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Datasheet for the decision of 3 June 2008

Case Number: T 0847/06 - 3.2.02

Application Number: 97302336.9

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IPC: A61B 17/12

Language of the proceedings: EN

Title of invention:
Soft-ended fibred micro vaso-occulusive device

Patentee:
Boston Scientific Limited

Opponent:
WOLFF, Francis Paul

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 54, 56

Keyword:
"Novelty, inventive step (no)"

Decisions cited:
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Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0847/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 3 June 2008

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 28 March 2006 revoking European patent No. 0800791 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 26 May 2006 against the decision of the opposition division posted on 28 March 2006 revoking the European patent 0 800 791. The fee for the appeal was paid on the same day and the statement setting out the grounds for appeal was received on 3 August 2006.

II. The opposition division held that the patent in suit did not meet the requirement of Art. 54 (lack of novelty of the subject-matter of claim 13 as granted) and 56 (lack of inventive step of the subject-matter of claim 1 according to the first and second auxiliary requests then on file) EPC 1973 having regard to the teaching of

D1 = EP - A - 0 778 006
D3 = WO - A - 96/00035
D4 = US - A - 5 382 259
D9 = WO - A - 94/15534.

III. Oral proceedings took place on 3 June 2008. With the letter of 14 May 2008 the proprietor announced that he would not be represented at the oral proceedings.

The appellant requested (in the written proceedings) that the decision under appeal be set aside and that the patent be maintained as granted or according to any of the two auxiliary requests attached to the letter of 2 August 2006.

The respondent requested that the appeal be dismissed.

IV. Claim 13 of the main request reads as follows:

"A vaso-occlusive device (136) comprising:
a) at least one helical coil (139) having opposing ends, a retainer access between those ends, an axial length, a passageway extending along said access;
b) a clip (141) having a closed end and arms extending from that closed ends, wherein the arms are passed through the retainer passageway from one opposing end to the other,
c) a multiplicity of fibres (143) retained within the closed end of the clip; and
d) a soft tip (137) adherent to at least one of said helical coil (139) opposing ends, the hardness of the soft tip being less than the hardness of the helical coil."

Claim 1 of the first auxiliary request reads as follows (the additions with respect to the main request in italics):

"A vaso-occlusive device (100) comprising:
a) at least one retainer (102) having opposing ends, a retainer axis (110) extending between those ends, an axial length (108), at least one passageway (106) extending along said axis;
b) a multiplicity of fibres (104) passing through at least a portion of said at least one passageway (106); and
c) at least one soft tip (121) adherent to at least one of said retainer (102) opposing ends, the hardness of the soft tip being less than the hardness of the retainer; *wherein the retainer has an external region and wherein at least a portion of said external region,*

beginning at the soft tip, is covered either with a braided polymeric covering or with polymeric fibres."

Claim 1 of the second auxiliary request reads as follows (the amendments with regard to the first auxiliary request in italics or crossed out):

"A vaso-occlusive device comprising:
a) at least one retainer having opposing ends, a retainer axis extending between those ends, an axial length, at least one passageway extending along said axis, *said retainer comprising a coil*;
b) a multiplicity of fibres passing through at least a portion of said at least one passageway; and
c) at least one soft tip adherent to at least one of said retainer opposing ends, the hardness of the soft tip being less than the hardness of the retainer;
wherein the retainer has an external region and wherein at least a portion of said external region, beginning at the soft tip, is covered ~~either~~ with a braided polymeric covering ~~or with polymeric fibres~~."

V. In support of his request the appellant relied essentially on the following submissions.

The difference between the subject-matter of claim 13 and the disclosure of D1, in particular the embodiment of Figure 6, was that D1 did not disclose that the hardness of the soft tip was less than the hardness of the helical coil. D1 did not disclose this feature since a general disclosure did not take away a particular case falling within the terms of that disclosure. The disclosure of a document was limited at what could directly and unambiguously derived

implicitly or explicitly from that document. D1 disclosed that the coil could be made in a variety of different ways, one of which was simply to melt the end of the coil, which clearly did not lead to a tip having a different hardness than the coil itself. A second method was to apply an epoxy resin to the coil. Nothing was said in this case about the relationship of the hardness of the resin to the hardness of the coil, and therefore the hardness of the resin could be greater, equal, or less than the hardness of the coil.

The subject-matter of claim 1 of the first auxiliary request was not obvious in the light of a combination of the teaching of D9 and D3. In particular since D3 did not disclose that the portion of the external region covered with polymeric fibres began at the soft tip.

The subject-matter of claim 1 of the second auxiliary request was also based on an inventive step. D4 did not disclose a retainer since the coil of D4 did not contain any internal fibres.

VI. The respondent contested the assertions of the appellant and maintained that the subject-matter of claim 1 of the main request was not novel over D1, that the first and second auxiliary requests did not comply with the EPC for lack of inventive step having regard to a combination of the teaching of D9 and D3 or D4 and D9 respectively.

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty of the subject-matter of claim 13 of the main request*

It is undisputed that the only difference between the disclosure of D1 (embodiment of Figure 6) and claim 13 is that D1 does not explicitly disclose that the hardness of the soft tip is less than the hardness of the helical coil.

