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 5 February 2007

Case Number: T 0921/06 - 3.2.02

Application Number: 05006630.7

Publication Number: 1559439

IPC: A61L 27/00

Language of the proceedings: EN

Title of invention:
Drug release stent coating process

Applicant:
Boston Scientific Scimed, Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 123(2)

Keyword:
"Novelty and inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0921/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 5 February 2007

Appellant: Boston Scientific Scimed, Inc.
One Scimed Place
Maple Grove, MN 55311 (US)

Representative: Peterreins, Frank
Patent- und Rechtsanwälte
Bardehle Pagenberg Dost
Altenburg Geissler
Galileiplatz 1
D-81679 München (DE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 28 February 2006 refusing European application No. 05006630.7 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
E. Dufrasne

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 28 February 2006 to refuse European patent application No. 05 006 630.7 which claims two priorities:

11 September 1995 US 08/526273 and
13 June 1996 US 08/663490.

A first ground of refusal was that claim 1 of the main request and second auxiliary request then on file failed to satisfy the requirements of Article 123(2) EPC since it comprised technical features which were never presented in combination in the application as filed.

In addition, the subject matter set out in the claims according to the main, first and second auxiliary requests then on file was held to lack an inventive step with respect to the disclosure of documents

D1: EP-A-0 623 354 and

D2: WO-A-92/15286.

II. Furthermore, the examining division considered document

D3: EP-A-0 701 802.

This document has a date of filing of 15 September 1995 (priority date 15 September 1994) and represents state of the art pursuant to Article 54(3) EPC.

III. On 10 April 2006 the appellant (applicant) lodged an appeal against the decision of the examining division and filed a statement setting out the grounds of appeal. The prescribed fee was also paid on the same day.

IV. As to meet the appellant's request to speed up the appeal proceedings, oral proceedings were held on 5 February 2006. The appellant requested that

- the decision under appeal be set aside and

- a patent be granted on the basis of the main request (claims 1 to 15 in two different versions for different designated states) filed at the oral proceedings.

Independent claims 1 and 8 of the version for the designated states AT, BE, CH, DK, ES, GR, IE, LI, LU, PT read as follows:

"1. A coated expandable vascular stent prosthesis having an open structure with filaments and having an external surface covered with a coating comprising a hydrophobic polymeric or elastomeric material incorporating an amount of biologically active material dispersed therein, wherein the material of the coating adherently conforms to and covers the filaments of the open structure of the stent,
characterized in that
the coating comprises a composite undercoat and a composite topcoat, wherein the material of the topcoat has a different formulation than the formulation of the material of the undercoat with respect to the matrix polymer material."

"8. A method of coating an expandable vascular stent prosthesis having an external surface covered with a coating comprising a hydrophobic polymeric or elastomeric material incorporating an amount of biologically active material dispersed therein, the method comprising the following steps:
applying multiple layers for forming an undercoat on the expandable stent prosthesis as a mixture, solution or suspension of hydrophobic polymeric or elastomeric material by spraying or dipping and finely divided biologically active material, and
applying multiple layers for forming a topcoat on the undercoat by spraying or dipping, wherein the material of the topcoat has a different formulation with respect to the matrix polymer material than the formulation of the material of the undercoat."

The independent claims 1 and 8 of the version for the designated states other than those mentioned in the first set differ from the first version by the following disclaimer:

"**with the proviso that the material of the topcoat is not fibrin.**"

The dependent claims 2 to 7 and 9 to 15 relate to preferred embodiments of the intravascular stent prosthesis set out in claim 1 and of the method set out in claim 8, respectively.

V. The appellant's arguments are summarized as follows:

In order to meet the requirements of Article 123(2) EPC, the redrafted claim 1 did no longer contain the combination of features that was objected to by the examining division.

As to the technical disclosure of documents D1 and D2, novelty of the claimed subject matter according to the first set of claims was not at issue in the impugned decision. Turning to inventive step, D1 disclosed an intravascular stent prosthesis comprising a drug loaded polymer coating to control the drug release after implantation in the blood vessel. Document D2 related to tracheal stents rather than vascular stents but nevertheless addressed the problem of controlling the therapeutic drug release profile after implanting the stent in the human body. The skilled reader was taught that the initial burst of drug release directly after implanting the stent prosthesis was slowed down by applying an outer drug-free layer (of ethylene vinyl acetate EVA) on the first EVA drug loaded coating. None of these documents, however, disclosed or suggested that two distinct coatings of different polymer materials should be used to improve the long term release of the therapeutic agent from the coating for months or even longer. The claimed subject matter therefore involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments, Articles 123(2) and 84 EPC

The revised wording of claims 1 and 8 of the first set of claims for AT, BE, CH, DK, ES, GR, IE, LI, LU, PT) is supported by originally filed claim 15 and the passages of the description page 6, lines 6 to 10, 21 to 26, page 7, lines 5 to 23; page 8, first line and lines 23 to 26; page 17, line 29 to page 18, line 4.

For the sake of clarity, the subject matter of claims 1 and 8 has been restricted to a "vascular stent prosthesis" rather than to stents for vascular implantation. This limitation is derivable from the description page 1, lines 20 to 26, page 2, lines 4 to 12 and is explicitly mentioned on page 4, lines 16 to 19.

It is noted that claim 1 no longer comprises the combination of technical features which in the impugned decision was found unallowable with respect to Article 123(2) EPC.

The dependent claims 2 to 7 and 9 to 15 have a basis in the application as filed, as indicated below:

Claims 2, 9:	page 6, lines 6 to 10,
claims 3, 10:	claims 2, 17 as originally filed
claim 4:	page 24, lines 14 to 16
claims 5, 11:	page 24, lines 22 to 24
claims 6, 12:	page 7, lines 18 to 23

claims 7, 13: page 4, lines 14 to 19
claim 14, 15: page 8, lines 23 to 26

The same amendments apply to the second set of claims for all other designated states. The additional feature "**with the proviso that the material of the topcoat is not fibrin**" is a permissible disclaimer to exclude subject matter specified in document D3 which is state of the art pursuant to Article 54(3) EPC.

Hence there are no formal objections to the claims of both versions.

3. Novelty; Article 54 EPC

The vascular stent prosthesis set out claim 1 and the method for coating such a stent prosthesis according to claim 8 differ from the prior art described in documents D1 and D2 by the different formulation of the polymeric or elastomeric material making up the undercoat (tie layer) and the topcoat (surface layer). By contrast, D1 and D2 refer to one or multiple coatings including a top coating, which are, however, all made up from the same polymeric material.

Document D3 teaches the selection of fibrin as a polymer coating which is disclaimed by the second set of claims. Hence, the subject matter set out in the second set of claims is clearly distinguished from the technical disclosure of D3.

The subject matter of claims 1 and 8 of both set of claims is, therefore, novel.

4. Inventive step; Article 56 EPC

4.1 Like the present application, document D1 relates to a coated expandable intravascular stent. In order to cope with the problem of restenosis following an angioplasty treatment, the drug-eluting coating is provided by applying to the stent body surface a solution which comprises a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent and then evaporating the solvent. The adhesion of the coating(s) and the drug delivery rate or "elusion" which allows for a sustained release of the drug to the vascular tissue is controlled (a) by selecting an appropriate biostable or biodegradable polymer and (b) by the variation of the drug-to-polymer ratio in the multiple layers (cf. D1, page 3, lines 1 to 19). Therefore, D1 qualifies as the closest prior art.

As it is evident from Figures 1 and 2 of D1, the drug release rate has been tested for a period of about 250 hours (about 10 days) or 140 hours, respectively. However, the drug release rate for very long time intervals such as months has not been considered.

Starting from this prior art, the problem underlying the present application resides in providing on the surface of an intravascular stent prosthesis a drug-eluting coating which is capable of a long-term delivery of the therapeutic substance for even months or longer (cf. the application, page 4, lines 5 to 13 and page 5, lines 14 to 18).

The solution to this problem is a stent prosthesis which comprises a composite polymeric or elastomeric

tie coating (or underlayer) covered by a top coating of a different polymeric or elastomeric formulation. In so doing, the long-term release of the therapeutic substance to the tissue of the blood vessel is reliably controlled for very long time periods. Enclosed with its submissions of 26 January 2006, the appellant presented test results proving that this object has been successfully achieved with a specific stent according to the invention.

4.2 Although D1 lists a number of biostable or biodegradable polymers that could be used depending on the desired rate of the release, no hint is found anywhere in this document motivating a skilled person to provide coatings of different formulations for slowing down the drug delivery rate (cf. D1, page 4, lines 10 to 30).

Document D2 is concerned with catheters, tubes and implants that abut tissue following implantation into the body, especially for the use in the naso-oto-pharyngeal areas of the body. This medical devices are provided with a biocompatible polymer coating incorporating a therapeutically active agent (e.g. an anti-inflammatory or anti-coagulant) for sustained release (cf. D2, page 6, Summary of the Invention; page 8, Detailed Description of the Invention). As set out on page 10, third full paragraph, the polymer coating should release the incorporated agent over a prolonged period of time, greater than one day up to several days or weeks. Thus document D2 addresses the problem underlying the present application. According to D2, however, the drug release is a function of the diffusion of the agent from the polymeric matrix as

well as of the thickness and chemical composition of the polymeric matrix. D2 also teaches that the initial "burst effect" of drug release can be abated by applying a drug-free coating over the drug loaded polymer layer (cf. page 11, last two lines from the bottom).

However, all stents disclosed as specific examples in D1 and D2 have been prepared by using the same polymer material for the different layers, and neither of these documents teaches or suggests that the polymer of distinct layers should consist of different formulations and be combined in the form of an undercoat and a topcoat to solve the above mentioned problem.

4.3 Given this situation, the claimed solution i.e. the stent prosthesis and the method for producing it set out in claims 1 and 8 are not derivable in an obvious manner from the disclosure of documents D1 and D2. The claimed subject matter therefore involves an inventive step.

4.4 The dependent claims 2 to 7 and 9 to 15 relate to preferred embodiments of the prosthesis according to claim 1 and of the method set out in claim 8, respectively. Hence, these claims are also allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of the main request (claims 1 to 15 in two different versions for different designated states) filed at the oral proceedings, with a description to be adapted to these claims.

The Registrar: The Chairman:

V. Commare T. K. H. Kriner