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D E C I S I O N
of 18 April 2004

Case Number: T 0091/04 - 3.2.2

Application Number: 96203322.1

Publication Number: 0776673

IPC: A61M 25/01

Language of the proceedings: EN

Title of invention:
Catheter guidable by means of flow

Applicant:
Cordis Corporation

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52, 56

Keyword:
"Inventive step - (no) "

Decisions cited:
-

Catchword:
-



Case Number: T 0091/04 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 18 April 2004

Appellant: Cordis Corporation
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 7 August 2003
refusing European application No. 96203322.1
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 7 October 2003 against the decision of the examining division, posted on 7 August 2003, refusing the European patent application No. 96 203 322.1. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 15 December 2003.

II. The examining division held in particular that the application did not meet the requirements of Articles 52 and 56 EPC having regard among other documents to the following document:

D1: US-A-5 336 205.

III. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or the second auxiliary request as submitted during the oral proceedings before the examining division on 8 July 2003.

IV. Claim 1 of the main request reads as follows:

"A flow-directed catheter comprising a tube-like body with a proximal and a distal end, a connecting member arranged to the proximal end and a tube-like end-section at the distal end which is pliable characterized in that the end-section is flexible so that it does not retain its shape and has an elastic modulus not exceeding 10 N/mm²"

V. Claim 1 of the auxiliary request reads as follows (the additions with respect to the main request are underscored) :

"A flow-directed catheter comprising a tube-like body with a proximal and a distal end, a connecting member arranged to the proximal end and a tube-like end-section at the distal end which is pliable characterized in that the end-section is flexible, so that it does not retain its shape and the position of the end section can be controlled by inserting liquid pulses into the catheter and has an elastic modulus not exceeding 10 N/mm²"

VI. In support of his requests, the appellant relied essentially on the following submissions laid down in the statement of grounds and in the letters of 3 December 2004 and 7 March 2005, sent as a reaction to communications of the board:

D1 referred to a catheter having a tip which was flexible compared to the proximal segment of the catheter. However, D1 did not teach that an increased flexibility of the tip would result in an improved manoeuvrability, nor gave it any indication how a further flexibility should be obtained. D1 aimed at maintaining a certain thickness of the catheter walls and thus did not aim at a maximum flexibility. Therefore D1 thought away from the invention according to the present application.

Starting from D1, the problem underlying the present invention was to improve the behaviour of the flow-directed catheter such that it could better reach

difficult areas in the blood system. Since there was no teaching in D1 that increasing the flexibility would improve this behaviour of the catheter, the subject-matter of claim 1 of the main request could not be regarded as obvious. Quite to the contrary, column 1, lines 31 to 43 of D1 made clear that using a highly flexible catheter was not favourable.

As for the auxiliary request, D1 only mentioned the combination of a stiff-shaped distal end section (as shown in Figure 2) and liquid pulses for propelling the distal end away from vessel walls. Therefore, the combination of an extremely flexible distal end and such pulses could not be regarded as obvious. On the contrary, the skilled person would expect that liquid pulses were not suitable for controlling an extremely flexible tip of a catheter.

Reasons for the Decision

1. The appeal is admissible.

2. *Inventive step*

2.1 Main request

D1 discloses a flow-directed catheter (see claim 1, column 6, lines 37, 38) comprising a tube-like body (102) with a proximal and a distal end (104, 106), a connecting member (150) arranged to the proximal end and a tube-like end-section (120) at the distal end which is pliable, whereby the end-section is flexible so that it does not retain its shape (see description, column 3, lines 6 to 12).

However, D1 does not disclose that the end-section has an elastic modulus not exceeding 10 N/mm^2 .

The object to be achieved by the application is to be seen in achieving a suitable pliability for the end-section (see description of the patent application, page 3, second paragraph).

The board does not agree to the appellant's view that the object underlying the application was to improve the behaviour of the flow directed catheter such that it can better reach difficult areas in the blood system. This formulation is too general, since D1 already contains a suggestion to design an end-section that will be carried by the blood flow to the target site and which is flexible enough to navigate the tortuous vessel pathway (see description, column 1, lines 44 to 60, column 3, lines 6 to 8), and since the application in the second paragraph of page 3 clearly states that the provision of an elastic modulus not exceeding 10 N/mm^2 serves to achieve a suitable pliability of the catheter's tip section.

The selection of the range of values claimed for the elasticity modulus for the end section of the catheter does not deliver any surprising effect, nor is there any prejudice in the state of the art against an elasticity modulus less or equal to 10 N/mm^2 . Therefore the skilled person faced with the cited object would choose an elasticity modulus out of the claimed range of values according to his needs without any inventive skill being involved.

Contrary to the assertion of the appellant, D1 does not teach away from making the tip of the catheter sufficiently flexible. It is true that D1 among other things suggests to design the distal end section so that it has a sufficient burst pressure. However, this does not mean that D1 does not also suggest to provide a flexible end section. On the contrary, D1 explicitly teaches to make the catheter's end section flexible enough such that the catheter can easily navigate a tortuous vessel pathway (see column 3, lines 6 to 8).

In the light of this teaching it is obvious for the skilled person that more tortuous vessel pathways require a higher flexibility of the catheter's end section.

The question how a further flexibility could be obtained is not relevant for the present case, since claim 1 only claims a particular elastic modulus, and not a method how to obtain this value.

2.2 Auxiliary request

The auxiliary request contains with respect to the main request the additional feature that the position of the end section can be controlled by inserting liquid pulses into the catheter.

The board agrees to the examining division's finding, according to which this feature merely requires that the claimed catheter has to be suitable for controlling the position of its end section by liquid pulses. Therefore, as also correctly stated by the examining division, any catheter having a flexible end section

and which as per definition comprises a hole, has to be considered suitable for being controlled by liquid pulses.

Consequently, D1, in addition to the features cited above (see section 2.1), also discloses that the position of the end section (120) can be controlled by inserting liquid pulses into the catheter.

Additionally, D1 even discloses an embodiment (see Figure 2) where the position of the end section is controlled by liquid pulses. Therefore the skilled person is aware of the fact that the position of an end section of a catheter, including the one shown in Figure 1 of D1, can be controlled by liquid pulses.

With respect to the above findings, the subject-matter of claim 1 of the auxiliary request differs from the catheter disclosed in D1, as does the subject-matter of claim 1 of the main request, only in that the end section has an elastic modulus not exceeding 10 N/mm^2 . However, as shown above (see section 2.1), the selection of an elastic modulus out of this range is obvious.

The appellant's argumentation that the combination of an extremely flexible distal end and a control of its position by liquid pulses could not be regarded as obvious, is not suitable for challenging the board's findings, since it is based on the assumption that only the embodiment shown in Figure 2 of D1 comprises the additional feature of claim 1 of the auxiliary request. However, as pointed out above, this is not correct, since also the catheter shown in Figure 1 of D1 has an

end section which can be controlled by inserting liquid pulses into the catheter.

3. With respect to the above findings, the subject-matter of claim 1 of the main and of the auxiliary requests does not involve an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner