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D E C I S I O N
of 31 October 2005

Case Number: T 1395/04 - 3.2.02

Application Number: 97304514.9

Publication Number: 815805

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:

Endoprosthesis assembly for percutaneous deployment and method
of deploying same

Patentee:

Cordis Corporation

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 56

Keyword:

"Inventive step (yes) "

Decisions cited:

-

Catchword:

-



Case Number: T 1395/04 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 31 October 2005

Appellant: Cordis Corporation
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Representative: Mercer, Christopher Paul
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 22 June 2004
refusing European application No. 97304514.9
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
M. Vogel

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 22 June 2004 to refuse European patent application No. 97 304 514.9.

The application was refused on the grounds that the subject-matter of claim 1 of the main request and the auxiliary request was not novel, or did not involve an inventive step, depending on how the term "braid" was defined.

The following documents were cited in the objections under Article 52(1) EPC:

D1: EP-A-0 689 805

D2: EP-A-0 603 959 (and D2': US-A-5 653 747 its US family member).

II. On 26 August 2004 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same date. On 1 November 2004 a statement of grounds of appeal was filed.

III. The appellant requests that the decision under appeal be set aside and that the application be granted on the basis of claims 1 to 8 of the main request or claims 1 to 7 of the auxiliary request filed with the grounds of appeal.

IV. Both requests have an identical claim 1 which reads as follows:

"An endoprosthesis assembly (10) for percutaneous deployment and implantation within a body passageway, comprising: a radially expandable cylindrical frame (12) having first and second ends, said frame (12) having a first unexpanded outer diameter and a second expanded outer diameter; a radially expandable elastomeric sleeve (14) surrounding a length of said frame (12) and having first and second ends, said sleeve (14) having a first unexpanded inner diameter and a second expanded inner diameter; wherein a second expanded inner diameter of said sleeve (14) is not greater than a second expanded outer diameter of said frame (12); wherein a second expanded inner diameter of said sleeve (14) is in a range from about 60% to about 380% greater than a first unexpanded inner diameter of said sleeve(14); and wherein the sleeve is strong enough to withstand the stress associated with expansion of the stent to the second expanded diameter, and is compliant enough to avoid collapsing the stent after the expansion is complete; characterised in that the sleeve is a braid comprising yarns woven in a diagonal crisscross pattern, the braid providing increased compliance for the sleeve (14)."

Reasons for the Decision

1. The appeal is admissible.
2. *Amendments*

Claim 1 is based on originally filed claim 1, and includes additional features which are supported by the description, at column 3, line 58 to column 4, line 4

and column 4, lines 13 and 14 (see EP-A-0 815 805), together with the feature that the sleeve is a braid comprising yarns woven in a diagonal crisscross pattern. This last feature is supported by Example 1, in which is described with reference to Figure 9, how yarns are braided into a sleeve, inevitably yielding a diagonal crisscross pattern.

The dependent claims are also fairly based on the original disclosure and the description has been amended for consistency with the new claims. Therefore, the requirements of Article 123(2) EPC are met.

3. *Novelty*

The impugned decision concedes that the cited prior art does not disclose a sleeve for a stent, which is made of yarns arranged in a diagonal crisscross pattern. This feature is recited at the end of claim 1 so that novelty of the claimed device is not in any doubt.

4. *Inventive step*

4.1 An important feature of endoprosthesis assemblies in general is the provision of a sleeve over an expandable stent frame because stent frames, when expanded, generally leave large void areas between the struts of the frame, and the sleeve is provided to alleviate the problems associated with those void areas, as described in column 2, lines 21 to 28 of EP-A-0 815 805.

4.2 The technical problems which the application addresses are (see Summary of the invention in columns 3 and 4) that the sleeve must have acceptable compliance

characteristics so that the structure can be deformed into a new, expanded shape, without breaking or tearing, a compliant sleeve over a frame must not impart large constrictive forces onto the frame, once expanded, which may cause the expanded sleeve to collapse, and the sleeve must also be as thin as possible when the sleeve is in its unexpanded state to minimise the size of the unexpanded endoprosthesis assembly without compromising the sleeve's strength or integrity. The sleeve of the application needs to be expandable to as much as a 380% greater diameter, without breaking or tearing.

4.3 The claimed device achieves these objectives by providing an elastomeric sleeve formed of a braid comprising yarns woven in a diagonal crisscross pattern.

4.4 The sleeve (graft member) in D1 (which discloses an endoprosthesis assembly according to the preamble of claim 1) is formed either of a porous film (D1, column 3, line 36) or of a woven, non woven or knitted material (column 3, lines 19 and 20). However, no details of the form of a woven material are given. D1 requires the material to have a yield point that is reached upon expanding the stent, otherwise the stent member will tend to collapse the graft member.

The sleeve in D2 and D2' is formed as a multi-layer wrap which may have up to or more than 100 layers of fibres around the frame (D2', column 4, line 47), and the fibres in each layer are all arranged parallel to each other and successive layers are bonded together (column 4, lines 48 to 53). The purpose of this wrap is to provide a microporous layer having an appropriate

porosity for facilitating normal cellular invasion (column 2, lines 38 to 40). Such a layer is not a braid, and it will not provide increased compliance.

- 4.5 The appellant has given a plausible explanation of why the forces involved are different in the case of a prior art woven material and the present braided material, which may be summarised as follows:

The woven material of D1 has multiple, generally parallel, circumferentially extending warps and generally parallel, longitudinally extending wefts that are interleaved with each other. Upon expanding the stent the longitudinal wefts will bear no load and all the expansion will instead be borne by the warps. To expand the diameter of the stent by 100% will mean that the circumference of the stent will alter by 100% and the warps will be stretched by 100%. With a braided material the "warp" and the "weft", since they both have a circumferential component, will both bear the load of the extension, so that each strand will bear less of a load and will stretch less.

Since the extension is less in the present case as a result of using a braided sleeve, the loads in the yarns of the present sleeve are reduced compared to those of D1 so that the yarns can be finer and the sleeve can be thinner. Moreover, the present device will work irrespective of whether the yield point of the material chosen for the sleeve is exceeded upon expanding the frame. Furthermore, the characteristics of the sleeve can be altered simply by altering the angles of the pitch of the braid.

4.6 The technical advantages provided by braiding a stent sleeve could not be envisaged upon reading D1 and D2 and D2'. Neither of these documents or other prior art known to the Board suggests making sleeves for stents by braiding, so that claim 1 involves an inventive step.

5. *Rule 86(4) EPC*

The primary examiner of the examining division was also the search examiner, and had evidently searched for documents disclosing woven stent sleeves since he uncovered such documents. The impugned decision argues that knitting and weaving are equivalent alternatives to braiding and, considering that braiding is the main technique used in application as originally filed, the search would have covered braided sleeves as well as woven ones, and a further search for this feature is unnecessary.

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 the following documents:
 - Claims 1 to 8 of the main request filed with the grounds of appeal,

- Description pages 2, 3, 13 as originally filed
- Description pages 1, 5, 11 as filed with the letter dated 26 November 2002
- Description page 6 as filed with the letter dated 28 October 2003
- Description page 4 as filed with the letter dated 10 May 2004
- Description pages 10, 12, 14 as filed with the letter dated 26 August 2004
- Description pages 7, 8, 9 as filed with the letter dated 27 October 2005
- Figures 1 to 9 as originally filed.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner