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Datasheet for the decision of 18 November 2008

Case Number: T 0197/06 - 3.2.02

Application Number: 00915745.4

Publication Number: 1148843

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Partial encapsulation of stents

Patentee:
Bard Peripheral Vascular, Inc.

Opponent:
Boston Scientific Corporation

Headword:
-

Relevant legal provisions:
EPC Art. 54(2),(3), 56, 87, 111, 114, 123

Relevant legal provisions (EPC 1973):
-

Keyword:
"Late-filed submissions (admitted)"
"Priority rights"
"Novelty and inventive step (yes, after amendments)"

Decisions cited:
G 0002/98

Catchword:
-

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Case Number: T 0197/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 18 November 2008

Appellant 1: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 12 December 2005 concerning maintenance of European patent No. 1148843 in amended form.

Composition of the Board:

Chairman: T. Kriner
Members: M. Noel
M. J. Vogel

Summary of Facts and Submissions

I. By the interlocutory decision dated 12 December 2005, the opposition division decided to maintain the European patent No. 1 148 843 in amended form.

II. An appeal was lodged against this decision by both, the appellant 1 (opponent) and the appellant 2 (patentee) by notices received on 9 and 13 February 2006, respectively. The appeal fees were paid on 8 and 13 February 2006, respectively. The statements setting out the grounds of appeal were filed by both appellants on 21 April 2006.

III. Oral proceedings were held on 18 November 2008, at the end of which the requests of the parties were as follows:

The appellant 1 requested that the decision under appeal be set aside and that the European patent No. 1 148 843 be revoked.

The appellant 2 requested that the decision under appeal be set aside and the patent be maintained on the basis of claims 1 to 6 filed during the oral proceedings.

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

D1: US-A-4 776 337
D4: EP-A-0 893 108
D5: USSN 60/118269 (Serial Number)
D6: WO-A-00/71057.

V. Independent claims 1 and 4 read as follows:

"1. A method for making a partially encapsulated radially expandable reinforced vascular graft (10), comprising providing a first expanded polytetrafluoroethylene layer of material (20), providing a second expanded polytetrafluoroethylene layer of material (40, 42, 50, 60, 70), disposing a radially expandable support layer consisting of at least one stent (30) over the first expanded polytetrafluoroethylene layer, placing the second expanded polytetrafluoroethylene layer (40, 42, 50, 60, 70) over the radially expandable support layer (30), and laminating the second expanded polytetrafluoroethylene layer (40, 42, 50, 60, 70) to the first expanded polytetrafluoroethylene layer, *characterized by* cutting a plurality of apertures (44, 52, 62, 72) into one of the expanded polytetrafluoroethylene layers (20, 40, 42, 50, 60, 70) and positioning the apertures (44, 52, 62, 72) with respect to the support layer, leaving portions of the support layer exposed through the apertures."

"4. A method for making a partially encapsulated radially expandable reinforced vascular graft, comprising providing a first expanded polytetrafluoroethylene layer of material (20) providing a second expanded polytetrafluoroethylene layer of material (40), disposing a radially expandable support layer comprising at least one stent (30) over the first expanded polytetrafluoroethylene layer (20), placing the second expanded polytetrafluoroethylene layer (40, 42, 50, 60, 70) over the radially expandable

support layer (30) and laminating the second expandable polytetrafluoroethylene layer (40, 42, 50, 60, 70) to the first expanded polytetrafluoroethylene layer (20), *characterized by* cutting a plurality of slits (52, 62, 72) into at least one of the tubular expanded polytetrafluoroethylene layers (50, 60, 70) before being positioned as part of the radially expandable reinforced vascular graft and positioning the slits (52, 62, 72) to span portions of the radially expandable support layer."

VI. The appellant 1 presented the following arguments:

In the preamble of claim 1 the feature "a support layer consisting of at least one stent" was not supported as such by the application as filed. The description only referred to one or more stents forming each a series of individual, sinusoidal ring stents. Therefore, the requirement of Article 123(2) EPC was not met.

A support layer consisting of or comprising at least one stent was also not disclosed by the first priority document D5. Neither did D5 disclose the step of cutting slits. Independent claims 1 and 4, therefore, were not entitled to the first priority under Article 87 EPC, and D6 was relevant prior art under Article 54(3) EPC.

D6 was filed late. This document was, however, admissible under Article 114(2) EPC as it was highly relevant and filed at the appeal stage to counter the reasons set out in the decision under appeal. D6 disclosed all the steps of the claimed methods

including cutting apertures or slits into the outer ePTFE layer.

D4 disclosed all the features of claim 1 with the exception of the cutting step. In D4 apertures were formed by helical winding of spaced apart ePTFE strips. However, the provision of apertures directly cut into the outer ePTFE layer represented an obvious alternative, having regard to the general knowledge of a person skilled in the art and the disclosure of D1. Therefore, the subject-matter of claim 1 did not involve an inventive step.

VII. The appellant 2 presented the following arguments:

A support layer consisting of or comprising at least one stent was implicitly disclosed by the first priority document D5. Furthermore, since the word "opening" was used in D5 to define as well an aperture as a slit, the subject-matter of independent claims 1 and 4 was concerned with the same invention as the one disclosed by D5 as a whole. Therefore, the claims were entitled to the first priority date of the patent application and D6 was not a prior art document.

Moreover, D6 should not be admitted into the proceedings as it was late-filed. Should the Board nevertheless decide to admit this document in view of its alleged relevance, it would appear appropriate to remit the case to the first instance for giving the proprietor an opportunity of having the case considered at two instances, in particular to determine the admissibility of D6 taking account of the priority rights.

Furthermore, even if D6 did disclose the step of cutting slits into the outer ePTFE layer, its subject-matter differed from the method claim 4 in that the cutting step took place after placing the outer layer over the stent.

D4 did not disclose any cutting of slits so that the method claim 4 was not concerned. With respect to the method claim 1, the method according to D4 differed from the claimed method in that the apertures were not achieved by cutting so that the step of positioning the apertures after cutting was not disclosed.

D1 disclosed a stent having openings formed into the outer coating, but the process of making these openings was not specified.

Since no prior art document suggested forming apertures or slits into one of the ePTFE layers by a cutting operation, the subject-matter of claims 1 and 4 was novel and not obvious vis-à-vis the state of the art in accordance with Articles 54 and 56 EPC.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments - Article 123(2) and (3) EPC

2.1 Independent method claim 1 is based on claim 25 of the application as filed and its subject-matter is focused

on the provision of apertures cut into one of the expanded PTFE layers as illustrated in Figures 1 to 3.

The expression "support layer comprising at least one stent" is to be found in original claim 25. The replacement of "comprising" by "consisting of" is admissible since it is clearly derivable from the description (see page 4, lines 15 to 18), that the "support layer" is actually the radially expandable stent itself and is constituted by a series of individual zigzag sinusoidal ring stents 30 as shown in Figure 1. The fact that the expression "support layer" has no counter-part in the description could give rise to a clarity objection under Article 84, 2nd sentence, but does not form the basis for an objection under Article 123(2) EPC.

In the characterising portion of claim 1 the consecutive operations of "cutting" and "positioning" (within the meaning of "placing" as recited in the preamble) are supported by original claims 25 and 27 taken in combination. The possibility of cutting into "one" of the ePTFE layers, i.e. as well into the inner layer 20 as into the outer layer 40, is supported by the alternative embodiment presented on page 7, lines 18 to 22, according to which both layers may be reversed, knowing that a "lacey graft" is identified as a layer with apertures as opposed to a layer with slits (see page 6, lines 12 to 13 and page 3, lines 2 to 4).

The replacement of "a portion" (of the support layer) by "portions" at the end of claim 1 is acceptable in view of the passage on page 5, lines 19 to 22 whereby "leaving the ends of the zigzags (of each ring stent)

uncovered" corresponds in claim 1 to "leaving portions of the support layer exposed through the apertures".

The dependent claims 2 and 3 are based on original claims 14 and 15, respectively.

2.2 Independent method claim 4 is based on claim 30 of the application as filed and its subject-matter is focused on the provision of a plurality of slits cut into at least one of the ePTFE layers as illustrated in Figures 4 to 6.

The above remark made with respect to the expression "support layer" in claim 1 applies in analogy to claim 4. In the characterising portion of claim 4 the step of cutting a plurality of slits "into at least one of the tubular expanded PTFE layers" means that the slits may be achieved by cutting into either one of the inner or the outer ePTFE layer or still both of them. These alternative embodiments are fairly supported by the application on page 7, lines 18 to 26, in which the orientation of the two layers (tubular grafts) may be reversed (line 20) or both layers may be configured similarly, i.e. duplicated (line 25).

The dependent claims 5 and 6 are based on original claims 17 and 18, respectively.

2.3 It results therefrom that the amendments of the claims do not extend their subject-matter beyond the content of the application as filed in compliance with Article 123(2) EPC. Furthermore, since the amendments result in limitations of the scope of protection compared to the

patent as granted the requirements of Article 123(3) EPC are also met.

3. Late-filed submissions - Article 114 EPC

D6 was filed by the appellant 1 together with its statement of grounds of appeal. Since D6 is considered as being highly relevant, the case could be remitted to the department of the first instance. However, in the present case it is not appropriate to remit it by reason of procedural economy and because this is not unfair to the parties. D6 was actually late-filed by appellant 1 in reaction to the reasoning given in the contested decision. On the other side appellant 2 submitted a number of amended sets of claims short before and during the oral proceedings in order to reinforce its position. Moreover, both parties have had sufficient time and opportunities to comment on the late filed submissions.

The Board, therefore, decided to admit D6 into the proceedings and to exercise the competence of the first instance to prosecute further with the case in accordance with Articles 111(1) and 114(1) EPC.

4. Priority right - Article 87 EPC

4.1 In accordance with Article 87(1) EPC a European patent application is only entitled to priority in respect of the same invention as disclosed in the previous application. This means that the priority in respect of a claim is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general

knowledge, from the previous application as a whole (see G 2/98). In this respect, identical wording is not required, provided that the essential features be derivable from the text as filed.

4.2 With respect to independent claim 1, the first priority document D5 discloses (see page 2, first paragraph), although using different wording, a method for making a partially encapsulated radially expandable reinforced vascular graft comprising all the steps of the method claim 1. In particular, D5 discloses on page 4, lines 4 to 25 with reference to Figures 1 to 3 a method of providing first and second ePTFE layers (respectively a tubular graft and a sleeve), disposing a radially expandable support layer consisting of at least one stent over the first ePTFE layer (graft; see page 4, lines 6 to 10 and Figure 2), placing the second ePTFE layer (sleeve) over the stents (page 4, lines 10 to 12 and Figure 1), and laminating the second ePTFE layer to the first one (see page 4, lines 13 to 16: "heat and pressure"). The method also includes the steps of cutting a plurality of apertures (openings) into one of the ePTFE layers (the outer sleeve; see page 4, lines 12 to 13 and Figures 1 and 4), and positioning the apertures with respect to the support layer (stents), leaving portions of the support layer exposed through the apertures ("covered/uncovered"; see page 4, lines 12 to 13 and 21 to 25 and Figures 1 and 4).

Therefore, D5 discloses the same invention as in claim 1 at issue and claim 1 is entitled to the priority date of D5. As a consequence, D6 which was filed after this date is not a state of the art under Article 54 EPC.

4.3 With respect to independent claim 4, D5 does not disclose the provision of slits. The photographs filed with the description show a plurality of openings substantially rectangular in shape. However there is no reason to conclude that these openings have been formed by cutting slits within the meaning of the present patent.

Therefore D5 fails to disclose an embodiment having slits cut into at least one of the ePTFE layers and claim 4 is not entitled to the priority date of D5. Consequently, D6 represents a valid state of the art under Article 54(3) EPC with respect to claim 4.

5. Novelty - Articles 54(2) and (3) EPC

5.1 D4 (see Figures 1A, 1B and 2 and the text referred to) discloses a method for making a partially encapsulated radially expandable vascular graft having all the structural and functional features recited in claim 1, with the exception of the cutting operation. This view was shared by all parties to the proceedings.

As a matter of fact, the stent-graft of D4 is formed by helical winding of a stent member comprising undulating elements around a thin tubular graft of ePTFE material. Then a strip or ribbon shaped coupling member of ePTFE material is helically wrapped around the stent member as shown in Figures 1B and 2 so as to leave the ends portions of the undulating elements uncovered, thereby forming between adjacent windings a series of spaced apart apertures. However, these apertures result from

the very formation of the outer ePTFE layer and not from a cutting operation practised into said layer.

Moreover, D4 does not disclose the provision of slits as recited in method claim 4 and illustrated in Figures 4 to 6 of the present patent.

Therefore, the subject-matter of independent claims 1 and 4 is novel vis-à-vis the document D4 under Article 54(2) EPC.

5.2 D6 (see Figure 5 and page 11, lines 13 to 21) discloses a method of making a stent-graft composite with increased flexibility having all the structural and functional features recited in claim 4 in dispute, in particular the provision of slits 22' by cutting the outer ePTFE layer of the stent-graft in order to expose the wave-like peaks 14' of the stent. However, it results from the above quoted paragraph of D6 that the slits are cut after the outer ePTFE layer has been placed, i.e. after the whole stent-graft composite has been assembled as shown in Figure 5. The positioning of the slits depends on the location of the wave-like peaks of the stent.

In contrast to this procedure, in the method according to claim 4, the slits are made by cutting slits into a tube of ePTFE material and the resulting outer layer is then placed over the stent, whereby the step of cutting occurs prior to the step of placing the outer layer over the stent, as mentioned in the application as filed on page 2, lines 27 to 30 and claim 34.

It results therefrom that the subject-matter of claim 4 is novel over the disclosure of D6 under Article 54(3) EPC.

6. Inventive step - Article 56 EPC

6.1 Claim 1

The distinguishing feature of claim 1 vis-à-vis the disclosure of D4, i.e. the provision of apertures by cutting them into one of the ePTFE layers, represents the solution of the objective problem of providing an alternating method for making a partially encapsulated vascular graft.

This feature cannot be suggested by D4, since the only methods proposed in this document for making the outer layer are directed to configurations where the strips or ribbon shaped coupling members are arranged either helically or longitudinally but always spaced from each other so as to form apertures between adjacent helical turns or between longitudinal strips (see column 7, lines 50 to column 8, line 8 and column 9, lines 13 to 21). Therefore, there is no suggestion for making apertures into the strips or ribbons themselves, let alone by a cutting operation.

D1 (see Figure 5 and column 9, lines 42 to 46) discloses openings formed into a coating surrounding a tubular shaped graft. This document does not specify the process for making said openings. Moreover, these openings are provided for the passage of body fluids, not for increasing the stent flexibility. Consequently,

D1 does also not suggest the provision of apertures by a cutting operation.

Therefore, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

6.2 Claim 4

As already mentioned above (point 2.2) the subject-matter of claim 4 is focused on the formation of slits into the ePTFE layers. Since D4 does neither disclose nor suggest the provision of slits as opposed to apertures into or between adjacent strips or ribbons, let alone by cutting into one of the ePTFE layers, since D1 does not refer to the making of slits, and since D6 is not to be considered for assessing the inventive step of claim 4 according to Article 56, second sentence EPC, the subject-matter of claim 4 could not be arrived at in an obvious way by the skilled person on the basis of the available prior art.

Therefore, the subject-matter of claim 4 also involves an inventive step within the meaning of 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 on the basis of

   – claims 1 to 6 filed during the oral proceedings, and
   – a description and drawings to be adapted to these claims.

The Registrar: The Chairman:

V. Commare T. Kriner