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**Datasheet for the decision
of 16 October 2012**

Case Number: T 0628/09 - 3.3.10

Application Number: 97931425.9

Publication Number: 959813

IPC: A61F2/06

Language of the proceedings: EN

Title of invention:

STENTED, RADIALY EXPANDABLE, TUBULAR PTFE GRAFTS

Patentee:

Edwards Lifesciences Corporation

Opponent:

Jackson, Derek Charles

Headword:

Relevant legal provisions:

EPC Art. 113(1), 100(c), 123(2)

EPC R. 111(2)

Keyword:

Procedural violation (no)

Added subject-matter (yes, all requests)

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T0628/09 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 16 October 2012

Appellant: Edwards Lifesciences Corporation
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted 14
January 2009 concerning maintenance of the
European Patent No. 959813 in amended form.**

Composition of the Board:

Chairman: P. Gryczka
Members: R. Pérez Carlón
D. Rogers

Summary of Facts and Submissions

- I. The present appeal lies from an interlocutory decision of the opposition division to maintain European patent No. EP 0 959 813 in amended form.
- II. An opposition had been filed, on the grounds that the subject-matter of the patent in suit contained added subject-matter (Article 100(c) EPC), that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person (Article 100(b) EPC) and that the subject-matter of the claims was not novel and did not involve an inventive step (Article 100(a) EPC).
- III. The opposition division decided that the subject-matter of claim 1 of the main request (patent as granted) was not novel over the disclosure of document D1, that the subject-matter of the then pending first auxiliary request was not inventive, and that the then pending second auxiliary request fulfilled the requirements of the EPC.
- IV. The patentee (appellant 2) and the opponent (appellant 1) appealed the decision.
- V. Claim 1 of the main request (patent as granted) reads as follows:

"A method for producing a radially expandable and collapsible stented tubular graft (10) comprising the steps of:

- a) providing a stent (14) of generally hollow, cylindrical shape, the stent being initially radially collapsible and subsequently radially*

expandable and having a plurality of radial openings when in the radially expanded diameter;
b) *providing a tubular layer (12, 16) of expanded sintered PTFE, coaxially disposed about the stent or within the stent; **characterized by** the steps of*
c) *depositing polymer particles on the stent and/or on the tubular layer and attaching the stent to the tubular layer."*

VI. Under cover of a letter dated 14 September 2012, appellant 2 submitted auxiliary requests 1 to 6 and 8 to 10; auxiliary request 7 was filed during the oral proceedings before the board, which took place on 16 October 2012.

VII. Claim 1 of all of the auxiliary requests differs from claim 1 of the main request only by feature c), which reads as follows:

First auxiliary request:

"c) depositing polymer particles on the stent and attaching the stent to the tubular layer."

Second auxiliary request:

"c) depositing polymer particles on the stent and on the tubular layer and attaching the stent to the tubular layer."

Third auxiliary request:

"c) depositing polymer particles of PTFE on the stent and/or on the tubular layer and attaching the stent to the tubular layer."

Fourth auxiliary request (as maintained by the opposition division):

"c) depositing polymer particles on the stent and/or on the tubular layer and attaching the stent to the tubular layer, and wherein the polymer particles are deposited using;

1) the steps of (i) immersing the stent in a liquid polymer dispersion; (ii) removing the stent from the liquid polymer dispersion; and (iii) drying that liquid polymer dispersion that remains on the stent;

2) electron beam deposition; or

3) dry, powdered polymer particles."

Fifth auxiliary request:

"c) depositing polymer particles on the stent and/or on the tubular layer and attaching the stent to the tubular layer, and wherein the polymer particles are deposited using;

1) the steps of (i) immersing the stent in a liquid polymer dispersion; (ii) removing the stent from the liquid polymer dispersion; and (iii) drying that liquid polymer dispersion that remains on the stent;

2) electron beam deposition onto the stent; or

3) dry, powdered polymer particles."

Sixth auxiliary request:

"c) depositing polymer particles on the stent and attaching the stent to the tubular layer, and wherein the polymer particles are deposited using;

1) the steps of (i) immersing the stent in a liquid polymer dispersion; (ii) removing the stent from the liquid polymer dispersion; and (iii) drying that liquid polymer dispersion that remains on the stent;

2) electron beam deposition onto the stent; or

3) dry, powdered polymer particles."

Seventh auxiliary request:

"c) depositing polymer particles on the stent using the steps of (i) immersing the stent in a liquid polymer dispersion; (ii) removing the stent from the liquid polymer dispersion; (iii) drying that liquid polymer dispersion that remains on the stent to form a polymer coating thereon; and attaching the stent to the tubular layer."

Eight auxiliary request:

"c) depositing dry, powdered polymer particles on the stent and/or on the tubular layer and attaching the stent to the tubular layer."

Ninth auxiliary request:

"c) depositing polymer particles on the stent using electron beam deposition and attaching the stent to the tubular layer."

Tenth auxiliary request:

"c) depositing polymer particles on the stent and/or on the tubular layer and applying solvent to attach the stent to the tubular layer."

VIII. Appellant 1 considered that the decision under appeal was sufficiently reasoned, and that the opposition division came to the conclusion that the patent as granted was not novel over D1 in the light of the disclosure of documents D2 and D3, on which the patent proprietor had sufficient opportunity to comment. For these reasons, no substantial procedural violation had occurred.

Appellant 1 submitted that the features "coating" and "depositing particles" were not equivalent; only those passages of the application as filed disclosing "depositing particles" could provide a basis for the amendments made. The feature "depositing particles" was always combined with additional features which were not present in independent claim 1 of any of the requests on file. For this reason, the characterising portion (c) of all the requests contained unallowable generalisations for which no basis could be found in the application as filed.

IX. Appellant 2 argued that the opposition division based its decision upon the personal experience of the members of the opposition division of medical products made of PTFE that they had seen at a trade fair. Since appellant 2 did not have an opportunity to comment on this information, the opposition division infringed its right to be heard, which amounted to a substantial procedural violation. Additionally, the decision was not sufficiently reasoned since the opposition division

came to the conclusion that the claimed subject-matter was not novel by merely stating that it was known that sintered PTFE material was stretchable, without any supporting evidence. This lack of reasoning amounted to a second substantial procedural violation.

Appellant 2 considered that the passages in the application as filed on page 17, lines 11-14; page 18, lines 6-10; page 19, lines 8-10; page 21, lines 28-36; page 20, lines 13-25; the first paragraph of section D on page 16; the three embodiments depicted in the description on page 7; page 8, line 1, and claims 93, 96, 98 and 100 provided a basis for the subject-matter of claim 1 of the main request and auxiliary requests 1 to 3, 5, 6 and 8. The subject-matter of claim 1 of the fourth auxiliary request found a basis on page 21, lines 27-36; on the first paragraph on page 17, and on claim 90 as originally filed. The subject-matter of claim 1 of the seventh auxiliary request found a basis on page 17, lines 11-14; on page 20, lines 20-25, and on claims 96 and 107 as filed. A basis for the subject-matter of claim 1 of the ninth auxiliary request could be found on page 10, lines 9-13, which referred to figure 3; on page 18, lines 6-10, and on claims 100 and 109. Finally, the tenth auxiliary request found a basis on page 8, lines 27-33, and on claim 32 as filed. The requirements of Article 123(2) EPC were thus fulfilled.

- X. Appellant 2 (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained upon the basis of, as a main request, the patent as granted; or upon the basis of any of auxiliary requests 1 to 10, auxiliary request 7 having been filed at the oral proceedings before the board,

the other auxiliary requests having all been filed under cover of a letter dated 14 September 2012.

Appellant 1 (opponent) requested that the decision under appeal be set aside and that the European patent No. 0 959 813 be revoked.

XI. At the end of the oral proceedings before the board, the chairman announced the decision.

Reasons for the Decision

1. The appeal is admissible.

Alleged procedural violations before the opposition division:

2. Appellant 2 requested reimbursement of the appeal fee and remittal of the case to the opposition division, on the grounds that two substantial procedural violations had been committed during the opposition proceedings.

In the view of appellant 2, the opposition division came to the conclusion that the subject-matter claimed in the patent as granted was not novel over the disclosure of document D1 by taking into account the personal experience of the members of the opposition division of medical products made from PTFE that they had seen at a trade fair. The appellant 2 had had no previous knowledge of the personal experience of the opposition division and was not given the opportunity to respond it, for example by providing additional information, performing experiments or consulting a technical expert. The opposition division infringed for this reason its right to be heard.

Appellant 2 also considered the decision of the opposition division not reasoned, because it relied on an unsubstantiated allegation, namely that it was known that sintered PTFE material was stretchable. This lack of reasoning also amounted to a substantial procedural violation.

3. The opposition division, in the first five paragraphs on point 2.3 of the contested decision, based its conclusion of lack of novelty on the disclosure of documents D1, D2 and D3, and it has not been disputed that the parties had sufficient opportunity to comment on them. This is also confirmed by the minutes of the oral proceedings before the opposition division, third paragraph on page 3. Said first five paragraphs on point 2.3 of the decision of the opposition division are self-contained and explain why, in its view, the subject-matter of claim 1 of the main request lacked novelty over document D1. The last paragraph on point 2.3 is, in fact, only the response to an argument of the proprietor. Therefore, the appealed decision is sufficiently reasoned and is based on facts and evidence that appellant 2 was aware of, and on which it could present its arguments.

As the decision is reasoned (Rule 111(2) EPC) and is based on facts and evidence that the parties had sufficient opportunity to comment upon (Article 113(1) EPC), the board concludes that no substantial procedural violation occurred.

Added subject-matter:

4. Main request:

4.1 Claim 1 of the patent as granted contains the feature "depositing polymer particles".

The opposition division agreed with appellant 2 and saw no difference between the terms "coating" and "depositing particles". For this reason, it concluded that the subject-matter of claim 1 as granted found a basis in the application as originally filed.

The board considers, however, that, although overlapping, these features are not equivalent: depositing only a few polymer particles would not form a coating, and a coating can be made without depositing particles, for example by depositing a monomer over a surface followed by in situ polymerisation, or by adding a preformed film over a surface. These terms are, hence, not equivalent for the person skilled in the art.

The application as originally filed does not define these terms as equivalent, either, as is apparent, for example, from page 16, lines 33-34, which reads "*coating of the stent and/or deposition of PTFE between layers to enhance bonding*", which shows that coating and particle deposition are considered different alternatives.

Therefore the terms "coating" and "depositing particles" are not equivalent taking into account either the general knowledge in the art, or the information in the description of the patent.

Those embodiments directed to "coating" cannot, hence, provide a basis for the feature "depositing particles".

4.2 Appellant 2 relied on the disclosure of independent claim 93 and its dependent claims 96, 98 and 100 as a basis for the subject-matter of claim 1 of the main request.

Independent claim 93 and its dependent claims 96, 98 and 100 contain features, such as the step of positioning the base graft or the stent on a mandrel, or the step of affixing the tubular layer to the stent by heating, which are not present in claim 1 of the main request. Therefore, these claims do not provide a basis for the subject-matter of claim 1.

4.3 Appellant 2 cited the first paragraph of section D on page 16 of the description as a basis for the characterising portion c) of claim 1 of the main request on file.

However, this sentence discloses "coating" and does not provide a basis for "depositing polymer particles" for the reasons explained under point 4.1.

4.4 Appellant 2 also relied on the disclosure on page 17, lines 11-14 of the application as filed as a basis for the subject-matter of claim 1 of the main request.

However, this passage discloses a specific method (immersion on an aqueous dispersion) of depositing specific particles (PTFE) and does not provide a basis for the subject-matter of claim 1, which is directed to depositing polymer particles, in general.

4.5 Appellant 2 has argued that the method disclosed on page 17, lines 11-14, was obviously applicable to every type of polymer particles and not only to PTFE.

However, even taking the most favourable view for appellant 2 that this method could be applied to other polymer particles, the passage cited discloses "depositing polymer particles by immersion on an aqueous dispersion" and not "depositing" in general, and, hence, does not provide a basis for the subject-matter of claim 1 of the main request.

- 4.6 Appellant 2 also cited page 18, lines 6-10 of the application as filed as a basis for the subject-matter of claim 1 of the main request.

This passage discloses a specific method of adding polymer particles (electron beam deposition) of a specific material (PTFE), whereas none of these features are present in claim 1 of the main request.

- 4.7 Appellant 2 also mentioned page 19, lines 8-10 of the application as filed as a basis for the subject-matter of claim 1 of the main request.

However, this passage only discloses the deposition of "raw PTFE resin powder" and not the deposition of polymer particles in general.

- 4.8 Appellant 2 alleged that the disclosure on page 21, lines 28-36 provided a basis for the generalisation of "PTFE particles" to "polymer particles" as in claim 1 of the main request.

However, this paragraph discloses "depositing polymer (e.g., PTFE) particles between the base graft 12 and outer tubular layer 16 by rolling the mandrel 50" and "particle deposition by using dry, powdered polymer resin", whereas claim 1 of the main request neither requires the step of rolling the mandrel nor is

restricted to dry, powdered resin particles.

- 4.9 Appellant 2 also cited as a basis for the subject-matter of claim 1 of the main request the disclosure on page 20, lines 13-15 of the original description.

However, this passage refers to rolling a mandrel-born graft in powdered PTFE resin, whereas these limitations are not features of claim 1 of the main request.

- 4.10 According to appellant 2, the three embodiments disclosed on page 7 of the description of the application as filed provided a basis for the subject-matter of claim 1 of the main request. Although these embodiments disclose stents, and not their preparation, it was apparent from page 6, lines 26-27 that the application as filed was also directed to methods for producing them.

As in the previous cases, this passage includes limitations, such as the density of the PTFE, which are not present in claim 1 of the main request, and cannot, hence, provide a basis for the subject-matter of said claim.

- 4.11 Finally, appellant 2 cited the disclosure on page 8, line 1, as a basis for the subject-matter of claim 1 of the main request. However, it refers to depositing PTFE particles and not polymer particles.

- 4.12 The subject-matter of claim 1 of the main request is, hence, an unallowable generalisation of the disclosure of the application as originally filed, and the ground for opposition under Article 100(c) EPC precludes the maintenance of the patent as granted.

5. *First and second auxiliary requests:*

Independent claim 1 of these requests differs from the subject-matter of claim 1 of the main request in that the polymer particles are deposited "on the stent" (first auxiliary request) or "on the stent and on the tubular layer" (second auxiliary request).

Claim 1 of these request does not include the additional features with which "depositing polymer particles" is disclosed in the application as filed (see point 4.2, 4.4-4.7 and 4.9-4.11 above).

Therefore, these requests are not allowable for the same reasons as the main request (Article 123(2) EPC).

6. *Third auxiliary request:*

This request is directed to depositing PTFE particles. However, the application as originally filed only discloses the deposition of PTFE particles in combination with specific deposition techniques (see point 4.4 to 4.7 above). The subject-matter of claim 1 of the third auxiliary request is, thus, an unallowable generalisation, with the consequence that said request is not allowable.

7. *Fourth auxiliary request:*

Claim 1 of this request contains the feature of depositing polymer particles by immersing the stent in a liquid polymer particle dispersion, by electron beam deposition, or by using dry, powdered, polymer particles.

As explained in points 4.4 to 4.7, these deposition

methods have only been disclosed in the application as originally filed in connection with PTFE, and no basis can be found for their generalisation to other polymers.

- 7.1 Appellant 2 has cited as a basis for the subject-matter of claim 1 of the fourth auxiliary request the disclosure on page 21, lines 27-36; on the first paragraph on page 17, and on claim 90 of the application as filed.

As explained with respect to the main request (see point 4.8) the paragraph on page 21, lines 27-36 discloses depositing polymer particles only in combination with "rolling a mandrel having the base graft and the stent disposed thereon in dry, powdered, resin", which is not a feature of claim 1 of the fourth auxiliary request.

Dependent claim 90 refers back to independent claim 75, and, hence, contains features such as the density of the PTFE, the step of positioning the base graft on a mandrel, and the step of heating, which are not required by the subject-matter of claim 1 of the fourth auxiliary request.

The first paragraph on page 17 of the application as originally filed is directed to "coating" and not to "depositing polymer particles". Additionally, the polymers "adhere to PTFE", whereas claim 1 does not restrict the type of polymer particles.

The subject-matter of claim 1 of the fourth auxiliary request is, thus, an unallowable generalisation (Article 123(2) EPC) and this requests is, therefore,

not allowable.

8. *Fifth and sixth auxiliary requests:*

Claim 1 of each of these requests is limited to specific methods for depositing polymer particles, which have been only disclosed in combination with PTFE (see point 7.) and cannot be generalised to every polymer particle for the same reasons as the fourth auxiliary request (Article 123(2) EPC).

These requests are, therefore, not allowable.

9. *Seventh auxiliary request:*

Claim 1 of the seventh auxiliary request contains the step of depositing polymer particles on the stent by immersing the stent in a liquid polymer suspension, removing the stent from the dispersion, and drying.

As a basis, appellant 2 has cited the disclosure on page 17, lines 11-14; claims 96 and 107, and page 20, lines 20-25.

Claims 96 and 107 do not provide a basis for the subject-matter of claim 1 of the seventh auxiliary request, since they contain features of the corresponding independent claims 93 and 102, such as positioning the base graft or the stent on a mandrel, or a heating step for affixing the layers, which are not required by the subject-matter of claim 1.

Page 20, lines 20-25 of the application as filed discloses alternative methods for depositing PTFE particles, such as painting or spraying, and not depositing polymer particles in general.

Page 17, lines 11-14 of the application as filed discloses depositing PTFE particles by immersion on an aqueous dispersion. Neither PTFE nor the nature of the liquid are features of claim 1 of the seventh auxiliary request and, therefore, its subject-matter represents an unallowable generalisation.

The seventh auxiliary request is thus not allowable (Article 123(2) EPC).

10. *Eighth auxiliary request:*

Claim 1 of the eight auxiliary request contains the feature "depositing dry, powdered polymer particles". As explained with respect to the main request (see points 4.7 and 4.9) this feature has only been disclosed in the application as filed in combination with a particular polymer (PTFE) which is not a feature of claim 1 of the eight auxiliary request (Article 123(2) EPC). For this reason, this request is not allowable.

11. *Ninth auxiliary request:*

Claim 1 of the ninth auxiliary request contains the feature "depositing polymer particles on the stent using electron beam deposition". However, this deposition technique has only been disclosed in the application as originally filed in combination with PTFE (see point 4.6).

Appellant 2 has cited the disclosures on page 10, lines 9-13 and on page 18, lines 6-10 as a basis for the subject-matter of claim 1 of the ninth auxiliary

request. However, both passages disclose depositing PTFE particles, not polymer particles.

Appellant 2 has also mentioned claims 100 and 109 as a basis for the subject-matter of claim 1 of the ninth auxiliary request. However, these dependent claims contain the subject-matter, respectively, of independent claims 93 and 102, and, therefore, features such as positioning the stent on a mandrel or affixing the layers by heating which are not included in claim 1 of the ninth auxiliary request.

This request is therefore not allowable (Article 123(2) EPC).

12. *Tenth auxiliary request:*

This request includes the feature "applying solvent to attach the stent to the tubular layer", which can be found on page 8, lines 27-33. However, the step of depositing particles is an unallowable generalisation of the disclosure of the application as filed for the reasons already explained with respect to the main request in point 4.

Appellant 2 has also cited claim 32 as originally filed as a basis for the subject-matter of claim 1 of the tenth auxiliary request. However, claim 32 refers back to claim 30, which is limited to PTFE particles. Hence, the subject-matter of claim 1 of the tenth auxiliary request represents an unallowable generalisation (Article 123(2) EPC), with the consequence that this request is not allowable.

13. For these reasons, none of the requests on file are allowable.

Order

For these reasons it is decided that:

The patent is revoked.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated