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**Datasheet for the decision
of 10 January 2013**

Case Number: T 0320/10 - 3.3.10

Application Number: 98908650.9

Publication Number: 968013

IPC: A61L 29/00, A61L 31/00

Language of the proceedings: EN

Title of invention:
Coated implantable medical device

Patentee:
Cook Medical Technologies LLC

Opponent:
Terumo Kabushiki Kaisha

Headword:
Coated implantable medical device/COOK INC.

Relevant legal provisions:
EPC Art. 100(c), 123(2)

Keyword:
"All requests - added subject-matter (yes): characteristic described for a structure included in a device not automatically transferable to the claimed device"

Decisions cited:
T 0314/07

Catchword:
-



Case Number: T 0320/10 - 3.3.10

DECISION
of the Technical Board of Appeal 3.3.10
of 10 January 2013

Appellant: Cook Medical Technologies LLC
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 22 December 2009
revoking European patent No. 968013 pursuant to
Article 101(3) (b) EPC.

Composition of the Board:

Chairman: P. Gryczka
Members: J. Mercey
C. Schmidt

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. 968 013.
- II. Notice of Opposition had been filed by the Respondent (Opponent) 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). The Respondent cited *inter alia* the following document during opposition proceedings:
- (1) EP-A-747 069.
- III. The decision under appeal was based on a main request and an auxiliary request, independent claim 1 of the main request reading as follows:
- "An implantable medical device (10), including:
a structure (12) adapted for introduction into a patient, the structure (12) having at least one surface and being composed of a base material (14);
at least one coating layer (16) posited on one surface of the structure (12), the coating layer comprising a non-porous material; and
at least one layer (18) of a bioactive material posited over at least a portion of the at least one coating layer (16), characterised in that the at least one layer (18) of bioactive material forms the outer or outermost layer of the device, and in that release of the bioactive material into a patient is controlled by said at least one coating layer (16)."

IV. The Opposition Division found that the subject-matter of claim 1 of the main request extended beyond the content of the application as filed, since there was no disclosure in the application as filed of *inter alia* the feature that "the at least one layer (18) of bioactive material forms the outer or outermost layer of the device". In this respect, it cited document (1) to illustrate the fact that the outer or outermost layer of the structure included in a medical device did not necessarily make up the outer or outermost layer of the medical device of the invention. The subject-matter of the then pending auxiliary request was found to meet neither the requirements of Article 123(2) nor 123(3) EPC.

V. With letter dated 19 December 2012, the Appellant submitted auxiliary requests 1 and 2.

Claim 1 of auxiliary request 1 read as follows:

"An implantable medical device (10), including:
a structure (12) adapted for introduction into a patient, the structure (12) having at least one surface and being composed of a base material (14);
a coating layer (16) applied directly to the outer surface of base material (14) of the structure (12), the coating layer (16) being an absorbent and/or adsorbent layer; and
a layer (18) of a bioactive material attached to the coating layer (16), the layer (18) of bioactive material forming the outer layer of the device, release of the bioactive material into a patient being controlled by the said coating layer (16)."

Claim 1 of auxiliary request 2 differed from claim 1 of the main request only in that the term "including" was replaced by the term "consisting of" and by the deletion of the specification that the coating layer (16) comprised a non-porous material.

VI. The Appellant argued that the subject-matter of claim 1 of all requests did not extend beyond the content of the application as filed. More particularly, it argued that the feature that the layer of bioactive material formed the outer layer of the device was supported by the application as filed, the presence of an additional outer porous layer not being described as essential to the invention. Indeed original claim 1 explicitly provided for an implantable medical device having only three components, namely a structure, a coating layer and a layer of bioactive material, wherein in its simplest form, the bioactive material was the outermost layer of the device. Most particularly, Figures 11 and 12 described at pages 19 to 22 of the application as filed supported a device in which the outermost layer of the structure was a bioactive material. The term "structure" as used in the application as filed was synonymous with the term "device", and related to the nature of the device, and not to any sub-part thereof. The Appellant further submitted that in view of the disclosure in the application as filed of the device delivering the bioactive material directly to the body portion/tumor, it was implicit that the bioactive material formed the outer or outermost layer of the device.

During the oral proceedings before the Board, held on 10 January 2013, the Appellant no longer maintained the objection raised in writing that the Opposition Division had committed a substantial procedural violation.

VII. The Respondent argued that all requests contained subject-matter extending beyond the content of the application as filed, since there was no disclosure therein of the feature that the layer of bioactive material formed the outer or outermost layer of the device. Although the medical device of claim 1 of the main request specifically defined only three components, the presence of further elements, such as a further layer posited over the bioactive material as disclosed in original claim 2, was not excluded. With regard to the parts of the application as filed referred to by the Appellant as providing a basis for the bioactive material forming the outer or outermost layer of the device, the text passages at pages 19 to 22 and Figures 11 and 12 either referred to very specific embodiments which could not be generalised and/or the bioactive layer formed the outer layer of a **structure** (12), but not necessarily of the **device** (10) *per se*. The Figures were merely schematic illustrations which might be just a portion of a device, it being possible that the structure (12) was configured in such a manner that it had no contact to the outside of the device (10). Direct delivery of the bioactive material as referred to in the application as filed meant merely local delivery.

VIII. The Appellant requested 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 main request on which the contested decision was based, or, subsidiarily, on the basis of either of auxiliary requests 1 or 2 submitted with letter dated 19 December 2012.

The Respondent requested that the appeal be dismissed.

IX. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Article 100(c) EPC*

2.1 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, implicit disclosure meaning no more than the clear and unambiguous consequence of what is explicitly disclosed.

2.2 In the decision under appeal, the Opposition Division found that *inter alia* the feature of claim 1 which defined that "the at least one layer (18) of bioactive material forms the outer or outermost layer of the

device" was not disclosed in the application as filed. Thus, this feature will hereinafter be examined for its basis in the application as filed.

- 2.3 The parts of the application as filed cited by the Appellant as support for this amendment to claim 1 were primarily Figures 11 and 12, together with the descriptions thereof from page 19, line 28 to page 22, line 4. These figures depict a device (10) including a structure (12), wherein "the outer layer of **structure (12)** is a bioactive material layer (18)" (see in particular Figure 11 and page 20, lines 9 to 14; emphasis added). Hence, these Figures and parts of the description disclose a device comprising a **structure** having an outer layer of bioactive material. The question thus arises whether the amendment of the claim directed to the bioactive material forming the outer or outermost layer of the **device** is nevertheless directly and unambiguously derivable from a passage of the application as filed not describing the **device** as such, but rather the **structure** included therein.
- 2.4 It thus needs to be examined whether the terms "device" and "structure" as used in the application as filed are synonymous with one another, as submitted by the Appellant, such that the outer layer of a structure would necessarily also form the outer layer of the device. Alternatively, it needs to be examined whether the structure included in or forming the device is automatically configured in such a way that the outer layer thereof is also the outer layer of the device. The Appellant further argued in this respect that the structure (12) related to the nature of the device (10), and not to any sub-part thereof.

2.5 However, original claim 1 defines the medical device (10) as "including" a structure (12) and in every Figure in the application as filed, including Figures 11 and 12, the device (10) and the structure (12) are always denoted separately, which implies that these two features need not necessarily be one and the same thing. This interpretation is further supported by page 9, line 30 to page 10, line 6 of the application as filed, which reads "the inserted structure 12 need not be an entire device, but can merely be that **portion** of a vascular or other device which is intended to be introduced into the patient. Accordingly the structure 12 can be configured as at least one of, or **any portion of**, a catheter, a wire guide, a cannula [...]. The structure 12 can also be configured as a combination of **portions** of any of them" (emphasis added). Thus the application as filed does not equate the term "structure" with the term "device".

2.6 The Appellant referred to page 6, line 29 to page 7, line 4 and to page 7, lines 15 to 18 of the application as filed to demonstrate that the terms "structure" and "device" were used synonymously.

However, both of these passages also specifically distinguish between these two terms: the passage bridging pages 6 and 7 reads "The device may include two or more layers of different bioactive materials **atop the structure**" (emphasis added), the "outermost layer" referred to on page 7, line 3 being the outermost layer of the "device **structure**" (see page 7, line 1) and not of the device **per se**. The passage referred to on page 7 reads "the structure **included** in

the device may be **configured** in a variety of ways" (emphasis added), i.e. structure and device are not presented as equivalents.

2.7 Even if the structure (12) may be considered to relate to the "nature of the device", and not to any sub-part thereof, as argued by the Appellant, said structure still needs to be "configured" in order for it to represent a medical device according to the invention (see page 7, lines 15 to 18 and page 9, lines 22 to 28 of the application as filed). The particular characteristics of the structure (12) described in the application as filed could be automatically transferred to the final medical device (10) only if these characteristics remained unchanged throughout the process, namely "configuration", of making the device (see T 314/07, point 2.2, not published in OJ EPO), in other words, if the location of the outer layer of the structure were not altered by the process steps leading to the final device, namely by the "configuration" as a vascular or other medical device which can include helical wound strands, perforated cylinders, or the like (see page 9, lines 23 to 28 of the application as filed).

2.8 However, the Appellant itself explained at the oral proceedings before the Opposition Division (see last paragraph of point 6 of the minutes thereof), with the help of document (1) as illustration, which also relates to a coated implantable medical device, that the planar object shown in Figure 7 therein, of which Figure 6A was a section view thereof, was subsequently coiled to form a cylindrical stent, namely the medical device *per se*. When discussing Figure 6A of the

document (1) in point 7.2 of its letter dated 26 April 2007 before the Opposition Division, the Appellant submitted that the layer of bioactive material (18'), namely heparin, was "located on an **internal** layer of the device". Thus although the bioactive material (18') may be considered to be located on the outer or outermost surface of the structure (12) in Figure 6A, the outer or outermost layer of the tridimensional device is a porous layer (20) and not the bioactive material (18') (see document (1), column 19, lines 13 to 19 and 28 to 33). Therefore, the location of the bioactive layer in the structure (12) may be altered by the process steps leading to the final medical device (10), with the consequence that the passages in the application as filed describing the bioactive material as being the outer layer of the structure (12) are not automatically applicable to the final medical device (10).

2.9 The Board thus holds that the outer or outermost layer of the structure (12) is not necessarily the outer or outermost surface of the device (10), such that the feature that the bioactive material forms the outer or outermost layer of the device cannot be directly and unambiguously derived from the application as filed.

2.10 The Appellant also argued that original claim 1 explicitly provided for an implantable medical device (10) having only three components, namely a structure (12), a coating layer (16) and a layer of bioactive material (18), wherein in its simplest form, the bioactive material was the outer or outermost layer of the device.

The Board does not dispute that such an embodiment is **embraced** by original claim 1. However, this is not the correct criterion for assessing whether subject-matter extending beyond the application as filed has been added or not. Instead, a **direct and unambiguous disclosure** of the feature in question is required. Original claim 1 does not specifically disclose that the bioactive material is the outer or outermost layer of the device and cannot be read as being restricted to such a possibility only, since the wording thereof is "open" in that it defines the device as "including" a structure, a coating layer and a bioactive material. That the subject-matter of original claim 1 embraces devices including a layer posited over the bioactive layer is tellingly illustrated by original dependent claim 2, which discloses exactly such an embodiment. Thus, original claim 1 cannot provide a basis for the contested feature.

2.11 The Appellant further submitted that since the device was intended to deliver bioactive material "directly into a body portion" (see page 3, lines 16 to 18 of the application as filed), such as "directly to the tumor" (see page 12, line 30 to page 13, line 2 and page 13, lines 14 to 16 of the application as filed), it was implicit that the bioactive material formed the outer or outermost layer of the device, since said direct delivery could not be achieved were another layer to be posited over the bioactive material.

However, "direct" delivery to a body portion would be understood by the skilled person to mean "local" delivery, namely that the medical device is implanted directly at the site to be treated. It does not

necessarily exclude the presence of, for example, a porous layer above the bioactive material, as indeed also foreseen by the application as filed (see original claim 2).

- 2.12 For the reasons given above, the Board concludes that there is neither an explicit nor an implicit disclosure in the application as filed of the feature that "the at least one layer (18) of bioactive material forms the outer or outermost layer of the device", such that claim 1 of the main request extends the subject-matter claimed beyond the content of the application as filed, thus justifying the ground for opposition pursuant to Article 100(c) EPC.

Auxiliary request 1

3. *Article 123(2) EPC*

- 3.1 Claim 1 of auxiliary request 1 differs from claim 1 of the main request *inter alia* in that the feature "the at least one layer (18) of bioactive material forms the outer or outermost layer of the device" has been replaced by "the layer (18) of bioactive material forming the outer layer of the device". Since, in contrast to the corresponding contested feature of the main request, this amendment has been introduced after grant, its allowability falls under the provisions of Article 123(2) EPC.

- 3.2 As there is no disclosure in the application as filed of a medical device wherein a bioactive material forms the outer layer thereof (see reasons given above in point 2), the Appellant's argumentation being

essentially the same as for the corresponding feature of the main request, the negative findings and conclusions reached with regard to the main request apply *mutatis mutandis* to this amendment to claim 1 of auxiliary request 1. The Appellant additionally submitted that the subject-matter of claim 1 of this request was fully in compliance with the broad feature disclosures of the embodiment of Figures 11 and 12. However, as already indicated in point 2.5 above, since Figures 11 and 12 also differentiate between the structure (12) and the medical device (10), said Figures do not equate the structure (12) with the device (10), such that they do not directly and unambiguously disclose a medical device wherein a bioactive material forms the outer layer thereof.

- 3.3 Thus, the Board concludes that claim 1 of auxiliary request 1 extends the subject-matter claimed beyond the content of the application as filed, contrary to the requirements of Article 123(2) EPC.

Auxiliary request 2

4. *Article 100(c) EPC*

- 4.1 Claim 1 of auxiliary request 2 contains exactly the same feature as claim 1 of the main request, namely that "the at least one layer (18) of bioactive material forms the outer or outermost layer of the device".

- 4.2 Therefore, the considerations having regard to the assessment of added subject-matter given in points 2.1 to 2.11 above and the conclusion drawn in point 2.12 above with respect to claim 1 of the main request apply

also to claim 1 of auxiliary request 2. Here again, the Appellant's argumentation that the subject-matter of claim 1 of this request focussed on Figure 11 of the application as filed must be rebutted for the reasons given in point 3.2 above.

4.3 Thus, claim 1 of auxiliary request 2 extends the subject-matter claimed beyond the content of the application as filed, thus justifying the ground for opposition pursuant to Article 100(c) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

P. Gryczka