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DES BREVETS

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File Number: W 45/92
International application No.: PCT/US 92/01732
Publication No.:
Title of invention: Improved prosthetic heart valve
Classification: A61F 2/24

D E C I S I O N
of 15 October 1993

Applicant: ONX, INC.

Headword:

PCT: Art. 17(3)(a); Rules 13 and 40

Keyword: "Lack of unity 'a posteriori'"



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Boards of Appeal

Chambres de recours

Case Number : W 0045/92
International Application No. PCT/US 92/01732

D E C I S I O N
of the Technical Board of Appeal
of 15 October 1993

Applicant : ONX, INC.
2204 Manana Street
Austin, Texas 78730 (US)

Representative : Fitch, Even, Tabin & Flannery
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Chicago, Illinois 60603 (US)

Subject of the Decision : Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fee) of the European Patent Office (branch at The Hague) dated 7 July 1992.

Composition of the Board :

Chairman : G. Szabo
Members : M. Noël
J. Van Moer

Summary of Facts and Submissions

- I. International patent application PCT/US 9 201 732 was filed on 3 March 1992.
- II. The EPO, acting as International Search Authority (ISA), sent the Applicant an invitation to pay two additional search fees in accordance with Article 17(3)(a) and Rule 40.1 PCT.

The ISA indicated that the subject-matter claimed related to three inventions set out in the following groups:

1. heart valve with a pair of occluders (or leaflets) (Claim 1, 2, 12, 13 to 15, 26, 27 to 28, 34, 35 to 36);
2. heart valve with one occluder (Claims 3, 4 to 11, 22, 23 to 25, 29, 30 to 33, 37); and
3. heart valve, with particular embodiment of the pivoting arrangement (Claims 16, 17 to 21).

The reasoning of the ISA was that the alleged inventive concept of the application as described in the part "Summary of the Invention" (pages 2 to 4) consisted of three major aspects clearly anticipated by the teaching of the prior art document WO-A-9 101 698 (cf. Summary and page 13, lines 4 to 19; Figures 13 and 14). Since this document deprived Claim 1 of novelty, the other independent claims appeared as different embodiments of a known technical concept. Each group of independent claims addressed the problem of closing the valve with a different technical solution, making therefore a case of non-unity.

III. Within the prescribed time limit the Applicant paid only one additional search fee, under protest, in accordance with Rule 40.2(c) PCT and requested that the fee be applied to the claims of the second group.

The Applicant argued essentially that the broad inventive concept embodied in the patent application was the same regardless of whether there was one occluder or two occluders. It was therefore submitted that the term " occluder means" was expressly selected in the claims of the second group so as to broadly cover both situations.

Since the mechanism for causing the valve members (occluders) to promptly pivot toward the closed position was the same, regardless of whether one or two valve members were involved, an additional search directed specifically to a single occluder would not turn up any reference more pertinent than the references that were cited, based upon extensive searching. Therefore, the arbitrary division of the claims into two groups for a valve with one or two occluders was clearly inappropriate.

Reasons for the Decision

1. The protest is admissible.
2. The Board's understanding of Rule 40.2(c) PCT is that its responsibility in examining protests is limited to deciding whether the protest is justified in respect of the additional fees actually paid under protest. This means that normally only the claims referred to in groups 1 and 2 are to be considered by the Board.

3. The groups listed by the ISA bring together independent claims and dependent claims. For this latter category the question of unity is not to be set as they all refer to a previous respective independent claim (Rule 13.4 PCT). Neither is the question of unity to be raised between independent claims unitarily classified within a same group. This does not mean that a proper investigation would necessarily confirm unity within the groups themselves, but it is also recognised that the search examiner might have concluded that with no or very little additional search the whole group can be covered.

The only outstanding issue therefore is whether a single general inventive concept as requested by Rule 13.1 PCT is to be found between independent claims (1, 12, 26, 34) of the first group and independent claims (3, 22, 29, 37) of the second group, respectively.

- 3.1 The objection made by the ISA refers to a lack of unity "a posteriori", i.e. after it was decided that the subject-matter of Claim 1 was not novel with respect to the disclosure made by WO-A-9 101 698.

Generally, lack of unity on an "a posteriori" basis is confined to clear cases, i.e. in which careful examination shows that the first mentioned independent claim **vis-à-vis** the state of the art would necessarily fail for lack of novelty or of inventive step, since this is immediately apparent (cf. G 1/89, OJ EPO 1991, 155, points 5, 8.1 and 8.2). The subject-matter of the main claim having thus been deprived of patentability, the other claims individually dependent thereon may no longer define a unitary invention.

- 3.2 In the Board's view, the present case shows a different situation.

Even if independent Claim 1 of the first group failed for the reasons above this would not affect the character of other, not dependant claims at all. The fact, as submitted by the ISA, that "the other independent claims thus appear as different embodiments of a known technical concept" does not mean that those other different solutions are not still linked together as to form a single general inventive concept at least with each other and possibly with the surviving Claim 2.

