Internal distribution code:

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

Datasheet for the decision of 16 June 2016

Case Number: T 1795/14 - 3.3.10

Application Number: 03764655.1

Publication Number: 1521603

IPC: A61L31/16, A61L29/16, A61L27/54

Language of the proceedings: EN

Title of invention:
COATED MEDICAL DEVICE

Patent Proprietor:
Cook Medical Technologies LLC

Opponents:
Boston Scientific Corporation
Hemoteq AG

Headword:

Relevant legal provisions:
EPC Art. 54(2), 100(a), 100(b), 100(c), 111(1), 123(2), 123(3)

Keyword:
Main request - added subject-matter (no), novelty (yes).
Remittal

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1795/14 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 16 June 2016

Appellant: (Patent Proprietor)	Cook Medical Technologies LLC 750 North Daniels Way Bloomington, IN 47404 (US)
Representative:	Jehan, Robert Williams Powell Staple Court 11 Staple Inn Buildings London, WC1V 7QH (GB)
Respondent: (Opponent 1)	Boston Scientific Corporation P.O. Box 1317 Seaston House, Hastings Christ Church, West Indies (BB)
Representative:	Peterreins Schley Patent- und Rechtsanwälte Soeltlstraße 2a 81545 München (DE)
Respondent: (Opponent 2)	Hemoteq AG Adenauerstrasse 15 52146 Würselen (DE)
Representative:	Arth, Hans-Lothar ABK Patent Attorneys Jasminweg 9 14052 Berlin (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 July 2014 revoking European patent No. 1521603 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	R. Pérez Carlón
	T. Bokor

Summary of Facts and Submissions

I. The appellant lodged an appeal against the decision of the opposition division revoking European patent No. 1 521 603.

II. Two notices of opposition had been filed on the grounds of added subject-matter (Article 100(c) EPC), insufficiency of disclosure (Article 100(b) EPC), and lack of novelty and inventive step (Article 100(a) EPC).

III. The documents filed during the opposition proceedings included the following:

D2: US 6,203,551 B1

IV. The opposition division concluded that claim 1 of the main request then pending, which is also the main request in these appeal proceedings, did not contain added subject-matter but was not novel over the implant device obtainable using the chamber disclosed in document D2.

V. Claim 1 of the main request reads as follows:

"A coated medical device comprising: an inflatable balloon (26) having a base material layer and a lipophilic bioactive material layer (28) posited on said base material layer; and an implantable stent (10) including a base material layer (14) and a lipophilic bioactive material layer (18) posited thereon, wherein said stent (10) is disposed around said balloon (26), wherein the bioactive material layer (28) on said balloon (26) extends beyond the ends of the stent (10) disposed around said balloon (26), and wherein the

lipophilic bioactive material layer (28) on said balloon (26) delivers a lipophilic therapeutic agent that treats, minimises or eliminates edge effects that cause trauma to the vessel wall and subsequent occlusion or stenosis of the vessel."

VI. The arguments of the appellant relevant for the present decision were the following:

On page 3, lines 3-7, in combination with claims 10-13 as filed, the application as originally filed provided the required basis for the features of claim 1. For that reason, the main request did not contain added subject-matter.

The medical device of claim 1 was novel over a balloon catheter with a stent mounted on it and resulting from using chamber (40) according to the embodiment of D2 represented by figure 3, as said embodiment did not disclose a balloon having a bioactive layer extending beyond the ends of the stents, let alone capable of treating, eliminating or minimising edge effects.

The appellant requested that the case be remitted to the opposition division for further prosecution.

VII. The arguments of respondent 1 (opponent 1) relevant for the present decision were the following:

The passage on page 3, lines 3-7 did not provide the required basis for claim 1, as it had to be read in combination with the sentence preceding it, which linked the treatment of edge effects with specific materials on the layer (18) posited on the stent. For that reason, claim 1 contained added subject-matter.

Figure 3 of document D2 disclosed a chamber (40) for coating a stent. As the chamber was mounted on the balloon, the latter would be coated at the same time as the stent by using said chamber. Thus, a medical device according to claim 1 was the inevitable result of using chamber (40) disclosed in document D2, with the consequence that the balloon of claim 1 was not novel.

If the appellant were to argue that not every balloon would be coated by applying a paclitaxel solution, the claimed invention could not be considered as sufficiently disclosed for it to be carried out by a person skilled in the art.

Respondent 1 did not object to the case being remitted to the opposition division if claim 1 were found to be novel and to have the required basis in the application as originally filed.

VIII. Respondent 2 agreed with respondent 1 concerning the lack of novelty of claim 1. It informed the board that it would not be attending the oral proceedings, which took place on 16 June 2016.

IX. The final requests of the parties were the following:

- The appellant requested that the decision under appeal be set aside, and that the patent be maintained in amended form on the basis of the main or first auxiliary requests filed with the grounds of appeal, or on the basis of one of the second to eleventh auxiliary requests filed with letter dated 26 February 2016. It further requested remittal to the first instance.

- The respondents requested that the appeal be dismissed.

X. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request, amendments

2. It has not been contested that the feature in claim 1

"wherein the lipophilic bioactive material layer (18) on said balloon (26) delivers a lipophilic therapeutic agent that treats, minimises or eliminates edge effects that cause trauma to the vessel wall and subsequent occlusion or stenosis of the vessel"

does not find a word-by-word basis in the application as originally filed.

The respondents did not challenge the fact that the remaining features of claim 1 resulted from the combination of claims 10, 11, 12 and 13 as originally filed.

Lastly, it is common ground that the application as originally filed discloses a medical device having a balloon whose bioactive layer is capable of treating edge effects (page 3, lines 3-7).

2.1 Respondent 1 argued that the application as originally filed required a bioactive layer suitable for treating edge effects on both the balloon and the stent (page 3,

lines 1-7). In contrast, although claim 1 required a bioactive material on the stent, that material did not necessarily have to be suitable for treating, minimising or eliminating edge effects, and no such embodiment was disclosed in the application as originally filed. For that reason, claim 1 contained added subject-matter.

The application as originally filed refers to edge effects on page 3, lines 3-8 and on page 13, lines 11-16. In both passages, the application discloses that the edge effects are *caused* by the stent and *treated* by the bioactive material on the balloon. There is no disclosure that the stent bears a bioactive material capable of treating edge effects.

2.2 Respondent 1 argued that the preferred embodiment of the application required paclitaxel on both the balloon and the stent. For that reason, the application as originally filed taught that both the balloon and the stent required the same type of bioactive material layer, namely one capable of treating edge effects.

However, the question is not whether the preferred embodiment of the application as originally filed requires the same drug on both the stent and the balloon, but whether it discloses a medical device having a stent with a lipophilic bioactive material layer posited thereon and a balloon which, independently of the type of bioactive material on the stent, has a layer which delivers a therapeutic agent that treats edge effects. As already mentioned above, the patent application discloses that the layer on the balloon is suitable for treating edge effects, independently of the type of bioactive material on the

stent.

2.3 For these reasons, claim 1 of the main request does not contain subject-matter going beyond that disclosed in the application as originally filed (Article 123(2), Article 100(c) EPC).

3. Claim 1 of the main request limits the subject-matter of claim 1 as granted by requiring that the layer on the balloon delivers a *lipophilic* therapeutic agent. The requirements of Article 123(3) EPC are thus fulfilled. This has not been challenged.

Main request, novelty

4. Claim 1 of the main request is directed to a medical device comprising a balloon (26) and an implantable stent (10). The balloon (26) has a base material layer coated with a lipophilic bioactive material layer (28). The implantable stent (10) also includes a base material layer (14) and a lipophilic bioactive material layer (18).

The stent is disposed around the balloon, and the bioactive material layer on the balloon extends beyond the ends of the stent.

Lastly, the lipophilic bioactive material layer on the balloon delivers a lipophilic therapeutic agent that treats, minimises or eliminates edge effects. This agent is preferably paclitaxel (see claim 3).

5. Document D2 discloses a chamber for applying therapeutic substances to an implant device such as a catheter having a balloon portion and a stent crimped or mounted on the balloon (column 2, lines 51-52),

which correspond to stent (10) and balloon (26) required by claim 1.

Said chamber encapsulates the stent and allows a user to deliver therapeutic substance(s) into the chamber (column 2, lines 54-46. With reference to the figures, document D2 discloses that the chamber has a pair of sealing members (54A), (54B) which seal the chamber against the balloon (column 4, lines 8-9) and facilitate the sliding of the chamber onto and off the balloon (column 4, lines 14-15).

Referring to figure 3, document D2 discloses that the stent (28) is crimped on balloon (26) in a compressed configuration. The materials suitable for the stent are given in column 6, lines 37-61, and include metals and polymeric materials. These materials correspond to the base material layer (14) required by claim 1.

The base material of the balloon (26) is disclosed on column 3, lines 48-50, and includes nylon and polyethylene, which are preferred materials according to the patent in suit (see claim 4 and [0024]).

According to example 1, a stent containing taxol (paclitaxel, which is a lipophilic therapeutic agent as required by claim 1) is obtained using chamber (40). Paclitaxel is also mentioned on column 6, line 1.

The question arises whether the medical device obtained using the chamber of D2 has a bioactive material layer on the balloon which extends beyond the ends of the stent.

5.1 It is not disputed that document D2 does not explicitly disclose that any therapeutic agent is present on any

part of the balloon.

5.2 The appellant did not dispute that the therapeutic agent would necessarily attach to the balloon if put in contact with it.

5.3 Document D2, however, explicitly refers to problems due to disturbance of the positioning of stent (28) and damage to its structure due to the use of the sliding chamber of figure 3 (column 4, lines 14-18). Although D2 discloses that sealing members (54A) and (54B) facilitate sliding, there remain reasonable doubts that the medical device obtained by using the chamber as depicted in figure 3 would necessarily have a stent and balloon positioned exactly as depicted therein and, for that reason, that the coating on the balloon extends beyond both ends of the stent.

The respondents argued that the embodiment depicted as figure 4 avoided the need for sliding and thus would solve any problem derived from the use of chamber (40) depicted in claim 1. Even though figure 4 does not disclose the disposition of the balloon and stent within the chamber (40), sealing members (54A) and (54B) are still present. These sealing members facilitate sliding in the same manner as in the embodiment of figure 3, but the same reasonable doubts arise regarding the positioning of the balloon and stent with respect to figure 3. In addition, D2 discloses that the embodiment of figure 4 is "more suitable for preventing significant disturbance to the positioning of the stent (28) and damage to structure of the stent" (column 4, lines 28-31), but D2 does not disclose that such disturbance or damage could be completely excluded. For that reason, the reasonable doubts which arise with respect to the embodiment of

figure 3 are not solved by reference to the embodiment of figure 4.

5.4 Claim 1 requires a layer on the balloon which delivers a lipophilic therapeutic agent that treats, minimises or eliminates edge effects.

Although the appellant acknowledged that, by contacting a balloon with paclitaxel, said therapeutic agent would be attached to the balloon, there is no disclosure in document D2 that the amount attached could be sufficient for the desired means, as D2 is silent about the amount of therapeutic substance used. In addition, the chamber of D2 is disclosed for medicating stents specially adapted to absorb or attach said agent and to release it at the site of treatment (column 3, lines 12-15) so it is reasonable to expect that a major part of the paclitaxel used would be attached to the stent. Thus, even if the amount of paclitaxel used for coating were known, and the stent did not change its relative position with respect to the balloon, obtaining a balloon coated with an effective amount of paclitaxel is not the inevitable result of using chamber (40) of D2.

5.5 For these reasons, it is concluded that the subject-matter of claim 1 is novel over the medical device which is the inevitable result of using chamber (40) in the manner disclosed in document D2.

Sufficiency of disclosure

6. Respondent 1 argued that, if it was decided that not every balloon would be coated by contacting an active substance with a balloon, the invention was not sufficiently disclosed, as there the patent in suit did

not teach the skilled person how to make such coating.

As the appellant acknowledged during the oral proceedings before the board that a balloon would inevitably be coated by using chamber (40) of document D2, this objection is moot.

Remittal:

7. According to Article 111(1) EPC, a board may either exercise any power within the competence of the department which was responsible for the appealed decision, i.e. decide on all issues, or it may remit the case to the first instance for further prosecution.

8. Since the decision under appeal has not dealt with all the grounds for opposition, the board considers it appropriate to remit the case to the opposition division for further prosecution on the basis of the claims according to the main request (Article 111(1) EPC). None of the parties objected to such remittal.

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 first instance for further prosecution.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated