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**Datasheet for the decision
of 16 December 2010**

Case Number: T 0413/09 - 3.2.02

Application Number: 96930693.5

Publication Number: 1019107

IPC: A61L 27/44

Language of the proceedings: EN

Title of invention:

Drug release stent coating process

Patentee:

Boston Scientific Limited

Opponent:

Cordis Medizinische Apparate GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 123(2), 111(1)

EPC R. 80

Relevant legal provisions (EPC 1973):

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Keyword:

"Extension of subject-matter (no)"

"Remittal (yes)"

Decisions cited:

-

Catchword:

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Case Number: T 0413/09 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 16 December 2010

Appellant:
(Patent Proprietor) Boston Scientific Limited
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Representative: Peterreins, Frank
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Representative: Janssen, Bernd Christian
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 5 December 2008
revoking European patent No. 1019107 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: M. Noël
Members: P. L. P. Weber
A. Pignatelli

Summary of Facts and Submissions

- I. The appeal is against the decision of the Opposition Division dated 5 December 2008 to revoke European patent 1019107 filed 5 September 1996 with the earliest priority date on 11 September 1995. The patent was revoked because the claims on file infringed Article 123(2) EPC. In particular in the set of claims as granted claim 5 was considered to infringe Article 123(2) EPC.

- II. Notice of appeal was filed by the patentee on 13 February 2009. The statement setting out the grounds of appeal was filed on 15 April 2009.

- III. The respondent (opponent) withdrew its opposition with letter dated 1 October 2009.

- IV. The appellant requests as main request that the decision of the Opposition Division be set aside and the patent be maintained on the basis of a set of claims 1 to 8 for the contracting state FI and a set of claims 1 to 8 for the contracting states AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LI, LU, NL, PT, SE, all filed on 15 April 2009. The appellant further requests to remit the case to the first instance for further examination.

As an auxiliary request the appellant requests that the patent be maintained on the basis of the claims of the auxiliary requests one to four filed on 15 April 2009.

The appellant further requests oral proceedings, in case the Board of appeal cannot agree to one of the above requests.

V. Claim 1 of the main request for the contracting state FI reads as follows:

"A coated implantable prosthesis having an external surface covered with a coating comprising:

(a) a first coating layer comprising an elastomeric material incorporating an amount of particulate biologically active material; wherein the average particle size of the biologically active material is less than or equal to about 15 μm ; and

(b) a second coating layer comprising a polymeric material disposed over the first coating layer; wherein the coating adheringly conforms to the prosthesis."

Claim 1 of the main request for the other contracting states AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LI, LU, NL, PT, SE reads as follows :

"A coated implantable prosthesis having an external surface covered with a coating comprising:

(a) a first coating layer comprising an elastomeric material incorporating an amount of particulate biologically active material; wherein the average particle size of the biologically active material is less than or equal to about 15 μm ; and

(b) a second coating layer comprising a polymeric material disposed over the first coating layer;

wherein the coating adheringly conforms to the prosthesis and wherein the drug loading is higher in the inner layer."

- VI. In the opposition proceedings the opponent considered D1: WO-A-96/32907, filed on 1 April 1996 with priority date on 19 April 1995, to be state of the art according to Article 54(3) EPC and to anticipate the subject-matter of claim 1.

When entering into the regional phase before the European Patent Office, the applicant of D1 paid the designation fees for AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LI, LU, NL, PT, SE but did not pay the designation fee for Finland (FI).

When entering into the regional phase before the European Patent Office, the appellant paid the designation fees for AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LI, LU, NL, PT, SE and also paid the designation fee for Finland (FI).

- VII. The arguments of the appellant can be summarized as follows:

The set of claims according to the main request differed from the granted claims in that claim 5 as granted was deleted and the remaining claims renumbered as the Opposition Division considered granted claim 5 to infringe Article 123(2) EPC. As claim 5 was now deleted the objection did not apply anymore.

Claim 1 of the main request submitted for the contracting states other than FI further included the

last feature that the drug loading was higher in the inner layer. This feature was disclosed on page 24 lines 20 to 24 of the original application as published (WO-A-97/10011).

Contrary the opinion of the Opposition Division, given in an obiter dictum, D1 did not disclose that the drug loading was higher in the inner layer.

Reasons for the Decision

1. The appeal is admissible.
2. Compliance of the amendments with Rule 80 EPC
 - 2.1 The filing of a set of claims for contracting state FI comprising granted claim 1 unchanged, and a separate set of claims for the contracting states AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LI, LU, NL, PT, SE whereby claim 1 includes an additional feature, is allowable under Rule 80 EPC as document D1 is not state of the art under Article 54(3) EPC for the contracting state FI, the designation fee for this state not having been paid by the applicant of D1 when entering the regional phase before the European Patent Office. Therefore the submission of separate sets of claims for different contracting states is allowable.
 - 2.2 The deletion of claim 5 is allowable under Rule 80 EPC as claim 5 as granted was objected to under Article 123(2) EPC which is a ground of opposition.

2.3 Although in the opposition proceedings the Opposition Division did not yet decide about novelty and inventive step the addition of a feature in claim 1 in order to improve the position of the appellant with regard to any novelty or inventive step objection is allowable under Rule 80 EPC as this rule only requires the amendment to be occasioned by a ground of opposition, and thus allows the patentee to amend its patent even if that ground has not been invoked by the opponent.

3. Compliance of the amendments with Article 123(2) EPC

3.1 In both sets of claims forming the main request the appellant removed the litigious granted claim 5 so that the objection under Article 123(2) EPC raised by the Opposition Division is no more applicable.

3.2 The feature added to claim 1 for the contracting states other than FI according to which the drug loading is higher in the inner layer is disclosed on page 24, lines 20 to 24 of the original application as published.

4. Since the objection upon which the impugned decision is based has been removed, remittal of the case to the first instance for further prosecution pursuant to Article 111(1) EPC, as requested by the appellant, is justified.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of the first instance for further prosecution, on the basis of the two sets of claims filed as main request with letter of 15 April 2009.

The Registrar:

The Chairman:

D. Sauter

M. Noël