BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 16 September 2008

Case Number: T 0061/05 - 3.3.10

Application Number: 99943847.6

Publication Number: 1105169

IPC: A61L 29/08

Language of the proceedings: EN

Title of invention:
Coated implantable medical device

Applicant:
Cook Incorporated

Headword:
Coated implantable medical device/COOK INC.

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
"Amendments: both requests (not allowable) - not unambiguously derivable from application as filed"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0061/05 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 16 September 2008

Appellant: Cook Incorporated
750 North Daniel's Way
P.O. Box 489
Bloomington, Indiana 47402-0489 (US)

Representative: Jehan, Robert
Williams Powell
Staple Court
11 Staple Inn Buildings
London WC1V 7QH (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 1 September 2004 refusing European application No. 99943847.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: P. Gryczka
Members: J. Mercey
J.-P. Seitz

Summary of Facts and Submissions

I. The appeal lodged on 1 November 2004 lies from the decision of the Examining Division posted on 1 September 2004 refusing European patent application No. 99943847.6 with the European publication No. 1 105 169 and International publication No. WO 00/10622.

II. In the decision under appeal, the Examining Decision held that the subject-matter according to the then pending sole request extended beyond the content of the application as filed (Article 123(2) EPC) and lacked novelty (Articles 52(1) and 54 EPC).

III. At the oral proceedings before the Board held on 16 September 2008, the Appellant (Applicant) submitted a main request and an auxiliary request, said requests superseding any previous request. Claim 12 of the main request read as follows:

"Paclitaxel applied to an implantable medical device (10) comprising a structure (12) adapted for introduction into a patient, the structure (12) having at least one surface and being composed of a base material (14); and at least one layer (18) of paclitaxel posited over at a portion of one surface in an amount of 35 to 400 µg and in a concentration from 0.06 mg/mm^2 to 60 mg/mm^2 for the treatment of restenosis."

Claim 1 of the auxiliary request read as follows:

"Paclitaxel applied to an implantable medical device (10) comprising a structure (12) adapted for

introduction into a patient, the structure (12) having at least one surface and being composed of a base material (14); and at least one layer (18) of paclitaxel posited on the at least one surface in a concentration from 0.06 mg/mm^2 to 60 mg/mm^2 for the treatment of restenosis."

IV. The Appellant argued that the amendments to the claims found support in the application as filed, and thus complied with the requirements of Article 123(2) EPC. More particularly, basis for claim 12 of the main request was to be found in claims 18 and 20 as originally filed, which disclosed the implantable medical device having a layer of paclitaxel. Support for the use in the treatment of restenosis was at page 23, lines 11 to 12, for the amount of paclitaxel was at page 24, line 29, page 25, lines 21 to 22 and Table 3 and page 26, lines 5 and 9, and for the concentration range of paclitaxel was at page 23, line 20 of the application as filed.

V. The Appellant requested that the decision under appeal be set aside and that the patent be granted on the basis of the main request or, alternatively, on the basis of the auxiliary request, both requests filed during the oral proceedings before the Board.

VI. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main and auxiliary request

2. *Article 123(2) EPC*

2.1 In order to determine whether or not an amendment offends against Article 123(2) EPC, it has to be examined whether technical information has been introduced which a skilled person would not have objectively and unambiguously derived from the application as filed.

2.2 Claim 12 of the main request and claim 1 of the auxiliary request are derived from the combination of originally filed claims 18 and 20, which disclose an implantable medical device having a layer of paclitaxel, whereby *inter alia* the fresh feature "in a concentration from 0.06 mg/mm^2 to 60 mg/mm^2" has been introduced. The Appellant argued that support for said concentration of paclitaxel was to be found at page 23, line 20 of the application as filed.

2.3 The Board, however, holds that this part of the application as filed cannot provide a basis for the amendment made to these claims, since this concentration range is disclosed only in combination with a particular implantable medical device, namely a stent (see page 22, line 11 and page 23, line 11) for studies performed on animals (see page 22, lines 11 to 12) and not for any implantable medical device as now claimed.

2.4 The Appellant argued that although the studies referred to on page 23, line 11 were performed on specific stents, the paragraph from lines 11 to 22 of page 23 related to the conclusions of such studies, which could be extended to other implantable medical devices. However, in the entire part of the application as filed which relates to the use of paclitaxel in the treatment of restenosis, namely the animal studies described from page 21, line 28 to page 25, line 29, only paclitaxel coated stents are described (see page 21, line 28; page 22, lines 11 and 29; page 23, lines 11, 23 to 24 and 29; and page 24, line 27). The use of paclitaxel in the treatment of restenosis is not described anywhere in the application as filed in a more general context. The Board thus holds that the skilled person would have associated the specific concentration ranges of paclitaxel indicated on page 23 with stents only, there being no unambiguous information in the application as filed that said paclitaxel concentrations may be extended to any implantable medical device as now claimed.

2.5 The Board concludes that claim 12 of the main request and claim 1 of the auxiliary request are amended in such a way that subject-matter extending beyond the application as filed is added, contrary to the requirements of Article 123(2) EPC, with the consequence that the main request and the auxiliary request are not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka