

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

D E C I S I O N
of 19 September 2005

Case Number: T 0868/03 - 3.2.02

Application Number: 95934437.5

Publication Number: 0814729

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:

Endoluminal encapsulated stent and methods of manufacture

Patentee:

Bard Peripheral Vascular, Inc.

Opponent:

Boston Scientific Corporation

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 54, 56

Keyword:

"Novelty - (yes) "

"Inventive step - (yes) "

Decisions cited:

T 0190/99

Catchword:

-



Case Number: T 0868/03 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 19 September 2005

Appellant: Bard Peripheral Vascular, Inc.
(Proprietor of the patent) 1625 West Third Street P.O. Box 1740
Tempe, AZ 85280-1740 (US)

Representative: Marsh, Roy David
Hoffmann Eitle,
Patent- und Rechtsanwälte
Arabellastrasse 4
D-81925 München (DE)

Respondent: Boston Scientific Corporation
(Opponent) One Boston Scientific Place
Natick
Massachusetts 01760-1537 (US)

Representative: Hermann, Gerhard
Vossius & Partner
Postfach 86 07 67
D-81634 München (DE)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
26 June 2003 concerning maintenance of the
European patent No. 0814729 in amended form.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
E. Dufrasne

Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged an appeal against the interlocutory decision of the opposition division relating to European patent No. 0 814 729. The decision was dispatched on 26 June 2003.

The appeal and the fee for the appeal were received on 11 August 2003. The statement setting out the grounds of appeal was received on 5 November 2003.

The opposition was filed against the whole patent and based on Article 100(a) EPC (lack of novelty and inventive step) and Article 100(c) EPC. The opposition division decided that the subject-matter of claim 1 of the patent as granted (main request) did not involve an inventive step, but that the claims of the auxiliary request then on file were allowable.

- II. The following documents were of particular interest in the appeal procedure:

D1: WO-A-95/05132
D2: US-A-5 123 917
D3: US-A-5 122 154
D6: DE-A-3 918 736.

The question of Article 100(c) EPC was not an issue in the appeal procedure.

- III. Oral proceedings were held on 19 September 2005.

Appellant requested that the decision under appeal be set aside and that the patent be maintained as granted

or, in the alternative, according to auxiliary requests 1, 2, 2A, 3, 3A, 3B, 3C, 4, 4A, 5 or 6 as filed with the letter dated 19 August 2005.

Respondent (opponent) requested that the appeal be dismissed.

IV. The independent claims 1 and 17 of the main request read as follows:

"1. A radially expandable reinforced vascular graft comprising: at least one tubular radially expandable support member (22) having a plurality of openings passing through walls of the support member, and at least first and second expanded polytetrafluoroethylene layers (24, 26) with a node-fibril microstructure, the said layers being respectively located circumferentially inside and outside the support member thereby surrounding and at least substantially enclosing the at least one tubular radially expandable support member, also passing into and through the plurality of openings (30) passing through the walls of the support member the graft being characterised in that:

- i) the polytetrafluoroethylene layers are is tubular and seamless; and
- ii) the microstructure of both the first and second expanded polytetrafluoroethylene tubular layers exhibit fibrils oriented parallel to the tube axis, whereby both the polytetrafluoroethylene layers are radially expandable with the support member to an expanded diameter.

17. A process for making a radially expandable reinforced vascular graft comprising the steps of:

- a) positioning over a support a first layer of substantially unsintered expanded polytetrafluoroethylene seamless tubular material with fibrils parallel to the tube axis;
- b) concentrically positioning a radially expandable support member circumferentially around the first substantially unsintered expanded polytetrafluoroethylene tubular material, such that at least a substantial longitudinal extent of the radially expandable support member contacts the first substantially unsintered expanded polytetrafluoroethylene material;
- c) concentrically positioning a second layer of substantially unsintered expanded polytetrafluoroethylene seamless tubular material, with fibrils parallel to the tube axis, circumferentially around the radially expandable support member and the first substantially unsintered expanded polytetrafluoroethylene material; and
- d) affixing said layer of support material to said first and second layers of biocompatible graft material such that all of said layers are substantially inseparable from one another and are radially expandable with one another."

Claims 2 to 16 and 18 are dependent claims.

V. The parties argued as follows:

Appellant

The person skilled in the art of materials science would understand that fibril orientation was a statistical property since it was not possible to arrange all the fibrils parallel to each other, and that he would also understand claim 1 to mean that the fibrils should be preferentially aligned axially. This feature was the cause of the effect mentioned in the claim that the graft should be radially expandable, which meant that stretching of the material was involved, as opposed to folding and unfolding like a concertina. By contrast, D1 and D2 described grafts which expanded like a paper bag, ie without stretching. Therefore, these documents did not describe radially expandable grafts.

The fact that D2 did not show folds in Figures 1 and 2 did not mean that they were absent in this graft since the drawing was not by the inventor but by a patent draftsman who would leave out incidental details for the sake of clarity. The passage in column 5, lines 51 clearly indicated that the graft of D2 was folded for delivery. Despite the use of the word "stretching" in this document the graft thereof was not radially expandable.

Respondent

In order to interpret claim 1 the patentee repeatedly referred to the description, which was considerably narrower than the claim, but at the same time it

intentionally maintained a broad wording of the claim. Claim 1 only required the PTFE layers to exhibit fibrils oriented parallel to the tube axis, it did not specify that the fibrils must be primarily so oriented. "Exhibit" means the same as "comprise" so other orientations were permitted by the claim wording. Thus, the fibrils shown in Figures 2, 3A, and 3B of D1 fulfilled this condition. Regarding the term "radially expandable" the claim wording covered both the paper bag type of expansion as well as a balloon type expansion, so again the grafts of D1 and D2 were covered by the claim in this respect.

The Example on page 12, lines 12 to 20 of D1 was a continuation of Example 1 described on page 11, line 4 onwards, so the tubular sleeve thereof had a uniaxial orientation of fibrils. Moreover, this tubular sleeve would have no seam.

The PTFE layers of D2 also had no seam as evidenced by Figures 1 and 2 in which no seam was shown. The passages in column 5, lines 50 to 55 and column 6, lines 14 to 16 meant that the graft was radially expandable in the sense of the patent in suit, ie it involved stretching of the layers. To the person skilled in the art this implied that the layers had a fibril structure with the fibrils oriented uniaxially.

Reasons for the decision

1. The appeal is admissible.

Main request

2. *Interpretation of claim 1*

2.1 The granted claims have given rise to considerable discussion between the parties as to how they are to be interpreted. The patent proprietor has argued that claim 1 is to be interpreted restrictively, while declining to include terminology which would lead to the claim being clearly so restricted, and the opponent has argued that were the terms used in the claim to be given their normal meanings, then the claim is so broad in scope as to virtually read onto D1 and D2.

2.2 According to the case law of the Boards of Appeal a claim must be construed as though it were read by a person skilled in the art who will derive a commonsense and realistic understanding of what is being claimed. Point 2.4 of the reasons of T 190/99 says: "The board adds that the skilled person when considering a claim should rule out interpretations which are illogical or which do not make technical sense. He should try, with synthetical propensity ie building up rather than tearing down, to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the patent (Article 69 EPC). The patent must be construed by a mind willing to understand not a mind desirous of misunderstanding." In other words the claims must be read in their proper context, which may well imply either limitations to or extensions of the scope thereof, regardless of the actual wording used.

2.3 In the present case the patent repeatedly describes the ePTFE material as having a uniaxially oriented node-fibril microstructure in which substantially all of the fibrils in the ePTFE microstructure are oriented parallel to one another in the axis of longitudinal expansion (for example, column 1, lines 27 to 35, column 6, lines 37 to 40, column 14, lines 47 to 50, column 27, and paragraph [0115]).

Paragraph [0115] summarises how this property is allied to the radial expansion process of the graft. When a sintered tubular ePTFE graft in which fibrils are uniaxially oriented parallel to the axis of longitudinal expansion is radially expanded, the fibril length remains substantially constant, but there is elongation of the nodes along the axis of radial expansion and substantially perpendicular to the axis of longitudinal expansion of the ePTFE tubular graft. Upon radial expansion of the stent-graft nodal elongation is found. Thus, radial expansion of the stent occurs with a concomitant change in the node-fibril microstructure of the ePTFE encapsulation surrounding the stent. This means that radial expansion of the graft is accompanied by a stretching of the node structure, which in turn is facilitated by the uniaxial orientation of the fibrils.

Therefore, from the patent it is clear that the preferred fibril orientation is linked with the radial expansibility of the stent. The fact that the last feature (ii) of claim 1 links the fibril structure and the radial expansion is in keeping with this view, the more so since the claim says that the microstructure of both the first and second expanded

polytetrafluoroethylene tubular layers exhibit fibrils oriented parallel to the tube axis, whereby both the polytetrafluoroethylene layers are radially expandable with the support member to an expanded diameter.

In other words the claim defines a cause and an effect. In order for the claim to make technical sense in the context, this part of the claim is understood by the Board to mean that the fibrils have a preferred orientation in order to facilitate the radial expansion, which involves stretching. The appellant confirmed this at the oral proceedings and in the written procedure by expressly stating that this is what the claim is intended to mean.

2.4 The arguments of the respondent in this respect did not persuade the Board otherwise for the following reasons:

While a reader of a claim is legitimately entitled to read the terms of a claim as broadly as possible, there are limits to which the scope of a claim may be stretched. As indicated in T 190/99 the claim must be construed with a will to derive a realistic understanding of the whole disclosure of the document, and according to Article 69 EPC, the description must be used to interpret the claims. If an interpretation of a claim is plainly at odds with the disclosure, then such interpretation is not permissible.

In the present case the description makes clear that radial expansion involves a concomitant change in the node-fibril microstructure of the ePTFE encapsulation, ie stretching thereof, and the appellant has committed itself both in writing and at the oral proceedings to

this position. Therefore, the fibrils of the ePTFE layers must necessarily be preferentially uniaxially aligned and the layers must stretch as the graft expands. To construe "radially expandable" as encompassing unfolding and uncrimping, and to include biaxially aligned fibrils, for example, as falling within the scope of claim 1, is clearly inconsistent with the description and not a fair interpretation of the claim.

3. *Novelty*

3.1 As may be ascertained from the foregoing, the Board understands "radially expandable" in claim 1, in the context, to mean that expansion of the graft from its delivery condition to its deployed condition involves some stretching of the ePTFE layers. Such stretching can be described as being distensible in the manner of a rubber balloon, in contrast to an expansion which is non-distensible and can be characterized as being like a folded paper bag which can be inflated to generally remove folding wrinkles but does not further inflate to any significant degree.

3.2 Document D1 discloses intraluminal grafts which are manufactured in the expanded state and collapsed or folded to decrease the diameter down to the delivery configuration. These grafts expand back by unfolding rather than by stretching, as described on page 9, lines 16 to 22 of D1. Although this description refers to Example 1, the grafts of the other Examples are used in the same manner.

The Examples of Document D1 mention the use of PTFE films having different fibril structures which include uniaxially-oriented fibrils, circumferentially-oriented fibrils, and biaxially-oriented fibrils, and combinations thereof. This document does not mention the reason for the use of PTFE having a fibril structure or the reason for the different fibril orientations, and the representatives of both parties were unable to suggest a sound reason for the use of these features in D1.

It was agreed by the parties that Example 3 of D1 described the closest prior art. There is first described on page 11, line 4 to page 12, line 11 with reference to Figure 6 a stent having a single exterior wrapped film with uniaxilly-oriented fibrils oriented parallel to the longitudinal axis of the stent. However, this Example does not disclose an internal film.

There is then described on page 12, lines 12 to 20 with reference to Figure 8 a stent having a tubular sleeve of ePTFE, provided both internally and externally, but no mention is made of the fibril orientation here. The Board does not share the respondent's view that this sleeve must have a fibril structure in which the fibrils are uniaxilly-oriented parallel to the longitudinal axis of the stent, since this example does not clearly follow on from the first part of this example, and appears to be quite different to that disclosed in the first part of Example 3, and also because the fibril structure appears to be entirely incidental in this document, neither worthy of mention as regards its effect, nor featuring in the independent claims of D1.

Therefore, no example of stent described in D1 clearly possesses both an internal and an external film of PTFE having a fibril structure which would enable it to stretch rather than simply unfold from a folded configuration. This document does not anticipate the graft of claim 1 of the patent in suit, accordingly.

- 3.3 Document D2 is said by the respondent to disclose a stent which is radially expandable and involves stretching of the films of PTFE which sandwich an intervening stent. However, in the absence of clear evidence in D2 to the contrary, the Board is of the opinion that this document describes, as does D1, only those grafts which expand by unfolding rather than by stretching.

Before the priority date of the patent in suit, the prior art described only foldable grafts, as exemplified by D1, D3 and D6. Had the grafts of D2 involved a different mechanism for expanding the grafts from the delivery condition to the deployed condition in use, such as stretching, then this would have represented a major departure from the prior art and would surely have been mentioned in this document. Moreover, this mechanism would involve some constructional feature (eg fibril orientation) to facilitate it, and this would also have been described if present. The silence of D2 in these respects suggests that conventional unfolding is used here to deploy the graft.

Moreover, the only passage of D2 which is of relevance in this respect is in column 5, lines 50 to 55 which

says that the graft is sufficiently pliable so that it can be folded during insertion into a vascular lumen and is sufficiently thin, in its unexpanded state, so that it does not impinge upon the vascular lumen when the graft is unfolded adjacent an atheromatous plaque. This is a clear statement which confirms that the expanding step involves unfolding rather than stretching.

Owing to the lack of disclosure of the fibril structure, this document does not anticipate the graft of claim 1.

The other documents do not disclose grafts coming closer to the claimed grafts. Therefore, the subject-matter of claim 1 is novel.

4. *Inventive step*

- 4.1 The parties agreed that the closest prior art document is described in Example 3 of D1. Example 3 describes a Palmaz stent having a single exterior PTFE layer whose fibrils are uniaxially oriented, but no internal PTFE layer is used. It may have been obvious to the person skilled in the art to add an internal PTFE layer to this structure but the fibril orientation of this additional layer would still be an unknown. This document does not place any importance on the fibril orientation, it may be circumferential as in Example 1 or biaxial as in Example 2, and there is no suggestion that the fibril orientation of this layer, should the person skilled in the art consider applying it, must be uniaxial.

The tubular sleeve variation described on page 12 is a different embodiment again. The Board does not share the respondent's opinion that the PTFE sleeve necessarily has uniaxially oriented fibrils, in the absence of some indication in this document that this is of any importance. Nor is the sleeve necessarily seamless. All the independent claims of this document define a seam as an essential feature so that the tubular sleeve of this embodiment must be presumed to possess one.

4.2 Document D1 discloses all the features of the preamble of claim 1, and also the feature that the PTFE layers are tubular. It does not disclose a seamless tubular layer or feature (ii) of claim 1 of the patent in suit.

4.3 The technical effect of feature (ii) has been discussed at length above, but boils down to the fact that the claimed graft, by virtue of the fibril orientation of the ePTFE layers, is radially expandable, ie involves stretching of the material. This is a departure from the prior art, in which expansion of the grafts was only from the folded condition to the unfolded condition.

Apart from the fact that this expansion mechanism is not taught in the prior art, it brings the advantages that the claimed graft has less folding bulk when mounted on a balloon for delivery, and the graft may be used for "snugging up", which is pushing the diameter from a nominal deployed diameter to a slightly greater diameter.

4.4 Document D2 also discloses a graft which is intended to be unfolded from its folded delivery configuration to its deployed condition, there is no discussion here of the fibril structure or any clear and unambiguous disclosure of stretching in the sense of the patent in suit.

4.5 Since neither the feature (ii) nor its technical effect are suggested in the prior art, this feature involves an inventive step.

The process claim 17 involves an inventive step for the same reasons.

4.6 Therefore, the claims of the main request involve an inventive step and meet the requirements of Article 52(1) EPC.

Order

For these reasons it is decided that:

The patent is maintained as granted.

The Registrar:

The Chairman:

V. Commare

T. Kriner