Furthermore, the reasons, submitted by the ISA to decide that Claim 1 was not novel, are neither valid nor founded. No comparison was actually made between the specific teachings of WO-A-9 101 698 and the features of the subject-matter of Claim 1. Instead, the ISA briefly compared the subject-matter of this document with "three major aspects" functionally defined from the specification, in particular from the summary part of the invention, namely:

- generation of a rotational momentum on the occluder(s)
- means for generating the rotational momentum (camming means); and
- displacement of instantaneous centre of rotation of the occluder(s)

These three broad aspects are, however, not the specific subject-matter of the present Claim 1. Further, a succinct examination made by the Board shows that the subject-matter of Claim 1 is novel over the cited prior art since the essential feature of the invention according to which "the occluder(s) can assume an orientation in the open position wherein inflow and

outflow surfaces are substantially parallel to the valve body center line" is not disclosed in the prior art document. Contrarily, in this document, in fully open position, the occluders (leaflets) are inclined according to an angle of opening identified by "a" and ranging between 70°C and 85°C (cf. page 9, last paragraph to page 10, first paragraph).

It is also doubtful whether the notches on the occluder **receiving** the projections on the side wall in the cited art function so "as to contact and **cam**" the projection in a manner which is indicated in the definition of **the interengagement** defined in the last part of Claim 1. To deny novelty without proper feature analysis is contrary to normal practice.

3.3 The distinction on the basis of variations within the term of "occluder" is basically irrelevant since both groups of claims use at least one occluder. The investigation to establish the presence of unity relies on the "**single** general inventive concept" which must be **common** to all inventions claimed. This can only be based on the features which all the claims in question **share** and not on any features which are different. The features which may generate a "single ... concept" also include the functional features which are to be attributed to the claims provided they are wholly or partially identical.

3.4 According to the decision in protest case W 6/90 (OJ 1991, 438), the approach to the problem is to identify the common features of the claims in question, including functional ones, and then decide whether or not these, or some of them, can make a contribution to the inventive step at all *prima facie*, i.e. to the recognition of the inventive step later on in the substantive examination. Only in cases where the

possibility of such contribution must be excluded, can disunity be declared.

3.5 The feature analysis in the present case shows that the only features which are shared by all claims in groups 1 and 2 include the common introductory parts such as the "heart valve ... valve body ... interior wall ... defining a central passageway ... for blood ... with central line (i.e. longitudinal axis) having occluder (means) ... with pivot arrangement for open ... and closed positions ...". These might have been in a common preamble of the claims, had they been drafted with distinct characterising clauses. The requirement to have projections appears to be also commonly expressed in all claims except Claim 12, where it might nevertheless be implied by the camming action, which could perhaps also be interpreted as being present in all groups. The only other feature which is a requirement common to all claims, expressly or by implication, that in consequence of all these an interengagement should be provided between the side portions of the occluder and the valve body. These are then the structural components of the single general concept linking the groups.

3.6 However, it is also necessary (cf. above W 6/90) to add any functional characteristics which are shared. The impugned invitation refers to the summary where the generation of a certain kind of rotational momentum and the displacement of the instantaneous center of the rotation are mentioned as common to all claimed variants (means for generation thereof and the camming means are part of the structural commonness). The shared structural and functional teachings provide therefore together the "single concept" in the case. Anything else not shared, i.e. the rich varieties in other features which only appear in some but not in other claims, are

not part of that concept. The same applies to whether the common necessity to have at least one occluder should materialise as a pair or a single item is, as a distinction, irrelevant.

3.7 The next step is to determine whether or not the concept is "inventive" in the context of the investigation. The term cannot be interpreted as a requirement for the common part to be inventive *per se* and therefore claimable as such. W 6/90 suggested that the investigation in this respect should concentrate on whether or not all or some of such features could contribute to the later detailed consideration of the inventive steps. Only if the already taught state of the art or common general knowledge shows, without reasonable doubt, that this is not possible in the circumstances, should disunity be declared.

3.8 In the present case the cited closest state of the art in respect of identity of features, WO-A-9 101 698, discloses the above-mentioned common features as well as the specific functional characteristics of the above single concept. Whilst these are presented in combination with an added variety of other features in the claims, it is clear that the basic set functions, as defined, in the state of the art identically and cannot therefore contribute to the inventive steps in each case.

It is also to be remembered of the newly introduced Rule 13.2 PCT (cf. also Rule 30(1) EPC):

"Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or

corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

This also implies the same requirement as the above cited decision W 6/90, namely the presence of "same or corresponding special technical features". The latter term recognises that the features should define a **contribution** to the invention vis-à-vis the prior art. The above recognised set or parts of it being also part of the most relevant state of the art in an identical manner cannot provide such contribution. Thus, the **various** inventions, if any, must lie in the unshared specific characterising features in each case. Since the hypothetical reformulation of the claims contains no more common feature between them in the characterising part, this confirms the conclusion of disunity (cf. W 32/92, 15 October 1992 to be published - see Headnote only in OJ, 1993/5, XI).

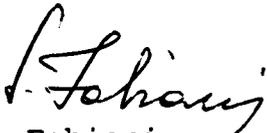
- 3.9 Although it appears when considering further features within the groups themselves that there may be no unity there either in the sense of the above principles, but it is accepted that when this requires no additional search, no objections should be raised and no additional fee should be requested. The Board therefore confined itself to the only remaining question, the possibility of unity between the two groups. This must be denied in the circumstances in view of an absence of the required "single and inventive" concept.

Order

For these reasons, it is decided that:

The protest is dismissed.

The Registrar:


S. Fabiani

The Chairman:


G. Szabo


29. 11. 93


07-12-93