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D E C I S I O N
of 28 March 1996

Case Number: T 0993/93 - 3.2.2

Application Number: 86305710.5

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Title of invention:
A heart valve prosthesis

Patentees:
McQueen, David M., et al

Opponent:
Huffstutler jr., M. Conrad

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step - (no)"

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Case Number: T 0993/93 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 28 March 1996

Appellants: (Proprietors of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 24 September 1993 revoking European patent No. 0 211 576 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: H. Seidenschwarz
Members: P. Dropmann
J.-C. De Preter

Summary of Facts and Submissions

I. A notice of appeal was filed against the decision of the Opposition Division revoking European patent No. 0 211 576 on the ground that the subject-matter of the amended claim 1 annexed to the decision lacked an inventive step having regard to document

D6: David M. McQueen and Charles S. Peskin, "Computer-assisted design of mitral valve prostheses", SECTAM XII, The Southeastern Conference on Theoretical and Applied Mechanics, Session TP1-3: Biofluid Mechanics, 10 to 11 May 1984, pages 271 to 276.

II. Oral proceedings before the Board were held on 28 March 1996.

III. The appellants (proprietors of the patent) requested that the decision under appeal be set aside and the patent maintained on the basis of claim 1 according to the auxiliary request filed with the statement of grounds dated 24 January 1994, claims 2 to 6 and 8 of the patent as granted, a description to be adapted, and the drawings of the patent as granted.

IV. The respondent (opponent) requested that the appeal be dismissed.

V. Claim 1 reads as follows:

"A heart valve prosthesis (10) comprising a valve body (12) having a passageway (18) for the flow of blood therethrough from upstream to downstream, and first and second leaflets (14, 16) individually pivotally supported in said passageway (18) and pivotal between a closed position inhibiting blood flow through said

passageway (18) and an open position allowing blood flow therethrough, said first and second leaflets (14, 16) defining three separate flow channels in said passageway (18), wherein said first and second leaflets (14, 16) are curved in a plane normal to their respective pivot axis and are arranged so that the convex sides (26, 28) of said first and second leaflets (14, 16) face each other when said leaflets (14, 16) are in said open position, characterised in that the concave (22, 24) sides of said first and second leaflets (14, 16) face upstream when in the closed position and each of the leaflets is pivotally supported (P,P') at a distance greater than one half of the arc length of the leaflet (14, 16) measured from the outer edge (36, 38) to the inner edge (40, 42) of said leaflet, and in that the valve further includes means (30, 32) in said valve body for limiting the maximum angle of opening of said leaflets to approximately 90° from a plane (M-M') transverse to said passageway, said first and second leaflets being pivotally supported at a position and having a curvature for maximising the minimum peak velocity flowing in all three flow channels and for maximising the ratio of the net stroke volume of blood crossing the valve per heartbeat to the mean pressure difference across the valve during forward flow of blood."

VI. The appellants essentially argued as follows:

Document D6 indeed represented the most relevant prior art. Since novelty was not contested, the only question to be answered was that of inventive step, i.e. whether the difference between the teaching of claim 1 and that of document D6 was obvious. The problems to be solved by the invention were (i) to alleviate stagnation in all three channels of the valve, i.e. the central channel, and the anterior and posterior side channels, by

maximising in all three channels the minimum peak velocity of blood flow which was decisive for the danger of stagnation, and (ii) simultaneously to optimise the hemodynamic performance of the valve measured by the ratio of the net stroke volume of blood crossing the valve per heartbeat to the mean pressure difference across the valve during forward blood flow.

These problems were solved by the curved bi-leaflet valve having the features defined in claim 1. There was no indication in document D6, which related to flat bi-leaflet valves, or elsewhere that both of these problems could simultaneously be solved in this way. Furthermore, document D6 was by no means an enabling disclosure and, therefore, extensive research was necessary to replace the two flat leaflets known from document D6 with curved leaflets. The ")(" valve configuration specified in claim 1 of the invention was chosen out of an infinite number of possibilities of curved leaflets. There was no analogy between curved single-leaflet valves and bi-leaflet valves since the flow through single-disc valves was not symmetrical. Therefore, the results from the curved single-leaflet valve could not be transferred to the bi-leaflet case. Moreover, document D6 recommended an asymmetrical design for the asymmetrical mitral position and thus taught away from the symmetrical design adopted in the invention. Hence, the choice of a symmetrical design for a prosthetic mitral valve could not be considered obvious.

VII. The respondent essentially argued in its counterstatement that claim 1 was obscure and its subject-matter did not involve an inventive step, in particular in the light of the state of the art known from document D6.

Reasons for the Decision

1. The appeal is admissible.

2. No formal objections under Articles 84 and 123(2) and (3) EPC arise against claims 1 to 6 and 8. The fact that claim 1 is broad in scope does not necessarily mean that it is obscure as argued by the respondent.

3. The Board accepts the findings of the Opposition Division that the subject-matter of claim 1 annexed to the decision under appeal is novel. This also applies to the valve prosthesis according to the present claim 1. The respondent admitted in its letter dated 24 March 1994 (cf. page 6) and during the hearing that the documents which were argued to be novelty-destroying during the opposition proceedings were published after the priority date, which can be accorded to the contested patent.

4. However, the heart valve prosthesis according to claim 1 does not involve an inventive step. The Board is convinced that the subject-matter of claim 1 is nothing but an obvious further development of the state of the art disclosed in document D6.

4.1 As agreed by the parties, document D6 represents the state of the art which is closest to the subject-matter of claim 1. The authors of this document are identical to the proprietors and inventors of the contested patent.

Document D6 discloses a computer-assisted design of mitral valve prostheses and describes in its first part (page 271, right column to page 274, first paragraph) a single-pivoting-disc valve model having a curved leaflet

and in its second part (page 274, second paragraph to page 276) a butterfly-bi-leaflet valve model having flat leaflets. The latter model (see Figure 5) comprises, using the wording of claim 1, a valve body having a passageway for the flow of blood therethrough from upstream to downstream, and first and second leaflets individually pivotally supported in said passageway and pivotal between a closed position inhibiting blood flow through said passageway and an open position allowing blood flow therethrough. Said first and second leaflets define three separate flow channels in said passageway. Each of the leaflets is pivotally supported at a distance greater than one half of the length of the leaflet measured from the outer edge to the inner edge of said leaflet. The valve prosthesis known from document D6 further includes means (constraints) in said valve body for limiting the maximum angle of opening of said leaflets to a certain value from a plane transverse to said passageway (cf. page 274, left column, last paragraph, and right column). An angle of 90° is particularly disclosed in document D6 (see Figure 6, fourth column, and page 275, right column, end of the first paragraph).

4.2 The subject-matter of claim 1 differs from the valve known from document D6 in the following features:

- The first and second leaflets are curved in a plane normal to their respective pivot axis end are arranged so that the convex sides of the first and second leaflets face each other when the leaflets are in the open position;

- the concave sides of the first and second leaflets face upstream when in the closed position; and

- the first and second leaflets are pivotally supported at a position and have a curvature for maximising the minimum peak velocity flowing in all three flow channels and for maximising the ratio of the net stroke volume of blood crossing the valve per heartbeat to the mean pressure difference across the valve during forward flow of blood.

4.3 The Board agrees with the appellants that the problem underlying the subject-matter of claim 1 is the combined problem of alleviating stagnation in all three channels of the valve and of optimising simultaneously the hemodynamic performance of the valve.

The problem is solved by providing the leaflets with a curvature and positioning their pivot points in accordance with the features set out in point 4.2 above.

4.4 Document D6 itself gives a hint that stagnation might possibly be alleviated by replacing the flat leaflets of the bi-leaflet valve known from document D6 by curved leaflets. Indeed, it is stated at page 276, last sentence of the second paragraph: "In the event that stagnation still seems to be a problem we will consider asymmetric designs and curved leaflets." It is also pointed out in document D6 (page 275, left column, lines 8 to 5 from the bottom) that the valve should be designed so as to avoid low values of the peak velocity; this obviously applies to all three channels. Furthermore, it is known from document D6 (see in particular page 275, Figure 8, and right column, first paragraph) that one aspect of the computational method described there is to maximise the ratio of the net stroke volume of blood to the mean pressure difference across the valve during forward blood flow, i.e. the hemodynamic performance.

Hence, neither the formulation of the problem nor the idea of curving the leaflets can be considered as making a contribution to a possible inventive step.

4.5 The question arises as to the kind of curvature which would be considered by the skilled person contemplating using curved leaflets as suggested at page 276, last sentence of the second paragraph of document D6 and cited in point 4.4 above.

There cannot be any doubt that the skilled person intending to study the influence of curvature would do no more than replace the flat bi-leaflets disclosed in Figure 5 of document D6 by curved bi-leaflets, leaving the other parameters unchanged, e.g. the pivot point locations, the maximum angle of opening of the leaflets and the symmetrical construction of the leaflets (cf. page 274, left column, last seven lines).

