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**Datasheet for the decision  
of 6 November 2012**

**Case Number:** T 1064/09 - 3.3.10

**Application Number:** 00903261.6

**Publication Number:** 1064034

**IPC:** A61L31/04, A61L31/10,  
A61L27/16, A61L27/34, A61F2/06

**Language of the proceedings:** EN

**Title of invention:**  
VASCULAR GRAFT WITH IMPROVED SURFACE FLOW

**Patentee:**  
Gore Enterprise Holdings, Inc.

**Opponent:**  
Boston Scientific Corporation

**Headword:**

**Relevant legal provisions:**  
EPC Art. 100(b), 111(1)  
EPC R. 80

**Keyword:**  
Amendments originated by a ground for opposition (yes) -  
remittal

**Decisions cited:**

**Catchword:**



**Beschwerdekammern  
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Chambres de recours**

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Case Number: T 1064/09 - 3.3.10

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.10**  
**of 6 November 2012**

**Appellant:**  
(Patent Proprietor)

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**Respondent:**  
(Opponent)

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**Representative:**

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**Decision under appeal:**

**Decision of the Opposition Division of the  
European Patent Office posted 27 March 2009  
revoking European patent No. 1064034 pursuant to  
Article 101(3)(b) EPC.**

**Composition of the Board:**

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

## Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 1 064 034.
- II. An opposition had been filed, on the grounds 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 (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 *inter alia* that the invention was sufficiently disclosed for it to be carried out, that the subject-matter of claim 1 of the then pending main request (patent as granted) was not novel, and that the first auxiliary request before it contained amendments which were not occasioned by a ground of opposition and thus was not admissible under Rule 80 EPC.
- IV. The main request, filed at the oral proceedings before the board, is identical to the second auxiliary request filed with the statement of grounds of appeal. Claim 1 thereof reads as follows:

*"A vascular graft comprising an article having a luminal surface with a surface value of about 1.7 microns RMS or less, the luminal surface comprising polytetrafluoroethylene and the luminal surface being oriented as a blood contact surface for the vascular graft, wherein said vascular graft comprises a substrate tube having applied to a luminal surface thereof a layer of porous expanded*

*polytetrafluoroethylene film."*

- V. The appellant (patent proprietor) agreed with the positive conclusion of the opposition division in relation with sufficiency of disclosure, and argued that the new main request complied with the requirements of Rule 80 EPC. The opposition division considered that claims 2-32 of the first auxiliary request before it were new claims, the addition thereof being not occasioned by a ground of opposition. These claims had been deleted. As the opposition division did not admit the first auxiliary request before it into the proceedings solely for this reason, the appellant requested that the case be remitted to the opposition division for further prosecution.
- VI. The respondent (opponent) argued that the invention was not sufficiently disclosed for it to be carried out by a person skilled in the art, since claim 1 did not specify a method for measuring the parameter "surface value of about 1.7 microns RMS or less". This parameter was dependent on variables such as the number of measurements, angle of measurement, and the resolution of the equipment, which were not features of claim 1, and the claims were not limited by the method of measurement explained in the description of the patent. The opponent also questioned whether profilometry measurement was a suitable method for analysing a vascular graft with a variable surface smoothness along its length, since such a graft would have different surface values depending on which portion of the graft was measured. In the view of the respondent, a large part of the claimed subject-matter was not at the disposal of the person skilled in the art, as there was no general principle in the patent for producing a vascular graft with the claimed surface value.

Additionally, example 7 had a surface value outside the claimed range, despite the fact that it had been obtained according to D1, and example 11 had a surface value within the limits claimed, but was disclosed as not according to the invention; the respondent concluded that it was not apparent how to obtain the claimed grafts. The respondent relied on the data in table I of the patent in suit for showing that an improvement in terms of graft patency had not been achieved.

- VII. Oral proceedings before the board took place on 6 November 2012 in the absence of the duly summoned respondent.
- VIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution upon the basis of claims 1-6 of the main request submitted at the oral proceedings before the board.

The respondent requested in writing that the appeal be dismissed.

- IX. At the end of the oral proceedings, the chairman announced the decision.

### **Reasons for the Decision**

1. The appeal is admissible.

Added subject-matter, Article 100(c) EPC:

2. Claims 1 to 6 of the main request are identical to claims 35-40 as granted. Since Article 100(c) has not been invoked as a ground of opposition, these claims

are not open to examination on added subject-matter by the board.

Sufficiency of disclosure, Article 100(b) EPC:

3. Claim 1 of the main request is directed to a vascular graft whose luminal surface has a surface value of about 1.7 microns RMS or less.
4. It is established jurisprudence of the Boards of Appeal that the requirements of sufficiency of disclosure are only met if the invention as defined in the claim(s) can be performed by a person skilled in the art throughout the whole area claimed without undue burden, using common general knowledge and having regard to further information given in the patent in suit.

In the present case, it has to be examined whether the patent in suit makes available to the person skilled in the art the subject-matter claimed, in particular having regard to the surface value parameter defined in claim 1.

The patent in suit discloses different methods for obtaining vascular grafts with the claimed surface value:

- Example 3 describes the preparation of a graft according to claim 1 by using the film disclosed in a prior art document as its inner surface.
- Examples 6 and 7 disclose grafts with densified ends with a surface value within the limits of claim 1.
- Grafts with a surface value as defined in claim 1 can be prepared, additionally, by stretching (example 9), and the surface value obtained can be

further lowered by burnishing (example 10).

The examples thus disclose different strategies for obtaining the claimed grafts. The board considers in the light of this information that the description of the patent sufficiently discloses the preparation of the claimed vascular grafts.

5. It remains to be addressed whether the patent in suit provides sufficient information for measuring the surface value parameter of claim 1.
  - 5.1 The respondent argued that the parameter "surface value of about 1.7 microns RMS or less" was dependent on variables which were not set out in the claims.
  - 5.2 The passages on paragraphs [68] to [72] of the patent as granted disclose the measurement protocol including the apparatus required, its settings, the number of measurements, the angle at which these measurement shall be carried out and the resolution. Paragraph [72] further provides a measurement protocol for samples of non-uniform smoothness. The respondent has not objected to the measurement protocol described in the description.

Thus, the description provides sufficient instructions for measuring the parameter "surface value of about 1.7 microns RMS or less", and it is established jurisprudence of the EPO that sufficiency of disclosure must be assessed on the basis of the application as a whole, including the description (see Case Law of the Boards of Appeal of the EPO, 6th edition 2010, II.A.1). Thus, the fact that the method of measurement is not fully set out in claim 1 is, in the present case, irrelevant to the question of sufficiency.



The board thus concludes that the claimed invention is sufficiently disclosed for it to be carried out by a person skilled in the art.

6. The respondent also called into question whether profilometry was suitable for defining a graft with a variable surface smoothness along its length, as different surface values could be obtained for the same substrate, depending on the exact placing of the measurement.

However, paragraphs [72] and [73] provide a protocol for measuring non uniform surfaces, either by performing a plurality of measurements, or by measuring only the densified ends thereof (see also example 6). The patent in suit provides, therefore, sufficient information for measuring the surface value of non uniform surfaces in terms of smoothness. In addition, claim 1 does not require that the claimed grafts have a surface value of about 1.7 microns RMS or less throughout the whole luminal surface of said graft, only that at least one value falls below the limit of about 1.7 microns RMS.

Whether different surface values could be obtained depending on the zone of the graft measured and on the conditions used is, thus, not an issue of sufficiency of disclosure. This argument of the respondent must therefore fail.

7. The respondent argued that a large part of the claimed subject-matter was not sufficiently disclosed for it to be carried out by a person skilled in the art.

However, for the reasons already explained (see point

4.), the board concludes that the patent in suit provides sufficient information for preparing the claimed grafts and, therefore, in the absence of evidence to the contrary, it is considered that the entire subject-matter of claim 1 is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

8. The respondent also referred to examples 7 and 11 of the patent in suit. Example 7 was allegedly made by following the process for preparing the claimed grafts, but the surface value of the obtained product lay outside the claimed range. Example 11 illustrated a graft with a surface value within the claimed range, but lacking the desired properties.

8.1 Example 7 discloses, however, a precursor tube, and not a graft according to claim 1. The precursor tube of example 7 is manufactured by the same process used in example 2, but with a different expansion rate.

The graft of example 7 is not a graft according to the claimed invention. The board thus cannot see a link between the results reported in this example and the alleged lack of disclosure of the invention.

8.2 Example 11 of the patent in suit describes an endoscope tubing made according to the state of the art, which has a surface value as required by claim 1 of the main request, but which is too dense for good handling and to be practically sutured. These drawbacks, however, do not detract from the fact that a vascular graft having the characteristics required by claim 1 can be produced following the information given in the patent in suit.

Thus, this argument of the respondent also fails to

persuade the board.

9. The respondent also argued that the alleged advantage in terms of improved graft patency was not achieved by the claimed grafts, as table 1 of the patent in suit showed that the claimed grafts performed worse than the control.

However, an improved graft patency is not a feature of claim 1. Whether this advantage is achieved by the subject-matter claimed could be, therefore, an issue relating to inventive step, but not to sufficiency of disclosure.

10. The board therefore concludes that the invention as defined in claims 1-6 of the main request is sufficiently disclosed for it to be carried out by a person skilled in the art and thus suffices the requirements of Article 83 EPC.

Rule 80 EPC:

11. The amendment in claim 1 of the main request, namely the addition of the feature that the vascular graft comprises a substrate tube having applied to the luminal surface thereof a layer of porous expanded polytetrafluoroethylene film, is an attempt to overcome objections of lack of novelty, and as such fulfills the requirements of Rule 80 EPC.

Remittal (Article 111(1) EPC).

12. The opposition division has not yet ruled on all the requirements of the EPC in relation to a vascular graft comprising a substrate tube as defined in claim 1 of the main request. The board therefore considers it

appropriate to exercise the power conferred on it by Article 111(1) EPC to remit the case to the opposition division for further prosecution on the basis of claims 1 to 6 of the main request filed during the oral proceedings before the board.

## 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 upon the basis of claims 1 to 6 of the main request submitted at the oral proceedings before the board.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated