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D E C I S I O N
of 26 April 2005

Case Number: T 0033/04 - 3.2.2

Application Number: 94916654.0

Publication Number: 0714269

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
An intraluminal stent graft

Patentee:
W.L. GORE & ASSOCIATES, INC.

Opponent:
Boston Scientific Corporation

Headword:
-

Relevant legal provisions:
EPC Art. 52, 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0033/04 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 26 April 2005

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

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

Respondent: (Proprietor of the patent)
W.L. GORE & ASSOCIATES, INC.
551 Paper Mill Road
P.O. Box 9206
Newark
Delaware 19714-9206 (US)

Representative:
McCallum, William Potter
Marks & Clerk Scotland
19 Royal Exchange Square
Glasgow G1 3AE
Scotland (GB)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 30 October 2003 rejecting the opposition filed against European patent No. 0714269 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: T. K. H. Kriner
Members: D. Valle
E. J. Dufrasne

Summary of Facts and Submissions

I. The appellant (opponent)lodged an appeal on 19 December 2003 against the decision of the opposition division, posted on 30 October 2003, on the rejection of the opposition against the European patent EP-B-714269. The fee for the appeal was paid on 18 December 2003 and the statement setting out the grounds of appeal was received on 8 March 2004.

II. The Opposition division held that the ground for opposition mentioned in Article 100(a) EPC of lack of inventive step did not prejudice the maintenance of the patent.

III. The following documents, cited during the opposition proceedings are relevant for the present decision:

D1 = "The Journal of Teflon", 1971, Volume 12 no 3 pages 2 - 4

D10= DE - A - 3 918 736.

IV. Oral proceedings took place on 26 April 2005.

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the appeal be dismissed and that the patent be maintained as granted.

V. Claim 1 reads as follows:

"A tubular intraluminal graft comprising:
a) a tubular, diametrically adjustable stent (10) having an exterior surface, a luminal surface and wall, and having a multiplicity of openings through the wall of the stent;
b) a tubular covering (41) (47) (61) (51) of porous expanded polytetrafluoroethylene (20) which covers the multiplicity of openings, said tubular covering affixed to the tubular, diametrically adjustable stent (10), said tubular covering being less than about 0.10 mm thick, and said tubular covering having an exterior surface, a luminal surface and a seam (45) (49) extending from the exterior surface through to the luminal surface of the tubular covering."

VI. In support of his request the appellant relied essentially on the following submissions.

The subject-matter of claim 1 did not imply an inventive step having regard to a combination of the teaching of D10 and D1.

D10 disclosed most of the features of claim 1. Only those features according to which an expanded, porous PTFE was used for the covering of the stent, and the covering was less than about 0.10 mm thick, were not described in D10.

Starting from D10, the object underlying the patent in suit could be regarded as to provide a graft which was less bulky than the known grafts. That meant in other words that the object was to provide a thinner

covering, since this was the only way to make a graft less bulky.

Polytetrafluoroethylene (PTFE) was a very common material in the field of intraluminal grafts. An "expanded" PTFE was necessarily "porous", since the expansion of the material resulted in a porous structure. Furthermore, the term PTFE usually meant in the field of intraluminal grafts of the invention an expanded PTFE (ePTFE). Even the description of the patent in suit supported this assertion (see column 1 lines 16 and 17). The trade name of ePTFE was GORETEX®, which was also cited in the patent in suit (see for example column 2, section [0009]). Therefore, the use of an expanded, porous PTFE for the covering of the stent according to D10 was obvious.

Furthermore, since D10 disclosed using as a covering sheet a very thin film peeled off a PTF (=PTFE) block (see column 2, lines 10 to 19) it was also obvious to provide a covering which was less than about 0,10 mm thick, in particular since D1 disclosed films of ePTFE having a thickness less than about 0.10 mm (see list at the bottom of the right column of page 4) and that also ePTFE and not only non expanded PTFE could be provided in the form of a block (rod).