Since the influence of curvature has already been studied in single-disc valves and led to positive results published in the same document D6 (see pages 271 to 274, first paragraph) and since, as stated at page 274, first sentence of the second paragraph, the design-parameter study of the bi-leaflet valve is similar in spirit to the single-disc study described in the first part of document D6, the Board is convinced that the skilled person would use the same kind of curvature as in the former studies as a starting point for such studies of curved bi-leaflet valves. This would also enable him to compare the results of his computer-assisted studies of curved bi-leaflet valves with the results achieved in the study of curved single-disc valves already described in document D6.

4.6 Thus, although there are several possibilities of curved leaflets as pointed out by the appellant, the curvature already studied in single-leaflet valves is the first and obvious one which the skilled person would consider when studying curved bi-leaflet valves as suggested in document D6. This means that the following distinguishing features mentioned in point 4.2 above are obvious:

- The first and second leaflets are curved in a plane normal to their respective pivot axis and are arranged so that the convex sides of the first and second leaflets face each other when the leaflets are in the open position; and

- the concave sides of the first and second leaflets face upstream when in the closed position.

The features that the convex sides of the first and second leaflets face each other when the leaflets are in the open position results from the fact that, as stated in point 4.5 above, the skilled person, when studying the influence of curvature in the above sense, would leave the pivot point locations of the flat bi-leaflet valve unchanged.

4.7 The appellants argued that there was no analogy between curved single-leaflet valves and bi-leaflet valves, since the flow through single-disc valves was not symmetrical, and that, therefore, the results from the curved single-leaflet valve could not be transferred to the bi-leaflet case. These arguments cannot be accepted by the Board. The question to be answered was not whether the results can be transferred from one design of mitral valve to another design, but rather which kind of curvature would be considered in the light of document D6 by the skilled person when studying curved

bi-leaflet valves as suggested at page 276, second paragraph of document D6. Furthermore, the argument that this document recommended an asymmetrical design and thus taught away from the symmetrical design adopted in the invention leaves out of consideration the fact that claim 1 is not restricted to a symmetrical design for a prosthetic mitral valve, but rather comprises in its scope both symmetrical and asymmetrical designs. Even if the appellants had restricted claim 1 to a symmetrical design as claimed in claim 2, such a design would be obvious because document D6 already discloses bi-leaflet valves which are symmetrical (cf. page 274, left column, line 7 to 5 from below) and the skilled person, when studying the influence of curvature, would keep the other parameters unchanged as noted in point 4.5 above.

4.8 Claim 1 further contains the distinguishing feature (cf. point 4.2 above) that the first and second leaflets are pivotally supported at a position and have a curvature for maximising the minimum peak velocity flowing in all three flow channels and for maximising the ratio of the net stroke volume of blood crossing the valve per heartbeat to the mean pressure difference across the valve during forward flow of blood.

This feature does not involve an inventive step either for the following reasons: The parameter "position of the pivot points of the leaflets" was already considered in document D6 (cf. page 276, second paragraph) with respect to stagnation in bi-leaflet valves. It was furthermore mentioned in this document (cf. page 275, left column, lines 8 to 5 from the bottom) that the valve should be designed so as to avoid low values of the peak velocity. In addition, the criterion "ratio of the net stroke volume of blood crossing the valve per heartbeat to the mean pressure difference across the valve during forward flow of blood" has been studied in

bi-leaflet valves (cf. document D6, Figure 8 and page 275, right column, first paragraph). As to the parameter "curvature C of the leaflets", it is known from document D6 (cf. page 272, left column, fourth paragraph) that the parameter "dimensionless radius R of curvature of the leaflet" (= the reciprocal of the curvature C) is a crucial design parameter of the single-disc model study and that the best choice of this parameter is determined by examining the peak anterior velocity, the net stroke volume and the mean forward pressure difference.

In view of the above teaching, it is obvious to determine, for curved bi-leaflet valves, the said parameters such that the minimum peak velocity in all three flow channels and the ratio of the net stroke volume to the mean pressure difference are maximised.

5. It follows from the considerations in points 4.1 to 4.8 above that the teaching in document D6 is so close to the subject-matter of claim 1 that there is no inventive step in accordance with Article 56 EPC. The subject-matter of claim 1 is thus not patentable under Article 52(1) EPC.

6. The features specified in dependent claims 2 to 6 and 8 do not add an inventive step to the subject-matter of claim 1 because the features of claims 2 to 4 and 8 are known from document D6 and the features of claims 5 and 6 are obvious in the light of the disclosure in document D6, Figure 1 and page 273, right column, first paragraph.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani H. Seidenschwarz