

Publication in the Official Journal *Yes* / No

File Number: T 243/89 - 3.2.2  
Application No.: 84 303 006.5  
Publication No.: 0 125 844  
Title of invention: Valved two-way catheter

Classification: A61M 25/00

D E C I S I O N  
of 2 July 1991

Applicant: Catheter Technology Corporation

Headword:

EPC Arts. 83, 84, 123(2), 96(2), 113(1); Rule 67

Keyword: "Subject-matter extending beyond the content of the application as filed (no, after amendments)" - "Change of category: additional method claim of making the apparatus (allowed)" - "Procedural violation (no)"

Headnote



Case Number : T 243/89 - 3.2.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 2 July 1991

**Appellant :** CATHETER TECHNOLOGY CORPORATION  
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**Decision under appeal :** Decision of Examining Division 128 of the  
European Patent Office dated 3 November 1988  
refusing European patent application  
No. 84 303 006.5 pursuant to Article 97(1) EPC.

**Composition of the Board :**

**Chairman :** G. Szabo  
**Members :** M. Noel  
J. Van Moer

## Summary of Facts and Submissions

- I. European patent application No. 84 303 006.5 (publication number 0 125 844) was refused by decision of the Examining Division dated 3 November 1988.

The reason for the refusal was that the application in the version as lastly amended on 11 April 1988 contained subject-matter extending beyond the content of the application as filed and thus did not satisfy the requirements of Article 123(2) EPC.

- II. The Appellant lodged an appeal on 2 January 1989 against the decision and the appeal fee was paid in due time. With the Statement of Grounds two alternative sets of amended claims were submitted.
- III. In a communication dated 7 March 1991 the Board informed the Appellant of its provisional opinion that the claims as amended still did not comply with Article 123(2).
- IV. Subsequent to this communication, the Appellant filed on 14 May 1991 a new set of Claims 1 to 14 and correspondingly revised pages of the description.

Independent apparatus Claim 1 and method Claim 14 read as follows:

"1. A valved catheter suitable for temporary or permanent implantation, said catheter comprising a catheter tube (12) formed from a resilient, flexible material, said catheter tube having a closed end (18) and adjacent thereto a slit (24) through the catheter wall, the slit (24) remaining closed under normal physiologic pressures, and the slit (24) allowing the catheter wall contiguous thereto to deform and the opposed faces of said slit to

withdraw from one another to form a temporary orifice in the catheter wall when a sufficient pressure gradient is applied thereacross such that the slit (24) forms a two-way valve (10) for the passage of fluid into or out of the catheter, characterised in that the said catheter tube has a hardness of less than 100 durometer, and that the catheter wall in the vicinity of the said slit (24) is focally weakened to be deformable upon the application of the said sufficient pressure gradient."

"14. A method for forming a valved catheter suitable for temporary or permanent implantation, said catheter comprising a catheter tube (12) formed from a resilient, flexible material, said catheter tube having a closed end (18) and adjacent thereto a slit (24) through the catheter wall, the slit (24) remaining closed under normal physiologic pressures, and the slit (24) allowing the catheter wall contiguous thereto to deform and the opposed faces of said slit to withdraw from one another to form a temporary orifice in the catheter wall when a sufficient pressure gradient is applied thereacross such that the slit (24) forms a two-way valve (10) for the passage of fluid into or out of the catheter, characterised by the said catheter tube having a hardness of less than 100 durometer and by focally weakening the said catheter wall in the vicinity of the said slit (24), thereby rendering the catheter wall deformable upon the application of the said sufficient pressure gradient."

- V. The Appellant requests that the Decision under appeal be set aside and that further prosecution of the case on the basis of the following documents be made:

description pages 1 to 3 and 6 to 14 of the patent application as published;

claims 1 to 14, filed on 14 May 1991;

drawings sheet 1/1 as published.

The Appellant further requests a refund of the appeal fee.

#### Reasons for the Decision

1. The appeal is admissible.
2. Apparatus Claims 1 to 13 - Amendments.
  - 2.1 Amendments made to apparatus Claims 1 to 13 are, in the Board's view, fairly supported and in exact correspondence with the original disclosure, according to the list submitted in the Appellant's response of 14 May 1991, point 2.
  - 2.2 In particular Claim 1 is based on two characterising features according to which
    - (a) the catheter tube has a hardness of less than 100 durometer, and
    - (b) the catheter wall in the vicinity of the slit is focally weakened to be deformable upon application of the said sufficient pressure gradient.

These features are to be found with the same terminology, in the following sections of the description:

as to feature (a), page 4, lines 31-33  
page 5, lines 4-7  
and page 8, lines 18-21

as to feature (b), page 5, lines 25-31

and from page 9, line 35 to page 10, line 4.

Consequently the subject-matter of Claim 1 is supported by the description as requested by Article 84 EPC and the amendments made are therefore not such as to extend beyond the content of the application as filed, as requested by Article 123(2) EPC.

2.3 It results unambiguously from the description that it is first of all the use of an extremely flexible and elastic material (cf. page 7, lines 5-14) as well as the presence of the slit (cf. page 5, lines 25-26 and page 9, line 35 to page 10, line 15) that causes the catheter wall to weaken in the vicinity of the slit valve.

An additional chemical treatment applied to the valve area and contiguous catheter wall cannot be considered, in the Board's view, as being essential nor necessary for enabling the slit valve to deform upon application of a pressure gradient. This treatment appears in the latter part of the description (cf. page 10, line 23) and is clearly described only as a preferred embodiment with the view of improving flexibility of the slit valve still further ("more pliable", "more easily deformable", "facilitating the valve function"). The weakening allows (page 10, line 33) that a lesser pressure gradient will be necessary to cause the slit valve to open (page 10, line 34 to page 11, line 2).

Neither Article 83 nor Article 84 of the Convention requests that the best mode of the invention be disclosed in the application or claimed in the main claim. According to Rule 29(1)(b) and (3) it is only expected that Claim 1

states technical features, the protection of which is desired, and that these features are essential for the solution.

Moreover, as long as a complete examination of the application with respect to the prior art cited has not seriously questioned the non-obviousness of Claim 1 in relation to the functional wordings of feature (b), or has not raised insufficiency alleging that no selection of pliable material without chemical treatment would properly function as a valve, there is no reason to object to the level of generalisation now to call for the introduction of more specific features.

In the present case, the Board is satisfied that no objection of clarity or insufficiency of disclosure could have so far been made under Article 83 or 84 EPC.

3. Method Claim 14 - change of category

Considering that there are no rigid lines of demarcation between the various possible forms of claims, namely claims based on a physical entity (product, apparatus) and claims based on a physical activity (method, process, use, cf. Decision G 2/88, OJ 4/1990, page 98, point 2.2) and that the presence of claims of different categories may assist the Applicant in obtaining full protection for his invention, the Board sees no reason to refuse the filing, even at a later stage of the examination procedure, of an additional method claim for forming the apparatus claimed in Claim 1, in view of the similar wording and thus of the close inter-relationship between both independent claims. Consequently, the same conclusions as above (point 2) for the apparatus claim apply to the method claim.

In particular, claims for methods of making or for assembling an entity claimed in another claim as such, should not be objected to on formal grounds once the product is properly defined even if the method itself is trivial. Provided the result of the activity is in itself patentable, such methods are also patentable unless the disclosure is insufficient (Articles 83 and 84 EPC) (cf. also analogy processes, T 119/82, OJ EPO 1984, 217). This is often so in cases where the product and method claims are exactly coterminous, as is the case shown in the present appeal, but the principle would not be applicable when the method is broader than the claimed product.

4. Further prosecution of the case

The Board cannot order grant of a patent on the basis of the documents specified in paragraph V above because the Examining Division has not yet considered whether the present claims, which have changed to a substantial extent as compared to the claims underlying the decision under appeal, meet the other requirements of the EPC in particular with regard to inventive step. In order to avoid loss of an instance, the Board considers it appropriate, in accordance with Article 111(1) EPC, to remit the case to the Examining Division for further prosecution.

In particular, amendments brought to the description in the Appellant's response of 14 May 1991 will not be considered by the Board itself, since further amendments might be made at a further stage of the substantive examination before the Examining Division, e.g. by taking account of the closest prior art document according to Rule 27(1) EPC.



5. Refund of the appeal fee

The request for refund of the appeal fee was based on the assertion that the objection under Article 123(2) made by the Examining Division was not valid and that the Examiner's refusal to accede to an informal interview constituted a procedural violation.

5.1 As to the first aspect, the Board is of the opinion that even if the reasoning made in the decision under appeal with respect to Article 123(2) were open to criticism from the Appellant's point of view, it remains at first that the Examining Division was still not convinced by the Appellant's arguments in his response of 11 April 1988 either. The Examining Division having found that the same objection as before still existed against the amended claims thereupon rightly issued a refusal. Article 113(1) does not require that the applicant be given a repeated opportunity to comment on the argumentation of the Examining Division so long as the decisive objections against the grant of the European patent remain the same insofar as the grounds for these objections have been presented to the applicant, completely and in due time (cf. T 161/82, OJ EPO 1984, 551, Point 11).

5.2 As to the second aspect, the Board observes that in his reply of 11 April 1988 (page 2) the Appellant requested only the arrangement of an informal interview, not the appointment of an oral proceeding such as provided by Article 116(1) EPC as a matter of right. By exercising objectively his discretion given by Article 96(2) EPC in the present circumstances the Examining Division deemed it unnecessary to continue with the procedure and consequently rightly issued a refusal.

5.3 In view of the above considerations the Board comes to the conclusion that the proceedings before the Examining Division did not in the present case suffer from a violation of a provision or principle of procedure in accordance with the EPC or its Implementing Regulations. Therefore, in the Board's judgment, there is no basis for a refund of the appeal fee under Rule 67 EPC.

### 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 the documents listed in section V above.
3. The request for refund of the appeal fee is rejected.

The Registrar:



S. Fabiani

The Chairman:



G. Szabo