VII. The respondent disputed the views of the appellant. His arguments can be summarized as follows:

D10 did not disclose a covering made of porous expanded polytetrafluoroethylene. The material suggested by D10 for the covering was polytetrafluoroethylene (identified in D10 with either of the two acronyms PTFE

or PTF), which was neither porous nor expanded. On the contrary, D10 taught away from using a porous expanded PTFE, since it suggested the provision of a covering either by sintering of a PTFE dispersion or by peeling off from a PTF block a thin film (skiving). It was evident for the person acquainted with these technologies, that both methods were only viable with non porous, non expanded PTFE. Furthermore D10 did not disclose the claimed thickness of the covering of less than about 0.10 mm. Using such small values for the covering thickness was not known in the medical field before the invention. Furthermore, D10 taught stitching the seam of the covering sheet. Stitching, however, was not possible when a thin covering, like in the claimed invention, was used, since it would break.

Since the combination of D10 and D1 or of other documents of the available prior art could not lead the skilled person to the claimed invention in an obvious way, the subject-matter of claim 1 did involve an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. *Inventive step*

2.1 D10 discloses a tubular intraluminal graft comprising a tubular, diametrically adjustable stent (2) having an exterior surface, a luminal surface and wall, and having a multiplicity of openings through the wall of the stent; a tubular covering (3) of

polytetrafluoroethylene (see column 1, lines 62 to 65) which covers the multiplicity of openings, said tubular covering affixed to the tubular, diametrically adjustable stent, and said tubular covering having an exterior surface, a luminal surface and a seam (see column 2, lines 10 to 15) which inevitably extends from the exterior surface through to the luminal surface of the tubular covering.

2.2 Starting from D10 the object to be achieved by the present invention is to minimize the bulk of the graft.

This object is achieved by the subject-matter of claim 1, and in particular by using as a material for the covering a porous expanded PTFE less than about 0.10 mm thick.

The board considers it obvious that the person skilled in the field of intraluminal grafts and faced with the problem of reducing the bulkiness of a graft according to D10 would look for a thin material which is appropriate for making a graft. Knowing that porous PTFE is suitable for medical purposes, in particular for making grafts (see D10, column 2, lines 5 to 9), he would certainly have considered D1 which is a document containing the technical data of GORETEX® (trade name for expanded PTFE). This document discloses at page 4 (see Forms of "GORETEX") a series of different forms under which GORETEX® is commercialized. These forms comprise a film with a thickness of 0,0254 to 0,915 mm. Therefore D1 encouraged the skilled person intending to reduce the bulk of the graft according to D10, to select a film of GORETEX® out of this range, and in particular a film as thin as possible.

2.3 The respondent's statement that D10 teaches away from the claimed invention is not convincing.

Although it is true that D10 discloses exclusively coverings of non expanded PTFE, that does not mean that the skilled person would have excluded the use of coverings of porous expanded PTFE. On the contrary, there was no prejudice against the use of this material for medical purposes, and even D10 itself describes such a use (see column 2, lines 5 to 9). Furthermore, contrary to the assertion of the respondent, D10 is not restricted to the use of sintered coverings or coverings made of sheets of PTFE obtained by skiving a block of PTFE, since the most general teaching of D10, as laid down in the claims, does not contain such a limitation.

The argument according to which a covering of less than about 0,10 mm was not known in the medical field before the invention, is also not convincing. Even if a thickness like the one disclosed by the invention had not been used before the invention in the medical field for the covering of a stent, that does not mean that it was not obvious to use it, in particular in the light of the object underlying the patent in suit and with respect to the fact that D10 already suggests a thin covering (see claim 1 of D10).

Finally D10 does not generally teach stitching the seam of the covering sheet. According to D10, this is merely an optional step (see column 2, lines 18 and 19: "kann"). Therefore the covering of D10 is not

restricted to coverings having a thickness which allows stitching of the seam.

3. *Conclusions*

From the above considerations, it follows that the subject-matter of claim 1 does not involve an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

V. Commare T. Kriner