However, D1 discloses also that the typical materials for the retainer, which - in the embodiment of Figure 5 - takes the form of a coil (see column 4, line 55), includes metals or alloys selected from the group consisting of various stainless steels, gold, tungsten, platinum, palladium, rhodium, rhenium and alloys thereof. Preferred is an alloy of platinum and tungsten (see column 4, lines 17 - 22). On the other hand the soft tip of the coil is made, according to D1, essentially in two ways: when the coil is of a material which easily melts, the end portion of the coil is melt to form the tip; otherwise an amount of epoxy or the like is applied to the coil to form the rounded end (see column 5, lines 6 - 10 and 26 - 27). Since the preferred material of the coil is a metal which does not easily melt, it follows that the preferred material of the soft tip is epoxy or the like which are materials which clearly have a lower hardness than the metal of the coil. Therefore it necessarily follows that the preferred embodiment of D1 shows the feature

that the hardness of the soft tip is less than the hardness of the helical coil.

Certainly, D1 lists a series of different possible choices for the material of the coil and of the soft tip, some of which do not comply with the provision of claim 13, however the preferred embodiment of D1 anticipates the feature of the claim and therefore the feature according to which the hardness of the soft tip is less than the hardness of the helical coil is directly and unambiguously disclosed in D1.

Accordingly the subject-matter of claim 13 of the main request is not novel over the device according to D1.

3. *First auxiliary request*

D9 (see in particular Figure 5) discloses a vaso-occlusive device comprising:
a) at least one retainer (154) having opposing ends, a retainer axis extending between those ends, an axial length, at least one passageway (see page 6, lines 22 - 25) extending along said axis;
b) a multiplicity of fibres (156) passing through at least a portion of said at least one passageway; and
c) at least one soft tip (122, 124, Figure 2) adherent to at least one of said retainer opposing ends wherein the retainer has an external region and wherein at least a portion of said external region is covered with polymeric fibres (see page 7, lines 2 - 5 in conjunction with page 6, lines 7 - 13).

Moreover, D9 describes on page 4, lines 23 - 26 that the caps may be produced from polymeric material or

glue, and on page 4, lines 27 - 34 that the wire for the retainer may be made of a radio-opaque material such as a metal. Consequently D9 discloses at least one embodiment where the caps are made of a relatively soft material and the retainer of a relatively hard material which inevitably means that the hardness of the soft tip is less than the hardness of the retainer.

Starting from D9, the object to be achieved by the subject-matter of claim 1 may be regarded as to enhance the formation of thrombosis.

According to claim 1 this object is achieved by the feature according to which the portion of said external region covered with polymeric fibres begins at the soft tip.

However, since it is obvious for the skilled person that the formation of thrombosis is enhanced when the polymeric fibres cover as much as possible of the external region of the retainer, he would arrange these fibres so that they begin as close as possible at the soft tip. Such an arrangement is also suggested by D3 (see Figure 1).

The argument of the appellant that D3 does not show fibres starting exactly from the soft tip is not convincing since the preposition "at" used in the claim does not have this precise meaning. The general meaning of the term "at" is for example according to the Oxford dictionary:

"The most general determination of simple localization in space, expressing, strictly, the simple relation of

a thing to a point of space which it touches; hence, usually determining a point or object with which a thing or attribute is practically in contact, and thus the place where it is, when this is either so small as to be treated as a mere point, or when the exact relation between the thing and the place is not more particularly expressed by the prepositions close to, near, by, about, on, in, over, under, etc., all of which may at times be covered by at."

Therefore the subject-matter of claim 1 of the first auxiliary request does not involve an inventive step.

4. *Second auxiliary request*

D4 (see in particular Figure 5) discloses a vaso-occlusive device (134) comprising at least one retainer (136) having opposing ends, a retainer axis extending between those ends, an axial length, at least one passageway extending along said axis, said retainer comprising a coil;
and at least one tip (142, 144) adherent to at least one of said retainer opposing ends, wherein the retainer has an external region and wherein at least a portion of said external region is covered with a braided polymeric covering (130).

Moreover D4 describes in column 2, lines 39 - 48 that the coil forming the retainer is preferably made of a platinum-tungsten alloy and in the paragraph bridging columns 2 and 3, that the caps may be made of independently applied materials such as glue or biocompatible solders, but typically are formed merely by melting the tips of the coils of the braided

polymer. Hence, since most of the suggested combinations refer to a relatively hard retainer material (platinum-tungsten) and a relatively soft tip material (glue, solders, polymer), D4 also discloses that the hardness of the soft tip is less than the hardness of the retainer.

The appellant's argument that the element (136) was not a retainer because it did not contain fibres is not convincing, since the element is at least suitable for retaining fibres, and since the fibres of the braided covering (130) are mounted on it.

Starting from D4 the object underlying the subject-matter of claim 1 may be regarded as to enhance the formation of thrombosis.

This object is achieved by the features according to which

(a) a multiplicity of fibres passes through at least a portion of said at least one passageway, and

(b) said external region which is covered with a braided polymeric covering begins at the soft tip.

As already pointed out in section 3 above, the provision of feature (b), is obvious for a skilled person trying to enhance the formation of thrombosis.

Furthermore, the provision of fibres within a retainer according to feature (a), in order to enhance the formation of thrombosis is suggested by D9 (see in particular Figure 5).

Therefore the subject-matter of claim 1 of the second auxiliary request does not involve an inventive step either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare T. Kriner