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**Datasheet for the decision
of 7 October 2022**

Case Number: T 1390/17 - 3.3.10

Application Number: 10181983.7

Publication Number: 2324867

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

Language of the proceedings: EN

Title of invention:
Angioplasty balloons drug-coated in an expanded condition

Patent Proprietor:
Cook Medical Technologies LLC

Opponents:
Medtronic, Inc./Medtronic Vascular Galway/
Invatec S.p.A.
BIOTRONIK AG
Boston Scientific Limited

Headword:
Angioplasty balloons drug-coated in an expanded condition/Cook
Medical Technologies

Relevant legal provisions:
EPC Art. 76(1), 111(1)

Keyword:

Divisional application - subject-matter extends beyond content
of earlier application (yes)

Appeal decision - remittal to the department of first instance
(no)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1390/17 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 7 October 2022

Appellant: Cook Medical Technologies LLC
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 18 April 2017
revoking European patent No. 2324867 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: J.-C. Schmid
F. Blumer

Summary of Facts and Submissions

- I. The Appellant (proprietor of the patent) lodged an appeal against the decision of the opposition division revoking European patent No. 2 324 867.

Claim 1 of the patent as granted reads as follows:

"1. A coated medical device for applying paclitaxel to a vessel wall, comprising:

a folded inflatable balloon consisting of a base material (26), and a layer comprising or being of lipophilic bioactive material (28) posited on said base material with the balloon in an expanded or inflated condition, wherein the lipophilic bioactive material (28) is paclitaxel; wherein the lipophilic bioactive material coats the outer surface of the balloon and between the folds of the balloon, and wherein the lipophilic bioactive material is not covered by nor contained within a time-release or containment layer."

- II. A notice of opposition had been filed by the respondents I, IV and V (opponents 1, 4 and 5, respectively) requesting the revocation of the patent in suit in its entirety on the grounds of Article 53(c) EPC, lack of novelty and inventive step (Article 100(a) EPC), insufficiency of disclosure of the invention (Article 100(b) EPC, and extension of the subject-matter of the patent in suit beyond the content of the application as filed (Article 100(c) EPC).

- III. The opposition division revoked the patent on the ground that claim 1 of the patent as granted and of auxiliary requests 1 to 3 did not fulfil the requirements of 123(2) EPC and for the same reasons those of Articles 76(1) EPC. According to the opposition division, all features of claim 1 were disclosed in the application as filed, but not in combination.
- IV. In the statement of the grounds of appeal, beside the submissions on substantive issues, the appellant argued that the opposition division committed procedural violations since it refused to postpone the oral proceedings scheduled for 8 March 2017 and failed to render a sufficiently reasoned decision.
- V. At the end of a first oral proceedings held on 30 November 2021 dealing with the alleged procedural violation the Board came to the conclusion that the decision under appeal was not tainted by a substantial procedural violation justifying a remittal to the opposition division.
- VI. The appellant (patent proprietor) requests that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution on the basis of the patent as granted (main request) or on the basis of one of auxiliary requests 1 to 7 filed with letter dated 5 September 2022.
- The respondents I, IV and V (opponents 1, 4 and 5) request that the appeal be dismissed.
- VII. At the end of the second oral proceedings held on 7 October 2022, the decision of the Board was announced.

Reasons for the Decision

Alleged procedural violations by the opposition division

1. The patent was revoked on the ground that claim 1 of the main request did not fulfil the requirement of Article 76(1) and 123(2) EPC.
2. The appellant criticised the opposition division's decision to refuse an adjournment of the oral proceedings requested on the grounds of a medical emergency arising shortly before the scheduled date. However, at the oral proceedings before the opposition division the appellant was represented by another professional representative who was able to defend the appellant. The refusal to adjourn the oral proceedings therefore does not appear to have had any negative consequences for the appellant. The board fails to see here a violation of the opposition proceedings. At the oral proceedings before the Board, the appellant did not elaborate further on this point.
3. During the oral proceedings held before the opposition division, the chair announced the conclusion of the opposition division that the requirements of Articles 76(1) and 123(2) EPC are not met, since the combination of the features of claim 1 could not be unambiguously derived from the application as filed. After a break, the appellant informed the opposition division that it had no further submissions. The board concludes therefrom that the appellant had sufficient opportunities to convince the opposition division that the application as originally filed discloses the

features of claim 1 in combination. The Appellant's right to be heard was therefore respected. Although the argumentation in the contested decision is rather short, it makes nevertheless understandable that the patent was revoked since the combination of features required by the amended claims was not disclosed in the parent application and in the patent application as filed. The Board arrives therefore at the conclusion that the contested decision is sufficiently reasoned.

4. Since the board arrives at the conclusion that the proceedings before the opposition division were not tainted by a procedural violation it decides not to remit the case to the opposition division on procedural grounds, but to examine it on the merits (Article 111(1) EPC).

Article 100(c) EPC; Article 76(1) EPC

Main request - patent as granted

The earlier application as filed is published as WO 2004/006976 A1.

5. Claim 10 of the earlier application as filed discloses a coated medical device, comprising an inflatable balloon having a base material layer, and a bioactive material posited on said base material. The section on page 2, lines 16 to 22 of the earlier application as filed discloses that the balloon is coated with the preferred lipophilic bioactive material with the balloon in an expanded or inflated condition. The balloon is then deflated or evacuated so that the balloon wall material can be folded for insertion into the vessel or for placement of another device over the folded outer surface of the balloon. The section on

page 3, lines 7 to 11 of the earlier application as filed discloses that the application of the coating of the balloon in an inflated condition allows for a full application of the bioactive material between the folds of the balloon. The section of page 1, lines 14 to 16 discloses that the bioactive material is a lipophilic material such as paclitaxel.

6. However, there is no basis in the earlier application as filed for the feature that the lipophilic bioactive material deposited on the surface of the balloon is not covered by nor contained within a time-release or containment layer.

6.1 The section on page 4, lines 27 to 30 of the earlier application as filed discloses that the time and cost of manufacturing the medical device is minimised by the absence of any step of incorporating the bioactive material into a containment layer, or applying a containment or time release layer over the bioactive material.

However, this section refers to advantages obtained by the aspect of the invention disclosed in the section starting on page 3, line 15 of attaining a desired surface roughness or texture on the surface of the device by surface treatment and applying the bioactive material directly to that roughened or textured surface without the need for an additional overlay or containment coating. In this aspect of the invention, at least a portion of the surface of the device is treated to produce a roughened, uneven or non-smooth surface, and the bioactive material is formed or laid on at least the portion of the surface.

Throughout the earlier application as filed, the disclosure of the absence of a containment layer or additional coating layers is linked to a desired surface roughness, or texturing, that must be provided on the base material surface to which the bioactive material is applied (page 5, lines 11 to 14; page 7, lines 12 to 16; page 8, last four lines; page 17, lines 8 to 10; page 26, lines 23 to 26).

Accordingly, the feature requiring the absence of a time-release or containment layer is inextricably linked to a medical device comprising a layer of bioactive material posited upon a roughened or textured surface of the base material and cannot be extracted from that specific context in which it is disclosed in the earlier application as filed to be applied to any medical devices.

6.2 Thus, inserting this feature in the medical device of claim 1 not requiring a roughened or textured surface provides the person skilled in the art with technical information which is not derivable from the earlier application as filed.

6.3 According to the appellant, the earlier application as filed contains disclosures of balloons not having a roughened or textured surface which are coated with a lipophilic bioactive material that is not covered by nor contained within a time release or containment layer (page 5, lines 14 to 23; page 19, lines 21 to 25; page 27, lines 12 to 15; page 29, lines 16 to 17; figures 3 and 8).

However, the absence of a feature in the disclosure of a medical device is not a disclosure of the absence of that feature in the medical device.

7. Thus, the board concludes that the coated medical device of claim 1 of the main request requiring that the lipophilic bioactive material not be covered by or contained within a time-release or containment layer, but not requiring a roughened or textured outer surface, is not directly and unambiguously derivable from the earlier application as filed.

Hence, claim 1 of the main request does not meet the requirement of Article 76(1) EPC.

Auxiliary requests 1 to 7

8. The medical devices of claim 1 of these auxiliary requests also do not require a roughened or textured outer surface, while including the feature that the lipophilic bioactive material which coats the outer surface is not covered by nor contained within a time-release or containment layer.

Thus, claim 1 of these requests also infringes article 76(1) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated