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**D E C I S I O N**  
**of 30 August 2005**

**Case Number:** T 0330/05 - 3.3.9

**Application Number:** 99954837.3

**Publication Number:** 1121162

**IPC:** A61L 29/16

**Language of the proceedings:** EN

**Title of invention:**

Loading and release of water-insoluble drugs

**Applicant:**

Boston Scientific Limited

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC Art. 123(2)

**Keyword:**

"Amendments - added subject-matter (no) "

"Remittal for further prosecution (yes) "

**Decisions cited:**

T 0296/96, T 0686/99, T 0727/00

**Catchword:**

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Case Number: T 0330/05 - 3.3.9

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.9  
of 30 August 2005

**Appellant:** Boston Scientific Limited  
The Corporate Centre  
Bush Hill  
Bay Street  
St. Michael  
Barbados  
West Indies (BB)

**Representative:** Altenburg, Udo, Dipl.-Phys.  
Patent- und Rechtsanwälte  
Bardehle, Pagenberg, Dost  
Altenburg, Geissler  
Postfach 86 06 20  
D-81633 München (DE)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 2 November 2004  
refusing European application No. 99954837.3  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** P. Kitzmantel  
**Members:** J. Jardon Alvarez  
M. B. Günzel

## Summary of Facts and Submissions

- I. This appeal lies from the decision of the Examining Division dated 2 November 2004, refusing European patent application 99 954 837.3, published as WO-00/21584 on 20 April 2000.
- II. The decision under appeal was based on Claims 1 to 23 filed on 21 September 2004. Independent Claims 1, 9 and 17 read as follows:

"1. A method for preparing a patterned stent having paclitaxel coated thereon comprising the steps of: providing a polyvinyl aromatic polymer; providing a patterned stent; coating at least a portion of the exterior surface of the patterned stent with the polyvinyl aromatic polymer to form a polymer coating; and applying a drug solution to the polymer, said drug solution comprising paclitaxel dissolved in an organic solvent.

9. A patterned stent for delivering a substantially water-insoluble drug at a desired location within a body, comprising a polymer coating (6) containing paclitaxel provided on at least a portion of said patterned stent, characterized in that said polymer coating (6) is a polyvinyl aromatic polymer coating.

17. A catheter (3) for delivering substantially water-insoluble drugs to a desired location within a body lumen (2), said catheter comprising:  
a shaft;

an expandable portion mounted on said shaft, said expandable portion including an inflatable balloon and a sheath (7) member extendable over said expandable portion; and  
a polymer coating (6) on at least a portion of said expandable portion of said catheter (3), characterized in that said polymer coating (6) is a polyvinyl aromatic polymer coating which is impregnated with paclitaxel."

The Examining Division refused the application for lack of compliance with the requirements of Article 123(2) EPC.

The Examining Division held that the skilled person reading the application documents as originally filed would not directly and unambiguously derive a patterned stent coated with a polyvinyl aromatic polymer/paclitaxel coating. In its opinion, the very general list of very different polymers, which were all taught to be suitable polymers for coating medical devices intended for delivery of water-insoluble drugs, did not amount to a teaching of a selection of any of the specifically mentioned polymers except for the polymers specified to be the preferred ones. The subject-matter of Claim 1 was artificially created by a triple selection of different aspects of the originally filed technical teaching.

III. The Notice of Appeal was filed on 15 December 2004 and the appeal fee was paid on the same day. The statement setting out the Grounds of Appeal was filed on 7 March 2005.

IV. On 4 July 2005 the Board dispatched the summons to attend oral proceedings. The annexed communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal expressed doubts as to whether the specification as originally filed disclosed the combination of a patterned stent coated with a polymer/paclitaxel matrix with each element of the polymer list given on pages 14 to 16.

V. In reply thereto, the Appellant submitted on 16 August 2005 auxiliary requests 1 to 3 in addition to the request already on file (main request: Claims 1 to 23 as submitted on 21 September 2004).

VI. During the course of the oral proceedings held on 30 August 2005 the Appellant withdrew all its previous requests and filed five new requests, namely, a main request based on Claims 1 to 16 of the previous main request and four auxiliary requests.

In the new main request, independent Claims 1 and 9 have the same wording as the claims on which the decision of the Examining Division was based (see above under II.).

VII. The arguments put forward by the Appellant in its written submissions and at the oral proceedings concerning its main request can be summarized as follows:

- There was no triple selection of different aspects from the originally filed disclosure: Claims 21 and 22 of the application as originally filed contained a clear teaching with respect to the

particular type of medical device (a patterned stent) to be used with a particular water-insoluble drug (paclitaxel) and on page 15, lines 1 to 19, there was a list of suitable coating polymers. Thus, the original application disclosed the combination of a patterned stent having a polymer coating impregnated with paclitaxel, which coating might be made from each of the polymers individually referred to in said list.

- Moreover, the description included examples with three different polymers and there was no evidence on file showing that the claimed process would not work with certain polymers. On the contrary, the description taught the exchangeability of the polymers of the list when applied to the patterned stent coated with a polymer/paclitaxel matrix (see in particular page 47, lines 19 to 21; see also page 28, lines 14 to 16 and page 5, lines 9 to 14).
  
- The Appellant further argued that the decisions cited by the Examining Division and the so-called 'novelty test' actually supported the admissibility of the amendments made by the Appellant. Not only would the skilled person seriously contemplate combining a patterned stent with a polymer/paclitaxel matrix as required by decision T 296/96 (because there was an explicit suggestion to do so in the original application, particularly when considering original claims 21 and 22 and the statement on page 5, lines 9 to 14), but also this combination was directly and unambiguously derivable from the information in

the application as filed, which is the criterion to be applied according to decision T 686/99.

VIII. The Appellant requested that the decision of the Examining Division be set aside and that a patent be granted on the basis of the following documents:

Claims 1 to 16 of the main request filed during the oral proceedings or

alternatively on the basis of the first, second, third or fourth auxiliary request filed during the oral proceedings, taken in this consecutive order.

As an auxiliary request the Appellant requested that the case be remitted to the Examining Division for further prosecution.

### **Reasons for the Decision**

1. The appeal is admissible.

#### *Main request*

2. *Amendments (Article 123(2) EPC)*

2.1 The subject-matter of Claim 1 combines features of original Claim 1 and of original Claims 21 and 22 (paclitaxel/patterned stent) with a feature disclosed on page 15, lines 8/9, of the application as originally filed, namely that the polymer is a polyvinyl aromatic polymer.

- 2.2 The question to be decided is whether the use of a polyvinyl aromatic polymer as a polymer for the coating material for a patterned stent to be impregnated with paclitaxel is directly and unambiguously derivable from the application as originally filed.
- 2.3 The content of the application as originally filed can be analysed as follows:
- 2.3.1 The claimed invention aims to provide a method and an apparatus for the localized delivery of substantially water-insoluble drug agents to predetermined locations within the human body (page 3, lines 10 to 13). As a most preferred embodiment the application describes a patterned stent partially coated with a polymer/paclitaxel matrix that provides sustained release of paclitaxel at the desired site within the lumen wall (page 5, lines 9 to 22; see also page 48, lines 13 to 21).
- 2.3.2 This most preferred embodiment is *inter alia* described in detail on page 5, lines 15 to 22, and on page 28, line 14 to page 29, line 22, where reference is made to the use of a "polymer" without specifying any particular polymer.
- 2.3.3 This information is given on pages 14 to 16. The relevant passage starting at the end of page 14 reads: "The polymer of the present invention is hydrophilic or hydrophobic and is selected from the group consisting of ..." followed by a list of polymers including polyvinyl aromatic polymers. Preferred polymers are stated to be: polyacrylic acid, a copolymer of polylactic acid and polycaprolactone (page 16, lines 5



and 14). The examples concerning the patterned stent use these preferred polymers and polyurethane (see examples 8, 10 to 13) but not polyvinyl aromatic polymers.

- 2.4 The crucial issue for the assessment of the admissibility under Article 123(2) EPC of the claimed subject-matter is thus whether it is evident beyond any doubt to the skilled person reading the original description that all the polymers listed on page 14, line 23 to page 16, line 5, are disclosed as coating materials for a patterned stent together with the use of paclitaxel as drug.

In the Board's view, this is indeed the case because not only is the skilled reader, in the absence of any teaching to the contrary, led by the whole disclosure of the application to conclude that each and every polymer listed on pages 14 to 16 is suitable for any of the medical devices covered by the original application, but also he is even specifically instructed by the statement introducing said polymer list ("**The** polymer of the present invention ... is selected from the group ..." [emphasis by the Board]) that the passage on page 5, lines 15 to 22, identifying a patterned stent comprising an outer coating of polymer/paclitaxel, is directed, with regard to the polymer material, to the use of any of the polymers set out in the **subsequent** list.

3. The Examining Division held in its decision that the subject-matter was a combination of three different aspects of the originally filed technical teaching, namely of:

- the type of medical device (patterned stent),
- the water-insoluble drug (paclitaxel) and
- the sustained release polymer (polyvinyl aromatic polymer),

which combination, in the Examining Division's view, was going beyond the original disclosure, the reason being that there was no pointer in the original disclosure to combine these three features each selected from a list comprising several alternatives.

In view of this alleged deficiency, the skilled person was not presented with a clear, direct and unambiguous disclosure of the claimed subject-matter. The Examining Division considered that the present situation fell within the considerations expressed by the boards of appeal in the cases T 686/99 of 22 January 2003 and T 727/00 of 22 June 2001, as well as T 296/96 of 12 January 2000 (none of them published in the OJ EPO), because the claimed combination was taken in an inadmissible fashion from a reservoir of features disclosed separately and independently from each other in the original application documents and because this new combination would not be seriously contemplated by a skilled reader of the application.

- 3.1 This reasoning cannot be accepted by the Board. As pointed out above (see 2.4) there is an explicit disclosure in the application as originally filed of the combination of a polymer coated patterned stent and paclitaxel, and the only feature added to this disclosure, namely the concretisation of the polymer

material, does not require any unforeshadowed "selection" because each of the polymers listed on pages 14 -16 is clearly and unambiguously disclosed as an appropriate alternative material.

It is not justifiable in this situation to interpret the disclosure as being restricted to the exemplified embodiments because this would run counter to the well established jurisprudence of the boards that the disclosure of a patent specification is not limited to preferred embodiments.

3.2 Thus, the present case is different from the situations in T 686/99 (see point 4.3 to 4.3.3. of the reasons) and in T 727/00 (see point 1.1.4 of the reasons) where the disallowed amendment resulted from a multiple selection within two lists of equally alternative features. In T 396/96 (see point 3.1 of the reasons) it was not permissible to define R as C<sub>1-12</sub> alkyl group because such a definition could not be directly derived from the application as originally filed. The situation in that decision cannot be equated with that of the present case. The Board's finding in the present case is thus not in contradiction with the finding in these decisions.

4. For these reasons the Board is therefore satisfied that the amendments to Claim 1 do not introduce subject-matter which goes beyond the contents of the application as originally filed.

4.1 The same arguments apply *mutatis mutandis* to independent Claim 9 which is directed to the patterned stent of original Claim 38.

The subject-matter of dependent Claims 2 to 7 is supported by original Claims 6 to 10 and 18; Claims 10 to 16 by original Claims 33, 40, and 43 to 46 and Claims 8 and 16 by page 15, lines 17 to 18.

5. The set of claims of the main request thus meets the requirements of Article 123(2) EPC.
6. *Remittal to the first instance (Article 111(1) EPC)*
  - 6.1 Since non-compliance of the claimed subject-matter with Article 123(2) EPC was the sole reason for refusing the European patent application relied on by the Examining Division, it appears appropriate, in agreement with the Appellant's auxiliary request, to remit the case to the first instance for further substantive examination of the case .

#### *Auxiliary requests*

7. In the circumstances there is no need to deal with the further auxiliary requests.

**Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further prosecution on the basis of the main request filed during the oral proceedings.

The Registrar:

The Chairman:

G. Röhn

P. Kitzmantel