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D E C I S I O N
of 27 September 2005

Case Number: T 1221/03 - 3.2.02

Application Number: 96200982.5

Publication Number: 0737488

IPC: A61M 25/10

Language of the proceedings: EN

Title of invention:

Balloon catheter with lobated balloon and method for
manufacturing such a catheter

Applicant:

CORDIS EUROPA N.V.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

"Extended subject-matter (yes) "

Decisions cited:

-

Catchword:

-



Case Number: T 1221/03 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 27 September 2005

Appellant: CORDIS EUROPA N.V.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 2 July 20003
refusing European application No. 96200982.5
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
E. Dufrasne

Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal on 27 August 2003 against the decision of the examining division posted on 2 July 2003 refusing the European patent application 96200982.5. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 12 November 2003.
- II. The examining division held that the application did not meet the requirement of Article 54 EPC (lack of novelty).
- III. Oral proceedings took place on 27 September 2005.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of:

- a main request consisting of claims 1 to 6, or
- a first, second or third auxiliary request all consisting of claims 1 to 3,

all submitted during oral proceedings.

- IV. Claim 1 of the main and of the first auxiliary request reads as follows:

"Catheter comprising a tube-like basic body with a proximal and a distal end and an expandable balloon member arranged close to the distal end of the basic body, the tube-like material of the balloon member comprising a number of relatively stiff sections

extending on a small diameter in a longitudinal direction of the basic body and relatively pliable sections that are pliable relative to the stiff sections extending in between, wherein in an expanded form of the balloon member the relatively stiff sections remain substantially at the same diameter as in a non-expanded form and the relatively pliable sections form lobes, characterized in that, the balloon member is pre-formed and that the number of relatively stiff sections of the tube-like material are integrally formed in said tube-like material and alternate with the sections of relatively pliable material, said relatively stiff sections and relatively pliable sections being formed of different materials."

Claim 1 of the second auxiliary request reads as follows:

"Catheter comprising a tube-like basic body with a proximal and a distal end and an expandable balloon member arranged close to the distal end of the basic body, the tube-like material of the balloon member comprising a number of relatively stiff sections extending on a small diameter in a longitudinal direction of the basic body and relatively pliable sections that are pliable relative to the stiff sections extending in between, wherein in an expanded form of the balloon member the relatively stiff sections remain substantially at the same diameter as in a non-expanded form and the relatively pliable sections form lobes, characterized in that, the balloon member is mould-formed and that the number of relatively stiff sections of the tube-like material are integrally formed in said tube-like material and

alternate with the sections of relatively pliable material, said relatively stiff sections and relatively pliable sections being formed of different materials."

Claim 1 of the third auxiliary request reads as follows:

"Method for manufacturing a catheter comprising the providing of a piece of tube-like basic material, the manufacturing of a balloon member by blow moulding inside a mould and the arranging of the balloon member to the basic body, wherein the manufacturing of the balloon member comprises the providing of a mould with a mould cavity of which the cross-section is lobated, the receiving inside the mould of a tube-like semimanufacture, the tube-like material being integrally formed with, in cross-section, alternating sections of different materials that are resp. relatively stiff and relatively pliable, positioning the semimanufacture with the sections of relatively stiff material against inwardly protruding ridges of the lobated mould cavity, and the deformation of the semimanufacture by blow moulding until it corresponds to the shape of the mould cavity."

V. In support of his request the appellant relied essentially on the following submissions.

The subject-matter of the independent claims 1 of all four requests did not go beyond the original disclosure. Claim 1 of the main, first and second auxiliary requests claimed in particular that the relatively stiff and the relatively pliable section were formed of different materials. This feature was

implicitly disclosed in column 1, lines 37 to 42 of the published application EP-A-0 737 488 (this section corresponds to page 2, lines 5 to 10 of the originally filed application). There it was described that the relatively stiff parts of the balloon member could be formed by manufacturing them so as to have a greater thickness, or by making them for example of a fibre-reinforced or cross-linked thermoplastic material respectively, and that preferably the measure as set out in claim 2 should be employed. This statement, in conjunction with the original claim 2, according to which the relatively stiff sections were formed by materials with a greater stiffness than the material of the relatively pliable section, would have been interpreted by the person skilled in the art in the general sense that the relatively stiff sections and relatively pliable sections could be formed of different materials.

The subject-matter of claim 1 of the third auxiliary request did not go beyond the original disclosure either. The feature that the tube-like material was formed with, in cross-section, alternating sections of different materials was disclosed in the original claim 6, on page 6, line 6 to 10, and on page 6, line 35, to page 7, line 18 of the originally filed application.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

2.1 Each of claim 1 of the main, first and second auxiliary requests contain the feature that the relatively stiff and the relatively pliable section are formed of different materials.

Only the sections on page 2, lines 5 to 10, in conjunction with claim 2, and on page 6, line 35, to page 7, line 18 of the originally filed application refer to the material to be used for the relatively stiff and relatively pliable sections of the balloon member. According to the disclosure of these sections, the relatively stiff sections have to be formed by a material having a greater stiffness than the material of the relatively pliable sections, for example by making the relatively stiff sections of a fibre-reinforced or cross-linked thermoplastic material. Since there are no further examples suggesting suitable materials for the relatively stiff and relatively pliable sections, the originally filed application teaches at best that the material for the relatively stiff sections differs from the material for the relatively pliable sections by the provision of a reinforcing means, as for example reinforcing fibres or cross linkages.

2.2 Claim 1 of the third auxiliary request contains the feature that tube-like material was formed with, in cross-section, alternating sections of different materials.

With respect to the method for manufacturing a catheter according to the third auxiliary request, the originally filed application describes on page 6, lines 6 to 10, that the semimanufacture of which the balloon has been manufactured has been obtained by strip-shaped co-extrusion of relatively stiff material and relatively pliable material. As shown above, the complete disclosure of the application as originally filed teaches that only certain kinds of materials have to be selected for the balloon member. Therefore the method disclosed in the originally filed application is restricted to a method where the semimanufacture of the balloon member is obtained by co-extrusion of such materials i.e. materials where the material for the relatively stiff sections differs from the material for the relatively pliable sections by the provision of reinforcing means.

However, the original disclosure does not for example cover the case where the relatively stiff and the relatively pliable sections are formed of different materials by joining said sections in a way different than co-extrusion (for example by welding, or heat-bonding).

2.3 Therefore, the features according to which the relatively stiff and the relatively pliable sections are formed of different materials, and the tube-like material was formed with, in cross-section, alternating

sections of different materials are not disclosed in the originally filed application. On the contrary, they extend to a general teaching which is not covered by the teaching of the application as originally filed.

These features are not implicitly disclosed in the original version of the application either. An implicit disclosure is a disclosure which is not literally contained in the document, but which can be derived from it directly and unambiguously. This is not the case here, since the original version of the application does not contain any hints that any type of different material can be used.

- 2.4 The appellant's argument according to which the disclosure that the relatively stiff parts of the balloon member could be formed by making them for example of a fibre-reinforced or cross-linked thermoplastic material respectively, but that preferably they are formed by materials with a greater stiffness than the material of the relatively pliable section (see original description, page 2, lines 5 to 10 and original claim 2), would have been interpreted by the skilled person in the sense that every kind of different materials could be employed, is not convincing. The original disclosure contains exclusively the information that fibre-reinforced or crosslinked thermoplastic material can be used for the relatively stiff sections of the balloon member. It is true that these materials are merely described as examples. However there is no other information which further materials would be suitable. In particular with respect to the description that the transverse connections in the crosslinked thermoplastic material

can be made by irradiation, and the information that the crosslinked material is a non-homogeneous material (see page 7, lines 1 to 18), the skilled person would assume that the balloon member can be made of a single thermoplastic material which in the relatively stiff sections has to be reinforced. One possibility for reinforcing these sections is to irradiate the material of the balloon member, and another to provide these sections with fibers. In the latter case, the semimanufacture of the balloon could be produced by co-extrusion of strip-shaped different materials one of which comprises fibres and one of which not. Hence the originally filed claim 2 cannot be understood in such a way that it covers any materials with different stiffness.

- 2.5 In the light of the above findings, all present claims 1 refer to a generalisation which was not disclosed in the originally filed application, and therefore contain subject-matter which extends beyond the content of the original disclosure.

Consequently the amended claims of the present main request and of the first, second and third auxiliary request violate Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner