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Datasheet for the decision of 25 October 2011

Case Number: T 0397/09 - 3.2.08

Application Number: 00907760.3

Publication Number: 1176926

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Inflatable intraluminal graft

Patent Proprietor:
TriVascular, Inc.

Opponent:
C. R. Bard, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 54(3)
RPBA Art. 13(1)

Relevant legal provisions (EPC 1973):
EPC Art. 100(a)(b)(c)

Keyword:
"Late-filed submissions (no good reason for delay - not admitted)"
"Added subject-matter (no)"
"Sufficiency of disclosure (yes)"
"Priority (valid)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
G 0004/92, T 0949/07

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0397/09 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 25 October 2011

Appellant: (Opponent)
C. R. Bard, Inc.
730 Central Avenue
Murray Hill, NJ 07974 (US)

Representative:
van Bouwelen, Franciscus Maria
Hoffmann - Eitle
Patent- und Rechtsanwälte
Arabellastraße 4
D-81925 München (DE)

Respondent: (Patent Proprietor)
TriVascular, Inc.
3910 Brickway Boulevard
Santa Rosa, CA 95403 (US)

Representative:
Vossius & Partner
Siebertstraße 4
D-81675 München (DE)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 10 December 2008 rejecting the opposition filed against European patent No. 1176926 pursuant to Article 101(2) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: M. Alvazzi Delfrate
U. Tronser

Summary of Facts and Submissions

I. By its decision posted on 10 December 2008 the opposition division rejected the opposition against European patent No. 1 176 926.

II. The appellant (opponent) lodged an appeal against said decision on 11 February 2009, paying the appeal fee on the same day. The statement of grounds for appeal was filed on 17 April 2009.

III. The appellant requested that the appealed decision be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or that the patent be maintained on the basis of one of the auxiliary requests 1 to 3 filed with the letter dated 18 October 2011.

IV. Claim 1 of the main request reads as follows:

"A collapsible stent graft (20), which comprises a collapsible inner tubular member (26) for lining a blood vessel and an inflatable member (22) extending around the inner tubular member (26) and attached thereto, whereby inflation of the inflatable member (22) expands the inner tubular member (26) from a collapsed state to an expanded state;
wherein an outer layer (24) is provided around the inner tubular member (26);
characterised in that the inner member and outer layer are formed from expanded PTFE film having a microstructure of uni-axially oriented fibrils and further characterised in that the inflatable member is

formed by partially fusing or adhering the outer layer to the inner tubular member such that the inflatable member is provided between those portions of the inner tubular member and the outer layer where the outer layer is fused or adhered to the inner tubular member, and in that the portions of the inner tubular member and the outer layer where the outer layer is fused or adhered to the inner tubular member provide uninfiated [sic] fused or adhered sections when the inflatable member is inflated."

V. The following documents play a role in the present decision:

D0: patent application GB 9904722.7 (priority document of the patent in suit);
D3: WO-A- 99 /39 662;
D5: US -A- 5 156 620;
D10: US-A- 3 953 566;
D15: M.E. McClurken et al. "Physical Properties and Test Methods for Expanded Polytetrafluoroethylene (PTFE) Grafts" (1986); and
D16: US-A- 5 718 973.

VI. The arguments of the appellant can be summarised as follows:

Added subject-matter

The application as originally filed did not disclose the feature introduced by amendment into claim 1 according to which the inflatable member is formed by partially fusing or adhering the outer layer to the inner tubular member such that the inflatable member is

provided between those portions of the inner tubular member and the outer layer where the outer layer is fused or adhered to the inner tubular member.

It was true that the application as filed disclosed, on page 4, lines 16-19, that the inflatable member is formed by partially fusing or adhering an outer layer to the collapsible tubular member. However, according to said passage the inflatable member was situated radially outward of the inner tubular member, since it was provided between the outer layer and the collapsible tubular member. By contrast, this feature was missing from present claim 1, according to which the inflatable member is provided between those portions of the inner tubular member and the outer layer where the outer layer is fused or adhered to the inner tubular member. Hence, the amendment under consideration cannot be based on said passage on page 4.

Moreover, it could not be derived by the specific embodiment disclosed on page 11, lines 10-16 either. According to this embodiment the graft comprised two fused ends, which were an essential feature, as explained on page 5, lines 12-13. Additionally, the inflatable member disclosed in said embodiment had a spiral shape. Since neither the fused ends nor the spiral shape were recited in claim 1, the amendment under consideration was an intermediate generalisation which extended beyond the content of the application as filed.

Sufficiency of disclosure

According to claim 1 the stent graft comprised an inflatable member. However, the patent did not explain how this member could be inflated and remain inflated in the human body. Therefore, the claimed invention was not sufficiently disclosed.

Document D5

D5 was prima facie highly relevant, as it was detrimental to novelty of the subject-matter of claim 1. It was true that this objection had been submitted only at a late stage of the proceedings. However, the reason for the late filing was that the appellant had been waiting to see how this document was assessed in the case of the appeal T 0949/07. Moreover, the appellant had tried to negotiate an agreement with the patent proprietor outside the present appeal proceedings. Hence, there was a justification for the delayed submission of this document and D5 should be admitted into the proceedings.

Priority

Although all the features according to claim 1 could be found in D0, this document did not provide an enabling disclosure for the claimed invention. First of all, as could be seen on page 9, lines 11-12, D0 did not relate to a stent graft but to a balloon graft. Moreover, the passages of the application underlying the patent which gave some information on the closing of the inflatable member and the way of lining a blood vessel with the claimed device, namely page 5, lines 8-18 and page 13,

line 5 to page 14 line 9 were not present in D0. Hence, there was no enabling disclosure for these features. Since the criteria for assessing the validity of a priority claim were the same used for assessing lack of novelty, the lack of an enabling disclosure in D0 resulted in an invalid priority claim.

Novelty and inventive step

Since the priority claim was not valid, D3, published in the priority interval of the patent in suit, was prior art relevant to the issues of novelty and inventive step.

D3 disclosed a stent graft with all the features according to claim 1. In particular, it described the use of ePTFE (expanded PTFE) for the tubular member and the outer layer. Tubular members of ePTFE were made by extrusion, a process which inevitably resulted in a microstructure of uni-axially oriented fibrils, as shown by D15 or D16. Hence, the tubular member and the outer layer known from D3 also exhibited this structure. Therefore, the subject-matter of claim 1 lacked novelty in view of D3.

In the written proceedings it was additionally submitted that the subject-matter of claim 1 did not involve an inventive step in view of the combination of D3 and D15.

VII. The arguments of the respondent can be summarised as follows:

Added subject-matter

The application as filed disclosed, on page 4, lines 16-19, that the inflatable member is formed by partially fusing or adhering an outer layer to the collapsible tubular member to provide an inflatable member. Said inflatable member could only be provided between those portions of the inner tubular member and the outer layer where the outer layer is fused or adhered to the inner tubular member. Hence, claim 1 had not been amended in a way extending beyond the content of the application as originally filed.

Sufficiency of disclosure

Inflatable stent grafts and other inflatable members to be inserted in the human body were well known in the art. It was also well known how to inflate them and how to maintain the member in the body inflated. Moreover, the patent in suit described different possibilities of realising this feature. Therefore, the claimed invention was sufficiently disclosed.

Document D5

D5 had been submitted only at a very late stage of the proceedings without any good reason. Moreover, it was not more relevant than the documents already in the proceedings. Therefore, it should not be admitted into the proceedings.

Priority

As for example visible from page 3, line 25, D0 related to a stent graft, although this element was also called a balloon graft on page 9, lines 11-12. Moreover, D0 disclosed all the features according to present claim 1 and provided sufficient information to realise the claimed invention. Therefore, the claimed priority was valid.

Novelty and inventive step

It was true that D3 disclosed a tubular member and an outer layer made of ePTFE. However, it did not disclose their structure. Since, as shown by D10, ePTFE could exhibit different microstructures, there was no evidence that said outer layer and tubular member exhibited a microstructure according to claim 1. Moreover, the outer layer made of ePTFE disclosed by D3 did not have a tubular shape. Hence, it could not be said that it had to be made by extrusion which, according to the appellant, implied a microstructure of uni-axially oriented fibrils. Therefore, the subject-matter of claim 1 was novel in view of D3.

In the written proceedings it was argued that, since the priority is validly claimed, D3 is not relevant to the issue of inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. Added subject-matter

During the examination proceedings claim 1 was amended by introducing the feature according to which the inflatable member is formed by partially fusing or adhering the outer layer to the inner tubular member such that the inflatable member is provided between those portions of the inner tubular member and the outer layer where the outer layer is fused or adhered to the inner tubular member.

The application as originally filed discloses, on page 4, lines 16-19, that the inflatable member is formed by partially fusing or adhering an outer layer to the collapsible tubular member so as to provide one or more inflatable members therebetween. It is clear that no inflatable member can be formed in the regions where the outer layer is fused or adhered to the inner tubular member. Hence, said passage of the application as filed can only be understood to mean that the inflatable member is provided between those portions of the inner tubular member and the outer layer where the outer layer is fused or adhered to the inner tubular member.

It is true, as submitted by the appellant, that the passage on page 4 defines that the inflatable member is situated radially outward of the inner tubular member. However, the same applies to the member in accordance with present claim 1, which states that the inflatable member formed between said portions extends around the inner tubular member.

Moreover, the passage on page 4, lines 16-19, does not refer to any specific embodiment. Therefore the amendment under consideration is not an inadmissible intermediate generalisation of the embodiment disclosed at page 11, lines 10-16, as argued by the appellant.

Therefore, the amendment under consideration does not extend beyond the content of the application as originally filed.

3. Sufficiency of disclosure

A European patent must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Since the patent is addressed to the person skilled in the art who may use his common general knowledge to supplement the information contained in the patent, it is not necessary to give details of well-known features to comply with this requirement.

In the present case there is no doubt that inflatable graft stents and other inflatable members to be inserted and to remain in the human body were well-known before the priority date of the patent in suit, as evidenced for instance by the prior art cited in paragraphs [0011] to [0014] of the patent in suit. Hence, the person skilled in the art had no difficulty in realising a member which could be inflated and remain inflated in the human body. Therefore, the claimed invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

4. Document D5

Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion. This discretion is exercised inter alia in view of the state of the proceedings and the need for procedural economy (see Article 13(1) RPBA, OJ EPO 11/2011, page 536). This need, together with the requirement of inter partes appeal proceedings that all parties involved in these proceedings have the guarantee of a fair and equitable procedure, demands that facts and evidence are brought to the attention of the adverse parties and of the board without delay and in sufficient time for their consideration (see G 4/92, point 5 of the Reasons, OJ 1994, 149).

In the present case the statement of grounds for appeal makes no reference to D5. Hence, the board of appeal has discretion as to whether or not to admit this document and consider the alleged lack of novelty based on it.

It is undisputed that, albeit no objection based on this document was raised during the opposition proceedings, D5 was known to the appellant at least since the beginning of said proceedings, as it was cited in the notice of opposition. However, the appellant waited more than four years after filing its notice of opposition and some 29 months after filing its statement of grounds for appeal before seeking to introduce an objection based on this document with the letter dated 23 September 2011, about one month before the date set for the oral proceedings.

No good reason can be seen for this delay. The appellant argued that it had waited to see how this document was assessed in the case of the appeal T 0949/07 and that it had tried to negotiate an agreement with the patent proprietor outside the present appeal proceedings. However, T 0949/07 refers to another independent case and waiting for an assessment of document in that case does not excuse the delay in submitting an objection which was considered relevant to the present appeal. Moreover, the decision concerning the appeal T 0949/07 was issued in August 2009, i.e. more than two years in advance of the letter dated 23 September 2011. As to the hope of negotiating an agreement with the patent proprietor, such negotiations are outside the scope of present appeal proceedings and cannot excuse a late filing of a document.

Under these circumstances the board finds that the submission at a very late stage of the proceedings of D5 is to be dismissed independently of the possible relevance of this document.

5. Priority

D0 relates, as present claim 1, to a stent graft (see for instance the paragraph bridging pages 3 and 4). The appellant pointed out that a balloon graft is mentioned at page 9, lines 11-12. However, said balloon graft is indicated with the same reference 20 used at page 9, lines 8-11 for the stent graft. Therefore, it is clear that in D0 the "balloon graft" is the same as the stent graft.

It is undisputed that D0 describes all the features according to present claim 1. Nevertheless, the appellant argued that the disclosure of the claimed invention to be found in this document was not enabling and that, as a consequence, the priority claim was invalid.

This argument is not convincing. Contrary to the appellant's view the person skilled in the art would have no difficulty, on the basis of the information provided by D0 and his common general knowledge, to find a way of closing the inflatable member and lining a blood vessel with the claimed device. As already explained above when assessing sufficiency of disclosure, possible ways of realising a member which could remain inflated in the human body were well known to the person skilled in the art before the priority date of the patent in suit. As to the way of lining a blood vessel with the claimed device, D0 discloses, for instance in Figures 5 and 6 or on page 5 line 22 to page 6, line 1 how the device can be fixed to a blood vessel. Hence, D0 provides sufficient information for the person skilled in the art to realise the claimed invention. Under these circumstances there is no need to consider whether or not the lack of an enabling disclosure can invalidate a priority claim. Therefore, the priority is validly claimed.

6. Novelty and inventive step

6.1 Since the priority of the patent in suit is validly claimed, D3, a PCT application with a filing date prior to the priority date of the patent suit and a

publication date subsequent to said priority date can only be prior art under Article 54(3) EPC. As such it can only be relevant for the assessment of novelty and not for inventive step.

6.2 For an invention to lack novelty, its subject-matter must be clearly and directly derivable from the prior art.

It is undisputed that D3 discloses a stent graft with a tubular member and an outer layer made of ePTFE. However, this document is silent as to the microstructure of these elements. The appellant submitted that said microstructure must exhibit uni-axially oriented fibrils since this was the inevitable result of extrusion, which was the process used for producing tubular members. However, this argument is not convincing, as D3 does not disclose that the outer layer made of ePTFE has a tubular shape. Hence, extrusion is not the sole possibility of obtaining said outer layer. For instance the process disclosed in D10 could be used, which can be applied to the production of all kinds of shaped articles such as films, tubes, rods and continuous filaments (see abstract) and which does not inevitably result in a microstructure in accordance with present claim 1 (see column 6, lines 36-41). Novelty of the subject-matter of claim 1 is acknowledged only for that reason.

6.3 The sole objection of lack of inventive step based on the documents admitted into the proceedings is based on the combination of D3 and D15. However, D3 is not part of the prior art to be considered for assessing inventive step. Under these circumstances, the board

has no reason to depart from the assessment made in the appealed decision that the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare T. Kriner