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D E C I S I O N
of 26 January 2006

Case Number: T 1189/03 - 3.2.02

Application Number: 95108462.3

Publication Number: 0686379

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:

Vascular graft

Patentee:

CARDIOVASCULAR CONCEPTS, INC.

Opponent:

Edwards Lifesciences Corporation, Law Department

Headword:

-

Relevant legal provisions:

EPC Art. 54, 123(2)

Keyword:

"Novelty (yes, after amendments)"

Decisions cited:

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Catchword:

-



Case Number: T 1189/03 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 26 January 2006

Appellant: CARDIOVASCULAR CONCEPTS, INC.
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 30 September 2003
revoking European patent No. 0686379 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: M. Noël
A. Pignatelli

Summary of Facts and Submissions

I. European patent No. 0 686 379 was revoked by decision of the opposition division dated 30 September 2003 on the ground of lack of novelty of its claimed subject-matter vis-à-vis the prior art document

D4: US-A-5 290 305.

II. The appellant (patentee) lodged an appeal against this decision by notice received on 26 November 2003 and paid the appeal fee on the same day. A statement setting out the grounds of appeal was filed on 29 January 2004 along with new sets of claims according to a main request and a first auxiliary request.

III. Following a summons to attend oral proceedings, on request of both parties, the respondent (opponent) informed the Board by letter dated 13 January 2006 that it will not be attending the oral proceedings.

IV. Oral proceedings were held on 26 January 2006 during which the appellant submitted new sets of amended claims.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and a patent be maintained on the basis of

- claims 1 to 6 of the main request or the first auxiliary request as filed during the oral proceedings before the opposition division, or

- claims 1 to 6 of the second or third or fourth auxiliary requests all filed during the oral proceedings before the Board of Appeal.

In its written submissions, the respondent implicitly requested that the appeal be dismissed.

- V. The independent claims according to the different requests read as follows:

Main request:

"1. A vascular graft comprising:

a perforate tubular self-expanding frame (102) having a proximal end, a distal end, and a lumen therebetween, and

an inner liner (108) extending from a near-proximal location on the lumen to a near-distal location on the lumen, wherein the liner (108) covers the lumen of the tubular frame (102) over the entire distance from said near-proximal location to said near-distal location, **characterised** in that said frame (102) has a resilient tubular frame structure including a plurality of adjacent radially compressible band members (104) not directly connected to each other, and wherein the band members (104) are secured independently to the inner liner (108) which thereby maintains the axial integrity of the graft."

First auxiliary request:

the content of claim 1 of the main request with the incorporation in its characterising portion of the

expression "and being separated from each other by gaps (106)" after the expression "not directly connected to each other".

Second auxiliary request:

"1. A vascular graft comprising:

a perforate self-expanding frame (102) having a proximal end, a distal end, and a lumen therebetween, and
an inner liner (108) extending from a near-proximal location on the lumen to a near-distal location on the lumen, wherein the liner (108) covers the lumen of the tubular frame (102) over the entire distance from said near-proximal location to said near-distal location, **characterized** in that said frame (102) has a resilient tubular frame structure including a plurality of adjacent radially compressible band members (104) not directly connected to each other, and wherein the band members (104) having a width in the range from 2 mm to 15 mm are secured independently to the inner liner (108) which thereby maintains the axial integrity of the graft."

Third auxiliary request:

the content of claim 1 of the second auxiliary request with the replacement in its characterising portion of the expression "having a width in the range from 2 mm to 15 mm" by the expression "comprising a zig-zag or Z-shaped element".

Fourth auxiliary request:

"1. A vascular graft comprising:

a perforate self-expanding frame (102) having a proximal end, a distal end, and a lumen therebetween, and
an inner liner (108) extending from a near-proximal location on the lumen to a near-distal location on the lumen, wherein the liner (108) covers the lumen of the tubular frame (102) over the entire distance from said near-proximal location to said near-distal location, **characterized** in that said frame (102) has a resilient tubular frame structure including a plurality of adjacent radially compressible band members (104) not directly connected to each other and wherein the band members (104) comprising a zig-zag or Z-shaped element which forms a continuous circular ring are secured independently to the inner liner (108) which thereby maintains the axial integrity of the graft."

"2. A vascular graft comprising:

a perforate self-expanding frame (202) having a proximal end, a distal end, and a lumen therebetween, and
an inner liner (206) extending from a near-proximal location on the lumen to a near-distal location on the lumen, wherein the liner (206) covers the lumen of the tubular frame (202) over the entire distance from said near-proximal location to said near-distal location, **characterized** in that said frame (202) has a resilient tubular frame structure including a plurality of adjacent laterally compressible axial members (204) not

directly connected to each other and being separated from each other by gaps (106), and wherein the axial members (204) comprise a multiplicity of repeating structural units, which are axially connected, whereby the axial members (204) are secured independently to the inner liner (206) which thereby maintains the radial integrity of the graft."

VI. At the oral proceedings the appellant upheld the novelty of the independent claims according to the different requests, arguing that in document D4 the circular members were reduced to simple wire rings having a width limited to the diameter of the wire and, therefore, insufficient to guarantee the axial integrity of the graft. Contrary to that, the band members and the axial members shown in Figures 1A and 1B of the present patent, respectively, extended circumferentially on a large width, so as to provide reinforcement of the axial and radial integrity of the graft.

The shape and size of these band members became more and more specific in the amendments brought successively to the independent claims from the second to the fourth auxiliary requests. These informations were not disclosed by document D4 so that at least the claimed subject-matter of the respective requests was novel.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request and first auxiliary request*

Document D4 discloses (Figures 1 and 2) a perforate tubular self-expanding frame 32 consisting of end wire rings 10, intermediate wire rings 12 and connecting wire rings 11, and having a proximal end, a distal end, and a lumen therebetween. An inner liner consisting of a flexible tubular member made of cloth, film or the like (see column 4, lines 58 to 60), covers the lumen of the tubular frame over the distance from a proximal location to a distal location on the lumen (see column 10, lines 29 to 33).

Moreover, the tubular frame structure 32 disclosed in D4 is resilient and includes a plurality of adjacent radially compressible band members in the form of said intermediate wire rings 12 (see column 2, lines 42 to 50). Since the band members of the graft as claimed are made of elements, the configuration and sizes of which are not specified, the claimed band members do not actually distinguish from the wire rings disclosed by D4. Furthermore, the wire rings 10, 12 of the graft according to D4 are not directly connected to each other, i.e. they are separated by gaps as clearly shown in Figures 1 and 2.

Entering further into details, D4 discloses that the connecting wire rings 11 and the intermediate wire rings 12 are not fixed to each other (see column 5, lines 31 to 32), but the intermediate wire rings are

partially fixed to the artificial blood vessel 7 (see column 5, lines 6 to 8). Since said artificial blood vessel (the graft) is composed of the flexible tubular member (the inner liner) and the frame 32 (see column 4, lines 58 to 61), it results that the intermediate wire rings (the band members) must be independently secured to the inner liner, with the inevitable consequence of maintaining the axial integrity of the graft, in accordance with the last feature of claim 1 in suit.

Therefore, the subject-matter of claim 1 according to the main request and the first auxiliary request, which only differs from the main request by the gaps between the band members, is not novel vis-à-vis the disclosure of D4 within the meaning of Article 54(1) EPC.

3. *Second and third auxiliary requests*

3.1 Claim 1 of the second and third auxiliary requests refers to the embodiment as shown in Figures 1, 1A and 2 of the present patent. In the characterising portion of claim 1 of the second auxiliary request there is stated that the band members (104) have a width in the range from 2 mm to 15 mm, and in the characterising portion of claim 1 of the third auxiliary request it is stated that the band members (104) comprise a zig-zag or Z-shaped element. Although these dimensions and shapes are mentioned in the description of the application as filed (see column 10, lines 24-29), they are restricted, however, to band members formed of zig-zag or Z-shaped elements which form a continuous circular ring, exclusively. No other embodiment can be deduced from the description or the drawings, so that

band members only having a width in the range as claimed (as for example solid band members) or band members only comprising a zig-zag or Z-shaped element (as for example such band members not forming a continuous circular ring) result in an inadmissible extension of the claimed subject-matter beyond the content of the application as filed.

Therefore, the subject-matter of claim 1 according to the second and third auxiliary requests does not meet the requirements of Article 123(2) EPC.

- 3.2 Furthermore, claim 1 according to the third auxiliary request differs from the main request only by the feature that the band members are comprising zig-zag or Z-shaped elements. Since the graft as presently claimed is not defined in a particular state of expansion or compression, it is allowed to consider the graft of D4 in any configuration, be it expanded or compressed. In Figure 27 the graft is illustrated in a collapsed state for insertion first into a squared tube 18 and then into a delivery catheter such as the catheter 8 shown in Figure 7A. In the compressed configuration shown in Figure 27 the wire rings 10, 12 are deformed so as to take a substantially wavy form, comprising zig-zag elements positioned between peaks and valleys (see column 11, lines 26 to 33). Consequently, the above cited feature is also known from D4.

Therefore, the subject-matter of claim 1 according to the third auxiliary request is not new over the disclosure of D4, either.

4. *Fourth auxiliary request*

4.1 In independent claim 1 according to the fourth auxiliary request there is specified: "the band members (104) comprising a zig-zag or Z-shaped element which forms a continuous circular ring are secured...". This feature is fairly supported and in accordance with the description of the application as filed (see column 10, lines 24 to 27). With respect to the version as granted, the added feature corresponds to a restriction of the protection.

In independent claim 2 according to the fourth auxiliary request, which refers to the second embodiment shown in Figure 1B, there is specified: "the axial members (204) comprise a multiplicity of repeating structural units, which are axially connected, whereby...". Also this feature is correctly supported by the application as filed (see column 4, lines 21 to 24) and represents a restriction of the protection.

The requirements of Articles 123(2) and (3) are, therefore, satisfied for the amendments made to the independent claims according to the fourth auxiliary request.

4.2 The incorporation in claim 1 of the fourth auxiliary request of the feature that the zig-zag elements of the band members form a continuous circular ring, provides a distinguishing feature over the disclosure of D4. Indeed, by specifying in claim 1 the circumferential distribution of the zig-zag elements, the wavy form of the compressed elements of the graft disclosed in

Figure 27 of D4 is now excluded from the scope of the claimed subject-matter.

Consequently, the subject-matter of claim 1 according to the fourth auxiliary request is new.

The subject-matter of the independent claim 2 of the same request is also new since there is no disclosure in D4 of a resilient tubular frame made of a plurality of axial members comprising a multiplicity of repeating structural units, axially connected, in accordance with the embodiment of Figure 1B of the present patent.

Therefore, the set of claims according to the fourth auxiliary request is acceptable, as to novelty.

5. *Remittal*

Since the decision of the opposition division was exclusively based on the ground of lack of novelty, now removed, the Boards finds it appropriate 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 fourth auxiliary request.

The Registrar:

The Chairman:

V. Commare

T. Kriner