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**Datasheet for the decision
of 1 April 2025**

Case Number: T 1180/22 - 3.3.10

Application Number: 15180475.4

Publication Number: 2962707

IPC: A61L29/16, A61L29/06

Language of the proceedings: EN

Title of invention:

DRUG DELIVERY BALLOONS WITH IMPROVED CRYSTAL SIZE AND DENSITY

Patent Proprietor:

Boston Scientific Scimed, Inc.

Opponents:

Terumo Kabushiki Kaisha
C.R. Bard, Inc.
MEDTRONIC INC.

Headword:

Relevant legal provisions:

EPC Art. 100(c), 123(2), 123(3)

Keyword:

Amendments - main request and auxiliary requests 2, 7 -
extension beyond the content of the application as filed (yes)
- auxiliary requests 1, 3-6, 8-10, 1a, 6a - broadening of
claim (yes)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
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Case Number: T 1180/22 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 1 April 2025

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 24 February 2022 revoking European patent No. 2962707 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: A. Zellner
 L. Basterreix

Summary of Facts and Submissions

- I. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division to revoke the European patent No. 2 962 707 (Article 101(3)(b) EPC).
- II. Three notices of opposition have been filed on the basis of Articles 100(a) EPC for lack of novelty and lack of inventive step (Articles 54 and 56 EPC), Article 100(b) EPC for lack of sufficiency of disclosure, and Article 100(c) EPC for unallowable amendments.
- III. In the appealed decision, the opposition division held that neither the claimed subject-matter of the patent as granted, nor that of auxiliary requests 1 to 10 was novel (Article 54 EPC). No decision was taken with respect to the objections concerning inventive step (Articles 100(a) and 56 EPC), sufficiency of disclosure (Article 100(b) EPC) and extension beyond the content of the application as filed (Article 100(c) EPC).
- IV. The appellant argued that the opposition division erred in their decision not to acknowledge novelty.
- V. Reference is made to the following documents:
- D10: WO 2011/008393 A2 (parent application as published)
 - D11: Application as filed (ep 155180475.4)
 - D22: Experimental Report, submitted by the appellant on 6 July 2022
 - D23: WO 2010/079218 A2

VI. Claim 1 of the **main request** (patent as granted) has the following wording:

"A drug delivery balloon comprising a layer of crystalline paclitaxel particles, wherein the particles have an average length of less than 100 μm length, wherein the particles are densely stacked substantially parallel to the surface of said portion; and wherein the layer of crystalline paclitaxel particles has a thickness of less than 10 μm ."

VII. All of the auxiliary requests 1 to 10, 1a and 6a have a single independent claim, which has the following respective wordings (amendments relative to claim 1 of the main request are highlighted by the board):

Auxiliary requests **1** and **3**:

"A drug delivery balloon comprising a layer of crystalline paclitaxel particles, wherein the particles have an average length of less than 100 μm length on at least a portion of the surface of the balloon, wherein the particles are densely stacked substantially parallel to the surface of said portion; and wherein the layer of crystalline paclitaxel particles has a thickness of less than 10 μm ."

Auxiliary request **1a**:

"A drug delivery balloon comprising a layer of crystalline paclitaxel particles on at least a portion of the surface of the balloon, wherein the particles have an average length of less than 100 μm length, wherein the particles are densely stacked substantially parallel to the surface of said portion; and wherein the layer of crystalline paclitaxel particles has a

thickness of less than 10 μm ."

Claim 1 of auxiliary requests **2** is identical to claim 1 of the main request.

Auxiliary requests **4** and **5**:

"A drug delivery balloon comprising a layer of crystalline paclitaxel particles, wherein the particles have an average length of less than 100 μm length, wherein the particles are densely ~~stacked~~packed on at least a portion of the surface of the balloon and substantially parallel to the surface of said portion; and wherein the layer of crystalline paclitaxel particles has a thickness of less than 10 μm ."

Auxiliary request **6**:

"A drug delivery balloon comprising a layer of crystalline paclitaxel particles, wherein the particles have an average length of less than 100 μm length on at least a portion of the surface of the balloon, wherein the particles are densely stacked substantially parallel to the surface of said portion; and wherein the layer of crystalline paclitaxel particles has a thickness of substantially less than 10 μm ."

Auxiliary request **6a**:

"A drug delivery balloon comprising a layer of crystalline paclitaxel particles on at least a portion of the surface of the balloon , wherein the particles have an average length of less than 100 μm length, wherein the particles are densely stacked substantially parallel to the surface of said portion; and wherein the layer of crystalline paclitaxel particles has a

thickness of substantially less than 10 μm ."

Auxiliary request **7**:

"A drug delivery balloon comprising a layer of crystalline paclitaxel particles, wherein the particles have an average length of less than 100 μm length, wherein the particles are densely stacked substantially parallel to the surface of said portion; and wherein the layer of crystalline paclitaxel particles has a thickness of substantially less than 10 μm ."

Auxiliary request **8**:

"A drug delivery balloon comprising a layer of crystalline paclitaxel particles, wherein the particles have an average length of less than 100 μm length on at least a portion of the surface of the balloon, wherein the particles are densely stacked substantially parallel to the surface of said portion; and wherein the layer of crystalline paclitaxel particles has a thickness of substantially less than 10 μm ."

Auxiliary requests **9** and **10**:

"A drug delivery balloon comprising a layer of crystalline paclitaxel particles, wherein the particles have an average length of less than 100 μm length, wherein the particles are densely ~~stacked~~ packed on at least a portion of the surface of the balloon and substantially parallel to the surface of said portion; and wherein the layer of crystalline paclitaxel particles has a thickness of substantially less than 10 μm ."

VIII. The appellant's arguments can be summarised essentially as follows:

Claim 1 of the main request meets the requirements of Article 123(2) and 76(1) EPC. A basis for the amendments with respect to the application as filed and to the parent application as filed can be found in the respective descriptions. The same applies to claim 1 of the auxiliary requests. None of the requests extend the protection conferred by the patent as granted. The requests therefore also meet the requirements of Article 123(3) EPC. The claimed subject-matter is novel and inventive over the prior art. The requests therefore also meet the requirements of Articles 54 and 56 EPC. Document D22, which contains experimental evidence supporting the appellant's arguments on novelty, is to be admitted. Document D23 is not to be admitted, because it is not *prima facie* relevant.

IX. Respondents I to III (opponents 1 to 3) argued essentially as follows:

Claim 1 of the main request is not allowable, because the claimed subject-matter finds no basis in the application as filed and the parent application as filed. The subject-matter of several of the auxiliary requests has been amended and extends beyond the protection conferred by the patent as granted. The subject-matter of none of the requests meets the requirements of Articles 54 and 56 EPC because of lack of novelty and lack of inventive step. The respondents also argue that claim 1 of auxiliary request 1 is not clear (Article 84 EPC).

- X. The board issued a communication with their preliminary opinion on the legal and factual issues of the case.
- XI. Respondent I declared with letter of 24 February 2025 not to attend the oral proceedings and withdrew their request to hold oral proceedings.
- XII. Oral proceedings before the board were held on 1 April 2025. The decision was announced at the end of the proceedings.
- XIII. The appellant requests that the decision of the opposition division be set aside and the patent be maintained on the basis of the patent as granted (main request), or as an auxiliary measure on the basis of auxiliary requests 1 to 10, filed with the statement setting out the grounds of appeal on 6 July 2022, or auxiliary requests 1a or 6a, filed on 28 November 2024. The appellant further requests that document D22 be admitted and that document D23 not be admitted into the proceedings.
- XIV. Respondents I to III request that the appeal be dismissed and document D22 not be admitted into the proceedings. Respondent I requests that document D23 be admitted into the proceedings. Respondent III requests that auxiliary requests 1a and 6a not be admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

Main request (patent as granted)

Amendments (Article 100(c) EPC)

2. The opposition division decided that the main request was not allowable for lack of novelty of the drug delivery balloon according to claim 1 (Articles 100(a) and 54 EPC). The opposition division did not take a decision on the question whether the main request meets the requirements of Article 123(2) EPC. The respondents submitted - as during the opposition proceedings - that claim 1 of the main request did not find a basis in the application as filed.

3. The appellant argued that embodiments 23, 24 and 26 of the application as filed (document D11) provided a basis for claim 1 of the main request, as well as the combination of claim 1 with embodiments 23 and 24, and the combination of claim 1 with lines 22 to 26 on page 10 of the description.

4. The board comes to the following conclusions:
 - 4.1 Claim 1 of the main request contains the feature "... wherein the particles are densely stacked substantially parallel to the surface of said portion; ...". The location of "... said portion ...", which has a thickness of less than 10 μm , of paclitaxel particles, which have an average length of less than 100 μm , and wherein the particles are densely stacked substantially parallel, is not defined in claim 1 of the main request. In fact the term "*said portion*" does not refer to a "*portion*" defined earlier in the claim. Therefore when reading the claim the skilled person is not able to recognise what "*portion*" of the balloon is meant by the expression "*said portion*". The board therefore arrives at the conclusion that the layer of crystalline paclitaxel having the characteristics defined in claim

1 of the main request, namely that *"... the particles have an average length of less than 100 μm length, wherein the particles are densely stacked substantially parallel to the surface; and wherein the layer of crystalline paclitaxel particles has a thickness of less than 10 μm ..."* can be located anywhere in or on the balloon.

4.2 The claims as originally filed cannot be a basis for claim 1 of the main request already since they do not include the feature *"... wherein the layer of crystalline paclitaxel particles has a thickness of less than 10 μm ."*

4.3 The passages in the description of the application as filed referred to by the appellant, however, do not provide a basis for claim 1 either:

4.3.1 The appellant referred as basis for the amendment to embodiments 23, 24 and 26 on page 17 of document D11.

4.3.2 Embodiment 23 has the following wording:

"A drug delivery balloon comprising a layer of crystalline drug particles of less than 100 μm average length on at least a portion of the surface of the balloon, said drug particles densely stacked substantially parallel to the surface of said portion."

4.3.3 Embodiments 24 and 26 refer back to embodiment 23 and 20 to 25, respectively. They disclose the additional features *"... wherein the layer of crystalline particles is less than 10 μm thick ..."* (embodiment 24) and *"... wherein the drug is paclitaxel ..."* (embodiment 26).

- 4.3.4 Accordingly, the drug delivery balloon disclosed in the combination of embodiments 23, 24 and 26 of D11 comprises a layer of crystalline paclitaxel particles of less than 100 pm average length, the layer being less than 10 µm thick and - in addition - the layer, is located on "... at least **a portion of the surface of the balloon ...**". Claim 1 of the main request, however, does not contain this specification (see point 4.1 of this decision).
- 4.3.5 The appellant argued that balloon catheters in general comprise several layers. The skilled person thus considered the omission of the feature "... at least a *portion of the surface of the balloon ...*" not to be new technical information. The skilled person was aware that the drug had to be on the surface of the balloon when used as intended. It was thus irrelevant whether the term was present in claim 1, or not, since every balloon had a surface, even if several layers of balloon material or other substances were present.
- 4.3.6 This argument is not convincing. Document D11 discloses on page 6, lines 9 to 12, embodiments wherein the drug containing layer is applied over an underlayer of material that has a high solubility in bodily fluids to undercut the drug facilitate breakup of the drug-containing layer upon balloon expansion. Such an embodiment does not comprise a layer of paclitaxel crystals on the surface of the balloon, since an additional layer is present between the balloon surface and the paclitaxel layer. In addition, the layer containing paclitaxel may also be covered with additional protective layers (see D11, page 5, line 33 to page 6, line 8).

- 4.3.7 Thus, the combination of embodiments 23, 24 and 26 of D11 does not provide a basis for claim 1 of the main request.
- 4.3.8 The appellant referred to a combination of claim 1 with embodiments 23 and 24 on page 17 of D11 as a basis for claim 1 of the main request.
- 4.3.9 This combination, however, does also not provide a basis for claim 1 of the main request. The combination still requires that the layer of crystalline paclitaxel particles be packed (or stacked) on at least a portion of a surface of the balloon.
- 4.3.10 The appellant referred to a combination of claim 1 with the disclosure on page 10, lines 22 to 26 of the description of document D11 as a basis for claim 1 of the main request.
- 4.3.11 This combination, however, does not provide a basis for claim 1 of the main request either, for the same reasons as given before.
5. Since there is no basis for claim 1 of the main request in the application as filed (D11), the main request does not meet the requirements of Article 123(2) EPC, and is thus not allowable. It is therefore not necessary to decide whether the claim finds a basis in the parent application as filed (D10), or not.

Auxiliary request 1

Amendments (Article 123(3) EPC)

6. Respondent's II and III argued that the subject-matter of claim 1 of auxiliary request 1 extended that of the

patent as granted, contrary to the requirements of Article 123(3) EPC.

7. The board comes to the following conclusions:

7.1 Claim 1 of auxiliary request 1 is directed at "... a drug delivery balloon comprising a layer of crystalline paclitaxel particles, wherein the particles have an average length of less than 100 μm length on at least a portion of the surface of the balloon, ...". The crystalline paclitaxel particles in that layer on at least a portion of the surface of the balloon therefore have a length of less than 100 μm . They also are densely stacked substantially parallel to the surface of said portion, and the layer of crystalline particles must have a thickness of less than 10 μm . The presence of additional crystalline paclitaxel particles, which are not on at least the portion of the surface of the balloon, is not excluded. These additional particles, however, are not limited in length. Neither is the layer of such particles limited to a thickness of less than 10 μm . The limitations only apply for particles in a layer on a portion of the surface of the balloon.

7.2 According to claim 1 of the patent as granted the balloon comprises a layer of crystalline paclitaxel particles, these particles have an average length of less than 100 μm , irrespective of the possible location of the layer in or on the balloon. Additionally, the thickness of the layer is less than 10 μm , and the particles are densely stacked. The balloon can comprise other layers, such as a protective polymeric layer or an underlayer (see page 5, line 33 to page 6, line 12). The application documents do not disclose the presence of additional layers of paclitaxel. The balloon according to claim 1 of the patent as granted does not

comprise layers of paclitaxel wherein the length and thickness limitations according to the claim do not apply.

7.3 Since the drug delivery balloon according to claim 1 of auxiliary request 1 is limited in terms of paclitaxel particle length, layer thickness and dense stacking parallel to the surface only within a layer of at least a portion on the surface of the balloon, but not within other layers which are not located on the surface of the balloon - as in claim 1 of the patent as granted - the claim extends the protection conferred by the patent as granted, contrary to the requirements of Article 123(3) EPC.

8. Auxiliary request 1 is, for these reasons, not allowable (Article 123(3) EPC).

Auxiliary requests 2 to 10, 1a and 6a:

9. The appellant did not provide any additional arguments concerning the allowability of the amendments of auxiliary requests 2 to 10, 1a and 6a.

10. The board comes to the following conclusions:

10.1 Claim 1 of auxiliary request 2 is identical to claim 1 of the main request. Auxiliary request 2 is not allowable for the same reasons as the main request (Article 123(2) EPC).

10.2 Claim 1 of auxiliary request 3 is identical to claim 1 of auxiliary request 1. The request is not allowable for the same reasons as auxiliary request 1 (Article 123(3) EPC).

- 10.3 Claim 1 of auxiliary requests 4 and 5 essentially differs from claim 1 of auxiliary request 1 in that it comprises the additional feature that the particles are densely "*packed*" instead of "*stacked*". The requests are not allowable for the same reasons as auxiliary request 1 (Article 123(3) EPC).
- 10.4 Claim 1 of auxiliary request 6 differs from claim 1 of auxiliary request 1 in that the layer thickness is "*substantially*" less than 10 μm . The request is not allowable for the same reasons as auxiliary request 1 (Article 123(3) EPC).
- 10.5 Claim 1 of auxiliary request 7 differs from claim 1 of the main request in that the layer thickness is "*substantially*" less than 10 μm . The request is not allowable for the same reasons as the main request (Article 123(2) EPC).
- 10.6 Claim 1 of auxiliary request 8 differs from claim 1 of auxiliary request 1 in that the layer thickness is "*substantially*" less than 10 μm . The request is not allowable for the same reasons as auxiliary request 1 (Article 123(3) EPC).
- 10.7 Claim 1 of auxiliary requests 9 and 10 differs from claim 1 of auxiliary request 4 in that the layer thickness is "*substantially*" less than 10 μm . The requests are not allowable for the same reasons as auxiliary request 1 (Article 123(3) EPC).
- 10.8 The appellant submitted that the subject-matter of claim 1 of auxiliary requests 1a and 6a is identical to claim 1 of corresponding requests on file, *i.e.* auxiliary requests 1 and 6 (see point V.2 of the submission of 28 November 2024). The requests are

therefore not allowable for the same reasons as auxiliary requests 1 and 6 (Article 123(3) EPC).

11. Since auxiliary requests 1a and 6a are not allowable, a decision on the request of respondent III not to admit them into the proceedings is not necessary.
12. The present decision is taken without taking account of the content of documents D22 and D23. A decision on their admission is thus not necessary.

Conclusion

13. The main request, as well as auxiliary requests 2 and 7 do not comply with the requirements of Article 123(2) EPC. Auxiliary requests 1, 1a, 3 to 6, 6a, and 8 to 10 do not comply with the requirements of Article 123(3) 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