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Datasheet for the decision of 12 January 2016

Case Number: T 2159/13 - 3.2.08

Application Number: 02756942.5

Publication Number: 1420717

IPC: A61F2/04

Language of the proceedings: EN

Title of invention:
SELF-SUPPORTING METALLIC IMPLANTABLE GRAFTS

Patent Proprietor:
Advanced Bio Prosthetic Surfaces, Ltd.

Opponent:
Acandis GmbH & Co. KG

Headword:

Relevant legal provisions:
EPC Art. 100(a)
CBE Art. 56

Keyword:
Admissibility of appeal - (yes)
Inventive step - (no) - auxiliary request (yes)

Decisions cited:

Catchword:

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Case Number: T 2159/13 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 12 January 2016

Appellant: (Patent Proprietor)	Advanced Bio Prosthetic Surfaces, Ltd. 4778 Research Drive San Antonio, TX 78240 (US)
Representative:	Conroy, John Fish & Richardson P.C. Highlight Business Towers Mies-van-der-Rohe-Straße 8 80807 München (DE)
Respondent: (Opponent)	Acandis GmbH & Co. KG Kolpingstrasse 5 76327 Pfinztal (DE)
Representative:	Kilchert, Jochen Meissner, Bolte & Partner GbR Widenmayerstrasse 47 80538 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 12 August 2013 revoking European patent No. 1420717 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	C. Herberhold
	D. T. Keeling

Summary of Facts and Submissions

I. By its decision posted on 12 August 2013 the Opposition Division revoked European patent EP-B-1420717.

II. The Opposition Division held that the ground of opposition under Article 100(c) EPC prejudiced the maintenance of the patent as granted. The auxiliary requests were found to not fulfil the requirements of Article 123(2) EPC or of Article 56 EPC (auxiliary request 2 then on file, corresponding to auxiliary request 10 of the appeal procedure).

III. The appellant (patent proprietor) lodged an appeal against that decision on 11 October 2013, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 5 December 2013.

IV. Oral proceedings before the Board of Appeal were held on 12 January 2016.

As announced in its letter dated 10 December 2015 the respondent (opponent) did not attend the oral proceedings. In accordance with Rule 115(2) EPC and Article 15(3) RPBA the proceedings were held in the respondent's absence.

At the end of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the 10th Auxiliary Request filed with the grounds of appeal dated 4 December 2013 or, in the alternative, on the basis of the Auxiliary Request

filed at the oral proceedings before the Board of Appeal.

The respondent requested - in the written procedure - that the appeal be rejected as inadmissible or that it be dismissed.

V. Claim 1 of the 10th auxiliary request reads as follows:

"An implantable medical graft, comprising:
(a) a tubular graft member comprising a vacuum deposited metal film having a first surface, a second surface and a thickness intermediate the first surface and the second surface wherein said thickness is between 0.1 µm and 75 µm; and
(b) a plurality of slot micro perforations formed in and passing through the thickness of the vacuum deposited metal film and communicating between the first surface and the second surface, wherein the plurality of slot microperforations are capable of undergoing geometric deformation upon application of a sufficient force and consist of generally elongated slots with terminal fillets on opposing ends of each elongated slot."

VI. Claim 1 of the auxiliary request filed during the oral proceedings differs from claim 1 of the 10th auxiliary request in that the graft is claimed as part of an implantable covered stent, the graft concentrically covering and coupled to the stent.

The exact wording is as follows (amended parts are underlined):

"<u>An implantable covered stent, comprising an implantable medical graft concentrically covering and</u>

coupled to a stent, the implantable medical graft comprising:
(a) a tubular graft member comprising a vacuum deposited metal film having a first surface, a second surface and a thickness intermediate the first surface and the second surface wherein said thickness is between 0.1 µm and 75 µm; and
(b) a plurality of slot micro perforations formed in and passing through the thickness of the vacuum deposited metal film and communicating between the first surface and the second surface, wherein the plurality of slot microperforations are capable of undergoing geometric deformation upon application of a sufficient force and consist of generally elongated slots with terminal fillets on opposing ends of each elongated slot."

Dependent claim 7 has been deleted and the remaining claims have been renumbered accordingly.

VII. The following documents played a role for the present decision:

E1: WO-A-00/04204;
E2: WO-A-01/53559;
E3: US-A-6,015,433;
E5: JP-A-11104153;
E6: US-A-6,240,616;
E7: US-A-4,657,544;
E8: "Stents versus Coronary-Artery Bypass Grafting for Left Main Coronary Artery Disease," by Seung et al., N. Engl. J. Med. Vol. 358, No. 17 (2008) p. 1781-1792;
E9: "Drug-Eluting Stents vs. Coronary-Artery Bypass Grafting in Multivessel Coronary Disease," by Hannan et al., N. Engl. J. Med. Vol. 358, No. 4 (2008) p. 331 -341;

E10: "Long-Term Safety and Efficacy of Stenting Versus Coronary Artery Bypass Grafting for Unprotected Left Main Coronary Artery Disease," by Park et al., JACC Vol. 56, No. 2(2010) p. 117—24;
E11: "One-year Outcomes of Coronary Artery Bypass Graft Surgery Versus Percutaneous Coronary Intervention with Multiple Stenting for Multisystem Disease: A Meta-Analysis of Individual Patient Data from Randomized Clinical Trials," by Mercado et al., J. Thorac. Cardiovasc. Surg. Vol. 130 (2005) p. 512-9.

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

Admissibility of the appeal

In the statement of grounds the appellant had indicated the reasons for setting aside the decision impugned and the extent to which it was to be amended. The appeal was thus admissible.

"Auxiliary request 10" (now main request) - Inventive step

Claim 1 of "auxiliary request 10" was directed to a tubular implantable medical graft. In the relevant technical field, a clear distinction was made between a "stent", which had diametric load bearing purposes, and a "graft" which exhibited diametric compliance. This could be seen not only from the present patent itself, but further from the use of the terms in prior art documents E1 and E5-E11. Although a broad definition of the term "graft" was used in the description, a narrow definition had to be considered in the case of claim 1. In fact, a tubular graft for the intended vascular use needed to be soft and pliable, the required amount of

flexibility being demonstrated in Figure 7 of the patent.
Hence, a stent, which necessarily had sufficient diametric strength to hold open a lumen and maintain patency of a vessel, could not be considered a reasonable starting point for a development leading to a graft. The combination of the teaching of documents E1 and E3, which both related to stents, could thus not lead to the implantable medical graft defined in claim 1, in particular because E1 could not be considered the closest prior art.

The only prior art document disclosing an implantable graft was E5, which consequently had to be considered the closest prior art. However, said graft did not comprise a vacuum deposited metal film but a woven or knitted polymeric cloth. None of the documents disclosing vacuum deposited metal films gave any indication that these did exhibit the diametric compliance required for a graft. It was thus inventive to provide a graft comprising a vacuum deposited metal film.

Even if E1 was considered to be the closest prior art, the provision of flexibility inducing fillets was contrary to the diametric strength required for a stent and thus non-obvious.

Hence, claim 1 of "auxiliary request 10" was inventive.

Auxiliary request filed during the oral proceedings before the Board

Claim 1 of this request defined an implantable covered stent comprising an implantable medical graft concentrically covering and coupled to a stent. Only

document E5 did disclose such an implantable covered stent, thus undeniably forming the closest prior art. As discussed before, none of the submitted evidence gave any indication towards an implantable medical graft comprising an appropriately compliant vacuum deposited metal film.

Claim 1 of the auxiliary request was thus inventive.

IX. The essential arguments of the respondent - made in the written proceedings - can be summarised as follows:

Admissibility of the appeal

In the statement of grounds the appellant only made reference to the first instance submissions without discussing the relevant arguments of the impugned decision. It could thus not be derived, why the impugned decision was considered erroneous. Hence, the appeal was inadmissible.

"Auxiliary request 10" (now main request) - Inventive step
(see point X of the respondent's reply dated 17 April 2014)

The opposition division had correctly decided that the subject-matter of claim 1 of what is now "auxiliary request 10" was not inventive in view of the combination of the teaching of E1 with E3. In particular, the term fillet defined nothing more than a "rounding". Such a rounding was however known from E3, column 5, lines 16-20 in order to reduce tensile stress. The subject-matter of claim 1 was thus not inventive.

Auxiliary request filed during the oral proceedings before the Board

No objections were put forward by the respondent against said request (which corresponds essentially to the 11th auxiliary request filed with letter dated December 8, 2015).

Reasons for the Decision

1. Admissibility of the appeal

The respondent requests that the appeal be rejected as non-admissible because, in its opinion, the appellant in the statement of grounds only made reference to the first instance submissions without discussing the relevant arguments of the impugned decision (point I of the reply dated 17 April 2014).

This objection is unfounded. Firstly, the requests filed with the statement of grounds are in substance unchanged in comparison with the opposition proceedings. Therefore, arguments made during the first instance proceedings are still of relevance.

Secondly, the grounds (unallowable extension over the application as originally filed, lack of inventive step) and the respective reasoning of the decision are addressed in detail on pages 2-15 of the statement of grounds of appeal, such that it can be immediately understood why the appellant considers the decision to be deficient.

The appeal is thus admissible.

2. "Auxiliary request 10" (now main request) - Inventive step

2.1 Can the devices disclosed in E1 and E3 be considered "grafts" in the sense of the patent?

As discussed in detail during the oral proceedings, the patent itself uses a very broad definition of the term "graft":

Firstly, according to paragraph [0002], lines 33-39 of the patent specification,

"the term "graft" is intended to indicate any type of device or part of a device that comprises essentially a material delimited by two surfaces where the distance between said surfaces is the thickness of the graft and that exhibits integral dimensional strength and that has microperforations that pass through the thickness of the graft" (emphasis added by the Board).

Secondly, as further discussed in paragraph [0037] of the specification, the total open surface area of the graft may be between 0.001 to 99% (column 9, line 58), and both the size of the microperforations in the deformed and undeformed state and the total open area of the graft in the deformed and undeformed state may be selected in view of the following non-exclusive factors based on the graft application:
1) the desired compliance of the graft,
2) the desired strength of the graft,
3) desired stiffness of the graft,
... (column 10, lines 4-14).

Thirdly, an intended use of an implantable member according to the invention as a free-standing

implantable endoluminal vascular graft is explicitly mentioned in paragraph [0040], lines 47-48 of the patent.

It follows from the above passages that a "graft" in the sense of the patent may well be a free-standing tubular object for intravascular use exhibiting a certain stiffness and strength, such as the devices disclosed in documents E1 and E3.

It may be true that the term "graft" is used in a more restricted sense in prior art documents E1 and E5-E11 and that a graft having a higher pliability and flexibility is demonstrated in Figure 7 of the patent. This does however not exclude the broader interpretation of the term in the context of the claim, in particular as this broader interpretation is explicitly envisaged in the patent specification.

The Board thus comes to the conclusion that the devices disclosed in documents E1 and E3 are to be considered implantable medical grafts in the sense of the patent and that E1 may therefore reasonably be considered the closest prior art.

2.2 E1 discloses:

An implantable medical graft (see point 2.1 above), comprising:
(a) a tubular graft member ("stent", see page 7, lines 19-34) comprising a vacuum deposited metal film (page 6, lines 18-22) having a first surface, a second surface and a thickness intermediate the first surface and the second surface wherein said thickness is

between 0.1 µm and 75 µm (page 5, lines 12, 13: 0.0002 inches = 5.08 microns); and
(b) a plurality of slot micro perforations (Figure 1) formed in and passing through the thickness of the vacuum deposited metal film and communicating between the first surface and the second surface, wherein the plurality of slot microperforations are capable of undergoing geometric deformation upon application of a sufficient force and consist of generally elongated slots".

2.3 The subject-matter of claim 1 differs from said disclosure in that terminal fillets are provided on opposing ends of each elongated slot. According to the patent column 11, lines 16-18, the fillets serve a stress relief function, the problem thus being to improve the stress distribution in the graft material through the interperforation regions.

2.4 Document E3, which likewise discloses a tubular intravascular graft (see point 2.1 above) and whose teaching would thus be available to the person skilled in the art dealing with that problem, suggests the provision of radiused endpoints of graft slots, rather than sharply square, which should serve to "minimize stress within the stent during deployment and use" (E3, column 5, line 16-20). Hence, the person skilled in the art would be incited to provide the slots of the E1 graft with "radiused endpoints" in order to solve the problem posed.

E3 relates to a rolled sheet graft very similar to the E1 graft. There is thus no indication that the provision of the radiused endpoints disclosed in E3 would be detrimental to the diametric strength required for the E1 graft as well as for the E3 graft.

2.5 The Board concurs with the Opposition Division that such radiused endpoints do fall under the term fillet. This is supported not only by the Wikipedia citation mentioned in the impugned decision (stating that a fillet was "a rounding of an interior or exterior corner of a part design", see point 12.1.3 of the decision) but also by the following definitions of the term "fillet" in engineering dictionaries: "A concave transition surface between two otherwise intersecting surfaces", McGraw-Hill, Dictionary of Engineering (1984); "The radius formed where two surfaces of a component meet", R. Timmings and P. Twigg, "The pocket illustrated dictionary of engineering terms", Butterworth Heinemann (2001).

2.6 Hence in providing the E1 graft with radiused endpoints - as suggested by E3 - the person skilled in the art arrives at subject-matter falling under the scope of claim 1 of auxiliary request 10, which is consequently not inventive.

3. The auxiliary request filed during the oral proceedings before the Board

3.1 Introduction into the proceedings

The admission into the proceedings of the auxiliary request is subject to the discretionary power of the Board (Article 13(1) RPBA).

The request corresponds, save for the change from a two-part form into a one-part form drafting, to auxiliary request 11 submitted with letter of 8 December 2015, whose introduction into the proceedings was not objected to by the respondent.

The Board itself sees no reason to disregard the present auxiliary request, whose subject-matter corresponds to the combination of claims 1 and 7 of the auxiliary request 2 underlying the appealed decision.

Therefore, the auxiliary request was introduced into the proceedings.

3.2 Articles 123(2), (3), 83 EPC

Claim 1 is based on claim 7 of auxiliary request 10 which overcomes the Article 123(2) and 100(c) objections considered in the impugned decision (see point 11.4) and which due to the use of the amended wording "consist of" in relation to the slot microperforations is restricted in scope with respect to claim 1 as granted.

An implantable covered stent, comprising an implantable medical graft concentrically covering and coupled to a stent was furthermore originally disclosed (see e.g. Figures 6-8 and the corresponding parts of the description as filed). The drawings provide the skilled person with sufficient information for at least one way to carry out the invention, contrary to the respondent's objections raised in the opposition proceedings (see page 7, point g) of the letter dated 27 January 2012). The requirements of Articles 83, 123(2) and (3) EPC are thus met.

3.3 Inventive step

3.3.1 Claim 1 of the request is directed to an implantable covered stent, comprising an implantable medical graft concentrically covering and coupled to a stent.

The closest prior art document should thus relate to an implantable covered stent rather than to a stent or graft in isolation. Document E5, which discloses a stent covered with a knitted or woven polymeric cloth graft, can therefore be considered the closest prior art.

3.3.2 The subject-matter of claim 1 differs from that prior art in that the graft does not comprise a knitted or woven polymeric cloth (see paragraphs [0007] and [0021] of E5) but a vacuum deposited metal film with the thickness and microperforations as defined in the claim.
According to the patent, paragraph [0003] "metals are generally considered to have superior biocompatibility than that exhibited by polymers used to fabricate commercially available polymeric grafts". The problem solved by the claimed invention is thus to improve biocompatibility of the E5 stent covering graft.

3.3.3 In this context the Board agrees with the appellant that the person skilled in the art would not consider the vacuum deposited metal film grafts disclosed in the available prior art documents to have the "fabric-like" pliability and flexibility of the E5 polymeric graft. It is thus considered non-obvious to replace the polymeric graft with a vacuum deposited metal film graft, which further comprises a plurality of slot microperforations which consist of generally elongated slots with terminal fillets on opposing ends of each elongated slot.

With respect to E2 (see the respondent's letter in opposition proceedings dated 27 January 2012, page 11, second paragraph), the very general remark in the last

paragraph of the description stating that "a variety of changes and modifications may be made" to the E2 invention is clearly not sufficient to render the scope of claim 1 of the auxiliary request obvious over said prior art.

3.3.4 Therefore, the subject-matter of claim 1 of the auxiliary request filed during the oral proceedings before the Board involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the following documents:

- Claims 1 to 13 of the Auxiliary Request filed at the oral proceedings;

- Description, columns 1 to 17, filed at the oral proceedings;

- Figures 1 to 10B of the patent as granted.

The Registrar: The Chairman:

C. Moser M. Alvazzi Delfrate

Decision electronically authenticated