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D E C I S I O N
of 26 February 2002

Case Number: T 0712/00 - 3.2.1

Application Number: 94926553.2

Publication Number: 0714487

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Language of the proceedings: EN

Title of invention:
A thin-wall polytetrafluoroethylene tube

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

Opponent:
Meadox Medicals, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0712/00 - 3.2.1

D E C I S I O N
of the Technical Board of Appeal 3.2.1
of 26 February 2002

Appellant: W.L. GORE & ASSOCIATES, INC.
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 11 May 2000
revoking European patent No. 0 714 487 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: F. A. Gumbel
Members: S. Crane
G. E. Weiss

Summary of Facts and Submissions

I. European patent No. 0 714 487 was granted on 22 April 1998 on the basis of European patent application No. 94 926 553.2.

II. The granted patent was opposed by the present respondents on the grounds that its subject-matter lacked novelty and/or inventive step (Article 100(a) EPC).

Of the prior art documents relied upon in the opposition proceedings only the following have played any significant role on appeal:

(D1) US-A-3 953 566

(D2) US-A-4 478 898

(D3) US-A-4 713 070

(D10) US-A-5 123 917

(D12) English translation of JP-A-49 22792

III. With its decision posted on 11 May 2000 the Opposition Division revoked the patent. The reason given for the decision was that the subject-matter of claim 1 as granted lacked inventive step with respect to the state of the art according to documents D3 and D1.

IV. A notice of appeal against this decision was filed on 11 July 2002 and the fee for appeal paid at the same time. The statement of grounds of appeal was received on 18 September 2000.

V. Oral proceedings before the Board were held on 26 February 2002.

At the oral proceedings the appellants (proprietors of the patent) submitted a new set of documents comprising claims 1 to 22, description and drawings (Figures 1 to 11c) on the basis of which they requested maintenance of the patent in amended form.

Claim 1 reads as follows:

"A thin-wall intraluminal graft comprising a tube having an exterior surface, a luminal surface, a wall thickness of less than about 0.25 mm, and a longitudinal axis, said tube being comprised of at least one first layer of previously stretched porous expanded polytetrafluoroethylene film with edges overlapped and at least one second layer of previously stretched porous expanded polytetrafluoroethylene film with edges overlapped wherein the porous expanded polytetrafluoroethylene film has a microstructure having fibrils oriented substantially parallel to each other and wherein the fibrils of the first layer of porous expanded polytetrafluoroethylene film are oriented substantially perpendicular to the fibrils of the second layer of porous expanded polytetrafluoroethylene film."

Dependent claims 2 to 22 relate to preferred embodiments of the intraluminal graft according to claim 1.

The respondents requested dismissal of the appeal.

VI. The arguments of the appellants in support of their

request were essentially as follows:

In comparison with claim 1 considered by the Opposition Division the present claim had been restricted to an intraluminal graft wherein the two layers were each of pre-stretched polytetrafluoroethylene (PTFE) film with overlapped edges, thus now clearly excluding those arrangements of the prior art relied upon in the contested decision where the inner layer had been in the form of a tubular extrusion. The presence of such an inner extruded layer had previously been thought necessary to give sufficient stability to receive the wrapped outer layer, but it had now been surprisingly found that this was not the case. Dispensing with the extruded layer enabled a very significant and advantageous reduction in the wall thickness in comparison with what was previously achievable.

Although document D2 disclosed forming a tube from two layers of PTFE sheet, each with respective overlapped edges, the layers were post-stretched rather than pre-stretched so that the relatively perpendicular orientation of the fibrils in the two layers, as required by claim 1 would not be obtained. Furthermore, the document did not relate to an intraluminal graft and contained no indication that wall thicknesses of the order of 0.25 mm or less were envisaged. Document D10 on the other hand did indeed relate to an intraluminal graft comprising a wall which could consist of two layers of PTFE film and had a thickness of less than 0.25 mm, however this document was silent as to both the nature of the PTFE layers and how they were formed. Thus neither of these documents could lead the person skilled in the art to the claimed invention.

