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D E C I S I O N
of 12 September 2002

Case Number: T 0891/01 - 3.2.2

Application Number: 95907960.9

Publication Number: 0738169

IPC: A61M 29/02

Language of the proceedings: EN

Title of invention:
Thermoplastic polyimide balloon catheter

Applicant:
Scimed Life System, Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52, 56

Keyword:
"Novelty and inventive step (yes)"
"Reimbursement of appeal fee (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0891/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 12 September 2002

Appellant: Scimed Life Systems, Inc.
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Representative: Maiwald, Walter, Dr. Dipl.-Chem.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 15 March 2001 refusing European patent application No. 95 907 960.9 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
J. C. M. De Preter

Summary of facts and submissions

I. The Appellant (applicant) filed an appeal against the decision of the Examining Division to refuse the patent application for lack of inventive step.

The decision, however, states (see point 5 of the reasons) that the subject-matter of a claim, wherein the balloon portion of a catheter was defined as being made at least in part of thermoplastic polyimide would have met the requirement of inventive step.

II. The following documents, cited in the decision under appeal, are relevant for the present decision:

D1: DE-A-4 025 346
D2: WO-93/20 881.

The document:

C1: US-A-4 952 357

has been cited in the application and it is also referred to in the present decision.

III. On request of the appellant, oral proceedings have been held on 12 September 2002. At the end of the oral proceedings the appellant requested that the decision under appeal be set aside, that a patent be granted on the basis of claims 1 to 15 submitted at the oral proceedings (main request) and that the appeal fees be reimbursed.

IV. Claim 1 as filed during the oral proceedings on 12 September 2002 reads as follows:

"A balloon catheter (10) for use in angioplasty comprising a shaft (12) portion having a proximal end and a distal end, and a balloon portion (14, 30) located at the distal end of said shaft portion, characterized in that the balloon portion (14, 30) of the balloon catheter (10) is comprised at least in part of thermoplastic polyimide."

V. The appellant argued essentially as follows.

Document D1 was essentially directed to the use of polyimide for transparent articles, its use for balloon catheters was not disclosed and no information was given about the dilatation properties of the material. Document D2 disclosed only the use of polyimide in combination with steel for the shaft of the catheter. Neither document D1 alone nor document D1 in combination with document D2 were therefore detrimental for the inventive step of claim 1.

The request for a reimbursement of the appeal fee was justified because the applicant successfully addressed and overcome all the objections of the Examining Division, whereas the Examining Division gave no arguments, just unsupported opinions for its rejection based on lack of inventive step of claim 1.

Reasons for the decision

1. The appeal is admissible.

2. *Amendments*

There are no reasons to question the amendments to the

last filed claims. Claim 1 has been amended with respect to the version taken as a basis for the decision under appeal by adding the features that the balloon is specifically designed for angioplasty and that the balloon portion is comprised of thermoplastic polyimide.

2. *Novelty*

Starting from document D1, which has been considered in the decision under appeal as the closest state of the art, claim 1 contains the additional, distinguishing features that:

(1) the catheter is a balloon catheter;
(2) the catheter is especially designed for use in angioplasty, and
(3) the portion of the balloon catheter, which is comprised at least in part of thermoplastic polyimide, is the balloon portion.

Starting from document C1, cited in the description of the patent application, and which is now considered as the more appropriate document to represent the closest state of the art for the amended claim 1, the distinguishing feature of claim 1 is that the polyimide material of the balloon is thermoplastic instead of thermoset.

3. *Inventive step*

The technical problem to be solved by the invention as claimed in claim 1 has to be seen in providing a reliable balloon catheter for angioplasty.

Neither document D1 nor document D2 disclose the use of a thermoplastic polyimide for the balloon portion of a balloon catheter for angioplasty.

Document C1 discloses a balloon catheter for angioplasty, the balloon of which is defined by a plurality of layers at least one of which is formed from a thermoset polyimide polymer material.

In angioplasty balloons, thermoset polyimide has been used because high tensile strength, flexibility and high burst pressure allows to manufacture balloons having a relatively small wall thickness. High pressure is often needed to treat some forms of stenosis, whereas small wall thicknesses enable the deflated balloon to remain narrow making it easier to advance the balloon through the arterial system. The thermoplastic quality of the polyimide provided by the invention allows to form it by tubular extrusion, avoiding complicated manufacturing procedures, as those required by thermoset materials. It offers also the possibility of secondary forming operations, since thermoplastic can be remelted, or reheated after extrusion, so that a balloon can be blown out of the extruded catheter tube. Finally, the prior art thermoset polyimide balloon of document C1 had a tendency to present more a catastrophic type of failure rather than the preferred longitudinal burst mode of the thermoplastic polyimide balloons of the invention.

No document of the available prior art contains an indication of the properties of the thermoplastic polyimide cited above which make it particularly suitable as material for balloons used in angioplasty. Document D1 cites such material, but without giving any

information relating to such properties.

Since there are no hints in the available prior art which can lead, starting either from document C1 or from document D1, in an obvious way to the invention, the subject-matter of claim 1 has to be considered as involving an inventive step.

4. *Reimbursement of the appeal fee*

The request for reimbursement of the appeal fee has to be rejected since there is no substantial procedural violation in the proceedings before the first instance. The communications of the first instance contain sufficient indications of the grounds for the impending refusal and a warning, so that the applicant could not have been taken by surprise by the decision.

Moreover, the Examining Division, in its communication of 8 December 1999, already pointed to the allowability of the claims now on file.

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 grant a patent on the basis of claims 1 to 15 submitted at the oral proceedings, the figures as originally filed and a description still to be adapted.

3. The request for reimbursement of the appeal fee is

rejected.

The Registrar: The Chairman:

V. Commare W. D. Weiß