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**Datasheet for the decision
of 7 December 2018**

Case Number: T 1158/15 - 3.2.08

Application Number: 01998009.3

Publication Number: 1347791

IPC: A61F2/90, A61L31/10

Language of the proceedings: EN

Title of invention:

DEVICE FOR IN VIVO DELIVERY OF BIOACTIVE AGENTS AND METHOD OF
MANUFACTURE THEREOF

Patent Proprietor:

Vactronix Scientific, Inc.

Opponent:

Medtronic, Inc. US/Medtronic Vascular Galway

Headword:

Relevant legal provisions:

EPC Art. 123(3)

Keyword:

Amendments - broadening of claim (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1158/15 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 7 December 2018

Appellant: Vactronix Scientific, Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 27 March 2015
revoking European patent No. 1347791 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: C. Herberhold
A. Jimenez

Summary of Facts and Submissions

- I. By decision posted on 27 March 2015 the opposition division revoked European patent No. EP-B-1 347 791.
- II. The appellant (patent proprietor) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. Oral proceedings before the Board were held on 7 December 2018.

At the end of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or of the auxiliary requests 1 or 2, all filed with the grounds of appeal dated 4 August 2015.

The respondent (opponent) requested that the appeal be dismissed.

- IV. Claim 1 of the patent as granted reads as follows:

"An endoluminal stent comprising:
a plurality of metal structural elements interconnected at a plurality of hinge regions and
(**feature A**) defining a plurality of internal cavities bounded by the plurality of structural elements and the plurality of hinge regions;
the endoluminal stent has a wall thickness and at least one of the plurality of internal cavities reside within the wall thickness of the endoluminal stent;

a plurality of micropores communicate between an external surface of the endoluminal stent and at least one of the plurality of internal cavities; the plurality of micropores are dimensioned to permit a bioactive agent to elute from the at least one of the plurality of internal cavities and through the associated plurality of micropores; and the plurality of internal cavities is discontinuous and

(feature B) reside within regions of the endoluminal stent that are substantially non-load bearing regions and the plurality of hinge regions are devoid of the plurality of internal cavities."

V. Claim 1 of the main request reads as follows:

"An endoluminal stent comprising:

a plurality of metal structural elements interconnected at a plurality of hinge regions and **(feature A')** defining a plurality of interstices bounded by the plurality of structural elements and the plurality of hinge regions;

the endoluminal stent has a wall thickness and at least one of a plurality of internal cavities reside within the wall thickness of the endoluminal stent;

a plurality of micropores communicate between an external surface of the endoluminal stent and at least one of the plurality of internal cavities;

the plurality of micropores are dimensioned to permit a bioactive agent to elute from the at least one of the plurality of internal cavities and through the associated plurality of micropores; and

the plurality of internal cavities is discontinuous and

(**feature B**) reside within regions of the endoluminal stent that are substantially non-load bearing regions and the plurality of hinge regions are devoid of the plurality of internal cavities."

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

Claim 1 of auxiliary request 2 reads as follows (amendments with respect to claim 1 of the main request have been underlined):

"An endoluminal stent comprising:

a plurality of metal structural elements interconnected at a plurality of hinge regions and (**feature A'**) defining a plurality of interstices bounded by the plurality of structural elements and a ~~the~~ plurality of hinge regions;

the endoluminal stent has a wall thickness and at least one of the plurality of internal cavities reside within the wall thickness of the endoluminal stent;

a plurality of micropores communicate between an external surface of the endoluminal stent and at least one of the plurality of internal cavities, whereby each of the internal cavities is associated with a plurality of micropores which communicate between an internal cavity and either a luminal or abluminal surface of the endoluminal stent;

the plurality of micropores are dimensioned to permit a bioactive agent to elute from the at least one of the plurality of internal cavities and through the associated plurality of micropores; and

the plurality of internal cavities is discontinuous and

(**feature B**) reside within regions of the endoluminal stent that are substantially non-load bearing regions and the plurality of hinge regions are devoid of the plurality of internal cavities."

The feature assignment (features A, A', A'' and B) has been introduced by the Board.

VI. The essential arguments of the respondent can be summarised as follows:

Extension of protection

Claim 1 of the main request had been amended by the omission of feature A, according to which the internal cavities were bounded by the hinge regions. Just as in the expression "a town being bounded by a river or a highway", the common understanding of the term "bounded" implied that the hinge regions marked or circumscribed the extension of the internal cavities, i.e. the internal cavities had to extend up to the hinge regions.

This interpretation of the term "bounded" was in accordance with its two occurrences in the patent specification: according to paragraph [0025], lines 10 to 15 the stent comprised a plurality of structural elements interconnected at a plurality of hinge regions and defining a plurality of interstices bounded by the

plurality of structural elements and the plurality of hinge regions. As could be seen in Figure 11 of the patent, the interstices extended fully up to the bounding structural elements and hinge regions. Likewise, paragraph [0027], lines 36 to 46 referred to a plurality of internal cavities 74 defined within the second layer 70 and bounded by the first layer 64 of device material. Again, the internal cavities defined by this boundary extended fully up to the borders, i.e. to the first layer 64. The use of the term in the description and the drawings, which in accordance with Article 69 EPC must be used to interpret the claims when there is potentially an issue under Article 123(3) EPC, was thus fully in line with the respondent's understanding.

The omitted feature A was furthermore not redundant in feature B, i.e. with the last feature of claim 1 as granted and of claim 1 of the present main request. Indeed, an embodiment was conceivable in which the internal cavities were located exclusively in a limited central part of the structural elements, with the remainder of the structural elements - from said central part up to the hinge regions - being devoid of any internal cavity. Such a stent fulfilled feature B in that the internal cavities resided in substantially non-load bearing regions and the plurality of hinge regions were devoid of the plurality of internal cavities. It thus fell under claim 1 of the main request. It did not, however, fall under claim 1 as granted, because internal cavities concentrated at the centre of the structural elements were far away from the hinge regions, and therefore were not bounded by the plurality of hinge regions.

Thus, feature A had a technical meaning and its omission in claim 1 of the main request resulted in an extension of the protection conferred by the European patent, contrary to the requirements of Article 123(3) EPC.

Analogous argumentation applied to claim 1 of the auxiliary requests, which likewise did not fulfil the requirements of Article 123(3) EPC.

VII. The essential arguments of the appellant can be summarised as follows:

No extension of protection

As evidenced by the dictionary definition submitted by the respondent, the term "bounded" had a clearly defined mathematical meaning. According to this definition, the "bounds" defined an upper or lower limit to a set, but without any requirement that the contents of such bounded set had to extend up to the bounds. This interpretation was also in accordance with the respondent's example of a town being "bounded by a river or highway", wherein the term likewise allowed for some intermediate land between the last houses and the river/highway.

Furthermore, and with respect to the passages in the patent specification cited by the respondent, the use of the term "bounded" was in full agreement with the above interpretation. Even if the interstices were defined as being bounded by the plurality of structural elements and the plurality of hinge regions, this did not mean that the interstices necessarily extended fully up to these structures. Structural elements or hinges could, for example, be covered by some coating

material, such that there always remained a distance between the interstices and the structures bounding them.

Therefore, feature A meant nothing more than that internal cavities had to be located somewhere in the structural elements, with the hinge regions remaining devoid of the plurality of internal cavities. Feature A was thus redundant in feature B. As claim 1 of the main request still comprised feature B, the omission of feature A did not lead to an extension of the protection conferred by the European patent.

Consequently, the requirements of Article 123(3) EPC were fulfilled.

Analogous reasoning applied to claim 1 of the auxiliary request, which were thus likewise in accordance with the requirements of Article 123(3) EPC.

Reasons for the Decision

1. Main request - Article 123(3) EPC

1.1 According to Article 123(3) EPC, the European patent may not be amended in such a way as to extend the protection it confers.

The protection conferred by a European patent shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims (Article 69(1) EPC).

1.2 In claim 1 of the present main request, feature A of claim 1 as granted has been replaced by feature A'. While feature A deals with and further defines

"internal cavities", feature A' deals with and further defines "interstices". Thus, although feature A' differs from feature A only in the replacement of the words "internal cavities" by "interstices", the two features define different entities.

The replacement of feature A with feature A' thus results in claim 1 of the main request not comprising feature A of claim 1 as granted.

1.3 Feature A reads as follows:

"...defining a plurality of internal cavities bounded by the plurality of structural elements and the plurality of hinge regions".

The parties agreed that feature A had a technical meaning. However, they differed in the particular meaning associated with the phrase "bounded by the plurality of structural elements and the plurality of hinge regions".

While the respondent was of the opinion that the term "bounded by" required the entity so defined to extend up to the bounding structure, the appellant insisted that the bounding structure defined nothing more than a limit which could not be exceeded by the defined entity, without the entity having to extend up to that limit.

The respondent referred in this context to the use of the term in the description and in the drawings, citing Article 69 EPC, which in the context of determining the extent of protection is appropriate.

1.4 The patent specification uses the term "bounded" twice. The first use is in the context of the embodiment of Figure 11 for the definition of the interstices (paragraph [0025], lines 10-15). The same definition has made it - as feature A'- into claim 1 of the main request.

The second use is in the context of stent manufacture for the definition of the internal cavities (paragraph [0027], lines 36-46, and Figure 13E, 74).

The respective figures are represented below:

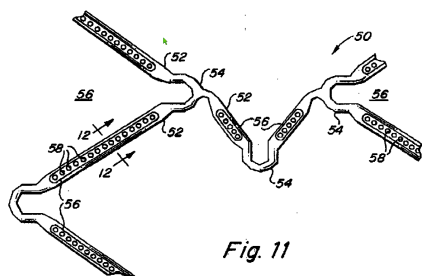


Fig. 11

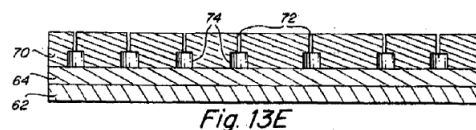


Fig. 13E

In both occurrences, the "bounded" entities, i.e. the interstices 56 (Figure 11) and the internal cavities 74 (Figure 13E), extend up to the bounding structure, i.e. to the structural elements 52 and hinge regions 54 and to the first layer 64 respectively. Even if a coating of the structural elements was conceivable, there is no mention of it in the relevant part of the specification, and the interstices would still essentially extend up to the bounding structures.

In view of the way the term is used throughout the specification, the Board comes to the conclusion that the mathematical interpretation of the term "bounded by", as advocated by the appellant, in the present context is not the correct one. Conversely, there needs to be at least some spatial relationship between the

'bounded entity' and the 'boundary', i.e. the internal cavities must come at least reasonably close to the plurality of hinge elements, just as for a town to be "bounded" by a river or a highway, the buildings must come reasonably close to the river or highway. This is also in accordance with the normal (i.e. non-mathematical) understanding of the term, which can be expressed by synonyms such as "limited by", "circumscribed by" or "defined by."

While what can be understood as 'reasonably close' must be decided on a case-by-case basis, the Board is of the opinion that internal cavities located only in the central part of the structural element (for example having a spatial extension below only two of the micropores 58 closest to the cut line 12 in Figure 11) could not be understood to be "bounded by the plurality of structural elements and the plurality of hinge regions". Such cavities would, however, reside within regions of the stent that are substantially non-load-bearing regions and the plurality of hinge regions would be devoid of the plurality of internal cavities, i.e. feature B would be fulfilled.

From the above example it has to be concluded that firstly features A and B are not redundant, and that secondly a stent with such centrally located internal cavities would fall under the protection of claim 1 of the main request but not under the protection of claim 1 as granted. Consequently, the omission of feature A results in an extension of the protection conferred by the European patent, contrary to the requirements of Article 123(3) EPC.

2. Auxiliary requests 1 and 2

The above reasoning applies *mutatis mutandis* to claim 1 of auxiliary requests 1 and 2, where feature A has likewise been omitted. This was common ground between the parties.

3. As none of the pending requests meet the requirements of the Convention, the patent must remain revoked (Article 101(3)(b) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated