

**Internal distribution code:**

- (A) [ - ] Publication in OJ  
(B) [ - ] To Chairmen and Members  
(C) [ - ] To Chairmen  
(D) [ X ] No distribution

**Datasheet for the decision  
of 12 June 2015**

**Case Number:** T 1098/14 - 3.2.02

**Application Number:** 02756387.3

**Publication Number:** 1438097

**IPC:** A61M25/00

**Language of the proceedings:** EN

**Title of invention:**

OCCCLUSION CATHETER HAVING COMPLIANT BALLOON FOR USE WITH  
COMPLEX VASCULATURE

**Applicant:**

Covidien LP

**Headword:**

**Relevant legal provisions:**

EPC Art. 84, 111(1)

**Keyword:**

Clarity (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern  
Boards of Appeal  
Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 1098/14 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 12 June 2015**

**Appellant:** Covidien LP  
(Applicant) 15 Hampshire Street  
Mansfield, MA 02048 (US)

**Representative:** Gray, James  
Withers & Rogers LLP  
4 More London Riverside  
London SE1 2AU (GB)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 3 January 2014  
refusing European patent application  
No. 02756387.3 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** M. Stern  
D. Ceccarelli

## **Summary of Facts and Submissions**

- I. The applicant lodged an appeal against the decision of the Examining Division, dispatched on 3 January 2014, refusing European application No. 02 756 387.3.
- II. In the appealed decision the Examining Division held that claim 1 of the main and auxiliary requests then on file contained a functional statement by which the claimed subject-matter was defined in relation to an anatomical region (i.e. the wall of a blood vessel), instead of defining the apparatus in terms of its technical features. Claim 1 did not enable the skilled person to determine which technical features were necessary to perform the stated functions. For these reasons the Examining Division concluded that claim 1 was unclear and therefore not allowable under Article 84 EPC.
- III. Notice of appeal was filed on 31 January 2014 and the appeal fee was paid the same day. A statement setting out the grounds of appeal was filed on 1 May 2014.
- IV. The appellant requested that the decision be set aside and the application allowed.
- V. Following the issue of the summons to oral proceedings and an annexed communication setting out the Board's provisional opinion dated 25 March 2015, the appellant filed on 19 May 2015 a revised main request replacing all requests on file. The oral proceedings were subsequently cancelled.

VI. Claim 1 of the (sole) main request reads as follows (amendments to claim 1 of the main request underlying the appealed decision are highlighted by the Board):

"A catheter (10) suitable for temporary vascular occlusion in a mammal wherein an embolizing agent which inhibits blood flow into an aneurysm is delivered into said aneurysm, said catheter, comprising a substantially tubular structure (34) with at least one lumen (32) and an inflatable balloon (20) located at a distal portion of said tubular structure and in fluid communication with said lumen (32),

wherein said inflatable balloon (20) comprises a material being a composition which is based on styrenic olefinic rubber and hydrogenated isoprene, and is inflatable at a pressure of up to 600 mg Hg which is less than the pressure required to deform the vascular wall containing the aneurysm, further wherein said balloon has a balloon length range of 4mm to 30mm and a diameter range of 1.5mm to 10mm and a length to diameter **ratio** range of 0.5:1 to 5:1,

~~and still further~~ wherein the balloon (20) in its inflated state, ~~conforms~~ **is suitable for conforming** to the irregular shape and structure of a vessel (14) to provide flow occlusion and/or attenuation to said vessel without appreciably deforming or stressing the vessel (14)."

### **Reasons for the Decision**

1. The appeal is admissible.
2. The claimed subject-matter concerns an inflatable balloon catheter for the treatment of an aneurysm.

- Claim 1 is properly based on the application as originally filed. It finds a basis in original claim 1; the sentence bridging pages 7 and 8; page 9, lines 9 to 12; page 10, lines 22 to 26; page 11, lines 3 to 4.
3. According to well-established practice, an apparatus claim may not only define structural features of the apparatus, but may also contain functional features defining the suitability of the apparatus or its constituent parts for performing certain functions. This is also the case here, where claim 1 defines the balloon catheter in terms of structural features (such as the material, length, diameter and length-to-diameter ratio of the balloon) and of the suitability of the catheter and the balloon for performing certain functions or fulfilling certain purposes.
  4. For example, in its opening lines claim 1 defines the balloon catheter as being "suitable for temporary vascular occlusion in a mammal wherein an embolizing agent which inhibits blood flow into an aneurysm is delivered into said aneurysm". The clarity of this functional feature was (correctly) not objected to in the appealed decision. It constitutes a testable criterion which the claimed balloon catheter needs to satisfy. Such testing is nothing out of the ordinary in the field of medical technology and involves only routine trials. The same considerations also apply to the functional feature in the last paragraph of claim 1 which defines the balloon in its inflated state as being "suitable for conforming to the irregular shape and structure of a vessel to provide flow occlusion and/or attenuation to said vessel without appreciably deforming or stressing the vessel".

5. It follows that the claim defines a balloon catheter in terms of both structural and functional features, the latter concerning its suitability for performing certain functions. The claim no longer includes any method steps (as in the previous requests which have been replaced) which defined the apparatus in terms of its use, rather than its suitability for such a use, and were thus considered by the Board to indeed compromise the clarity of the claim.
6. It is moreover clear how claim 1 needs to be construed with regard to the suitability for performing the recited functions. A known prior-art catheter having all the specified structural features and in a form suitable for the stated functions or purposes, even if the catheter had not been described for those functions or purposes, would deprive the claim of novelty.
7. As a consequence, the Board is satisfied that the subject-matter of claim 1 meets the clarity requirement of Article 84 EPC.
8. The present decision rules only on whether claim 1 is clear within the meaning of Article 84 EPC, the only objection on which the appealed decision refusing the application was based.

The Board consequently finds it appropriate to remit the case to the Examining Division to continue the examination proceedings on the basis of the present request (Article 111(1) EPC).

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated