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**Datasheet for the decision
of 18 August 2009**

Case Number: T 0949/07 - 3.2.02

Application Number: 00965353.6

Publication Number: 1214020

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:

Prosthesis for abdominal aortic aneurysm repair

Patentee:

Bard Peripheral Vascular, Inc.

Former Opponent:

Boston Scientific Corporation

Headword:

-

Relevant legal provisions:

EPC Art.-

Relevant legal provisions (EPC 1973):

EPC Art. 54(1)(2)

Keyword:

-

Decisions cited:

G 0009/92, T 0033/04, T 0591/90, T 0412/91, T 0230/01

Catchword:

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Case Number: T 0949/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 18 August 2009

Appellant 1: Bard Peripheral Vascular, Inc.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
10 April 2007 concerning maintenance of the
European patent No. 1214020 in amended form.

Composition of the Board:

Chairman: M. Noel
Members: C. Körber
J. Geschwind

Summary of Facts and Submissions

- I. By interlocutory decision posted on 10 April 2007 the opposition division decided to maintain European patent No. 1 214 020 in amended form. The patentee's main request, maintenance of the patent as granted, was not allowed for lack of novelty vis à vis D2.
- II. Appeals were lodged against this decision by both the patentee and the opponent, by notices received on 5 and 20 June 2007, respectively, with the appeal fees paid on the same respective days. The statements setting out the grounds were received on 14 and 21 August 2007, respectively.
- III. With letter dated 5 August 2009, the opponent withdrew its appeal as well as its opposition against the patent in suit, the patentee thus remaining the sole appellant against the interlocutory decision.
- IV. Oral proceedings were held on 18 August 2009, at the end of which the appellant requested that the decision under appeal be set aside and that the patent be maintained as granted.
- V. The following documents are of importance for the present decision:

D2: US-A-5 156 620
D3: US-A-5 507 770
D6: Printout from Wikipedia of the definition of "Gore-Tex"
D13: US-A-3 953 566.

VI. Claim 1 of the patent as granted reads:

"A prosthetic device (10) for endovascular repair of an aneurysm comprising:

a first expanded polytetrafluoroethylene tubular member;

a second expanded polytetrafluoroethylene tubular member coaxial with and of a diameter larger than a diameter of said first tubular member so that an annular structure with an inflation space (32) is formed between the thus-formed inner and outer walls of the device, said first and second tubular members being sealingly attached at proximal and distal ends, thereof to delimit the annular inflation space;

port means for injection of an inflating fluid into the space between said tubular members; and connections (35) between the inner and outer walls which define at least one elongate compartment of the inflation space, said compartment extending the length of the inflation space."

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

D2 did not disclose tubular members made from **expanded** polytetrafluoroethylene (**ePTFE**). In D2, the only word that caused doubt was the word "Gore-Tex®" in column 4, line 10. In general, it was known that a trademark was inaccurate with respect to the disclosure of technical features. Moreover, it was clear that the reference to "Gore-Tex" (if seen to be a reference to ePTFE) was a

mistake which would be immediately recognised by a skilled reader.

Firstly, in line 10, the drafter of D2 explained, right away in parentheses after the trademark "Gore-Tex®", that he actually referred to PTFE. Secondly, only two sentences later, it became clear that the drafter knew about the difference between PTFE and ePTFE as he further referred to "a material such as expanded polytetrafluoroethylene (ePTFE), which is an accepted vascular conduit". It followed that the specification of "Gore-Tex" as PTFE material (not ePTFE) was deliberate. Thirdly, D2 stated in column 4, line 12: "Preferably, such inner surface is coated with a material such as polytetrafluoroethylene (ePTFE)". If the material of the inner tubular member were to be ePTFE there would be no benefit in coating it with ePTFE.

Furthermore, the skilled reader would immediately rule out ePTFE because this material was known to be porous and permeable to air. This would lead to leakage of the pressurised air introduced into the chamber formed between the tubes. Air could thus pass into the blood, resulting in embolisms and danger for the patient. Moreover such leakage would be contrary to a proper functioning of the device disclosed in D2 where air was introduced into the chamber to expand it up to its engagement with the interior wall portions of the blood vessel. Even a minimal degree of porosity, or of expansion of the PTFE, would lead to some permeability to air, which was unacceptable. The idea that PTFE could be stretched up to a point where it would become expanded without forming pores through which nitrogen

and oxygen molecules could flow, would be completely unrealistic. Reference was further made to D13, indicating that the permeability of ePTFE to nitrogen was at least 100 times higher than that of conventional PTFE. Accordingly, the disclosure of "Gore-Tex" in D2 was accidental, and, if it were to be taken as ePTFE, the disclosure would be non-enabling. Reference was made to various decisions in these respects, *inter alia* T 591/90, T 412/91 and T 230/01.

Reasons for the Decision

1. The appeal is admissible.
2. Since the patentee remains the sole appellant in the present appeal proceedings, the Board cannot challenge the maintenance of the patent in amended form by virtue of the *reformatio in peius* principle, according to which the sole appellant may not be put into a worse situation than if he had not appealed (G 9/92).
3. Novelty - claim 1 as granted
 - 3.1 Following the wording of claim 1 of the patent in suit, document D2 discloses (see Figures 1 and 4 and column 4, lines 4 to 11) a prosthetic device 10 for endovascular repair of an aneurysm comprising a first expanded polytetrafluoroethylene tubular member 12; a second expanded polytetrafluoroethylene tubular member 14 coaxial with and of a diameter larger than a diameter of said first tubular member so that an annular structure with an inflation space 16 is formed between the thus-formed inner and outer walls of the device

(Figures 2 and 9), said first and second tubular members being sealingly attached at proximal and distal ends thereof to delimit the annular inflation space (column 4, lines 25 to 28); port means 23 for injection of an inflating fluid into the space between said tubular members (column 4, lines 48 to 54); and connections 15 between the inner and outer walls which define at least one elongate compartment of the inflation space, said compartment extending the length of the inflation space (column 4, lines 15 to 18). With respect to the last feature, it is to be noted that, according to paragraph [0020] of the patent in suit, the simplest embodiment of the claimed device has connections between the inner and outer walls only at the distal and proximal ends.

The device disclosed in D2 is intended to be used as a graft to repair aortic aneurisms, as in the patent in suit, or as a stent for holding open a blood vessel (column 1, lines 27 to 33).

3.2 The appellant contests that the tubular members in D2 are made from **expanded** polytetrafluoroethylene (ePTFE). This view cannot be shared by the Board for the following reasons.

3.2.1 According to the relevant evidence on file (D3, column 2, lines 53 to 55; D6, 3rd paragraph; T 33/04, point 2.2 of reasons), the term "Gore-Tex" is to be understood as being a reference to expanded PTFE. From these documents it is also evident that ePTFE is a frequently employed material for medical devices such as implants and endovascular protheses. The fact that "Gore-Tex" is a registered trademark does not raise any

ambiguity in this regard. The indication of the term "polytetrafluoroethylene" in parentheses just after the term "Gore-Tex" in line 10 of column 4 in D2 cannot be seen limiting its use to non-expanded PTFE. The term "polytetrafluoroethylene" is rather to be considered as a generic reference to this material, either expanded or not. Accordingly, an error or mistake is not apparent to the skilled reader here. Similarly, the fact that in lines 12 to 15 of column 4 of D2 ePTFE is specifically recommended as a coating material does not imply necessarily that the preceding mention of "polytetrafluoroethylene" in parentheses refers to non-expanded PTFE.

Accordingly, the appellant's argument that the use of the term "Gore-Tex" in D2 is to be regarded as a misleading and accidental disclosure is not accepted by the Board. The present situation is quite different from that underlying the decisions T 591/90 and T 412/91, both cited by the appellant in this respect.

3.2.2 A coating of ePTFE cannot be said to be of "no benefit" if the material of the underlying tube is also ePTFE. An ePTFE coating may very well be beneficial and useful, for instance when an ePTFE coating is applied which has a different degree of porosity or a different orientation than the underlying ePTFE tube. Moreover, D2 also suggests that the underlying tube may be made from a different material, viz. Dacron® (line 10 of column 4).

3.2.3 The appellant's argument that the disclosure of D2 would not be enabling if ePTFE were used for the tubular members forming the inflatable chamber because

of its porosity to air, resulting in hazardous and undesired leakage, is not persuasive for the following reasons.

Firstly, the disclosure of ePTFE in D2 is not limited to expanded PTFE having a high porosity.

Secondly, the inflation medium disclosed in D2 is not limited to air, but includes "other fluid[s]" (see, for instance, column 5, lines 32 and 36, and column 10, lines 15 and 51). Since claim 1 at issue refers to "an inflation fluid", i.e. a gas or a liquid (e.g. saline, cf. line 33 of column 5 of the patent in suit), ePTFE represents a suitable leak-tight material for the tubings of D2, at least for a liquid inflation fluid.

Thirdly, even though the permeability of ePTFE to nitrogen may be 100 times higher than that of conventional PTFE as disclosed in D13, the available range of nitrogen permeabilities for ePTFE's is extremely broad (seven orders of magnitude, as may be seen from line 65 of column 4 in D13). When using air as an inflation medium, the skilled person would reasonably select a type of ePTFE having a small degree of porosity, yielding a permeability near the lower end of the range disclosed in D13 (e.g. 10^{-8} metric units). Leakage of air is thus avoided under all practical circumstances. The appellant's argument that even a minimum of leakage of air would be unacceptable is based on a theoretical and non-realistic view that would even rule out the use of non-expanded, conventional PTFE. According to D13, PTFE usually has a 100-fold lower nitrogen permeability than ePTFE, but still a value of 10^{-10} metric units that allows "minimum

leakage". Moreover, it becomes clear from Table 4 that also an unexpanded PTFE film may in fact have a much higher permeability to air, viz. 4×10^{-5} metric units, which is well within the above-mentioned range for ePTFE's.

Finally, it must be taken into account that inflation with air or other fluid in D2 is only temporary during a preliminary phase of relatively short duration before a final reinforcing medium (plastic material) is introduced (column 2, lines 60 to 66; column 4, lines 51 to 53; column 7, lines 14 to 28).

Altogether, the present case is not comparable to the situations underlying the decisions cited by the appellant with respect to non-enabling disclosures. It is to be noted that non-enabling disclosures must be proven unequivocally (T 230/01, point 5.2 of the reasons), which is not the case here.

- 3.3 Accordingly, D2 discloses all the features of claim 1 as granted. Therefore its subject-matter is not new within the meaning of Article 54(1) and (2) EPC 1973.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

D. Sauter

M. Noël