VII. The reply of the respondents can be summarised as follows:

The amendments made to claim 1 were objectionable in several respects. In the first place, it was not clear what structural limitations were supposed to be imposed by the restriction of the claim to an "intraluminal graft" especially as none of the particularly described preferred embodiments related to such an article. Secondly, the reference in the claim to the layers of PTFE film being "previously stretched" had no clear counterpart in the original disclosure and being a process feature it was in any case inherently incapable of defining the product claimed. Furthermore, the requirement that the film each layer had its "edges overlapped" was inconsistent with several of the preferred embodiments described where a flanged seal between the edges was employed. It was also inconsistent with the embodiment where a layer was formed from a plurality of complete wrappings of film. Lastly, insofar as in the only embodiments described the edges of the film extended parallel to the direction of the respective fibrils, the absence of this feature in claim 1 constituted an addition of subject-matter by way of inadmissible intermediate generalisation. In summary, amended claim 1 therefore offended against Articles 84 and 123(2) EPC.

There were a number of possible starting points for the evaluation of inventive step, but all of them led to the same conclusion that the subject-matter of claim 1 was obvious.

In particular, document D12 taught in very clear terms the advantage associated with arranging the two

expanded PTFE layers of an intraluminal graft with their respective fibrils oriented substantially perpendicularly to each other. In the light of document D2 it was obvious to replace the extruded inner layer of the graft of document D12 by a wrapped film in order to reduce the overall wall thickness. Films of the required thickness to achieve this were well known in the art, see for example document D1.

Alternatively, starting from documents D10, which already disclosed an intraluminal graft with a wall comprising two PTFE layers and having a thickness of less than 0.25 mm, it was obvious to the person skilled in the art that this could only be obtained by wrapping PTFE film to form the layers, since extrusion of tubular layers in this thickness was not feasible. Having regard to document D12 it was also obvious that the fibrils in the respective layers should be oriented perpendicularly to each other.

Another alternative starting point was document D2. Using the tube making technique disclosed there in conjunction with PTFE films as described in document D1, which was specifically referred to in document D2, would inevitably lead to a tube having all the features specified in present claim 1.

Reasons for the Decision

1. The appeal complies with the formal requirements of Articles 106 to 108 and Rules 1(1) and 64 EPC. It is therefore admissible.

2. On page 3, fourth paragraph, of the original

application (references are to the published A-document), which application - with the exception of some deleted embodiments - corresponds to the granted patent, it is stated that the properties of the thin-wall PTFE tube of the invention make it particularly useful as an intraluminal graft. There then follows the explanation that such a graft is capable of being implanted into a living body in the collapsed state and can therefore be inserted into a conveniently accessible, smaller diameter portion of a body conduit and then transferred to another, larger diameter portion of the body conduit where it is needed with the use of a catheter type of delivery system. One end of the intraluminal graft is then secured by suitable means such as the use of one or more metallic expandable stents. The use of the inventive intraluminal graft thus allows for the effective repair of living blood vessels without the trauma typically associated with conventional invasive vascular surgery.

In the paragraph bridging pages 4 and 5 other possible uses for the tube are indicated, including ducting for air or gases, flexible bellows, flexible coverings for expansible mechanical devices and filters.

Although the utility of the particular embodiments described with reference of Figures 1 to 11c is not specifically stated, it will be clear to the person skilled in the art that the relevant tubes are from their construction and size useful as intraluminal grafts. The same is true of Examples 1 to 5. In all of these particular embodiments the tubes are made by wrapping two layers of porous expanded PTFE film about a mandrel. The film is of the type disclosed in document D1 and has a microstructure comprising nodes

interconnected by fibrils. The film is made by stretching in a single direction which is thus the direction in which the fibrils are oriented. Each layer of film is formed into a tubular configuration with seamed edges, the seam extending longitudinally of the tube or helically around it, with the respective layers being arranged such that the orientation of the joints in one layer is substantially perpendicular to that of the fibrils in the second layer. The seam may take the form of one edge of strip of film overlying the other (eg Figure 2) or of the two edges being brought together to form a flange-like seal which is then folded over to flatten it (eg Figures 6 and 6a). Also it is possible for the layer to comprise a number of complete turns about the mandrel, cf Figure 3.

Having set out the background, it is now possible to turn to the objections raised against the amendments made to claim 1.

The introduction of the limitation that the tube is an intraluminal graft is not actually open to any objection under the EPC, since it is taken directly from dependent claim 33 as both originally filed and granted. This was effectively conceded by the respondents at the oral proceedings before the Board, who nevertheless maintained that it imposed no genuine technical restriction on the subject-matter of the claim. The Board cannot agree. As can be readily seen from the short discussion of the content of the original application and granted patent, an intraluminal graft must have properties, eg flexibility, non-toxicity and bio-compatibility, which make it suitable for use in the manner described.

The introduction into the claim of the requirement that the porous expanded PTFE film has been "previously stretched" is intended to distinguish it from arrangements where the PTFE material of the tube is stretched to make it porous after the tube has been assembled, and is effective in doing so. The term can only be sensibly understood as referring to the nature of the film before it is assembled into the claimed structure and is a genuine technical feature of the film. Furthermore, the term is clearly supported by the reference to document D1 and the paragraph bridging pages 8 and 9 of the application.

The Board also has no difficulty with the introduction into the claim that the respective layers are of PTFE film with "edges overlapped". This term is of broader ambit than that argued by the appellants, ie that the bottom surface of one edge overlies the top surface of the other edge (eg the embodiment of Figure 2), and includes a flanged seam where the edges overlie each other with their respective inner surfaces in contact (eg the embodiment of Figure 6). If there were any doubt here then it must also be noted that the flanged seal is in practice flattened to produce an overlap in the more narrow sense indicated above, cf Figure 6A. Furthermore, the term does not exclude the possibility of these being overlap of the "edges" to such an extent that the wrapping of the film into a tubular configuration comprises a number of complete turns, as shown in Figure 3.

Lastly in this context the Board notes that in the embodiment of Figure 2 the respective overlapped edges of both films extend longitudinally of the tube, with the fibrils of the inner film layer extending

longitudinally (ie parallel to the edges) and fibrils of the outer film layer extending perpendicularly to the edges. Thus the premise on which the respondents have constructed their objection to the amended claim constituting an inadmissible intermediate generalisation is incorrect and there is no justification for requiring further amendment of the claim to include the feature that in each layer the fibrils extend parallel to the respective overlapped edges.

In conclusion, the Board is therefore satisfied that present amended claim 1 is not objectionable under Articles 84 and 123(2) EPC. Also all of the amendments effect a restriction of the scope of granted claim 1, so there is no objection under Article 123(3) EPC.

With the exception of the correction of a clerical error in claim 10, present dependent claims 2 to 21 correspond to the same granted claims, whereas dependent claim 22 corresponds to granted claim 34.

The description has been amended to bring it into line with the amended claims, in particular by the excision of all embodiments and examples which were either specifically directed to products other than an intraluminal graft or whose suitability for use as such was questionable. As indicated above, the person skilled in the art would understand on reading the original application that the embodiments and examples now remaining were implicitly concerned with products intended or suitable for use as intraluminal grafts. Thus there is no objection to the amended description under Article 123(2) EPC.

3. The novelty of the subject-matter of present claim 1 is not in dispute. Document D12 discloses a vascular graft, which also constitutes an intraluminal graft in the broadest sense of the term, comprising an inner extruded layer of porous expanded PTFE and a helically wrapped outer layer of the same material. The respective orientation of the fibrils in the two layers is such that these extend substantially perpendicular to each other, in order to improve resistance to rupture, as is the case in the claimed graft. The thickness of the inner layer is however of the order of 1 mm and the thickness of the outer layer 0.08 mm, so that the overall wall thickness of the graft is several times greater than the maximum allowed by present claim 1. Document D10 relates to an intraluminal graft comprising radially extendible scaffold members, eg of stainless steel, which may be arranged between inner and outer tubular layers of PTFE having respective thickness of 0.05 mm or less and 0.05 to 0.10 mm. Thus the graft of document D10 indeed has an overall wall thickness below the maximum defined in claim 1, the document does not however specify how the tubular PTFE layers are formed or the nature of the PTFE material involved. The other cited prior art documents are more remote from the claimed subject-matter.

In the opinion of the Board the most appropriate starting point for the evaluation of inventive step is the graft disclosed in document D12, as described above. This document contains more relevant information about the graft than the passage of document D3 describing prior art, on which the Opposition Division mainly relied when revoking the patent, or the reference to prior used grafts in the present patent specification. In the latter context the appellants did

however concede that the commercially available grafts had a wall thickness less than that disclosed in documents D12, ie down to 0.4 mm.

Be that as is may, the aim of the invention was to provide an intraluminal graft having a reduced wall thickness which nevertheless retained good strength against rupture during implantation. The essence of the invention resides in the recognition that it was possible to dispense with the tubularly extruded inner layer of PTFE, which was stretched into its porous expanded state after extrusion, and replace it with a layer of pre-stretched PTFE film which was formed into a tube with overlapped edges.

As evidence of the obviousness of this step the respondents rely in particular on document D2. In this document the description of the prior art refers to the difficulty in making a porous PTFE tube having a thin wall by, the method of extruding a tubular product and then stretching it. The document contains a number of proposals, of which that of Figure 7 is the most relevant. Here a sheet of extruded PTFE, rolled to the required thickness, is wound from a drum and formed around a mandrel into a tubular shape with overlapped longitudinal edges. Thereafter this inner layer of PTFE is covered with a helical wrapping of another sheet of PTFE to form an outer layer. It is indicated that the preferred arrangement is when the molecular orientation of the PTFE in the first layer is parallel to the axis of the tube and the molecular orientation of the PTFE in the second layer is circumferential. After formation of the two layers the tube is stretched longitudinally to produce the desired degrees of porosity.

The molecular orientation of the PTFE referred to in document D2 is not synonymous with the porous expanded structure of nodes and substantially parallel fibrils of the PTFE film used in the invention, and well known *per se*. The molecular orientation of a plastic material on being stretched or rolled is a well-known phenomenon which has nothing to do with the formation of a porous structure comprising nodes and fibrils. Where reference is made in documents D2 (column 4, lines 19 to 29) to a porous PTFE composed of nodes and fibrils the context is that of the finished tube after it has been stretched, not the original form of the material of the layers that make it up. Thus this document does not give a clear teaching to the person skilled in the art that the way forward in reducing the wall thickness of the type of graft known from document D12 is to form the inner layer of pre-stretched porous expanded PTFE film with overlapped edges.

An alternative approach adopted by the respondents was to rely not so much on a combination of the teachings of documents D12 and D2, but more on document D2 as being the starting point for the evaluation of inventive step, particularly with view to the reference therein to document D1. However, there is nothing in document D2 which teaches that both the starting PTFE sheet materials used to form the tube as described with respect to Figure 7 should be of the type disclosed in document D1, ie with a porous expanded structure comprised of nodes and oriented fibrils. Furthermore, at least as far as the inner layer is concerned, the choice of such a material on the basis of general knowledge would be inappropriate, given the fact that it presents high resistance to stretching in the direction in which the fibrils are oriented. Thus this

approach also fails to demonstrate that the subject-matter of claim 1 is obvious.

The third and last way of tackling the question of inventive step which needs to be considered is that starting from document D10. Given that this document already discloses an intraluminal graft having a wall comprised of two layers of PTFE and having a combined wall thickness of less than 0.25 mm, the respondents argue that the person skilled in the art charged with the burden of putting this disclosure into practical effect would inevitably had to have recourse to the measures adopted by the appellants and would accordingly have arrived at the claimed subject-matter. However, that argument relies upon a chain of assumptions at least some of which appear to rely wholly or in part on hindsight knowledge of the invention. The fact of the matter is that the person skilled in the art is left in the dark as to how the tube is to be formed in practice, all that he knows is that the wall thickness should be considerably less than that which has been previously obtainable. The present invention consists in more, however, than a mere statement that an intraluminal graft can have a wall thickness of 0.25 mm or less, it resides instead in the particular measures adopted to achieve that end.

Turning to the arguments of the respondents in more detail, these are that the person skilled in the art would (a) choose a porous expanded PTFE material with a microstructure of nodes and oriented fibrils for the two layers, as this material was known to be suitable for the purpose, (b) realise or determine that tubular layers of the required thickness could not be produced as tubular extrusions, (c) come to the conclusion,

guided possibly by document D2, that the only workable possibility was to use PTFE films formed into a tubular configuration with overlapped edges and (d) arrange those films such that the respective fibril orientations were mutually perpendicular in order to give the resulting wall sufficient resistance to rupture. However, especially given that PTFE is only mentioned as an example in document D2, the obvious route for the skilled person even if he were to get as far as completing step (b) would seem to be to look for a different starting material which was easier to work with.

Having regard to the above the Board comes to the conclusion that the subject-matter of present claim 1 cannot be derived in an obvious manner from the state of the art and therefore involves an inventive step (Article 56 EPC).

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 with the order to maintain the patent as amended with the following documents:

Claims 1 to 22, description and drawings submitted at the oral proceedings of 26 February 2002.

The Registrar:

The Chairman:

S. Fabiani

F. Gumbel