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Datasheet for the decision of 22 January 2010

Case Number: T 1138/07 - 3.2.02

Application Number: 00914507.9

Publication Number: 1148842

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Partial encapsulation of stents using strips and bands

Patentee:
Bard Peripheral Vascular, Inc.

Opponent:
Boston Scientific Corporation

Headword:
-

Relevant legal provisions:
EPC Art. 54(1)(2), 56

Relevant legal provisions (EPC 1973):
EPC Art. 100(a), 54(3)

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

Decisions cited:
-

Catchword:
-

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Case Number: T 1138/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 22 January 2010

Appellant: (Opponent)	Boston Scientific Corporation One Boston Scientific Place Natick Massachusetts 01760-1537 (US)
Representative:	Nash, David Allan Haseltine Lake LLP Redcliff Quay 120 Redcliff Street Bristol BS1 6HU (GB)
Respondent: (Patent Proprietor)	Bard Peripheral Vascular, Inc. 1415 West 3rd Street Suite 109 P.O. Box 1740 Tempe AZ 85280-1740 (US)
Representative:	HOFFMANN EITLE Patent- und Rechtsanwälte Arabellastrasse 4 D-81925 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 2 May 2007 rejecting the opposition filed against European patent No. 1148842 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: M. Noël
Members: C. Körber
A. Pignatelli

Summary of Facts and Submissions

I. By its decision posted on 2 May 2007 the Opposition Division rejected the opposition against European patent No. 1 148 842. The opposition was filed against the whole patent and based on Article 100(a) EPC 1973 (lack of novelty and inventive step).

II. The appellant (opponent) lodged an appeal against this decision by notice received on 11 July 2007, with the appeal fee being paid on the same day. The statement setting out the grounds was received on 12 September 2007. The counter-statement of the respondent (patent proprietor) was received on 20 December 2007.

III. The parties were summoned to oral proceedings to be held on 8 January 2010. In an annex to the summons, the Board indicated its preliminary opinion. By letter of 16 November 2009 the appellant withdrew his request for oral proceedings. The respondent had requested oral proceedings only in the event of any decision contemplated other than the patent being maintained in unamended form. With communication of 11 December 2009 the Board informed the parties that the oral proceedings were cancelled and that the debate would be closed with effect from 8 January 2010. No further submissions were filed by the appellant.

IV. The appellant requested that the appealed decision be set aside and the patent be revoked. He further requested that a sample of tape submitted by the respondent with letter dated 12 March 2007 not to be admitted into the proceedings.

The respondent requested that the patent be maintained as granted as his main request, or in amended form according to two auxiliary requests filed with letter of 7 December 2009.

V. The following documents are of importance for the present decision:

D1: WO-A-01/01887
D2: EP-A-0893108
D3: WO-A-97/21403
D4: EP-A-0792627
D5: WO-A-95/26695.

VI. The independent claims of the main request read:

"1. A vascular graft, comprising a first expanded polytetrafluoroethylene layer (20), a support layer (30) comprising at least one stent, wherein said support layer (30) comprises a plurality of ringed stents and is placed around said first expanded polytetrafluoroethylene layer (20) and a second expanded polytetrafluoroethylene layer (50), characterized in that the second polytetrafluoroethylene layer comprises a plurality of longitudinal strips."

"13. A method for making a partially encapsulated vascular graft, comprising the steps of providing a generally tubular expanded polytetrafluoroethylene layer of material (20) and placing a support layer (30) over said tubular layer (20), wherein the support layer (30) comprises a plurality of ringed stents, and characterized in comprising the steps of:

cutting a plurality of slits in a terminal portion of said tubular layer (20) not covered by said stents, resulting in a plurality of longitudinal strips (50);

weaving said longitudinal strips (50) alternatingly over and under each successive ringed stent, wherein a first longitudinal strip is woven over a first ringed stent, and wherein a second longitudinal strip is woven under the first ringed stent; and

laminating said longitudinal strips (50) to said tubular layer (20)."

Claims 2 to 12 and 14 to 16 are dependent claims.

Expanded polytetrafluoroethylene will be referred to as ePTFE in the following.

VII. The argumentation of the appellant can be summarized as follows:

The features of claim 1 were anticipated by the embodiment of claims 4 and 5 shown in Figures 4 and 5 of D1, with a plurality of ringed stents being disclosed at page 8, lines 7 to 8. The term "longitudinal" in claim 1 of the patent in suit simply meant that the strips were elongated, and taking into account the statement at column 5, lines 24 to 25 of the patent specification, helically arranged strips as disclosed in D1 would also fall under the scope of claim 1.

Since the patent in suit was not entitled to its first priority date of 2 February 1999, D1 would be novelty destroying for claim 1 under Article 54(3) EPC 1973.

D2 was also novelty destroying, particularly in view of claim 3 and Figure 13B disclosing a plurality of ringed stents and column 9, lines 18 to 19 referring to a plurality of "longitudinally extending strips".

Inventive step was challenged starting from D2 or D3, in combination with D4 or D5, both disclosing ringed stents. D2 also addressed the problem of wrinkling or "telescoping", as referred to in the patent in suit and the appealed decision. Accordingly, the problem to be solved by the claimed invention had to be reformulated so as to provide an alternative to the helical stents disclosed in D2. Since D2 already gave a hint towards other stent constructions, and in view of D4 and D5 disclosing ringed stents, this alternative solution was obvious. Moreover, the patent in suit did not indicate any advantage associated with the use of ringed stents or any proof of the anti-compression resistance accomplished by the longitudinal strips. Furthermore, the mere provision of the strips, as defined in claim 1, without further specification of the disposition of the second ePTFE layer with respect to the support layer and the lamination of the longitudinal strips, would not solve the problem of telescoping.

Since claim 11 was obvious from Figures 7 and 8 of D2, claim 13, amounting to a method for making the structure of claim 11, was also not inventive.

VIII. The argumentation of the respondent can be summarized as follows:

D1 was not novelty destroying for claim 1 since it was clear that the term "longitudinal" defined the direction of the strips, rather than their shape. Interpreting the term "helically" at column 5, lines 24 to 25 of the patent specification as including a number of full helical turns around the device would not be in accordance with the purpose of allowing radial expansion. Moreover, there was no basis for combining the embodiments of Figures 4 and 5 of D1 with that of Figure 2A, disclosing a plurality of ringed stents. As a consequence, examination of the validity of the first priority of the contested patent could be left aside.

D2 only disclosed helical or spiral stents, without any reference to ringed stents. According to column 10, lines 42 to 49, the tubular sections 50 shown in Figure 13B were of the same construction as the stent 6 shown in Figures 1 to 11, i.e. helical. The fact that it was also stated that the sections "may have various construction" did not necessarily mean that the stents were ringed. Moreover, it could not be derived directly and unambiguously from D2 that the cited passage applied to the alternative configurations to the main embodiment of D2 disclosed at column 9, lines 18 to 22, mentioning longitudinally extending strips.

With respect to inventive step, D4 had to be regarded as the proper starting point rather than D2 which did not relate to ringed stents and the telescoping problem associated therewith. The avoidance of wrinkle formation during compression mentioned in D2 was not related to

longitudinal telescoping, but rather to unilateral compression during bending along the longitudinal axis. The longitudinal strips as defined in claim 1 avoided telescoping when the ringed stent graft was crimped down to a tiny diameter for inclusion in a catheter delivery system. The material of the strips suffered a plurality of folds along lines roughly parallel with the long axis of the ringed stent. A column of corrugated material withstood endwise collapse much better than a column of thin uncorrugated material.

None of the documents cited by the appellant taught the use of longitudinal strips of ePTFE to address the problem of telescoping in a ringed stent graft. Neither the longitudinal outer liner 208 shown in Figure 1B of D4 nor the longitudinal strips mentioned in D2 at column 9, lines 18 to 21 taught the technical effect of providing longitudinal strength for a ringed stent support layer.

Reasons for the Decision

1.1 The appeal is admissible.

1.2 In view of its lack of relevance and evidential weight, the sample of tape submitted by the respondent with letter of 12 March 2007 is not admitted into the procedure.

2. *Novelty*

2.1 Document D1

D1, which represents prior art under Article 54(3) EPC 1973 provided that the first claimed priority date of the present patent is valid, fails to disclose the feature of the plurality of strips being **longitudinal**, as required by the characterising portion of claim 1.

The term "longitudinal" relates to the orientation of the strips and is to be understood as "extending lengthwise on the vascular graft". This becomes clear from the overall context of the patent specification and in particular from Figures 2 and 3 depicting the strips 50.

The Board does not accept the appellant's interpretation of the term "longitudinal" relating to the shape of the strips, having a length which is greater than their width. All "strips" have a length greater than their width, and the additional limitation "longitudinal" would be superfluous if the appellant's interpretation were to be accepted.

In the embodiment of claim 4 of D1, shown in Figs. 4 and 5 and cited against claim 1 by the appellant, the outer tubular body 24 includes a weave or braid of individual tapes or strips. These strips are arranged helically around the graft, with a number of full turns around the graft from one end to the other. This arrangement cannot be regarded as "longitudinal" within the meaning of the patent, even when taking into account other possible configurations as recited in lines 24 and 25 of column 5

of the patent specification: "the strips 50 may themselves zigzag or may be helically arranged". "Zigzag" may be understood in a sense that the orientation of the strips is not purely longitudinal (i.e. parallel to the longitudinal axis of the graft), but that they may undulate over and under successive rings as shown in Figures 2 and 3 of the patent. By "helically" may be understood that the strips may be arranged at a small angle to the longitudinal axis of the graft. Interpreting the term "helically" in claim 1 broadly so as to include helical strips with a number of full turns around the graft from one end to the other would be contrary to the principle of the invention, as explained below under point 3.1. The claimed subject-matter is specifically restricted to longitudinal strips, which is not disclosed by D1.

The second ePTFE layer 16 in D1, also referred to by the appellant, consists of a single strip only, which is also arranged helically around the graft, with multiple full turns around the graft from one end to the other (see Figures 2A and 3A). The embodiment shown in Figure 2B is of no relevance since the strips 8' are arranged circumferentially rather than longitudinally.

Accordingly, D1 fails to disclose the feature of the plurality of strips being **longitudinal**, as required by claims 1 and 13. For this reason alone, D1 is not novelty-destroying for claims 1 and 13 under Article 54(3) EPC 1973.

It follows that the validity of the claimed priority need not be examined.

2.2 Document D2

D2 discloses a vascular graft comprising a first ePTFE layer 4, a support layer 6 comprising at least one stent, wherein said support layer 6 comprises a plurality of stents (claim 3) and is placed around said first ePTFE layer 4, and a second ePTFE layer 8 comprising a plurality of helically arranged strips (column 9, lines 13 to 18).

However, D2 fails to disclose that the support layer 6 comprises a plurality of **ringed** stents **and** that the second ePTFE layer 8 comprises a plurality of **longitudinal** strips.

The stent member 6 shown in Figures 1 to 11 is a spiral stent, not a ringed stent, the term "ring" implying a closed structure. Column 4 of D2, lines 14 to 18, states that the preferred stent is arranged in a helical configuration for various technical performance reasons as set out in the passages that follow. In the passage in column 10, lines 42 to 54 relating to Figure 13B and claim 3 it is stated that the tubular members or sections 50 may have the same construction as the stent member shown in Figures 1-11 (which is spiral or helical) or "may have various construction[s]". This latter statement is, however, not specific enough to anticipate ringed stents. The same applies to the passage beginning at the foot of column 11 of D2, on "Stent Materials". Again, one finds reference to "helically wound" (line 51) and while "other constructions also may be used" (line 54) the only example of any other such construction is that of flat stock wound into a cylinder (line 56). Throughout D2 there is no mention of ringed

stents as an alternative to the specifically disclosed helical stents.

The appellant has combined the disclosure given at column 10, lines 42 to 49 of the tubular sections with the mention at column 9, lines 18 to 22 of longitudinally extending strips in a novelty attack on claim 1. However, D2 does not directly and unambiguously disclose these two embodiments in combination. Moreover, longitudinally extending strips are said to be used "when the coupling member is used in conjunction with other stent member configurations". However, these other configurations are not revealed anywhere in D2.

Since the stents forming the support layer of D2 are not disclosed as ringed in combination with the strips forming the second ePTFE layer being longitudinal, as required by the wording of claims 1 and 13, their subject-matter is novel over D2.

2.3 None of the available prior art documents teaches all the features of claims 1 and 13 in combination. Consequently, their subject-matter is new within the meaning of Article 54(1) and (2) EPC.

3. *Inventive step*

3.1 Document D4 as starting point

Document D4 represents the state of the art coming closest to the invention. It discloses a vascular graft comprising the features of the preamble of claim 1 as recited in paragraph [0005] of the patent specification. A structure comprising a plurality of ringed stents as

disclosed in D4 has axial gaps between the rings and is therefore prone to collapse lengthwise like a concertina. The invention deals with this type of vascular graft and aims to avoid the drawback of "telescoping" associated therewith.

Starting from the disclosure of D4, the objective problem to be solved is to improve flexibility of the graft while maintaining its shape upon expansion or contraction (cf. paragraph [0007] of the patent).

This problem is solved according to the invention by the second ePTFE layer comprising a plurality of longitudinal strips as defined in the characterising portion of claim 1. The first distinguishing feature, the **longitudinal** orientation of the strips avoids telescoping (see column 5, lines 6 to 15 of the patent specification) and gives longitudinal support and strength by "doubling up" the layers. The second distinguishing feature, the use of a **plurality** of strips, means that the graft remains flexible to expand radially by allowing spaces to form or grow between the strips as the graft expands radially.

Since D4 fails to disclose or suggest such longitudinal strips, the subject-matter of claim 1 is not obvious from this document considered in isolation. Moreover, since none of the other prior art documents addresses the above-mentioned problem associated with vascular grafts comprising a ringed structure or suggests the characterising features of claim 1, its subject-matter involves an inventive step within the meaning of Article 56 EPC.

3.2 Document D2 as starting point

Inventive step has been challenged by the appellant starting from D2 or D3 in combination with D4 or D5, these latter both disclosing ringed stents (column 3, lines 50 to 51, and page 1, line 20, respectively).

D2 is not an appropriate starting point for an inventive step attack against claim 1. A helical stent, particularly one as tightly wrapped and with a linking member 20 between each turn as in D2, has virtually no axial gaps and thus does not suffer from weakness against axial telescoping or against buckling of the graft, in contrast to a graft of the type that incorporates a plurality of ringed stents axially spaced apart by gaps, as in the present patent. Accordingly, a vascular graft having a ringed stent support structure as disclosed in D4 is to be considered as the appropriate starting point.

The subject-matter of claim 1 is distinguished over D2 by the stents being ringed and the strips forming the second ePTFE layer being longitudinal, as indicated in point 2.2 above. D3, by the same inventors as D2, has only been mentioned briefly as being "very similar" in the statement of grounds of appeal and is not closer to the invention than D2.

The appellant states that there is no technical contribution associated with the use of ringed stents in a graft and that they are commonly known, as indicated by their presence in the preamble of claim 1. However, as mentioned in column 3, line 44, to column 4, line 4, of the patent specification, such ringed stents do

provide a number of advantages. However, a vascular graft with ringed stents supported around an ePTFE layer is weak against longitudinal compression because the ringed stents have axial gaps between them. Such ringed stents are themselves unable to resist telescoping or buckling of the graft at the spaces between them unless further support is provided. This problem is solved by the provision of longitudinal strips as indicated above.

In the embodiments of Figures 1 to 11 of D2 and Figures 1A and 1B of D4, the layer corresponding to the second layer of claim 1 of the patent in suit always follows the path of the stent (Figure 1 of D2: the stent 10 and the coupling member or ribbon 8 are both arranged helically; in Figure 1A of D4, the components 104 and 110 are both arranged circumferentially; in Figure 1B of D4, the components 204 and 208 are both arranged longitudinally). The invention goes against this teaching and provides ringed stents, which are circumferentially wrapped around the first ePTFE layer in combination with longitudinal strips of a second ePTFE layer. Unlike in the prior art, the longitudinal strips do not follow the path of the stents forming the support layer.

The passages in column 7, lines 14-20 and 38-44, and column 8, lines 33-34 of D2 deal with the avoidance of wrinkle formation during compression. This is not related to longitudinal telescoping, as argued by the appellant, but rather to unilateral compression during bending along the longitudinal axis (column 4, lines 10-13; column 7, lines 5-9).

None of the documents cited by the appellant teaches the use of longitudinal strips of ePTFE to solve the problem of telescoping in a ringed stent graft. There are only two instances of longitudinal strips mentioned in the cited prior art. The longitudinal outer liner 208 shown in Figure 1B of D4 is described solely for the purpose of covering the longitudinal members 204 (column 11, lines 26 to 32). The mentioning of longitudinal strips in D2 at column 9, lines 18 to 21 merely refers to the use in "other stent member configurations", which are not described further. Neither of these references to some kind of longitudinal strips gives a hint towards providing longitudinal strength to a ringed stent support layer, in order to avoid telescoping.

Accordingly, the subject-matter of claim 1 is not obvious from D2 and D4 in combination. D5 is not closer to the invention than D4.

3.3 It results from the foregoing that the subject-matter of claims 1 and 13, which latter comprises the features of claim 1 in terms of method steps, involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Sauter M. Noël