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**Datasheet for the decision  
of 9 September 2009**

**Case Number:** T 1925/06 - 3.2.02

**Application Number:** 96919276.4

**Publication Number:** 0830110

**IPC:** A61F 2/06

**Language of the proceedings:** EN

**Title of invention:**

Externally supported tape reinforced vascular graft

**Patentee:**

Edwards Lifesciences Corporation

**Opponent:**

Vascutek Limited

**Headword:**

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**Relevant legal provisions:**

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**Relevant legal provisions (EPC 1973):**

EPC Art. 83, 52, 56

**Keyword:**

"Insufficiency of disclosure (no)"  
"Inventive step (yes)"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 1925/06 - 3.2.02

**DECISION**  
of the Technical Board of Appeal 3.2.02  
of 9 September 2009

**Appellant:** Vascutek Limited  
(Opponent) Newmains Avenue, Inchinnan  
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**Representative:** Ouzman, Beverly Nicola Claire  
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**Respondent:** Edwards Lifesciences Corporation  
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**Representative:** Probert, Gareth David  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
26 October 2006 concerning maintenance of  
European patent No. 0830110 in amended form.

**Composition of the Board:**

**Chairman:** M. Noël  
**Members:** P. L. P. Weber  
A. Pignatelli

## Summary of Facts and Submissions

I. The appeal is filed by the opponent against the decision of the opposition division dated 26 October 2006 that account being taken of the amendments according to the 1st auxiliary request made by the proprietor of the patent during the opposition proceedings, the patent and the invention to which it relates were found to meet the requirements of the convention.

The notice of appeal was filed on 21 December 2006 and the appeal fee paid on the same day.

The statement setting out the grounds of appeal was filed on 2 March 2007.

II. The following documents were cited by the parties:

- D1: English language translation of JP Patent Application No. 49-22792,
- D2: US-A-3479670
- D3: US-A-5061276
- D4: EP-A-0232543
- D5: US-A-3962153
- D6: US-A-4187390
- D7: US-A-4306318
- D8: WO-A-8800813
- D9: Advertisement from Gore Industries
- D10: Printout from Bard/Impra website  
<http://www.bardimpra.com/about/tech.cfm>
- D11: Copy of Declaration by Craig Dunlop as to the Impra TAPERFLEX graft

- D12: Copy of Declaration by Craig Dunlop as to the  
Impra TAPERFLEX graft (27.03.03)
- D13: WO-A-9505277
- D14: First Declaration of Donald B. Reid (not dated)
- D15: Schematic illustration of different grafts
- D16: Declaration of Louie Seiler (23.08.06)
- D17: Instructions for use for GORE-TEX vascular grafts
- D18: Declaration of Daniel McCoy (25.09.06)
- D19: First Declaration of Donald Shannon (25.09.06)
- D20: Article by D.B. Reid and J.G. Pollock: "A  
Prospective Study of 100 Gelatin-Sealed Aortic  
Grafts"
- D21: Extract from the programme of EVC 2006
- D22: Second Declaration of Donald Shannon along with  
Experimental Data (Exhibit A) (08.03.07)
- D23: Third Declaration of Donald Shannon (07.08.09)
- D24: Second Declaration of Mr Donald B. Reid (01.09.09)

III. Oral proceedings took place on 9 September 2009, in the course of which the respondent (proprietor of the patent) withdrew its objection raised in reply to the statement setting out the grounds of appeal that the appeal was not admissible.

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

The respondent requested as main request that the appeal be dismissed or that the patent be maintained on the basis of claims 1 to 14 of the auxiliary request 1 or of claims 1 to 16 of the auxiliary request 2 or of claims 1 to 16 of the auxiliary request 3, all filed with letter of 19 September 2007.

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

"An externally supported, tape-reinforced, tubular prosthetic graft comprising:

a tubular base graft (10) formed of expanded, sintered fluoropolymer, said tubular base graft (10) having an inner luminal surface and an outer surface;

a strip of reinforcement tape (14) helically wrapped around the outer surface of the tubular base graft (10) in a first helical pitch, said strip of reinforcement tape (14) having an inner surface which is in abutment with the outer surface of the tubular base graft (10), and an outer surface;

and an external support member (18);

characterised in that

the external support member (18) is formed of non-elastic fluoropolymer beading, and is helically wrapped around the outer surface of the reinforcement tape (14) in a second helical pitch which is different from the first helical pitch of said reinforcement tape (14)."

Method claim 6 of the main request reads as follows:

"A method of manufacturing an externally-supported, tape-reinforced, tubular prosthetic graft, said method comprising the steps of:

a) providing a tubular base graft (10) formed of expanded, sintered fluoropolymer material, said tubular

base graft having an inner luminal surface and an outer surface;

b) providing at least one strip of reinforcement tape (14) formed of expanded, sintered fluoropolymer film;

c) wrapping said reinforcement tape (14) helically around the outer surface of the tubular base graft (10) in a first helical pitch;

d) causing the helically wrapped reinforcement tape (14) to become attached to the tubular base graft (10);

e) providing an external support member (18) formed of non-elastic fluoropolymer beading;

f) helically wrapping the external support member (18) around the helically wrapped reinforcement tape (14) in a second helical pitch which differs from said first helical pitch; and,

g) causing the helically wrapped external support member (18) to become attached to the helically wrapped reinforcement tape (14).

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

Insufficiency of disclosure

The wording of claim 1 was extremely broad as it covered a multiplicity of combinations for which no specific embodiment could be found in the description

so that it was not possible to carry out the invention across the whole claimed range.

No details were given in the patent as to the conditions required for heat laminating the non-elastic fluoropolymer beading to the tape. A general reference to the use of a heating apparatus without mentioning suitable temperature and time was not sufficient to obtain the alleged effect. In order to be able to peel away the beading without causing concurrent peeling or fraying of the underlying reinforcement tape it was clear that the degree of bonding required between the beading and the tape layer was the critical element. However, the patent specification was silent on this requirement. The person skilled in the art was therefore faced with the task of conducting a significant amount of experimentation to try and obtain the desired effect.

The reference in claim 1 to a tubular base graft formed of "expanded, sintered fluoropolymer" generally was too broadly formulated as the only example given in the whole patent specification was the use of ePTFE and the person skilled in the art was not aware of any other expanded sintered fluoropolymer material to be placed into a vascular graft.

The different claimed helical pitches were supposed to bring the desired effect of avoiding peeling or fraying. However, extensive testing not only showed that the effect could not be obtained over a significant portion of the range covered by the claim, but also when the reinforcement tape was heated prior to the application of the beading, the bond strength of the beading to the

reinforcement tape was higher than the attachment strength of the tape to the underlying graft, with the unwanted result of peeling away the reinforcement tape. A lot of parameters had to be considered before the desired result was possibly obtained. The present patent specification did not provide the person skilled in the art with sufficient information to reliably succeed over the whole claimed breadth.

#### Inventive step

The graft disclosed in document D9 was similar to that claimed, with the exception that external annular rings were provided in D9 instead of a helically wrapped monofilament bead in the present patent.

The graft disclosed in this document was functionally equivalent to the claimed graft as was supported by the declarations of Mr Reid (D14) and Mr Seiler (D16). As also in this graft the external support member could be peeled off without concomitant peeling of the underlying tape (see D14) the problem of freely peeling away the external support member as set out in the patent had already been solved. The problem addressed by the claimed graft therefore resided only in the provision of an alternative form of external support. Helically wound external support members on vascular grafts were well-known in the art (see for instance D2, D3, D7, D8 and D10), as was admitted in the patent. The claimed graft was thus a clear and simple alternative to the graft of D9, readily available to the person skilled in the art.



The subject-matter of claim 1 was also not inventive starting from the graft known from D1. The claimed graft differed therefrom by the provision of an additional external helically wrapped support member to prevent kinking of the tubular graft.

The problem addressed by the claimed graft thus could be seen in the provision of means in order to reduce or prevent collapse or kinking of the graft.

The provision of a support member helically wrapped around the outer surface of the reinforcement tape, and the use of a non-elastic fluoropolymer for making such support member, was, however, obvious in view of the teaching of documents D8 or D2 which suggested the use of polypropylene. No unexpected advantages were obtained from the substitution of polypropylene by fluoropolymer.

The subject-matter of claim 1 therefore did not involve any inventive step.

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

Insufficiency of disclosure

According to the case law sufficiency was denied only in case of serious doubts. Moreover the burden of proof lay with the opponent.

In several prior art documents it was mentioned that when it came to bonding together layers of near materials, heating time and temperature were important,

as was also mentioned for instance in paragraphs 38 and 42 of the patent specification. The person skilled in the art knew that these parameters were important for obtaining a specific bonding strength between the two layers and no doubt that these principles were also applied when it came to bonding the beading filament to the reinforcement tape.

The tests carried out by the opponent were made at a single temperature and for a single period of time. Nevertheless they showed that the invention was feasible since at least some of the grafts exhibited the desired effect. In addition it had to be noted that not all the embodiments falling under the wording of a claim had to show the same degree of success for an invention to be capable of being carried out. The invention, therefore, was sufficiently disclosed.

#### Inventive step

Starting from the graft according to D9 claim 1 differed in that a spiral was used instead of rings and this spiral was wound at a winding angle different to that of the reinforcement tape. As was apparent from the declaration by Mr McCoy (D18) the use of a helical external support was quite different from the use of a ringed support. There was no reason why a person skilled in the art would consider replacing the rings by a helically wound beading. In order to solve the fraying problem the author of D9 chose to retain the tape reinforcement graft with rings and later made them easier to remove by using an attachment film as taught in D17. The allegations of the appellant were, therefore, inconsistent. In D2 the different layers of

mono filaments were fused together and to the underlying graft so that they could not be selectively peeled from each other.

Starting from D1 there was no obvious way to arrive at the invention. The vascular grafts of D1 comprise a basis graft of ePTFE which was wrapped with an ePTFE reinforcement tape. The graft shown in D2 was of a completely different material, namely of fabric comprising knitted Dacron or Teflon, so that it was not apparent why a person skilled in the art would choose to look to D2 at all and if he did so he could not arrive at the invention as D2 taught to melt the filaments so that they flowed into the interstices of the knitted fabric.

Also document D8 was concerned with a fabric tube so that it did not suggest the invention either.

## **Reasons for the Decision**

1. The appeal is admissible.
2. *Sufficiency of disclosure*
  - 2.1 The appellant considers that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. It considers that
    - (i) no details were given in the patent of the conditions required for heat laminating the non elastic fluoropolymer beading to the tape in such a manner that the desired effect was obtainable,

(ii) only one example of "expanded sintered fluoropolymer" was given in the patent description, so that the invention cannot be performed over the whole claimed range,

(iii) according to the claimed subject-matter, the helical pitch of the external bead should be "different" from the helical pitch of the reinforcement tape, however extended testing with different angles showed that the expected advantage could not be achieved across a significant range covered by the claims.

2.2 In the Board's view the claim recites all the features which are necessary for obtaining the desired effect and the description gives the skilled person enough information for carrying out the invention by making some reasonable testing.

What is claimed is a tubular prosthetic graft so that already this information teaches the person skilled in the art that all materials which are not suitable for use as a prosthetic graft and all the bonding strengths between the different layers which are not satisfactory for making a prosthetic graft are to be excluded from the protection. In particular insufficient bonding strength between the layers might lead to hazardous separation of the layers when the prosthetic graft is placed into the body. This cannot have been reasonably meant. The same is true for expanded sintered fluoropolymers or non-elastic fluoropolymers which might not be usable for prosthetic grafts.

The patent teaches the skilled person that by wrapping the external support member around the reinforcement

layer with a different helical pitch to that used for the reinforcement layer, peeling or fraying of the reinforcement tape from the adjacent end portions of the tubular graft, as recited in paragraph [0008] of the patent, could be avoided.

More precisely the patent teaches at several places (see for example the paragraphs [0039] or [0041] of the description) that the second pitch has to be substantially **different from** or **opposite** to the first one.

In paragraph [0041] it is further specified: "*In some embodiments, such as the embodiment shown in Figures 3-4, the size of the angles A1 and A2 at which the tape 14 and reinforcement member 18 are applied to the base graft 12 may be of **differing** or equivalent size, but the direction of the angles will be **opposite** one another, thereby resulting in **differing** helical configurations or pitch of the tape 14 and external support member 18. In other embodiments the directions of the angles A1 and A2 may be the same, but the angular size of such angles A1 and A2 will differ, thereby resulting in directionally similar but **different** helical configurations or pitches of the reinforcement tape 14 and external support member 18.*" (bold added).

Therefore, it is clear from the description what is meant under "different helical pitches" or similar expressions.

Further it is stated at the end of paragraph [0040] that "*Typically, the helical configuration or pitch of*

*the external support member 18 will remain constant for each size of the graft.*" Therefore, the selected pitch depends on the size of the graft.

It is consistent case law that the wording of a claim has to be read in the light of the whole patent specification and in particular in the context of the disclosed invention. It results that the word "different" in claim 1 has to be interpreted in such a way that helical pitches which are nearly similar for the reinforcement tape and the beading and which both extend in the same direction are not meant (or are excluded).

The extent to which the helical pitches are "different" or "opposite", remains to be determined experimentally by the skilled person but it is to be noted that the appellant himself proved that at least for some of its experimental grafts it was possible to obtain the desired effect on the basis of the features of claims 1 and 6 (cf. declaration of Mr Shannon of 8 March 2007 D22 with attached Exhibit A).

- 2.3 As to the lamination of the external support member onto the reinforcement tape, the board considers as sufficient the mention in the description that the beading is heat-laminated to the outer surface of the reinforcement tape (see paragraph [0042] of the patent specification). The skilled person is able on the basis of his technical knowledge to adjust the parameters of the lamination, in particular the temperature and duration, to obtain the desired effect, following in this respect the example given in paragraphs [0036] to [0038] of the patent dealing with the previous step of

laminating the reinforcement tape onto the tubular base graft.

It should be remembered here that sufficient disclosure does not require the patent specification to give all detailed information about every possible embodiment falling within the scope of the claim. The skilled person is expected to use his common general knowledge and routine techniques to perform the invention and so to put the invention into practice without undue burden.

2.4 Finally the Board considers that while the applicant has described an embodiment of the graft using ePTFE, in the absence of any evidence to the contrary there is no reason to believe that another expanded sintered fluoropolymer would not be suitable. As mentioned above the skilled person will only consider the materials suitable for the manufacture of prosthetic graft and ignore the others.

2.5 Hence in the Board's judgement the invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Therefore, the requirements of Article 83 EPC are met.

### 3. *Inventive step*

3.1 The appellant considered the subject-matter of claim 1 not inventive starting either from D9 or D1 as closest prior art.

3.2 In the Board's opinion D9 must be considered as the closest prior art since the reinforced vascular graft described therein has all the features contained in the

first part of claim 1 and additionally an external support member in the form of rings. The prosthetic graft of D1 does not have any external support member at all.

The prosthetic graft according to D9 has rings made of FEP (fluorinated ethylene-propylene) as external reinforcement member. The graft according to the claimed invention differs therefrom in that "the external support member (18) is formed of non-elastic fluoropolymer beading, and helically wrapped around the outer surface of the reinforcement tape (14) in a second helical pitch which is different from the first helical pitch of said reinforcement tape (14)."

The provision of a spirally wrapped beading instead of spaced rings clearly gives more flexing resistance and more column strength to the graft and the fact of using a pitch different from the pitch of the reinforcement tape diminishes the risk of fraying or peeling of the reinforcement tape from the tubular graft when the outer spirally wound beading is removed from the tape at the extremities of the graft for suturing the reinforced graft to the patient vascular system.

The problem solved by the invention resides in the provision of an improved graft reducing the risk of peeling or fraying when the external support member is partly removed at the ends of the graft, as recited in paragraph [0009] of the patent specification.

While it is known (and accepted by the respondent) to place spirally wound external support members on spirally reinforced grafts, none of the documents cited



in the appeal proceedings suggests using different pitches within the meaning of the present patent, as demonstrated in point 2.2 above.

D2 shows a graft made of a knitted fabric tube on which two filaments (not a reinforcement tape and an external support member) are successively wound with different pitches and are then melted together to form a rigid, integral grid that is united with the fabric tube. (see col. 2 lines 36 to 53). Supposing this document were nevertheless considered by a person skilled in the art, it could only suggest melting two filaments onto a base graft. But the above mentioned problem of avoiding peeling or fraying of the reinforcement tape from the graft of D9 would not be solved by the teaching of D2.

The appellant tries to demonstrate that the problem of peeling and fraying which is mentioned in the patent as the problem to be solved did not actually exist and that spiral beading and circumferential rings were equivalent (see the second declaration of D. Reid, point 3 and the declaration of L. Seiler, points 4 and 5).

The Board does not accept this argument. The appellant himself, in order to prove insufficiency, has made tests which clearly show that peeling and fraying was a problem when it came to declare that it could not find the proper winding angle and the proper binding of the layers for a majority of samples, in order to avoid fraying. In addition even its expert (see declaration of L. Seiler, point 8) accepts that the winding of the beading at a different pitch diminishes the risk of peeling the underlying tape.

3.3 The appellant alleged that the subject-matter of claim 1 would not be inventive when starting from D1. The Board considers that even if the person skilled in art wanted to improve the kinking and crush resistance of this known graft only comprising a base graft and a reinforcement tape but no external support member, there is no incentive whatsoever in the cited prior art which would lead the person skilled in the art to adopt the solution of claim 1 of the patent in suit.

The numerous cited documents show various graft embodiments, but none of them suggests using a different pitch for wrapping the external support member onto the underlying reinforcement tape also helically wrapped on the tubular graft.

In particular the documents cited by the appellant do not hint to the solution of claim 1. For instance D8 shows a knitted graft reinforced by a polypropylene support member helically wrapped around it and fused thereto. Fig.3b shows a double helix wrap, but as in D2 the two filaments are fused to one another and to the underlying knitted graft. D8 even suggests to have the support less extensive at the ends of the graft so as to facilitate working with the graft for implant purposes (see page 11, lines 10 to 15) which is thus a solution different from providing a different helical pitch as proposed in claim 1 of the patent in suit.

The graft of D3 has no reinforcement tape and there is no suggestion whatsoever to make the fiber windings removable at the ends of the graft. On the contrary it is considered that the ends of the grafts which receive

the greatest amount of stress should be provided with a higher number of fiber windings (see col.19, lines 14 to 27). The same is true for the graft of D7 on which the elastic fibers are bond and heat-set (see col.2 lines 1 to 8, col.3, line 62 to col.4, line 4) to increase the mechanical properties in particular at the ends of the graft where suturing takes place (see col.4 lines 55 to 59). The Impra-Flex graft of D10 does not show more.

3.4 It results from the foregoing that the subject-matter of claim 1 of the main request involves an inventive step within the meaning of Article 56 EPC.

3.5 The independent method claim 6 defines all the steps which are necessary for manufacturing the prosthetic graft of claim 1, including helically wrapping the external support member around the helically wrapped reinforcement tape, thereby applying a different helical pitch (feature (f)).

Therefore, the same considerations and conclusions made above for the device apply similarly to the method claim which also involves an inventive step.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

D. Sauter

M. Noël