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**Datasheet for the decision
of 14 October 2009**

Case Number: T 1020/08 - 3.3.10

Application Number: 97109380.2

Publication Number: 0832655

IPC: A61L 33/00

Language of the proceedings: EN

Title of invention:

Drug release stent coating and process

Patentee:

Boston Scientific Scimed, Inc.

Opponents:

Cordis Medizinische Apparate GmbH
Cordis Italia S.p.A.

Headword:

Drug release stent coating/BOSTON SCIENTIFIC SCIMED

Relevant legal provisions:

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

Relevant legal provisions (EPC 1973):

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Keyword:

"Withdrawal of the opposition by opponents/respondents in
appeal pendings"

"Auxiliary requests: amendments (not allowable) - not directly
and unambiguously derivable from application as filed, neither
explicitly nor implicitly"

Decisions cited:

T 0789/89, T 0330/05

Catchword:

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Case Number: T 1020/08 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 14 October 2009

Appellant: Boston Scientific Scimed, Inc.
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Representative: Peterreins, Frank
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 18 April 2008
revoking European patent No. 0832655 pursuant
to Article 101(2) EPC.

Composition of the Board:

Chairman: P. Gryczka
Members: J. Mercey
F. Blumer

Summary of Facts and Submissions

- I. The Appellant (Proprietor of the Patent) lodged an appeal on 30 May 2008 against the decision of the Opposition Division dated 18 April 2008 revoking European patent No. 832 655 and on 14 August 2008 filed a written statement setting out the grounds of appeal.
- II. Notice of Opposition had been filed by Opponents I and II requesting revocation of the patent in its entirety on the grounds of *inter alia* extending the subject-matter of the patent in suit beyond the content of the application as filed (Article 100(c) EPC).
- III. The Opposition Division held that the amendments made to the patent according to the then pending main request and auxiliary requests 1 to 5 extended the subject-matter of the patent in suit beyond the content of the application as filed. Most particularly it found that the feature "wherein the topcoat and undercoat have different formulations with respect to the matrix polymeric material" was not disclosed *per se*, let alone in combination with the remaining features of claim 1 of any request, more particularly with the undercoat incorporating an antibiotic.
- IV. With letter dated 1 September 2009, the Appellant filed a new main request and auxiliary requests I to VII, claim 1 of the main request reading as follows:

"An implantable medical device having an outer surface, covered at least in part by a conformal coating comprising an undercoat of a hydrophobic biostable elastomeric material which does not degrade

incorporating an amount of an antibiotic therein for timed delivery therefrom,
and a topcoat comprising a non-thrombogenic polymeric material, which at least partially covers the undercoat,
wherein the topcoat and the undercoat have different formulations with respect to the matrix polymeric material,
and the implantable medical device is a stent for vascular implantation."

Claim 1 of auxiliary request I read:

"An implantable medical device having an outer surface, covered at least in part by a conformal coating of a hydrophobic biostable elastomeric material which does not degrade incorporating an amount of an antibiotic therein for timed delivery therefrom,
and means associated with the conformal coating to provide a non-thrombogenic surface after said timed delivery of the antibiotic, comprising an outer layer at least partially covering the conformal coating, the outer layer comprising a non-thrombogenic polymeric material,
wherein the outer layer and the conformal coating have different formulations with respect to the matrix polymeric material,
and the implantable medical device is a stent for vascular implantation."

Claim 1 of auxiliary request II differed from claim 1 of auxiliary request I in that the conformal coating comprised several layers and the feature "the outer layer and the conformal coating have different

formulations with respect to the matrix polymeric material" was replaced by the feature "the outer layer having a different composition with respect to the matrix polymeric material".

Claim 1 of auxiliary request III differed from claim 1 of auxiliary request II in that feature "the outer layer having a different composition with respect to the matrix polymeric material" was replaced by the feature "the outer layer and the layers of the conformal coating having a different composition with respect to the matrix polymeric material".

Claim 1 of auxiliary request IV differed from claim 1 of auxiliary request III in that the feature "the outer layer and the layers of the conformal coating having a different composition with respect to the matrix polymeric material" was replaced by the feature "the outer layer having a different composition with respect to the antibiotic and the matrix polymeric material".

Claim 1 of auxiliary request V differed from claim 1 of auxiliary request IV in that the feature "the outer layer having a different composition with respect to the antibiotic and the matrix polymeric material" was replaced by the feature "the outer layer and the layers of the conformal coating having a different composition with respect to the antibiotic and the matrix polymeric materials".

Claim 1 of auxiliary request VI differed from claim 1 of auxiliary request V in that the feature "the outer layer and the layers of the conformal coating having a different composition with respect to the antibiotic

and the matrix polymeric materials" was replaced by the feature "the outer layer having a different composition with respect to the antibiotic, the matrix polymeric material and the crosslinking agent".

Claim 1 of auxiliary request VII differed from claim 1 of auxiliary request VI in that the feature "the outer layer having a different composition with respect to the antibiotic, the matrix polymeric material and the crosslinking agent" was replaced by the feature "the outer layer and the layers of the conformal coating having a different composition with respect to the antibiotic, the matrix polymeric materials and the crosslinking agent".

- V. The Appellant argued that claim 1 of all requests found a basis in the application as filed. More particularly, the basis for the feature "wherein the topcoat and the undercoat have different formulations with respect to the matrix polymeric material" in the main request was to be found in particular at page 19, lines 9 to 14, but also at page 8, lines 5 to 11 and page 13, lines 25 to 26 of the application as filed. The corresponding feature in the auxiliary requests I to VII did not essentially differ with respect to the subject-matter defined, but merely with respect to the wording thereof, this being based more closely on the actual wording of the application as filed, namely on that at page 19, lines 9 to 14 thereof. Basis for the antibiotic being incorporated in the conformal coating was to be found at page 12, line 10 of the application as filed. The Appellant also argued that the amendment was not a result of multiple selections from different lists,

citing decision T 330/05 (not published in OJ EPO) in this respect.

The Appellant argued that the terms "undercoat" and "topcoat" used several times in the application as filed were often synonymous with the terms "underlayer" and "conformal coating", and "outer layer" and "top layer", respectively. It submitted that although these terms were not used in a consistent manner throughout the application as filed, it was clear that the "outer layer comprising a non-thrombogenic material" according to claim 9 and the "top layer" referred to on page 19, line 14 of the application as filed, were identical to the "topcoat" of granted claim 1. Therefore, claim 1 of each request, regardless of the specific wording thereof, was directed to a stent comprising at least two layers/coatings/coats having different formulations/compositions with respect to the matrix polymeric material, one of them incorporating the antibiotic and the other providing a non-thrombogenic surface.

In the wording "upper undercoat layers" on page 19, lines 10 to 11 of the application as filed, the word "undercoat" was a typographical error, as was the reference to a "topcoat" in feature (a) of original claim 23. It was clear to the skilled person from original claim 9, which described an outer layer comprising a non-thrombogenic polymeric material, that the nature of the matrix polymeric material was crucial to the invention, there additionally being no overlap between the two lists of suitable matrix polymeric materials for the undercoat and overcoat given on

page 11, line 26 to page 12, line 7 of the application as filed.

- VI. After originally requesting dismissal of the appeal on the basis that all of the requests violated *inter alia* Articles 100(c) and 123(2) EPC, Opponents I and II withdrew their oppositions with letters dated 1 October 2009 and 2 October 2009, respectively.
- VII. The Appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or, subsidiarily, on the basis of any of the auxiliary requests I to VII, all requests submitted with letter dated 1 September 2009, or, alternatively, to remit the case to the department of first instance for further prosecution.
- VIII. Oral proceedings were held on 14 October 2009. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.
2. When, as here, the Opposition Division has revoked the patent the withdrawal of the oppositions in the appeal proceedings by the Respondents/Opponents has no direct procedural significance other than that the former Opponents are no longer considered as party to the proceedings as far as the substantive issues are concerned (see T 789/89, OJ EPO 1994, 482).

All requests

3. *Article 100(c) and 123(2) EPC*

3.1 In order to determine whether or not an amendment adds subject-matter extending beyond the content of the application as filed, it has to be examined whether technical information has been introduced which a skilled person would not have directly and unambiguously derived from the application as filed, either explicitly or implicitly.

3.2 In the decision under appeal, the Opposition Division found that the feature "wherein the topcoat and undercoat have different formulations with respect to the matrix polymeric material" was not disclosed *expressis verbis*, let alone in combination with the remaining features of claim 1 of any request, more particularly with the undercoat incorporating an antibiotic. Thus, this feature will hereinafter be examined for its basis in the application as filed.

3.3 Claim 1 of all requests, as conceded by the Appellant at the oral proceedings before the Board, is directed to a stent comprising at least two coatings, the undercoat (named "conformal coating" in auxiliary requests I to VII, but hereinafter always referred to as "the undercoat") comprising a hydrophobic biostable elastomeric material and an antibiotic, and the topcoat (named "outer layer" in auxiliary requests I to VII, but hereinafter referred to as "the topcoat") comprising a non-thrombogenic polymeric material, wherein these two coatings have different formulations (or different "composition" according to auxiliary

requests II to VII, but hereinafter referred to as "formulation") with respect to *inter alia* the matrix polymeric material.

3.4 This feature required by all requests that these two coatings have different formulations with respect to the matrix polymeric material is not disclosed explicitly in the application as filed. The Appellant submitted, however, that this feature was implicitly disclosed, citing in particular page 19, lines 9 to 14, but also at page 8, lines 5 to 11 and page 13, lines 25 to 26 of the application as filed in this respect.

3.5 The passage at page 19, lines 9 to 14 of the application as filed, on which the Appellant most heavily relies for support for this feature, reads as follows:

"Several applied layers make up what is called the undercoat as at 18. In one process, additional upper undercoat layers, which may be of the same or different composition with respect to bioactive material, the matrix polymeric materials and crosslinking agent, for example, may be applied as the top layer as at 20"

the reference signs referring to those in Figure 1 of the application as filed.

The layers here referred to as being of the same or different composition with respect to *inter alia* the matrix polymeric materials are "additional upper undercoat layers", i.e. they are described as layers belonging to the undercoat, to which the bioactive material, which according to claim 1 of all requests is

an antibiotic, is incorporated. Thus, the reference in this passage to the "top layer" means merely the outer layer of the undercoat, which is itself made up of "several applied layers" and not the topcoat comprising a non-thrombogenic polymeric material as required by claim 1 of all requests. There is no disclosure in the passage at page 19, lines 9 to 14 that the particular "top layer" disclosed therein should comprise a non-thrombogenic polymeric material. Thus the "top layer" (20) at page 19, line 14, which is described as possibly having a different composition with respect to the polymeric material, is not unambiguously the non-thrombogenic polymeric material containing topcoat defined in claim 1 of all requests.

Thus, the passage at page 19, lines 9 to 14 of the application as filed cannot form a basis for the antibiotic containing undercoat and non-thrombogenic polymeric material containing topcoat having different formulations with respect to the matrix polymeric material, since it is not clear whether the top layer referred to therein is the polymeric material containing topcoat of claim 1.

In addition, the phrase "additional upper undercoat layers, which may be of [...] different composition with respect to [...] the matrix polymeric materials" can also be read to mean that the various upper undercoat layers, regardless of whether these make up the topcoat of claim 1 or not, may have a different composition amongst themselves, and not necessarily with respect to the undercoat.

3.5.1 The Appellant argued that the word "undercoat" in the wording "additional upper undercoat layers" was an obvious typographical error, with the consequence that the skilled person would in fact read "additional upper layers" and would thus understand these "upper layers" to correspond to the topcoat of claim 1. The Appellant further argued that it was clear from this passage at page 19 in combination with Figure 1 as originally filed, that "the top layer as at 20" must be the topcoat according to claim 1, as no other topcoat was thereafter applied, Figure 1 showing that **either** the top layer was applied at 20 **or** the top layer was applied at 32 (for fluorosilicone) or 42 (for polyethylene glycol), the layers 32 or 42 not being applied additionally to the layer 20.

However, it is not evident that there is an error in the aforementioned wording, since the wording as it stands makes technical sense (cf. point 3.5 above). Moreover, Figure 1 is a flow diagram wherein the arrows are so arranged that the possibility of carrying out steps 32 and/or 42, i.e. surface treatment with the non-thrombogenic polymeric materials fluorosilicone and/or polyethylene glycol, after step 20, i.e. after application of the "top layer", is indicated, this interpretation being corroborated by the passage at page 21, lines 20 to 28 of the application as filed, which describes that a stent having an undercoat comprising multiple applied layers can subsequently be surface treated with a non-thrombogenic polymeric material.

3.5.2 The Appellant further argued that it was apparent to the skilled person from original claim 9, which

disclosed a medical device comprising an outer layer comprising a non-thrombogenic polymeric material, that the nature of the matrix polymeric material was crucial to the invention. That the matrix polymeric material should be different in the topcoat and undercoat was evident from the two lists of suitable matrix polymeric materials for the undercoat and overcoat given on page 11, line 26 to page 12, line 7 of the application as filed, there being no overlap between the materials listed. The Appellant submitted that the skilled person would thus understand the passage at page 19, lines 9 to 14, when taken in the context of the description as a whole, when reading it in a reasonable manner, to mean that it was essential to the invention that the topcoat and undercoat be different with respect to the matrix polymeric materials.

However, the combination of original claims 1 and 9 merely discloses a medical device having an undercoat of a hydrophobic elastomeric material and a topcoat comprising a non-thrombogenic polymeric material. This is not a disclosure that the topcoat and the undercoat have different formulations with respect to the matrix polymeric material. The paragraph bridging pages 11 and 12, consists merely of lists of "suitable" polymers for the undercoat and topcoat, said lists not being exhaustive, such that it is not excluded by this paragraph that the polymers for the undercoat and topcoat may be the same. In addition, these two lists overlap: silicones, more particularly substituted polysiloxanes, included in the list of suitable polymers for the undercoat is a generic term embracing fluorosilicones, included in the list of suitable polymers for the topcoat. Indeed, on page 14, lines 8

to 14, it is indicated that unmedicated silicone may be used as the top layer, silicone being however cited in the list at page 11, line 27 as an example of a suitable polymer for use in the undercoat, i.e. the topcoat and undercoat may be of the same polymeric material. The application as filed thus does not disclose that it is essential to the invention that the topcoat and the undercoat have different formulations with respect to the matrix polymeric material.

- 3.6 The phrase at page 13, lines 25 to 26 of the application as filed upon which the Appellant also relies reads "the combination of different matrix polymer materials at different layers", the Appellant arguing that it was apparent to the skilled person that these "different layers" corresponded to the topcoat and undercoat according to claim 1 of all requests.

However, the "different layers" in this phrase are not necessarily the bioactive material-containing undercoat and the non-thrombogenic polymeric material-containing topcoat, because the application as originally filed also discloses other types of layers, not least of which are the layers making up the undercoat disclosed at page 19, lines 9 to 11 (cf. point 3.5 above). Additional disclosures that the undercoat may comprise "a plurality", "a certain number" or "multiple" layers may be found at page 8, lines 1 to 2, page 9, lines 21 to 22 and page 21, lines 26 to 27, respectively. Since the reference to "different layers" in this passage is not specifically to the antibiotic containing undercoat and non-thrombogenic polymeric material containing topcoat, it cannot be derived directly and unambiguously therefrom that these two specific layers

have different formulations with respect to the matrix polymeric material.

- 3.7 The Appellant also referred to the passage at page 8, lines 5 to 11 of the application as filed which reads "In many applications the layered coating is referred to or characterized as including an undercoat and topcoat. [...] Typically these are of different formulations with most or all of the active material being contained in the undercoat and a non-thrombogenic surface is found in the topcoat."

However, this passage merely suggests that the difference in formulation between topcoat and undercoat derives from the inclusion of a biologically active material or non-thrombogenic surface, respectively. There is no disclosure whatsoever that the topcoat and undercoat should have different formulations with respect to the matrix polymeric material. Thus, the passage at page 8, lines 5 to 11 of the application as filed cannot form a basis for the antibiotic containing undercoat and non-thrombogenic polymeric material containing topcoat having different formulations with respect to the matrix polymeric material

- 3.8 The Appellant also argued that the amendment was not a result of multiple selections from different lists, citing decision T 330/05 (*loc. cit.*) in this respect. However, said decision is not relevant to the present case, since in the present case, the reason that the Board does not find the amendment in question to be allowable (cf. points 3.5 to 3.7 above) is not that it results from an unallowable selection from lists, but rather that each of the three different passages

referred to individually by the Appellant as a basis in its own right for said amendment (cf. point 3.4 above), does not disclose the feature in question, namely that the topcoat and undercoat should have different formulations with respect to the matrix polymeric material.

- 3.9 For those reasons, the Board concludes that there is neither an explicit nor an implicit disclosure in the application as filed of the features:
- "the topcoat and the undercoat have different formulations with respect to the matrix polymeric material" into claim 1 of the main request;
 - "the outer layer and the conformal coating have different formulations with respect to the matrix polymeric material" into claim 1 of auxiliary request I;
 - "the outer layer having a different composition with respect to the matrix polymeric material" into claim 1 of auxiliary request II;
 - "the outer layer and the layers of the conformal coating having a different composition with respect to the matrix polymeric material" into claim 1 of auxiliary request III;
 - "the outer layer having a different composition with respect to the antibiotic and the matrix polymeric material" into claim 1 of auxiliary request IV;
 - "the outer layer and the layers of the conformal coating having a different composition with respect to the antibiotic and the matrix polymeric materials" into claim 1 of auxiliary request V;
 - "the outer layer having a different composition with respect to the antibiotic, the matrix polymeric material and the crosslinking agent" into claim 1 of auxiliary request VI;

"the outer layer and the layers of the conformal coating having a different composition with respect to the antibiotic, the matrix polymeric materials and the crosslinking agent" into claim 1 of auxiliary request VII,
such that these amendments extend the subject-matter claimed beyond the content of the application as filed, thus justifying the ground for opposition pursuant to Article 100(c) EPC in the case of the main request, and being contrary to the requirements of Article 123(2) EPC in the case of auxiliary requests I to VII, with the consequence that the main request and auxiliary requests I to VII are not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

P. Gryczka