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D E C I S I O N
of 14 July 2005

Case Number: T 0498/04 - 3.2.2

Application Number: 94918157.2

Publication Number: 0774987

IPC: A61M 25/10

Language of the proceedings: EN

Title of invention:
Selective arrangement of lubricous coatings on balloon catheters

Patentee:
SCIMED LIFE SYSTEMS, INC.

Opponents:
1) Terumo Kabushiki Kaisha
2) BIOTRONIK GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 83

Keyword:
"Novelty (yes)"
"Inventive step (yes)"
"Sufficient disclosure (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0498/04 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 14 July 2005

Appellant I: (Opponent II)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 12 February 2004 concerning maintenance of European patent No. 0774987 in amended form.**

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
U. Tronser

Summary of Facts and Submissions

I. The appellant I (opponent II) lodged an appeal on 8 April 2004 against the interlocutory decision of the opposition division posted on 12 February 2004 on the amended form in which the European patent EP-B-774 987 could be maintained. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 18 June 2004.

II. The appellant II (patentee) lodged an appeal on 7 April 2004 against this decision. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 7 June 2004.

III. The opposition division held that:

- the subject-matter of claim 1 of the main request then on file (claim 1 as granted) was not novel having regard to

  D12 = US-A-5 135 516 or
  D7 = US-A-5 176 698 or
  D8 = US-A-5 156 595,

- the subject-matter of claim 1 of the first and the second auxiliary request then on file was not clear,

- whereas the third auxiliary request then on file complied with the provisions of the EPC and therefore could be granted.

IV. In addition to the documents cited above, the following further document has been cited during the appeal proceedings:

D2 = US-A-2 927 584.

V. Oral proceedings took place on 14 July 2005.

The appellant I requested that the decision under appeal be set aside and that the patent No. 774 987 be revoked.

The appellant II requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of:

Claims: 1 to 20, and

Description: columns 1 to 6 as submitted during oral proceedings, and

Figures: 1 to 4 as granted.

VI. Claim 1 of this request which corresponds to claim 1 as granted reads as follows:

"A balloon catheter (10) including a shaft (22) and a balloon (18) associated therewith, the balloon (18) having a proximal end portion, a distal end portion, a central portion (30), and a first lubricous means with said balloon catheter characterized in that, said first lubricous means being bonded to the balloon catheter (10) and being constructed and arranged to provide more lubricity with respect to a major portion of the shaft

(22) than with respect to at least a portion of the balloon (18)."

VII. In support of his request the appellant I relied on the following submissions.

The invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC) since the patent specification did not contain sufficient indications regarding the material of the balloon. The list of materials contained in the paragraph [0024] of the description was too broad and vague. Hence the skilled person did not know which material had to be selected to ensure that the balloon was less lubricous than the shaft.

The subject-matter of claim 1 was not novel having regard to the disclosure of the documents D7, D8 or D12. It was evident that these documents explicitly disclosed all the features of claim 1, except the one according to which the lubricity with respect to a major portion of the shaft was higher than with respect to at least a portion of the balloon. However, this feature was implicitly disclosed in D7, D8 and D12, since they disclosed that the shaft was covered by a lubricous coating to provide a slippery surface to facilitate the insertion of the catheter (see D7, column 4, lines 1 to 7; D8, column 2, line 64, to column 3, line 6; D12, column 5, lines 41 to 47), whereas the balloon was left uncovered. It was therefore clear that the uncovered balloon should have less lubricity.

The subject-matter of claim 1 did at least not involve an inventive step having regard of each of the documents D7, D8 or D12 in combination with D2. D2 referred to the problem of the invention consisting of anchoring the balloon against the walls of a vessel. Alternatively, starting from D2, the problem of the invention was to facilitate the passage of the shaft of the catheter along the vessel. This problem and the solution according to the invention of covering the shaft with a lubricous means was however known from D7, D8, or D12.

VIII. The appellant II disputed the views of the appellant I and in support of his requests relied on the following submissions.

The invention was feasible. The indication of the materials for the balloon in the description was sufficient for the skilled person in order to choose the suitable material for each specific embodiment of the invention.

The subject-matter of claim 1 was novel. None of the documents of the available prior art disclosed that the lubricant means was constructed and arranged to provide more lubricity with respect to a major portion of the shaft than with respect to at least a portion of the balloon. Contrary to the statement in the reasons for the decision under appeal, D12 did not show in Figure 3 a balloon catheter having the shaft and the balloon made of the same material. It was true that the description, column 5, lines 42 and 43, disclosed that only the shaft was coated with a lubricous means, however that did not necessarily mean that the

lubricity of the shaft should be higher than that of the balloon.

The teaching of D2 would not have been considered by the skilled person, since this document did neither refer to the purpose of the invention nor disclose the solution delivered by the patent in suit. The purpose of the catheter according to D2 was to anchor the balloon against a vessel in order to avoid bleeding. To this purpose the balloon was provided with a flocked surface. On the other hand, the problem of the invention was to avoid the watermelon-seed effect and the means to avoid this effect was to provide the shaft with a lubricous means to the effect that the shaft was more lubricous than the balloon. Therefore, the subject-matter of claim 1 also involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. *Article 83 EPC*

The invention is disclosed in the patent specification in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. It is not necessary to specify in the claim the material for the balloon for the sake of feasibility, since the skilled person will find with a routine workshop activity among the group of polyolefin copolymers the suitable material which in combination with the lubricous means applied on the shaft provides more

lubricity with respect to a major portion of the shaft than with respect to at least a portion of the balloon.

3. *Novelty*

3.1 D2 discloses a balloon catheter (10) including a shaft (11) and a balloon (19) associated therewith, the balloon having a proximal end portion, a distal end portion and a central portion.

However, D2 does not disclose a first lubricous means bonded to the balloon catheter and constructed and arranged to provide more lubricity with respect to a major portion of the shaft than with respect to at least a portion of the balloon.

3.2 Each of D7 and D8 discloses a balloon catheter (D7:10 / D8:10) including a shaft (D7:14 / D8:12) and a balloon (D7:16 / D8:16) associated therewith, the balloon having a proximal end portion, a distal end portion, a central portion, and a first lubricous means with said balloon catheter (D7: see column 4, lines 1 to 7 / D8: see column 2, lines 12 to 14, 64 to 68), said means being bonded to the balloon catheter (implicit).

However, D7 and D8 do not disclose that the lubricous means are constructed and arranged to provide more lubricity with respect to a major portion of the shaft than with respect to at least a portion of the balloon.

Certainly, both D7 and D8 suggest to provide the shaft with a coating of silicon (for example: polydimethyl-siloxane) or Teflon (polytetrafluoroethylene) and to

make the balloon from a polymeric material such as a polyolefin copolymer, which often is a material having less lubricity than the coating of the shaft. However, it is not proven that all such materials have less lubricity than the coating according to the invention, and neither D7 nor D8 explicitly disclose that the lubricous means provides more lubricity with respect to a major portion of the shaft than with respect to at least a portion of the balloon.

The consistent view of the boards of appeal of the EPO is that for an invention to lack novelty its subject-matter must be clearly and directly derivable from the prior art. Therefore the mere assumption that the provision of a lubricous coating only on the shaft would result in a catheter where the shaft is more lubricous than the balloon is not sufficient to challenge the novelty of the subject-matter of claim 1, in particular since the purpose of the coating on the shaft could also consist in providing the shaft with the same lubricity as the balloon.

3.3 D12 (see in particular Figure 3) discloses a balloon catheter (24) including a shaft (26) and a balloon (25) associated therewith, the balloon having a proximal end portion, a distal end portion, a central portion, and a first lubricous means with said balloon catheter, said means being bonded to the balloon catheter (see column 5, lines 41 to 47 and column 6, lines 27 to 32) and being constructed and arranged to provide lubricity with respect to a major portion of the shaft.

However, claim 1 does not disclose that the lubricous means provides more lubricity with respect to a major

portion of the shaft than with respect to at least a portion of the balloon.

Certainly, as is stated in the decision under appeal, D12 discloses a lubricous coating limited to the shaft. However D12 does not disclose that the lubricity of the shaft is higher that that of the balloon. D12 fails to clearly disclose that the shaft and the balloon shown in Figure 3 are made of the same material. It is not justified to derive from the absence of a separation line between the balloon and the shaft in the cross section of Figure 3 that the materials of the shaft and of the balloon are the same, since patent drawings are essentially schematic drawing and not detail drawings.

3.4 With respect to the above findings the subject-matter of claim 1 is novel.

4. *Inventive step*

4.1 According to the case law of the boards of appeal of the EPO (see 4th edition, English version, I.D.3.1, page 102) the closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications.

In the present case, each of the documents D7, D8 and D12 can be considered as representing the closest state of the art, since these documents, like the patent in suit, refer to a balloon catheter for performing

angioplasty and disclose the most relevant technical features described in claim 1.

By contrast, D2 is not suitable for being considered as the closest state of the art. This document concerns haemostatic catheters which are inserted in body vessels (typically the urethra) and inflated against bleeding areas on the walls of the vessel. In order to avoid slipping away from the wet, bleeding areas, the balloon is provided with a flocked surface. Therefore the catheter according to D2 is not intended for performing angioplasty in which the balloon is used to open narrowed or blocked blood vessels.

4.2 Starting from the state of the art according to D7, D8 or D12, the object underlying the patent in suit is to be seen in avoiding the so-called watermelon-seed effect. This effect arises when the balloon is inflated against a localized obstruction in a vessel (stenosis) to force the stenosis open. To this purpose the balloon has to remain in place during inflation across the narrower section of the vessel. However, since the walls of the vessel are longitudinally slanted before and behind the narrower section, the balloon can slip away during inflation.

The object cited above is achieved by the balloon catheter of claim 1 in particular by the provision of the lubricous means which is constructed and arranged to provide more lubricity with respect to a major portion of the shaft than with respect to at least a portion of the balloon.

4.3 Since the available prior art does not disclose any means to avoid the watermelon-seed effect, let alone the provision of lubricous means as defined in claim 1, the balloon catheter according to claim 1 cannot be regarded as being obvious.

4.4 From the above considerations, it follows that the subject-matter of claim 1 involves an inventive step.

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 with the order to maintain the patent on the basis of:

Claims: 1 to 20 and

Description: columns 1 to 6 as submitted during oral proceedings, and

Drawings: Figures 1 to 4 as granted.

The Registrar: The Chairman:

G. Magouliotis T. Kriner