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D E C I S I O N
of 2 June 2006

Case Number: T 0345/05 - 3.2.02

Application Number: 96106578.6

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IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:
Interventional catheter

Patentee:
Schneider (Europe) GmbH

Opponent:
Terumo Kabushiki Kaisha

Headword:

-

Relevant legal provisions:

EPC Art. 54

Keyword:

"Novelty (yes, after amendments - Auxiliary request 6) "

Decisions cited:

-

Catchword:

-



Case Number: T 0345/05 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 2 June 2006

Appellant:
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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 26 January 2005
revoking European patent No. 0803264 pursuant
to Article 102(1) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 21 March 2005 against the decision of the opposition division posted on 26 January 2005 to revoke the European patent EP-B-803 264. The fee for the appeal was paid on 21 March 2005 and the statement setting out the grounds for appeal was received on 31 May 2005.

II. The opposition division held that the patent did not meet the requirements of the EPC, since the subject-matter of claim 1 as granted lacked novelty having regard to the document:

D2 = WO-A-95/28982.

III. Oral proceedings took place on 2 June 2006.

The appellant requested that the decision under appeal be set aside, that novelty be recognised for the subject-matter of the claims of the main request (claims 1 to 10 as granted) or, in the alternative, of one of the auxiliary requests 1 to 6, and that the case be remitted to the first instance for further prosecution.

The respondent (opponent) requested that the appeal be dismissed.

Furthermore the respondent requested not to admit the auxiliary request 6 into the proceedings.

IV. Claim 1 as granted reads as follows:

"An interventional catheter comprising a catheter tube (1, 12, 23) having two superposed layers (2-3, 13-14, 24-25) of materials secured together and with mechanical properties differing from one another, a guidewire lumen (5, 16, 29) in said catheter tube for the sliding fit of a guidewire (6, 17, 30), and a balloon (7, 20) with a distal end (8, 21) sealingly surrounding said catheter tube, whereby the catheter tube has an inner layer (2, 13, 24) forming the guidewire lumen (5, 16, 29) and an outer layer forming an outer surface of the catheter tube (1, 12, 23), characterized in that it comprises mediator layer means (4, 15, 26) arranged between said inner layer (2, 13, 24) and said outer layer (3, 14, 25) for the adhesive anchorage of said layers thereto."

Claim 1 according to the first auxiliary request filed with letter of 2 May 2006 differs from claim 1 as granted in that the expression "mediator layer means" has been replaced by the term "mediator layer".

Claim 1 according to the second auxiliary request filed with letter of 2 May 2006 differs from claim 1 as granted in that the following feature has been added to the end of the claim:

"wherein said mediator layer means (4, 15, 26) have mechanical properties differing from mechanical properties of the inner and outer layers (2-3, 13-14, 24-25)".

Claim 1 according to the third auxiliary request filed with letter of 2 May 2006 differs from claim 1 of the second auxiliary request in that the expression "mediator layer means" has been replaced by the term "mediator layer".

Claim 1 according to the fourth auxiliary request filed with letter of 2 May 2006 differs from claim 1 as granted in that the following feature has been added to the end of the claim:

"wherein said inner layer (2, 13, 24), said mediator layer means (4, 15, 26), and said outer layer (3, 14, 25) are coextruded".

Claim 1 according to the fifth auxiliary request filed with letter of 2 May 2006 differs from claim 1 of the fourth auxiliary request in that the expression "mediator layer means" has been replaced by the term "mediator layer".

Claim 1 according to the sixth auxiliary request filed with letter of 18 May 2006 differs from claim 1 as granted in that the following feature has been added to the end of the claim:

"wherein said mediator layer means (4, 15, 26) are formed on the basis of a low density polyethylene".

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

The sixth auxiliary request filed with letter of 18 May 2006 had to be regarded as a reaction to the

letter of the respondent dated 11 May 2006 in which evidence in form of an excerpt from the Merriam Webster dictionary about the term "adhesive" had been submitted.

The subject-matter of claim 1 of all present requests was novel over the disclosure of D2. It was true that the features of claim 1 of all present requests were anticipated by D2, except for the feature of all requests according to which the mediator layer means was provided for the adhesive anchorage of the mediator layer means to the inner and outer layers, and for the feature of the auxiliary request 6 according to which the mediator layer means was formed on the basis of a low density polyethylene.

The expression "adhesive anchorage" referred to a bonding system which was different from mechanical locking, physical bonding or even welding. An adhesive anchorage required the use of a material which provided adherence. This interpretation was supported by the declaration of Dr. Robert W. Warner filed with the letter of 2 May 2006.

D2 referred to a catheter, wherein a mediator layer was wedged between an inner and outer layer. This wedging was a mere mechanical connection which could not be regarded as an adhesive anchorage. Even D2 itself made a clear distinction between adhesion and wedging, since it pointed out that in some applications good adhesion between the layers was necessary while in other applications that was not necessary (see page 33, line 29 to page 34, line 2).

Furthermore, D2 did not disclose that the intermediate stiff layer was made of a low density polyethylene (LDPE) as required by claim 1 of the sixth auxiliary request. On the contrary it disclosed on page 33, second paragraph, that it was e.g. made of high density polyethylene (HDPE) or other materials which were clearly unsuitable for providing adherence with the inner and outer layers.

VI. The respondent disputed the views of the appellant and maintained that the sixth auxiliary request should not be admitted into the proceedings, since it was so late filed that its filing represented an abuse of the proceedings.

The subject-matter of claim 1 of all present requests was not novel over the disclosure of D2, in particular over the catheter shown in Figure 1E.

The term "adhesive anchorage" had to be interpreted in a broad sense, so that it comprised also the anchorage by wedging according to D2. This position was supported among other things by the definition of "to adhere" in the Merriam Webster dictionary: "to hold fast or stick by or as if by gluing, suction, grasping, or fusing".

With respect to the auxiliary request 6 it had to be considered that according to claim 3 of D2 the intermediate layer had a stiffness which was intermediate between the outer and inner layer. Therefore it was not excluded that the intermediate layer could be made of LDPE.

Reasons for the Decision

1. The appeal is admissible.
2. *Late filed request*

The auxiliary request 6 filed with the letter of 18 May 2006 is admitted into the proceedings, since it has to be regarded as a direct reaction to the arguments and evidence filed by the respondent with the letter of 11 May 2006. Consequently the filing of this request does not amount to an abuse of the proceedings. Furthermore, the newly filed claims are not complex, and they do not require a special effort for their comprehension, since the only amendment in view of the claims as granted is the incorporation of the additional feature of claim 7 as granted into the new claim 1.

3. *Novelty*
- 3.1 Main request and auxiliary requests 1 to 5

D2 (see in particular Figure 1E) undisputedly discloses an interventional catheter comprising a catheter tube having two superposed layers (11, 15) of materials secured together and with mechanical properties differing from one another (see page 12, lines 10 to 19), a guidewire lumen (14) in said catheter tube for the sliding fit of a guidewire, and a balloon (see page 29, last paragraph) with a distal end sealingly surrounding said catheter tube (the balloon necessarily has to sealingly surround the catheter at its distal end, in order to function properly), whereby the

catheter tube has an inner layer (15) forming the guidewire lumen (14) and an outer layer (11) forming an outer surface of the catheter tube, the catheter comprising mediator layer means arranged between said inner layer (15) and said outer layer (11) for the anchorage of said layers thereto (see page 12, line 27 to page 13, line 1).

Additionally D2 discloses that

- the mediator layer means is formed by a mediator layer (see Figure 1E);
- the mediator layer means has mechanical properties differing from mechanical properties of the inner and outer layers (see page 12, lines 10 to 19); and
- the inner layer, the mediator layer means, and the outer layer are coextruded (see claim 37).

Therefore, the novelty of the subject-matter of claim 1 of the main request and of the auxiliary requests 1 to 5 over the disclosure of D2 depends exclusively on the question whether or not the mediator layer means according to D2 are means for the adhesive anchorage of the inner and outer layer thereto.

According to the Merriam-Webster Online Dictionary (an excerpt of which has been filed by the respondent with the letter of 28 April 2006) the technical term "adhesive" means "tending to adhere or cause adherence", the technical term "adherence" means "the act, action, or quality of adhering", and the technical term "adhere" means "to hold fast or stick by or as if

by gluing, suction, grasping, or fusing". Hence, the general meaning of the term "adhesive anchorage" obviously comprises chemical, physical (in particular mechanical) and metallurgical anchorages.

The patent in suit itself does not contain any hint that this term has to be construed as a particular bonding system which was different from mechanical locking, physical bonding or fusing. It is true, that some sections of the description (see for example column 3, lines 3 to 10, and lines 54 to 58) point out that the adhesive anchorage may be achieved by material properties. However, that does not mean that other forms of adhesive anchorages are excluded from the wording of claim 1, in particular since neither the patent in suit nor any other document in the proceedings provide a clear and unique definition of the term "adhesive anchorage" which is more restricted than the one according to the Merriam-Webster Online Dictionary. Therefore the Board cannot follow the interpretation of the wording of claim 1 given in the declaration of Dr. Robert W. Warner.

The appellant's argument that even D2 made a clear distinction between an anchorage by adhesion and an anchorage by wedging, is not convincing. The sentence on page 33, line 29 to page 34, line 2 according to which "... in some applications ... good adhesion between layers is necessary while in other applications that is not a requirement" does not allow the conclusion that the anchorage by wedging shown in Figure 1E is not an adhesive anchorage. This would have been possible only if the sentence did not contain the adjective "good". However, with respect to the presence

of this adjective, the sentence merely says that the adhesive anchorage by wedging can be improved by further adhesive anchorages.

Under consideration of the above findings, the Board came to the conclusion that mediator layer means according to D2 have to be regarded as means for the adhesive anchorage of the inner and outer layer thereto.

Accordingly, the subject-matter of claim 1 of the main request and of auxiliary requests 1 to 5 is not novel over the disclosure of D2.

3.2 Auxiliary request 6

The feature of claim 1 of the auxiliary request 6, according to which the mediator layer means are formed on the basis of a low density polyethylene is contained in claim 7 as granted which is directly dependent on claim 1 as granted. Both claims correspond to the originally filed claims 1 and 7 as published in EP-A-0 803 264. Claims 2 to 9 of the auxiliary request 6 correspond to the originally filed claims 2 to 6 and 8 to 10. Therefore, the claims of the auxiliary request 6 meet the requirements of Article 123(2) and (3) EPC.

D2 does not disclose a mediator layer means which is formed on the basis of a low density polyethylene. On the contrary it cites on page 33, lines 14 to 18 high density polyethylene as a preferred material for the stiff intermediate layer, a material which is clearly distinguished from low density polyethylene.

The respondent's argument, that with respect to the disclosure of claim 3 of D2 according to which the intermediate layer had also an intermediate degree of stiffness, the intermediate layer could also be made of low density polyethylene, is not convincing. Firstly claim 3 does not clearly refer to a low density polyethylene, and secondly, there is no evidence that low density polyethylene is the only suitable material for a layer having an intermediate degree of stiffness.

Consequently, the subject-matter of claim 1 of the auxiliary request 6 is novel.

4. Since the decision under appeal dealt only with the question of novelty of the subject-matter of the claims, the Board considers it appropriate - in accordance with the appellant's request - to remit the case to the first instance for further prosecution.

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 auxiliary request 6 filed with the letter of 18 May 2006.

The Registrar:

The Chairman:

V. Commare

T. Kriner