Internal distribution code:

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

Datasheet for the decision of 1 December 2022

Case Number: T 0827/19 - 3.3.10

Application Number: 11758026.6

Publication Number: 2611476

IPC: A61L29/14, A61L29/16

Language of the proceedings: EN

Title of invention:
COATING PROCESS FOR DRUG DELIVERY BALLOONS USING HEAT-INDUCED REWRAP MEMORY

Patent Proprietor:
Boston Scientific Scimed, Inc.

Opponent:
Cook Medical Technologies LLC

Headword:

Relevant legal provisions:

Keyword:
Inventive step - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0827/19 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 1 December 2022

Appellant: (Opponent)	Cook Medical Technologies LLC 750 North Daniels Way Bloomington, IN 47404 (US)
Representative:	Williams Powell 5 Chancery Lane London WC2A 1LG (GB)
Respondent: (Patent Proprietor)	Boston Scientific Scimed, Inc. One Scimed Place Maple Grove, MN 55311-1566 (US)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Straße 3 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 4 January 2019 rejecting the opposition filed against European patent No. 2611476 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chair	P. Gryczka
Members:	R. Pérez Carlón
	F. Blumer

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division rejecting the opposition against European patent No. 2 611 476.

II. Notice of opposition had been filed on grounds including lack of inventive step (Article 100(a) EPC).

III. The following documents were filed:

D1 US 2010/0145266 A1
D1a WO 2004/028582 A1
D3 US 5,681,522

IV. Claim 1 of the patent as granted, which represents the main request of the respondent (patent proprietor) in these appeal proceedings, reads as follows:

"A method of producing a drug coated balloon that comprises the steps of: subjecting a balloon catheter with a folded and wrapped balloon thereon to a pre-annealing step at a temperature above room temperature and below a temperature at which the balloon is blown to induce a fold/wrap memory in the resulting pre-annealed balloon; unfolding the pre-annealed balloon sufficiently to expose the full circumferential surface of the balloon by application of an inflation pressure that retains said fold/wrap memory; applying a drug coating formulation to the unfolded balloon surface; releasing pressure to relax the balloon and induce creasing along fold memory; and evacuating the balloon slowly to induce refolding and rewrapping of the balloon."

V. The opposition division concluded that the claimed invention was sufficiently disclosed. Any of D1, D4 or D5 could be considered the closest prior art, and none of them disclosed a pre-annealing step. The problem underlying the claimed invention was the provision of an improved method for obtaining a drug-coated balloon with a more homogeneous drug coating. The claimed solution, characterised by a pre-annealing step, would not have been obvious, as a skilled person would not have combined the teaching of D2 or D3, which related to uncoated stents, with that of D1, D4 or D5.

VI. With the reply to the grounds of appeal, the respondent filed its first to fourth auxiliary requests.

Claim 1 of the auxiliary request 1 corresponds to claim 1 of the main request.

Claim 1 of auxiliary request 2 requires the drug to be paclitaxel.

Claim 1 of auxiliary requests 3 and 4 requires the coating to comprise a dose density of paclitaxel between 0.25 and 5 micrograms per square millimetre.

VII. The arguments of the appellant concerning the issue of inventive step were as follows.

Example 2 of document D1 was the closest prior art. It disclosed a method having all the features of claim 1 with the exception of the pre-annealing step. The problem of providing a homogeneous coating had already been solved by Example 2 of D1, and therefore the problem underlying the claimed invention was to be seen as the mere provision of an alternative method of producing a drug-coated balloon. The claimed solution,

characterised by a pre-annealing step, would have been obvious to a skilled person in view of the teaching of D3 and was thus not inventive.

VIII. The arguments of the respondent concerning the issue of inventive step were as follows.

Example 2 of document D1 did not disclose either a balloon having fold memory or a pre-annealing step. The problem underlying the claimed invention was to provide a method of producing a drug-coated balloon with improved coating integrity and reliable dosage on the balloon. The claimed solution would not have been obvious to a skilled person, as they would not have consulted a document such as D3, which related to uncoated balloons. The claimed method was thus inventive.

IX. Oral proceedings before the board of appeal took place on 1 December 2022.

X. The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed, or, in the alternative, that the patent be maintained on the basis of one of auxiliary requests 1 to 4, all auxiliary requests as filed with the reply to the grounds of appeal dated 25 September 2019.

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

Reasons for the Decision

1. The appeal is admissible.

2. Inventive step

2.1 Closest prior art

2.1.1 The parties considered that Example 2 of document D1 was the closest prior art. The board sees no reason to disagree.

Example 2 of D1 discloses a method for coating a multifold balloon [0112] by expanding it, roughening its surface [0113], dipping the balloon into a paclitaxel solution in dimethyl sulfoxide [0115] and drying it. A largely uniform layer of paclitaxel forms on the catheter balloon [0116]. After the dipping step has been repeated three times, the balloon is dried under vacuum conditions [0116], sterilised and covered with a protective sheath for transport and storage [0119].

2.1.2 It was undisputed that Example 2 of D1 did not disclose a pre-annealing step at a temperature above room temperature and below a temperature at which the balloon is blown.

2.1.3 The respondent argued that, in addition, the balloon used in Example 2 of D1 as the starting material lacked fold/wrap memory.

Example 2 of document D1 uses a multifold balloon as described in document D1a [0112]. D1a relates to medical devices for dispensing medicaments. It discloses, on page 6, line 29 and following, coating in its expanded state a balloon that has preformed folds;

the folds are recovered once pressure is released. Thus, the coated balloon of Example 2 of D1 - like that of D1a - has fold/wrap memory, as required by claim 1.

The respondent argued that Example 4 of D1a required a folding device to refold the coated balloon. The need for such a device suggested that the balloons of D1a lacked wrap memory.

However, D1a only relates to balloons with fold memory; no other type of balloon is disclosed. Despite the use of a folding device in one of the examples of D1a, a skilled person reading the text would consider the balloon in that example to be in line with the whole disclosure of D1a and thus to have wrap memory.

2.2 Technical problem underlying the invention

The respondent formulated the technical problem underlying the claimed invention as being to provide a method of producing a drug-coated balloon which made it possible to improve the coating integrity and to improve the reproducibility of the drug dosage on the balloon.

2.3 Solution

The claimed solution is the method of producing a drug-coated balloon of claim 1, characterised by a pre-annealing step.

2.4 Success

The respondent argued that the pre-annealing step, by inducing fold/wrap memory,the pre-annealing step made the use of any equipment folding device. The claimed

method thus allowed reduced handling of the balloon once coated and therefore led to less damage to the coating.

However, Example 2 of document D1 only discloses, after coating, a sterilisation step and the provision of a protective sheath. No step that would be deleterious to the coating is apparent.

In addition, the wording of claim 1 does not exclude further handling steps after coating. Any effect which might result from omitting said handling steps is thus not achievable by every embodiment of the claimed method.

For these reasons, it cannot be concluded that the claimed method necessarily reduces handling and thus coating damage.

The problem as defined by the respondent has not therefore been credibly solved by the claimed method.

2.5 Reformulation of the technical problem

In accordance with the case law (Case Law of the Boards of Appeal, 10th edition, 2022, I.D.4.3.1), alleged but unsupported advantages cannot be taken into consideration in determining the problem underlying the invention.

The alleged improvement in coating integrity and reliability of the dosage of drug on the balloon compared to that achieved by the method of D1 is not credibly achieved by every embodiment of the claimed method.

The technical problem as defined above thus needs to be reformulated as being to provide an alternative method for producing a multifold drug-coated balloon.

This technical problem has been credibly solved by the method subject-matter of claim 1, characterised by including a pre-annealing step.

2.6 It thus remains to be decided whether the proposed solution to the objective problem defined above would have been obvious to the skilled person in view of the prior art.

D1 does not disclose how to obtain the multifold balloons to be coated in Example 2. The skilled person would have searched for ways of producing them and would have focused on methods known to be advantageous. By doing so, the skilled person would have come across a document such as D3.

D3 relates to multifold balloons. It discloses an annealing process which reduces the rewrapped profile of balloon catheters after deflation (column 2, lines 14 to 17; example). Deflation is a required step of an angioplasty; ideally the balloon should rewrap itself around the catheter and (column 3, lines 21 to 24 and 33). Annealing imparts memory to the balloon (column 3, lines 34 to 36). The process is carried out at the temperatures set by claim 1 (column 4, lines 16 to 24).

D3 thus teaches that annealing is a particularly suitable technique for inducing folding memory. If seeking an alternative, the skilled person would have applied that technique to the preparation of the multifold balloons used in Example 2 of D1 and would thus have arrived at the claimed invention without

requiring inventive skill.

The respondent argued that the skilled person would not have turned to a document such as D3, which related to uncoated stents and thus aimed at a different purpose.

However, the skilled person would have taken into consideration suitable methods for obtaining multifold balloons, which do in fact constitute the starting material of the coated balloon of Example 2 of D1. The respondent's argument is thus not convincing.

2.7 The subject-matter of claim 1 is thus not inventive (Article 56 EPC), with the consequence that the ground of opposition laid down in Article 100(a) EPC precludes the maintenance of the patent as granted.

3. Auxiliary requests

3.1 Claim 1 of auxiliary request 1 corresponds to that of the main request. The reasoning already provided thus also applies thereto.

3.2 Claim 1 of auxiliary request 2 requires the drug to be paclitaxel. Example 2 of D1 discloses a method for coating a balloon with precisely this drug. The reasoning with respect to inventive step remains unchanged.

3.3 Claim 1 of auxiliary requests 3 and 4 requires the coating to comprise a dose density of paclitaxel between 0.25 and 5 micrograms per square millimetre.

The respondent argued that the effect of the claimed invention in terms of coating stability was particularly relevant at low drug loading. Any damage

to the coating would lead to a non-therapeutic dose of the drug.

However, document D1 discloses that the method of Example 2 can achieve a drug loading of 1 to 20 micrograms per square millimetre [0118]. Thus, the drug loading required by claim 1 does not represent an additional distinguishing feature over the prior art.

In addition, the reasons as to why the alleged effect of enhancing the coating integrity has not been achieved by every embodiment of the claimed method (see point 2.4 above) are not modified by virtue of the drug dose density on the balloon.

3.4 For these reasons, it is concluded that the reasoning with regard to inventive step explained in the context of the main request apply in the same manner to the subject-matter of claim 1 of all the auxiliary requests, with the consequence that none of them is allowable.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar: The Chair:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated