heart valve (21-27), the prosthesis having coronary openings (47) formed by trimming away the left and right coronary arteries (3,5) of the segment, while leaving an intact band of aorta surrounding the coronary openings at the outflow side and a rim (39) at the inflow side, and a minimal biocompatible suturable covering (32) along said inflow rim (39)."

This claim omits the following features of claim 1 (highlighted in bold type) of the application as originally filed:

- (a) the band of aortic wall left intact surrounding the coronary openings is **at least about 2 millimeters wide**
- (b) the suturable covering is **affixed along the entire right coronary septal shelf externally**
- (c) the covering is affixed along the inflow rim **both internally and externally**
- (d) the covering **covers at the outflow rim the area running internally directly above the pseudoannulus line and along the coronary openings**
- (e) the covering **leaves uncovered a portion of aortic wall from 2 to 3.5 mm in width between the edges of the cloth and each valve commissure**

- (f) **wherein the band of aortic wall can be trimmed without destroying the shape and function of the valve**

Claim 1 of the first auxiliary request reads as follows:

"A stentless aortic animal heart valve prosthesis, which is reversible and comprises a segment (4) of an aortic root (9) tanned at low pressure and retaining the natural shape and flexibility and having an intact heart valve (21-27), the prosthesis having coronary openings (47) formed by trimming away the left and right coronary arteries (3,5) of the segment, while leaving an intact band of aorta surrounding the coronary openings at the outflow side and a rim (39) at the inflow side, and a minimal biocompatible suturable covering (32) affixed along said inflow rim (39), both internally and externally, and along the exterior surface of the entire right coronary septal shelf."

Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request essentially in that it additionally specifies that the covering leaves uncovered a portion of aortic wall from 2-3.5 mm in width between the edges of the cloth and each valve commissure, and also specifies the dimension of the intact band of aorta as being at least 2 mm wide.

V. The appellant argued as follows:

The examining division made a decision based on what it considered to be "essential" features necessary to solve a technical problem which it defined itself, but which was not the problem set out in the application,

in the paragraph linking pages 2 and 3. The latter problem, concerning increased turbulence and rigidity caused by a prior art stent, was adequately solved by the features of claim 1 of the main request. In this respect, the minimal biocompatible suturable covering on the inflow rim and the intact band of aorta provided structural integrity and sewing means, and at the same time decreased turbulence, while the tanning provided flexibility. Therefore, the claim defined all the essential features of the invention.

This point of view was consistent with the "Summary of the Invention" on page 4, in which the paragraph in lines 12 to 23 defined the essential features of the invention, which were condensed to the subject-matter of new claim 1. The remainder of the general description and the specific description starting on page 9 clearly described preferred and non-essential features and other details. Only those features referred to as being "of the invention" were essential features.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request*

The Board is invited to approve a claim to a stentless aortic animal heart valve prosthesis which is based on claim 32 of the application as filed, but is now directed to such a prosthesis in which the features (a) to (f) have been omitted.

The criteria for allowing the deletion of a feature from the claims were set out in the decision T 331/87 (OJ EPO, 1991, 22), according to which the deletion of a non-essential feature from the main claim may not be in breach of Article 123(2) EPC if the person skilled in the art would directly and unambiguously recognise that (1) the feature was not explained as essential in the disclosure, (2) it was not, as such, indispensable for the function of the invention in the light of the technical problem it served to solve, and (3) the replacement or removal required no real modification of other features to compensate for the change.

In the present case, it remains to be decided which of the features (a) to (f) was explained as being non-essential and which indispensable.

The appellant's argument, that only the first paragraph under the "Summary of the Invention" on page 4 defines the essential features of the invention, and the remainder of the general description and the specific description describes preferred and non-essential features, is not valid for the following reasons:

The present application is an International application, whose layout is governed by the PCT. The heading "Summary of the Invention" in such applications defines the broadest aspect of the invention, and this section is followed by a description of specific features. It is the whole of the statement under this heading that is to be considered as the broadest definition of the invention and there is no basis for the appellant's contention that only the first paragraph under this heading is of importance in this respect.

The appellant's further argument that the present technical problem is that defined on page 3, lines 5 to 10 and that the minimal biocompatible covering as defined in claim 1 solves this problem and, therefore, defines all the essential features, is also not valid for the following reasons:

The stent and the sewing ring of prior art valve prostheses, that are the source of turbulence and rigidity, are to be replaced so as to overcome the stated problem. However, anything that substitutes the stent and sewing ring, in this case the minimal biocompatible suturable covering (see the sentence linking pages 5 and 6), must take over their corresponding functions in full, i.e. it must maintain the structural integrity and have the sewing capability of prior art prostheses, it being well known that the trimmed valve of an animal aortic heart is inherently weak and the valve leaflets are flimsy and require support.

Bearing in mind this requirement, the Board comes to the conclusion that the following features are not essential for solving the problem:

Feature (a): The intact band of aorta is necessary to maintain proper alignment of the valve commissures and prevent distortion of the valves during suturing (page 10, lines 19 to 24).

The exact width of the intact band of aorta necessary for this would depend on the size of the heart valve, which could vary widely depending on whether an infant or an adult is to be the recipient, and also on which animal the valve was removed from, its age, etc.

therefore, the limitation of "at least 2 mm" is clearly an unnecessary limitation in the claim.

Feature (d): It is clear from the description (see page 4, lines 30 to 33, page 6, lines 20 to 24, in which "inflow" at line 24 should read "outflow" for consistency with the remainder of the description, and page 15, lines 5 to 13), that a part of the aortic segment at the outflow side around the coronary openings may be trimmed away. This possibility is illustrated in the brochure of the appellant "Edwards Prima Plus Stentless Bioprosthesis".

If the option exists of cutting away this part of the aorta, then it is illogical to insist that a cloth covering over this area of the aorta is essential since it too would be cut away with the aorta part, were this option to be exercised. Therefore, feature (d) is clearly optional.

Feature (e): This feature is supported by the description on page 12, line 17 to page 13, line 6. This passage describes the covering at the outflow side of the valve, and states that the cloth is sewn only on the internal portion of the outflow side. Figure 4 shows the detail of this area of the valve and that the cloth covers the area along the pseudoannulus. Therefore, feature (e) is linked to feature (d), and if the latter is optional then so is the former. Again, if this area of the aorta is cut away, then feature (e) becomes irrelevant, and is not essential, accordingly.

Feature (f): This relates only to the intended use of the prosthesis and its omission does not affect the scope of the claim, which is to a device.

On the other hand, the Board considers the features (b) and (c) to be essential features. This view is supported by the Summary of the Invention, which states (see page 5, line 28 to page 6, line 6) that the covering helps to maintain the natural shape of the aortic segment and functions like a sewing ring. For this, it extends along the inflow rim, both internally and externally, and along the exterior surface of the entire right coronary septal shelf. Nowhere else in the application, for example on page 11, line 25 to page 12, line 3, are these described as preferred features, nor is their inclusion in claim 1 not in keeping with the objects of the invention.

Therefore, the Board considers these features to be essential in order provide structural integrity, and hence to solve the problem of the invention, and finds no support in the application as originally filed, that these features were optional or non-essential. For these reasons features (b) and (c) may not be omitted from the original main claim 32.

For the above reasons the main request is not allowable, because it fails to meet the requirement of Article 123(2) EPC.

3. *First auxiliary request*

Claim 1 of this request includes the features (b) and (c) that the Board considers essential to the invention, and is allowable, accordingly.

4. *Other matters*

The Board considers claim 1 of the main request to meet

not only the requirement of Article 123(2) EPC, but also of Art 84 EPC, and to be in order as regards formal aspects. However, an examination as to substantive aspects, particularly as to the requirements of Article 52(1) EPC, has yet to be performed on the application.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of claim 1 of the first auxiliary request submitted at the oral proceedings of 30 August 2000.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß