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**Datasheet for the decision
of 7 July 2015**

Case Number: T 0256/14 - 3.2.08

Application Number: 01918860.6

Publication Number: 1267749

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Language of the proceedings: EN

Title of invention:
ENDOLUMINAL IMPLANTABLE DEVICES AND METHOD OF MAKING SAME

Patent Proprietor:
Advanced Bio Prosthetic Surfaces, Ltd.

Opponent:
Acandis GmbH & Co. KG

Headword:

Relevant legal provisions:
EPC Art. 123(2), 123(3), 84

Keyword:
Amendments

Decisions cited:

Catchword:



**Beschwerdekammern
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Case Number: T 0256/14 - 3.2.08

**D E C I S I O N
of Technical Board of Appeal 3.2.08
of 7 July 2015**

Appellant: Advanced Bio Prosthetic Surfaces, Ltd.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 29 November
2013 revoking European patent No. 1267749
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairman T. Kriner
Members: M. Alvazzi Delfrate
D. T. Keeling

Summary of Facts and Submissions

- I. By its decision posted on 29 November 2013 the opposition division revoked European patent No. 1 267 749. The Opposition Division was of the view that none of the requests then on file complied with the requirements of Article 123(2) and (3) and Article 84 EPC. No decision was taken on novelty and inventive step, which were also raised as grounds of opposition.
- II. The appellant (patent proprietor) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. At the end of the oral proceedings before the Board of Appeal, held on 7 July 2015, the requests were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or on the basis of one of the auxiliary requests 1, underlying the appealed decision, or 1a filed at the oral proceedings before the Board or 2a, 2b, 2c, 3a, 3b and 3c all filed with letter of 31 March 2014, or 4 to 10 also underlying the appealed decision.

The respondent (opponent) requested that the appeal be rejected as inadmissible, or in the alternative that the appeal be dismissed, that the auxiliary requests not be admitted into the proceedings, and that the case be remitted to the Opposition Division for discussion of the issues of novelty and inventive step, in the event that novelty and inventive step were to be examined.

IV. The independent claims (1 and 23) of the **main request** read as follows:

"1. An endoluminal stent (20), comprising a generally tubular stent member comprised of a plurality of metal structural members (22) separated by a plurality of open regions (24), and a metal graft member (44,54) having a plurality of openings, concentrically engaged upon the generally tubular stent member and extending across each of the plurality of open regions."

"23. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter, comprising the steps of:

- a. providing a substrate having an exterior surface capable of accommodating metal deposition thereupon;
- b. depositing a stent-forming metal onto the substrate by a vacuum deposition method;
- c. etching regions into the deposited stent-forming metal to form a differentiated plurality of structural members (22) and a plurality of open regions (24) between adjacent pairs of the structural members thereby forming a metal graft member extending across each of the plurality of open regions; and
- d. removing the substrate from the endoluminal stent formed thereupon."

Auxiliary request 1 differs from the main request in that claim 1 reads as follows (emphasis added), while independent method claim 23 is unamended:

"1. An endoluminal stent (20), comprising a generally tubular stent member comprised of a plurality of metal structural members (22) separated by a plurality of open regions (24), and a metal graft member (44,54) having a plurality of openings, concentrically disposed engaged upon the generally tubular stent member and extending across each of the plurality of open regions, so as to cover either the luminal or the abluminal surface of the stent, wherein the graft member is mechanically joined to a plurality of structural support members."

Auxiliary request 1a differs from auxiliary request 1 by the deletion of dependent claims 2-7, 10, 17 and 18 and the corresponding renumbering of the claims.

Auxiliary requests 2a to 2c, 3a to 3c and 4 to 10 did not play a role for the present decision.

V. The appellant's arguments can be summarised as follows:

Admissibility of the appeal

The request submitted with the statement of grounds was the same as the main request underlying the appealed decision, i.e. the maintenance of the patent as granted. At least in respect of this request there was no doubt that the appeal was substantiated. Therefore, the appeal was admissible.

Admissibility of the auxiliary requests

Auxiliary requests 1 and 4 to 10 were already part of the opposition proceedings. Therefore, they could not be disregarded.

Auxiliary requests 2a to 2c and 3a to 3c were submitted with the statement of grounds as a reaction to the decision under appeal. As to auxiliary request 1a it did not raise any complex issue, because it merely involved the deletion of some dependent claims. Therefore, auxiliary requests 1a, 2a to 2c and 3a to 3c should also be admitted into the proceedings.

Main request

Claim 1 of the main request was directed to a "stent-graft", wherein the graft member was concentrically engaged upon the generally tubular stent member. This was disclosed on page 19 and in example 8 of the application as originally filed. It was true that these passages appeared to mention two grafts, covering the abluminal and the luminal surface of the stent. However, according to the first sentence on page 19 it was possible to have only one of the proximal or distal graft regions projecting outwardly from the structural support. In this case only one surface of the stent would be covered by the graft. Therefore, also the possibility of a graft covering only one surface was disclosed and claim 1 complied with the requirements of Article 123(2) EPC.

The method of claim 23 did not recite the feature that the graft was concentrically engaged with the stent. Hence, the claimed method was not a mixture of the methods disclosed in the application for the production of "web-stents" and "stent-grafts". Since its steps were all disclosed in the application as filed, claim 23 also complied with the requirements of Article 123(2) EPC.

Auxiliary requests 1 and 1a

In claim 1 the graft member was "concentrically disposed" upon the generally tubular stent member and "mechanically joined" to a plurality of structural support members of the stent. Therefore, it was necessarily concentrically engaged upon the stent member. Accordingly, no feature was deleted from claim 1 and the requirements of Article 123(3) EPC were satisfied.

Moreover, claim 1 also clearly satisfied the requirements of Article 123(2) EPC, because the claimed product, with the mechanically joined graft and structural members and the possibility of covering only one of the luminal and abluminal surface, was described on page 11 of the application as originally filed.

The same applied to claim 23, which corresponded to claim 23 of the main request.

Since the dependent claims objected to in auxiliary request 1 were deleted in auxiliary request 1a, the latter request complied also with the requirements of Article 84 EPC.

VI. The respondent's arguments can be summarised as follows:

Admissibility of the appeal

From the statement of grounds of appeal it was not clear which auxiliary requests were to be considered. Moreover, new auxiliary requests were filed with the statement of grounds, so that it appeared that the

reasoning of the appealed decision was not put into question. Hence the appeal should be found inadmissible.

Admissibility of the auxiliary requests

No substantiation was provided in respect of auxiliary requests 1, 4 to 10 in the statement of grounds of appeal. As to auxiliary requests 2a to 2c and 3a to 3c they were submitted for the first time together with the statement of grounds of appeal, although it would have been possible to submit them at an earlier stage. The same applied to auxiliary request 1a, which was submitted only at the oral proceedings before the Board. Thus, all the auxiliary requests should not be admitted into the proceedings.

Main request

The application as originally filed did not disclose a stent in accordance with claim 1. In particular the embodiment shown in Figures 4 and 5 and described on page 19, lines 3 to 23 and example 8 clearly comprised two grafts, one on the luminal and one on the abluminal surface. As to the first sentence of page 19 and Figure 3 to which it referred, they did not relate to graft members concentrically engaged with the stent. Therefore, claim 1 did not comply with the requirements of Article 123(2) EPC.

The same was true of claim 23, which was a mixture of the methods disclosed for the production of "web-stents", employing the etching step, and "stent-grafts" with the graft concentrically engaged with the stent.

Auxiliary request 1 and 1a

In claim 1 of auxiliary request 1 the feature according to which the graft member is "concentrically engaged" upon the generally tubular stent member had been deleted. Therefore the protection was extended, contrary to the provisions of Article 123(3) EPC.

Moreover, claim 1 was also contrary to the requirements of Article 123(2) EPC since the passage on page 11 upon which it was allegedly based did not describe that the graft and the stent were concentrically disposed and disclosed the mechanical joining only in combination with other features.

In respect of method claim 23 the same objections made for the main request applied.

Finally, in auxiliary request 1 there was a contradiction between claim 1 and dependent claims 7 and 10, so that the requirements of Article 84 EPC were not satisfied.

Reasons for the Decision

1. Admissibility of the appeal

It is undisputed that the main request submitted with the statement of grounds of appeal is for the maintenance of the patent as granted. Moreover, the statement of grounds of appeal explains why, in the appellant's view, the decision of the Opposition Division concerning the patent as granted i.e. the main request was wrong. Hence, it complies with the

requirements of Rule 99(2) EPC, so that the appeal is admissible.

2. Admissibility of the auxiliary requests

2.1 The respondent objected to the introduction of auxiliary requests 1 and 4 to 10 into the proceedings arguing that no substantiation was provided in respect of these requests in the statement of grounds of appeal. However, auxiliary requests 1 and 4 to 10 were requests underlying the appealed decision. Hence, they were already part of the opposition proceedings and, having been resubmitted together with the statement of grounds of appeal, never ceased to be part of the proceedings. Accordingly, the Board has no discretionary power to disregard them. Indeed neither Article 13 RPBA nor Article 12(4) RPBA would grant such power. Hence, auxiliary requests 1 and 4 to 10 are part of the proceedings.

2.2 Auxiliary requests 2a to 2c and 3a to 3c were submitted for the first time together with the statement of grounds of appeal. Accordingly, Article 12(4) RPBA gives the Board the power to hold inadmissible these requests.

However, auxiliary requests 2a to 2c and 3a to 3c attempt to address the objections in view of the dependent claims (under Article 123(2) EPC and Article 84 EPC) of auxiliary requests 2 and 3 underlying the decision under appeal, which were raised for the first time at the oral proceedings before the Opposition Division. Hence, they are considered a reaction to the decision under appeal. Therefore, they are admitted into the appeal proceedings.

2.3 Auxiliary request 1a was submitted at the oral proceedings before the Board. Therefore, its admission into the proceedings is also subject to the Board's discretion (Article 13 RPBA). However, this request differs from auxiliary request 1 solely by the deletion of some dependent claims which have been objected to by the respondent. Hence, it cannot take the respondent by surprise and does not raise any complex new issue which may cause an adjournment or a delay into the proceedings. Under these circumstances, auxiliary request 1a is admitted into the proceedings despite the fact that it was submitted in an advanced phase of the proceedings.

3. Main request - Article 123(2) EPC

3.1 The application as originally filed concerned grafts for increasing the rate at which endothelial cells form after angioplasty (page 2). In particular it disclosed a "graft" embodiment, i.e. a graft with integral strength (pages 3 and 4), a "stent-graft" embodiment, i.e. a stent with a discrete covering (page 2, lines 28-30 and page 4, line 21 to page 5, line 10) and a "web-stent" embodiment, i.e. a stent wherein interstices between the structural members of the stent are subtended by a web (page 5, lines 12 to 25).

3.2 Claim 1 is directed to an endoluminal stent, comprising a generally tubular stent member and a metal graft member "concentrically engaged" upon the generally tubular stent member. Accordingly, claim 1 relates to a stent with a discrete covering, i.e. the so-called "stent-graft" embodiment.

The Opposition Division was of the opinion that the application as originally filed disclosed a stent

member and a metal graft which were concentrically engaged without being necessarily mechanically engaged only for an embodiment which comprised two grafts (a luminal and an abluminal) encapsulating the stent (point 17. of the decision under appeal).

Indeed, both in the embodiment shown in Figures 4 and 5 and described on page 19, lines 3 to 23 and in the embodiment of example 8 described on page 28, lines 4 to 22 the stent-graft comprises a luminal and an abluminal graft.

The appellant cited, as a basis for a single metal graft member concentrically engaged upon a stent member, the first sentence on page 19, according to which either or both the proximal and distal graft regions project outwardly from the structural support. However, this passage refers to Figure 3, which does not show a stent with a graft member concentrically engaged upon it, but a stent with two graft portions extending from its proximal and distal ends. It is true that according to the alternative embodiment illustrated in Figures 4 and 5 and described on page 19, lines 3 to 23 the grafts concentrically engaged with the stent member can be obtained by luminally inverting or abluminally everting a protruding graft portion. However, in this alternative embodiment the stent graft always comprises both an abluminal and a luminal graft which may be formed either by said inversion or eversion step (page 19, lines 6 to 10) or prefabricated and mechanically joined to the stent member (page 19, lines 10 to 17). Accordingly, the passage on page 19 does not provide a basis for the amendment under consideration.

Nor is this basis to be found in example 8, which has also been cited by the appellant, because this example as well relates to a stent with a luminal and an abluminal graft (page 28, lines 16 to 20).

Hence, the application as originally filed does not disclose a stent with only one graft member concentrically engaged upon it without being mechanically joined to the stent. Therefore, claim 1 of the main request comprises subject-matter which extends beyond the content of the application as originally filed.

4. Auxiliary request 1 - Article 123(3) EPC

In claim 1 of auxiliary request 1 the feature according to which the graft member is "concentrically engaged" upon the generally tubular stent member has been deleted from the claim's wording.

However, the claim now requires the graft member to be "concentrically disposed" upon the generally tubular stent member and "mechanically joined" to a plurality of structural support members of the stent. These features imply that the graft is concentrically engaged with the stent. Therefore, the fact that the graft member is "concentrically engaged" upon the generally tubular stent member is, albeit not explicitly stipulated, still inherent in the wording of the claim.

Accordingly, claim 1 has not been amended in such a way as to extend the protection it confers.

5. Auxiliary request 1 - Article 123(2) EPC

- 5.1 Claim 1 of auxiliary request 1 has been amended to recite that the graft member covers either the luminal or the abluminal surfaces of the stent and is mechanically joined to a plurality of structural support members.

The application as originally filed discloses on page 11, last paragraph how a stent graft is provided. According to this passage the graft member is mechanically joined to the plurality of structural support members, and covers that surface of the plurality of structural support members which is to form either the luminal or abluminal surface of the stent-graft device. Since the stent has a generally tubular shape, the graft covering its luminal or abluminal surface must be concentrically disposed upon it. Hence, the application as originally filed discloses a metal graft member concentrically disposed upon the stent member so as to cover either the luminal or the abluminal surface of the stent and mechanically joined to a plurality of structural support members.

It is true that the passage on page 11 also discloses further features, namely that the graft is formed as a film of material and joined to one or both of the proximal and distal ends of the plurality of structural support members. However, for the person skilled in the art it is clear that these features can be dispensed with without altering the function of the stent-graft. This is also apparent in view of the generic definition of a stent graft, which comprises, according to page 4, lines 22-24 a graft member formed as either a thin sheet or a tubular member and mechanically joined to cover a plurality of structural support members.

Therefore, the application as originally filed discloses the features which have been added into claim 1 of auxiliary request 1. Accordingly, this claim complies with the requirements of Article 123(2) EPC.

5.2 It is undisputed that each of the steps of the claimed method is disclosed in the application as originally filed (see for instance pages 5 and 6 or claim 17).

The Board concurs with the respondent that the passage on page 6, lines 15 to 19 discloses the use of etching for the production of a "web-stent". Therefore, it remains to be established whether, as submitted by the respondent, the claim is directed to the production of "stent-graft", thus resulting in a combination of steps which was not originally disclosed.

Claim 23 neither mentions the wording "stent-graft" nor comprises the feature according to which the graft is concentrically disposed about the stent. Steps a, b and d of the claimed process do not define which kind of stent is produced. Step c consists of etching regions into the deposited stent-forming metal to form a differentiated plurality of structural members and a plurality of open regions between adjacent pairs of the structural members, thereby forming a metal graft member extending across each of the plurality of open regions. Hence, the graft member is formed by etching the metal to form the structural members and the open regions between them. In this way the interstices between the structural members of the stent are subtended by a graft. Accordingly, step c and the whole claim relate to a method of forming a "web-stent" (see page 6, first full paragraph).

Therefore, claim 23 complies with the requirements of Article 123(2) EPC.

6. Auxiliary request 1 - Article 84 EPC

As correctly pointed out by the respondent, auxiliary request 1 comprises some dependent claims, for instance claim 7 which defines that the graft member is positioned intermediate the luminal and abluminal surfaces of the structural members, which are in contradiction with claim 1, which requires that the graft member covers either said luminal or abluminal surface. In view of this contradiction, which results from the amendments carried out post-grant, the claims do not comply with the requirements of Article 84 EPC.

7. Further prosecution

The independent claims of auxiliary request 1a correspond to those of auxiliary request 1, which comply with the requirements of Article 123(2) and (3) EPC for the reasons explained above. Moreover, no objection under Article 84 EPC has been raised against this request, which no longer comprises dependent claims in contradiction with the independent claims. Hence, it is necessary, in order to assess the allowability of this request, to examine the other grounds of opposition (lack of novelty and inventive step) which have been raised against the patent.

However, the Opposition Division has not yet taken a decision on these grounds. Therefore, the Board considers it appropriate to exercise its discretion under Article 111(1) EPC by remitting the case for

further prosecution on the base of auxiliary request
1a.

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 for further prosecution.

The Registrar:

The Chairman:



V. Commare

T. Kriner

Decision electronically authenticated