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D E C I S I O N
of 14 March 2003

Case Number: T 0488/01 - 3.2.2

Application Number: 93111939.0

Publication Number: 0636382

IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:
Puncture resistant balloon catheter

Patentee:
Cordis Corporation

Opponent:
Terumo Kabushiki Kaisha

Headword:
-

Relevant legal provisions:
EPC Art. 52, 54, 56, 123

Keyword:
"New subject-matter (no)"
"Novelty (yes)"
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0488/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 14 March 2003

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 28 February 2001 concerning maintenance of European patent No. 0 636 382 in amended form.**

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
R. T. Menapace

Summary of Facts and Submissions

I. The appellant (opponent) filed an appeal against the decision of the opposition division to maintain the patent in amended form.

II. The opposition was based on the grounds of lack of novelty and inventive step, of insufficient disclosure and of extended subject-matter.

III. Following documents cited during the opposition proceedings are relevant for the present decision:

E2: JP-A-4 144 572

E8: EP-A-540 290

E9: EP-A-553 960

E11: "CenBASE/Materials", Vol. 4: "Property and application index", Eds. Nunez et al, John Wiley and Sons Inc., 1990, pages 390, 391, 403 to 405, 441, 442, 448 to 450

With letter of 11 March 2003, the opponent cited *inter alia* the additional document:

E19: EP 0 483 941.

IV. Following a request from both parties, oral proceedings were held on 14 March 2003. At the end of the oral proceedings the requests of the parties were as follows:

The appellant (opponent) requested that the decision

under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the appeal be dismissed and that the patent be maintained either in the version underlying the decision under appeal (main request) or on the basis of claim 1 as submitted as second auxiliary request with letter of 14 February 2003 (auxiliary request).

V. Claim 1 of the main request as submitted with letter of 2 February 2001 reads as follows:

"A kit of a balloon catheter, which comprises: a flexible, elongated member; an inflatable balloon (10) carried on the elongated member; an inflation chamber defined with said balloon; and an inflation conduit communicating with the inflation chamber, said balloon being made of a flexible inelastic plastic material, having an elongation to break of substantially not more than 30 percent and a Shore 'D' durometer of at least about 70 and having an outer surface which is surrounded by an elastomeric sleeve (20) bonded to said outer surface to provide pin hole and/or abrasion resistance to said balloon (10); and an expansible stent, which is adapted to be carried in use about the outer surface of the elastomeric sleeve (20)."

Claim 1 of the auxiliary request as submitted with letter of 14 February 2003 reads as follows (the additions in relation to the main request are underlined):

"A kit of a balloon catheter, which comprises: a

flexible, elongated member; an inflatable balloon (10) carried on the elongated member; an inflation chamber defined with said balloon; and an inflation conduit communicating with the inflation chamber, said balloon being made of a flexible inelastic plastic material, having an elongation to break of substantially not more than 30 percent and a Shore 'D' durometer of at least about 70 and having an outer surface which is surrounded by an elastomeric polyurethane sleeve (20) bonded to said outer surface to provide pin hole and/or abrasion resistance to said balloon (10), on which sleeve a lubricating hydro-gel formulation is carried in use; and an expansible stent, which is adapted to be carried in use about the outer surface of the elastomeric sleeve (20)."

VI. The appellant argued as follows. The auxiliary request should not be admitted in the proceedings because it had been filed too late and because it contained subject-matter (hydro-gel formulation) which was not contained in the original claims. However, in the event that the request was admitted, he requested that the documents filed with letter of 11 March 2003 be admitted in the procedure as a direct reaction to the newly filed request.

Claim 1 of the main request contained additional subject-matter since in the original disclosure - see EP-A-636 382, column 3, from line 34 - it was merely stated that the balloon might carry an expansible stent. There was no original disclosure of a loose combination of a stent and a balloon as required by the kit claimed in claim 1. The particular use as originally disclosed was not identical to an actual combination as required by the claimed kit. Furthermore

claiming a kit represented an extension of the protection.

Claim 1 of the main request lacked novelty having regard to document E9. The only features of claim 1 not explicitly disclosed by this document were that the balloon was flexible and the range of values for the elongation to break and for the hardness. However, all balloons were inherently flexible and the claimed values were well established, as it was also acknowledged by the patent in suit, see column 1, from line 14, where it was stated that the materials of the claimed balloon were commonly used. According to column 4, from line 46, the claimed materials were acknowledged as conventional. Furthermore document E11, page 390, disclosed the range of values of the elongation to break for one of the materials used to carry out the invention (PET). Such values covered two clearly distinct ranges: from 500 to 100 and from 50 to 1,4. There was no doubt that the person skilled in the art would choose an elongation to break among the lower range. A low elongation to break meant further a crystalline structure, that is a high hardness, in the range disclosed at page 448 of the same document and which corresponded to the claimed values. The claimed values represented therefore for the person skilled in the art an inevitable choice.

Regarding the inventive step of claim 1 of the main request, reference was made to document E8 which disclosed a balloon catheter made of PET (column 4, from line 45). As shown above by the discussion on novelty, it was obvious to choose the values of the hardness and of the elongation to break of the PET material within the claimed range. Document E8

disclosed further - at column 2, from line 20 - securing the stent on the balloon by compression. This could cause abrasion of the balloon material and the formation of pin holes on it. It was obvious for the person skilled in the art to avoid abrasion and the formation of pin holes by means of a protecting elastic sleeve as disclosed by document E2. The sleeve disclosed in document E2 had nothing to do with that of document E8. Document E8 disclosed locating a sleeve above the stent for stent retention and in order to avoid abrasion of the wall of the blood vessel by the stent, the sleeve of document E2, on the contrary, was designed to protect the balloon.

Regarding the auxiliary request, it was noted that document E2, page 18, from line 7, disclosed polyurethane as preferred material for the sleeve, as the claimed invention. Such material was obviously suitable for receiving a hydrogel formation. Polyurethane was a conventional material for use in balloon catheters, being biocompatible and possibly antithrombotic, see also document E2, page 19, line 8, and the patent in suit, end of column 2, column 3, from line 6, column 5, from line 10. Document E19, column 5, from line 11, disclosed that it was common general knowledge to use hydrogel formation on a balloon catheter.

VII. The respondent argued as follows: The auxiliary request had been filed within the time limit and it should not have been unexpected, because it had been already filed in opposition proceedings.

The newly filed documents including E19 should not be admitted into the procedure because they were late

filed.

Claim 1 of the main request did not go beyond the original disclosure since the clause: "may carry" contained in column 6, line 36 of the description clearly meant that in use the balloon and the stent could form a kit.

The disclosure of document E9 did not imply that a material was selected the parameters of which fell into the range indicated in claim 1. The materials enumerated in document E11, from page 390 onwards, were not specific for balloon catheters. From the long list of polyester materials contained in document E11, from page 390 onwards, only a few complied with the provisions of the claim. Starting from page 448 of document E11, a very long list, covering seven columns, of materials was given. Among them, merely the first four complied with the elongation to break and the hardness values claimed. A crystalline material did not necessarily imply that such material had the claimed values of hardness and elongation to break.

The subject-matter of claim 1 of the main request also involved an inventive step. Starting from document E8, there was no reason to combine its teaching with that of document E2 in the way of claim 1, that is to transfer the external sleeve to below the stent. Document E2 was not involved with stent delivery as document E8. The working conditions of a stent delivery balloon were completely different from those of an expansion balloon. The problem of abrasion was solved in document E8 by means of the external sheet, see end of column 4. Inserting an additional sheet between the stent and the balloon in the catheter of document E8

would mean increasing the pressure necessary for delivering the stent, which was obviously disadvantageous.

Regarding the auxiliary request, the wording "in use" contained in claim 1 meant that the outer surface of the sleeve was suitable for carrying a hydrogel formulation. Document E2 did not disclose that the polyurethane used for the sleeve could provide a base for a hydrogel formulation. Document E17, by stating that the coating had been found to be not durable, see page 2, from line 44, proved that it was not general knowledge using a hydrogel coating.

Reasons for the Decision

1. The appeal is admissible.

2. *Newly filed documents and amendments.*

The technical content of the amended version according to the auxiliary request corresponds in substance to that of the second auxiliary request filed on 5 January 2001 with the Opposition Division. Since this auxiliary request there needed not be considered but got its bearing only when resubmitted during appeal, the appellant was now entitled to respond by citing additional documents (*inter alia* E19).

Consequently, document E19 and the auxiliary request were filed in time and, therefore had to be considered in the appeal proceedings.

3. *Original disclosure*

The description as originally filed, see EP-A-0 636 382, column 3, lines 34 to 38, states "If desired, the balloon catheter of this invention may carry an expansible stent about the outer surface of the elastomeric sleeve, so that the expansible stent may be expanded by the balloon into engagement with the wall of the blood vessel". This wording implies the option that the catheter is associated with an expansible stent adapted to be carried about the outer surface of the elastomeric sleeve to a location in a body vessel where it is to be expanded. A "kit" of a catheter and a stent is the adequate category to express this option.

It is true that the mechanical parameters of the materials making up the elastic sleeve and the inelastic balloon material, respectively, are disclosed in combination in claim 18 as originally filed. It would, therefore, *prima facie* not be allowable to break this combination and to transfer only the parameters referring to the balloon into an amended claim 1. In the originally filed description (see EP-A-0 636 382, column 9 to 17), however, the features relating to the elastomeric sleeve and those relating to the inelastic balloon material and their different purposes are treated separately.

The claim as granted is directed to a "ballon catheter" having certain features. The present claim 1 now claims a "kit" consisting of a balloon catheter, which has features additional to those of the catheter in the version as granted, and of a stent specifically adapted thereto. This means, that the protection conferred has been restricted from a product with unlimited options for its use to the same product which is limited to be

used in combination with a specifically adapted stent.

The additional features contained in claim 1 of the auxiliary request are supported by column 2, from line 46 of EP-A-636 382.

Consequently, no violation of Article 123(2) or (b) can be detected.

4. *Main request*

4.1 Novelty

Lack of novelty has been objected exclusively based on document E9, which is a piece of state of the art according to Article 54(3) EPC. This document does not explicitly disclose the feature of claim 1 that the balloon has an elongation to break of substantially not more than 30 percent and a Shore 'D' durometer of at least about 70.

The statement in the patent in suit that the materials provided for the balloon are commonly used does not necessarily imply that the parameters of all those materials fall into the claimed ranges.

According to document E9 (see column 8 lines 16 to 26), the inner layer of the balloon may be made of an inelastic but expandable material such as, PE, PE-600 or PET. Even if the suggestion of the appellant was followed and PET chosen as the favourite material, this would not imply that the selected PET material would have e.g. an elongation to break of not more than 30 percent.

According to document E11, the elongation value of the PET materials enumerated there vary from 1.40 to 500 percent. Since the lowest values are mostly to be achieved by fibre glass reinforcement which disqualifies the material for the use as balloon material, the practitioner could well end up choosing a material having an elongation of 41 percent or as high as 100 percent, even if he automatically excluded the materials having still higher elongation values. The teaching of document E9 does, therefore, not imply that the values of the mechanical parameters of the balloon material meet the requirements of claim 1.

Accordingly the subject-matter of the claim 1 of the main request is novel over document E9.

4.2 Inventive step.

Document E8 has been unanimously recognized to represent the closest state of the art for the test of inventive step. This document discloses, like the invention, a kit of a balloon catheter made of PET and a stent. The subject-matter of claim 1 differs therefrom by the claimed parameters of the elongation to break (substantially not more than 30 percent) and of the shore 'D' durometer (at least about 70) and by an elastomeric sleeve bonded to the outer surface of the balloon to provide pin hole and/or abrasion resistance to said balloon.

Since these known balloons are typically very thin-walled, they can be easily punctured through abrasion, or they can even suffer from pin holes caused by the molding process. Pin holes and ruptures may occur especially when such catheter balloons are used in

contact with rough surfaces, such as those of a stent. Furthermore, the balloon should be easily collapsible down to a small diameter upon deflation. Accordingly, there is a need to protect the balloon against abrasion, to avoid the effect of pin holes formed during molding and to avoid "winging", in which the inflated balloon collapses on deflation into an enlarged-width, flat configuration, which is difficult to extract from the blood vessel, see patent in suit, column 1, from line 23, column 2, from line 38. Such problem is partially recognised by the document E8, see paragraph bridging columns 4 and 5.

The person skilled in the art looking for hints to solve the problem above will consider document E2 which deals also with balloon catheters like the invention. Document E2 discloses a balloon made of crystalline plastic material such as PET, like one of the preferred materials of the invention. Document E2 also knows the problem of the invention, (see page 4, from line 7 from the bottom,) stating that the balloon should have satisfactory strength and durability in order not to cause the balloon to be damaged and broken at the time of the insertion or in the way of pumping; (see page 5, first paragraph and page 8, first paragraph, stating that a thick balloon can not be easily wrapped).

In order to solve the problem arising from a balloon catheter according to document E8, document E2 suggests like the invention, to provide the balloon with an outer elastomeric sleeve (see for example page 7, last paragraph).

According to the patent in suit, one of the preferred materials for the balloon is PET in crystalline form.

This material is, however, known for this purpose as a preferred material by documents E8 and E2.

Whenever increased dimensional stability is required of a balloon material, the person skilled in the art will inevitably select, e.g. from document E11, those commercially available materials which have a higher degree of crystallinity. Since a higher crystallinity implies a lower value for the elongation to break and a higher durometer value, he will necessarily end up in the claimed ranges without an inventive step being involved.

Accordingly, the subject-matter of claim 1 of the main request does not involve an inventive step.

5. *The auxiliary request*

Claim 1 according to the auxiliary request differs from the one of the main request by the additional features that the material of the sleeve is polyurethane and that in use the sleeve carries a lubricating hydrogel formulation.

The material of the sleeve is disclosed by document E2, page 18, first paragraph.

According to the respondent, the second feature has to be interpreted to mean that the material of the sleeve is suitable to carry a lubricating hydrogel formulation. It is known that polyurethane is suitable for receiving a lubricating hydrogel formulation, see for example E19, column 5, from line 11.

Accordingly the subject-matter of claim 1 of the auxiliary request does not involve an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

V. Commare W. D. Weiß