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**Datasheet for the decision
of 21 July 2011**

Case Number: T 1009/07 - 3.2.08
Application Number: 01968890.2
Publication Number: 1317227
IPC: A61F 2/00
Language of the proceedings: EN

Title of invention:
Implantable prosthesis

Patentee:
C.R. BARD, INC.

Opponent:
Ethicon Inc.

Headword:

-

Relevant legal provisions:

EPC Art. 123(2)
RPBA Art. 13(1)
EPC R. 80

Relevant legal provisions (EPC 1973):

EPC Art. 56, 84, 114(2)

Keyword:

"Late-filed request (admitted)"
"Added subject-matter (no)"
"Clarity (yes)"
"Inventive step (yes) - after amendments"

Decisions cited:

-

Catchword:

-



Case Number: T 1009/07 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 21 July 2011

Appellant II:
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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
European patent No. 1317227 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

- I. By decision posted on 10 April 2007 the opposition division decided that European patent No. 1 317 227, amended according to the fourth auxiliary request then on file, and the invention to which it related met the requirements of the EPC.
- II. Appellant 1 (patent proprietor) lodged an appeal against this decision on 19 June 2007, paying the appeal fee on the same day. The statement setting out the grounds for appeal was filed on 20 August 2007.
- III. A further appeal was filed by appellant 2 (opponent) on 18 June 2007, and the appeal fee was paid on the same day. The statement setting out the grounds for appeal was filed on 20 August 2007.
- IV. Oral proceedings were held before the board of appeal on 21 July 2011.
- V. Appellant 1 requested that the appealed decision be set aside and that the patent be maintained on the basis of the following documents:
 - claims 1 to 27 according to the second auxiliary request (now main request) submitted with letter dated 21 June 2011;
 - description columns 1 to 8 and Figures 1 to 7 as filed during the oral proceedings.
- VI. Appellant 2 requested that the appealed decision be set aside and that the patent be revoked.

VII. Independent claims 1 and 6 underlying the present decision read as follows:

"1. An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising: a layer of repair fabric (22) that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including a first surface (30), a second surface (32), and an outer peripheral edge (28); a barrier layer (24) that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion of the first surface and adjacent tissue and organs; and a peripheral barrier (26) that inhibits the formation of adhesions with tissue and organs, the peripheral barrier extending between said first and second surfaces (30,32) about at least a portion of the outer peripheral edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs, wherein the peripheral barrier includes an outer margin of the layer of repair fabric, wherein the outer margin has been melted and resolidified to render the portion of the outer peripheral edge of the layer of repair fabric substantially impervious to tissue ingrowth."

"6. An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising: a layer of repair fabric (22) that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including a

first surface (30), a second surface (32), and an outer peripheral edge (28); a barrier layer (24) that inhibits the formation of adhesions with tissue and organs, the barrier layer having an outer margin and being configured to inhibit the formation of adhesions between at least a portion of the first surface and adjacent tissue and organs; and a peripheral barrier (26) that inhibits the formation of adhesions with tissue and organs, the peripheral barrier extending between said first and second surfaces (30,32) about at least a portion of the outer peripheral edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs, wherein the peripheral barrier is formed from the outer margin of the barrier layer, said outer margin of the barrier layer being wrapped about said portion of the outer peripheral edge of the repair fabric so that it extends from the first surface and across the thickness of the outer peripheral edge of the repair fabric, the outer margin of the barrier layer also extending over a portion of the second surface of the layer of repair fabric adjacent the outer peripheral edge."

VIII. The following documents are relevant to the present decision:

- D1: WO-A- 99 06079;
- D5: US-A-3 416 524;
- D7: B.G. Matapurkar et al. 'A New Technique of "Marlex®-Peritoneal Sandwich" in the Repair of Large Incisional Hernias', World Journal of Surgery, Vol. 15 (1991), pages 768-770;

- D8: M.L. Baptista et al., 'Abdominal Adhesions to Prosthetic Mesh Evaluated by Laparoscopy and Electron Microscopy', Journal of the American College of Surgeons, March 2000; and
- D9: US-A-5 593 441.

IX. The arguments of appellant 2 can be summarised as follows:

Admissibility of the new main request

The amended claims of the new main request had been filed only one month in advance of the oral proceedings, although they corresponded in essence to amended claims which were already considered in the appealed decision. This behaviour was to be considered abusive and the new main request should not be admitted into the appeal proceedings.

Rule 80 EPC

Filing two independent claims could not be considered as occasioned by a ground for opposition. Therefore, with respect to Rule 80 EPC too the new main request should not be admitted.

Article 123(2) EPC

The application as filed did not disclose that the peripheral barrier extended between the first and the second surface. Accordingly, Article 123(2) EPC was contravened.

Article 84 EPC1973

The wording "the peripheral barrier extending between said first and second surfaces" could be interpreted in two different ways, namely to mean that said barrier extended through the thickness of the fabric or that it was in contact with both surfaces of the fabric, as in Figure 6 of the application. Therefore, this wording introduced a lack of clarity into claims 1 and 6.

Additionally, claim 6 was redundant and lacked clarity because the feature that the outer margin of the barrier layer was wrapped about the portion of the outer peripheral edge of the repair fabric so that it extended from the first surface and across the thickness of the outer peripheral edge of the repair fabric repeated the feature that the peripheral barrier extended between the first and the second surface. Since it was not clear whether or not these features had the same meaning, claim 6 was not clear.

Inventive step - claim 1

D9 disclosed an implantable prosthesis with a barrier layer according to claim 1. Starting from this prosthesis, the object underlying the invention according to claim 1 was to be seen in limiting the formation of adhesions.

This object was achieved by providing a peripheral barrier in accordance with claim 1.

The problem of adhesion formation at the outer peripheral edge of the prosthesis was well known in the

art, as shown by D7 and D8. Therefore, the person skilled in the art would have tried to protect said edge by some kind of barrier. Looking for a way of realising said barrier he would have considered D5, which also dealt with the problem of adhesions. This document disclosed, in column 2, lines 38-46, that a material with non-adherent characteristics could be formed by a process comprising fusing a resin. Therefore, it was obvious to achieve said object by providing a peripheral barrier formed by melting and re-solidifying an outer margin of the repair fabric to render it substantially impervious to tissue ingrowth.

Hence, the subject-matter of claim 1 did not involve an inventive step.

Inventive step - claim 6

D1 disclosed an implantable prosthesis with a barrier layer according to claim 6 which, in order to protect the prosthesis from visceral contacts, projected beyond the prosthesis.

Starting from this prosthesis, the object underlying the invention according to claim 6 could also be seen in limiting the formation of adhesions in an implantable prosthesis.

This object was achieved by a peripheral barrier in accordance with claim 6.

D7 dealt with the problem of adhesions and taught folding the prosthesis and the leaf of the hernial sac,

which acted as a protective barrier to limit the formation of adhesions.

With respect to this teaching, it was obvious to take the portion of the barrier projecting beyond the prosthesis shown in D1 and to fold it around the repair fabric to form a protective peripheral barrier.

Hence, the subject-matter of claim 6 did not involve an inventive step either.

- X. The arguments of appellant 1 can be summarised as follows:

Admissibility of the new main request

Although the claims according to the new main request had been submitted only with letter dated 21 June 2011, they were essentially based on the granted claims. Therefore, they could not have taken appellant 2 by surprise and should be admitted into the proceedings.

Rule 80 EPC

The two independent claims were directed to two alternative embodiments which fell under the scope of granted claim 1. The amendments were to be considered as occasioned by grounds of opposition, in particular those defined in Article 100(a) EPC, in compliance with Rule 80 EPC.

Article 123(2) EPC

Although the application as filed did not literally disclose that the peripheral barrier extended between the first and the second surface, this arrangement was present in all the embodiments shown in the figures, which depicted a barrier that completely covered the edge extending from the first surface to the second surface. Therefore, the claims had been amended in compliance with Article 123(2) EPC.

Article 84 EPC 1973

The feature that the peripheral barrier extended between the first and second surfaces clarified that the barrier completely covered the edge of the repair fabric, from the first surface to the second surface, as shown in the figures. Therefore, this feature did not render the claims unclear.

In claim 6 the above feature was not merely repeated but was further defined by the features relating to the particular way of forming the peripheral barrier. Accordingly, no lack of clarity was introduced in claim 6.

Inventive step - claim 1

Starting from the prosthesis disclosed in D9, whose outer peripheral edge was completely exposed to tissue ingrowth, the object underlying the invention according to claim 1 was in fact to limit the formation of adhesions.

Said object was achieved by the provision of a peripheral barrier in accordance with claim 1.

This was not rendered obvious by the prior art. It was true that the problem of adhesion formation was known from D7 and D8. However, these documents did not propose solving it by providing a peripheral barrier, but by adopting specific surgery techniques.

Document D5 was even less relevant, since it related to a different technical field, namely surgical dressings, and did not mention the problem of limiting the formation of adhesions in an implantable prosthesis at all. Moreover, in D5 the material which was fused was not the repair fabric and the fused portion did not protect the edge of the dressing.

Accordingly, the subject-matter of claim 1 involved an inventive step.

Inventive step - claim 6

Starting from the prosthesis disclosed in D1, it was true that the object underlying the invention according to claim 6 was to limit the formation of adhesions in an implantable prosthesis.

This object was achieved by providing a peripheral barrier according to claim 6, formed by wrapping the outer margin of the barrier layer about the outer peripheral edge of the repair fabric.

The prior art did not render it obvious to achieve said object according to claim 6. Neither D1 nor D7

disclosed a peripheral barrier, let alone its use to achieve said object.

Therefore, the subject-matter of claim 6 also involved an inventive step.

Reasons for the Decision

1. The appeals are admissible.
2. Admissibility of the main request

According to Article 13(1) of the Rules of Procedure of the Boards of Appeal (Supplement to OJ EPO 1/2011, page 38), 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 (see also Article 114(2) EPC 1973). That discretion is to be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

In the present case the independent claims are in essence directed to embodiments which were covered by granted claim 4 (present claim 1) and granted claims 8 and 9. Moreover, they were submitted one month in advance of the oral proceedings.

It is true that, despite corresponding in essence to requests which were already the subject of the appealed decision, they were not filed at the beginning of the appeal proceedings. However, no abuse of the procedure can be seen in this in the present case, especially

since appellant 2 itself amended its case in submitting with letter dated 9 June 2011 that the claimed subject-matter lacked inventive step starting from D1, an argument which, despite having been submitted in the opposition proceedings, was comprised neither in the statement of the grounds of appeal nor in the reply to the grounds of appellant 1.

Under these circumstances, claims 1 to 27 according to the second auxiliary request (now main request) submitted with letter dated 21 June 2011 were admitted into the appeal proceedings.

3. Rule 80 EPC

According to Rule 80 EPC the description, claims and drawings of a European patent may be amended, provided that the amendments are occasioned by a ground for opposition.

In the present case granted claim 1 covered a number of alternative embodiments concerning different ways of realising the peripheral barrier (see Figures 3,6 and 8-10 of the patent as granted). The two independent claims now under consideration cover two of those alternative embodiments, and restrict the scope of the claimed invention. Since the presence of two different independent claims is necessary to cover said two embodiments, the amendments are an appropriate and necessary response designed to avoid revocation of the patent on the ground that the subject-matter of claim 1 as granted was not novel or did not involve an inventive step. Therefore, they are clearly occasioned by a ground for opposition.

4. Article 123(2) EPC

Both independent claims have been amended to recite that the peripheral barrier extends between the first and the second surface.

This wording was not literally disclosed in the application as filed. However, all the embodiments shown in the drawings exhibit a barrier that completely covers the edge extending from the first surface to the second surface, i.e. a barrier extending between said two surfaces. Therefore, the amendment under consideration is directly and unambiguously derivable from the application as filed.

5. Article 84 EPC1973

- 5.1 Appellant 2 argued that the wording "the peripheral barrier extending between said first and second surfaces" introduced a lack of clarity into claims 1 and 6, since it may be interpreted to mean either that said barrier extended through the thickness of the fabric or that it is into contact with both surfaces of the fabric.

A peripheral barrier extending between the first and the second surfaces is to be understood as a barrier which completely covers the edge extending from the first surface to the second surface. This is in accordance with the embodiments shown in Figures 3, 6 and 8 to 10 of the application and covers both the interpretations proposed by appellant 2. Accordingly,

it does not introduce a lack of clarity into the claims.

- 5.2 Claim 6 has been further amended to state that the peripheral barrier is formed from the outer margin of the barrier layer, said outer margin of the barrier layer being wrapped about said portion of the outer peripheral edge of the repair fabric so that it extends from the first surface and across the thickness of the outer peripheral edge of the repair fabric, the outer margin of the barrier layer also extending over a portion of the second surface of the layer of repair fabric adjacent the outer peripheral edge.

Contrary to the view of appellant 2, this feature is not a mere repetition of the feature that the peripheral barrier extends between the first and the second surface, but defines how this is realised in a specific case. Therefore, those two features are not equivalent and the presence of both of them in the claim does not cause a lack of clarity.

6. Inventive step - claim 1
- 6.1 D9 undisputedly discloses an implantable prosthesis (10) for repairing a tissue or muscle wall defect, the implantable prosthesis comprising: a layer of repair fabric (12) that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including a first surface, a second surface, and an outer peripheral edge; a barrier layer (14) that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion

of the first surface and adjacent tissue and organs (see claim 1).

- 6.2 Starting from the prosthesis disclosed in D9, the object underlying the invention according to claim 1 is to be seen in further limiting the formation of adhesions in an implantable prosthesis.

This object is achieved in accordance with claim 1 by providing a peripheral barrier that inhibits the formation of adhesions with tissue and organs, the peripheral barrier extending between the first and second surfaces about at least a portion of the outer peripheral edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs, wherein the peripheral barrier includes an outer margin of the layer of repair fabric, wherein the outer margin has been melted and resolidified to render the portion of the outer peripheral edge of the layer of repair fabric substantially impervious to tissue ingrowth. While in the prosthesis according to D9 the outer peripheral edge is completely exposed to tissue ingrowth, in the patent at least a portion of it is covered by a peripheral barrier which prevents the formation of adhesions.

- 6.3 It is true that the problem of the formation of adhesions at the outer peripheral edge of the prosthesis is known from D7 and D8. However, these documents do not mention any peripheral barrier and tackle this problem by adopting specific surgical

techniques. Therefore, they cannot suggest the achievement of the above object according to claim 1.

As to D5, this document does not relate to an implantable prosthesis, but to a surgical dressing. Therefore, the person skilled in the art would not have taken it into consideration in order to achieve the above object starting from D9, which relates to an implantable prosthesis for reinforcing the abdominal wall and close abdominal wall defects (see column 1, lines 16-23).

Moreover, even considering for the sake of argument that he would have consulted this document, he would have found no teaching hinting at the claimed invention. It is true that D5 discloses fusing a resin to form a barrier layer against adhesions (see column 2, lines 42-46). However, the material which is fused in D5 is not the repair fabric and the fused portion does not protect the edge of the dressing. This function is rather realised by the crown or frame 12, which is applied in a step subsequent to the fusing step (see column 2, lines 51-60). Therefore, D5 cannot render it obvious to form a peripheral barrier by melting and solidifying an outer edge of the repair fabric.

Accordingly, the subject-matter of claim 1 involves an inventive step.

7. Inventive step - claim 6

7.1 D1 discloses an implantable prosthesis for repairing a tissue or muscle wall defect, the implantable

prosthesis comprising: a layer of repair fabric (2) that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including a first surface (5), a second surface (4), and an outer peripheral edge; a barrier layer (5) that inhibits the formation of adhesions with tissue and organs, the barrier layer having an outer margin and being configured to inhibit the formation of adhesions between at least a portion of the first surface and adjacent tissue and organs.

- 7.2 Starting from the prosthesis disclosed in D1 the object underlying the invention according to claim 6 is to be seen again in further limiting the formation of adhesions in an implantable prosthesis.

This object is achieved by providing a peripheral barrier that inhibits the formation of adhesions with tissue and organs, the peripheral barrier extending between said first and second surfaces about at least a portion of the outer peripheral edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs, wherein the peripheral barrier is formed from the outer margin of the barrier layer, said outer margin of the barrier layer being wrapped about said portion of the outer peripheral edge of the repair fabric so that it extends from the first surface and across the thickness of the outer peripheral edge of the repair fabric, the outer margin of the barrier layer also extending over a portion of the second surface of the layer of repair fabric adjacent the outer peripheral edge.

7.3 The prior art does not render it obvious to achieve said object according to claim 6.

D1 itself teaches, in order to protect the prosthesis from visceral contacts, the use of an absorbable film which projects beyond the prosthesis and which is intimately linked to the fabric by surface penetration so as not to constitute a plane of division or delamination (see page 8, lines 7-16). Therefore, it teaches away from wrapping an outer margin of the barrier layer about a portion of the outer peripheral edge of the repair fabric to form a peripheral barrier layer, as such peripheral barrier layer would not be linked to the fabric by surface penetration.

D7 cannot teach forming the peripheral barrier from the outer margin of the barrier layer either, since the prosthesis shown in this document has no barrier layer at all.

In view of these considerations, an inventive step is also acknowledged for the subject-matter of claim 6.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of the first instance with the order to maintain the patent on the basis of the following documents:
 - claims 1 to 27 according to the second auxiliary request (now main request) submitted with letter dated 21 June 2011;
 - description columns 1 to 8 and Figures 1 to 7 as filed during oral proceedings.

The Registrar:

The Chairman:

V. Commare

T. Kriner