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Datasheet for the decision of 3 December 2013

Case Number: T 0533/10 - 3.2.02

Application Number: 99966072.3

Publication Number: 1139884

IPC: A61B17/12

Language of the proceedings: EN

Title of invention:
VASOOCCLUSIVE COIL WITH VARIABLE STIFFNESS

Applicant:
Micrus Endovascular Corporation

Headword:

Relevant legal provisions:
EPC Art. 123(2), 54(1), 54(2), 56

Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

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Case Number: T 0533/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 3 December 2013

Appellant: (Applicant)	Micrus Endovascular Corporation 821 Fox Lane San Jose, CA 95131 (US)
Representative:	Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road London WC1X 8BT (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 7 October 2009 refusing European patent application No. 99966072.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: E. Dufrasne
Members: D. Ceccarelli
M. Stern

Summary of Facts and Submissions

I. The applicant has appealed the Examining Division's decision, dispatched on 7 October 2009, to refuse European patent application No. 99 966 072.3.

II. The Examining Division refused the application because it found that the subject-matter of both independent claims 1 and 10 of the only request on file lacked an inventive step.

III. The notice of appeal was received on 7 December 2009 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 16 February 2010.

IV. The Board provided its provisional opinion in a communication dated 11 July 2013.

V. In response to the Board's provisional opinion, the appellant filed amendments with letters dated 1 November 2013 and 11 November 2013.

VI. The appellant requested that the decision under appeal be set aside and that the case be remitted to the Examining Division for grant based on claims 1 to 11 filed with letter dated 1 November 2013, description pages 2, 4, 7 and 8 filed with letter dated 11 November 2013, pages 5, 6 and 9 filed with letter dated 1 November 2013 and pages 1 and 3 as published, and drawing sheets 1/2 to 2/2 as published.

VII. The following documents are of importance for the present decision:

D1: EP-A-0 747 014;
D2: EP-A-0 747 012;
De: EP-A-0 873 734.

VIII. Independent claims 1 and 10 read as follows (compared to respective claims 1 and 10 of the request on which the impugned decision was based, additions are underlined, deletions are struck through):

Claim 1

"An occlusive device (10) for use in interventional therapy and vascular surgery adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature of a patient, comprising:

a variable stiffness coil (12) formed from at least one flexible strand of a shape memory material, said variable stiffness coil (12) having a primary coil configuration,

wherein said flexible ~~shape memory material~~ strand is formed from a shape memory ~~shape~~ material having an Austenite phase finish temperature set to ~~about~~ -5°C to 10°C by heating the coil at 475 °C to 525 °C for 1 to 20 minutes, and having a plurality of segments (14) artificially aged at a temperature of ~~about~~ 375°C to 425°C for a period of ~~about~~ 5 seconds to 30 minutes to raise the Austenite phase finish temperature of the segments to ~~about~~ 35°C to 50°C to cause the plurality of segments to have reduced stiffness,

wherein the coil exhibits variable stiffness along the length of the coil so that the coil can permanently deform in a random configuration after introduction into the vasculature."

Claim 10

"A method for making a variable stiffness occlusive coil (12) for use in interventional therapy and vascular surgery adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature of a patient, comprising providing a coil (12) formed from at least one flexible strand of superelastic material that is a shape memory metal, the shape memory metal being nickel titanium alloy, said coil (12) having a primary coil configuration having an initial stiffness, characterized by:

setting an Austenite phase finish temperature of the coil (12) to ~~about~~ -5°C to 10°C by heating the coil at 475 °C to 525 °C for 1 to 20 minutes;

artificially aging a plurality of segments (14) of said coil (12) at a temperature of ~~about~~ 375°C to 425°C for a period of ~~about~~ 5 seconds to 30 minutes to raise the Austenite phase finish temperature to ~~about~~ 35°C to 50°C to cause said plurality of segments (14) to have reduced stiffness as compared to the remainder of the coil (12)."

Claims 2-9 and 11 are dependent claims.

IX. The appellant's arguments are summarised as follows:

The Examining Division's selection of document D2 as the closest prior art for the subject-matter of both independent claims 1 and 10 was incorrect, since document D2 did not disclose "a shape memory material", the latter being an essential feature of the invention. In contrast, document D1 related to vaso-occlusive coils comprised of a wire formed from a shape memory alloy. Hence, document D1 was the closest prior art.

Document D1 did not disclose the feature that the coil exhibited variable stiffness along its length so that the coil could permanently deform in a random configuration after introduction into the vasculature, which was based on page 1, lines 4 to 5, page 4, lines 23 to 24, and page 3, lines 29 to 30 of the application as filed. Rather, document D1 disclosed a device comprising softer material provided as a layer at the surface of the device and building a single contiguous section, and not as segments along the length of its coil. Nor did document D1 disclose Austenite phase finish temperatures of its materials.

The objective technical problem was to provide a device that filled an aneurysm more evenly and completely over long periods of time.

Starting from document D1, the skilled person would not arrive at the invention because of the significant structural alterations that would be required and the lack of motivation for making such significant modifications without an expectation of success. None of the cited documents provided such motivation. Moreover, document D1 explained that its materials were desirable because they maintained their shape despite being subjected to high stress. This implicitly excluded Austenite phase finish temperatures as claimed, since segments with such Austenite phase finish temperatures, when subject to body temperature, did not maintain their shape despite being subjected to high stress. Hence, document D1 even taught away from the invention as defined in claim 1.

The same arguments applied to the subject-matter of claim 10.

Reasons for the Decision

1. The appeal is admissible.

2. *Basis in the original application - Article 123(2) EPC*

The subject-matter of claim 1 is based on claims 1, 8, 12, 13 and 14, together with page 1, lines 2 to 5, page 4, lines 14 to 18, page 5, lines 16 to 17, page 7, lines 26 to 29, and page 8, lines 16 to 19 of the original application as published.

The subject-matter of claim 10 is based on claims 10, 12, 13 and 14, together with page 5, lines 16 to 17 of the original application as published.

The Board is satisfied that the requirements of Article 123(2) EPC are fulfilled.

3. *Novelty - Article 54(1) and (2) EPC*

Novelty was not questioned in the impugned decision. The Board, too, concludes that the subject-matter of claims 1 and 10 is novel over the cited prior art. In particular, documents D1 and D2 do not disclose any Austenite phase finish temperature of the material of their respective coils and document De does not disclose an occlusive device or coil.

4. *Inventive step - Article 56 EPC*

The invention relates to an occlusive device to be inserted into a portion of a vasculature of a patient (e.g. an aneurysm in the brain) and a method of manufacture of the device. When said device is inserted into said portion of vasculature, the latter becomes

occluded (e.g. through the induced formation of an embolus). The occlusive device is in the form of a coil made of a shape memory material and comprises a plurality of segments with a determined Austenite phase finish temperature causing a reduced stiffness with respect to the rest of the coil. Once delivered, due to its shape memory and to the presence of said segments, the coil will permanently deform in a random (e.g. spherical or helical) configuration in order to occlude the portion of vasculature in a suitable manner.

Both documents D1 and D2 disclose an occlusive device to be inserted into a portion of a vasculature of a patient and comprising a coil. However, document D2 does not disclose a shape memory material as a constituent of the coil. In column 4, lines 18 to 22, referred to in the decision under appeal, document D2 merely discloses metals of the Platinum Group and their alloys. There is, however, no direct and unambiguous disclosure of shape memory alloys. In document D1 - column 4, line 52 to column 5, line 5 on the one hand, and column 5, lines 8 to 16 on the other hand - the respective different properties and advantages of metals of the Platinum Group and of shape memory alloys are compared. Since document D1 discloses a coil made of a shape memory alloy, the Board agrees with the appellant that the closest prior art for both independent claims 1 and 10 is not document D2, as stated in the decision under appeal, but rather document D1.

Document D1 discloses an occlusive device for use in interventional therapy and vascular surgery adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature of a patient (column 1, lines 1 to 2), comprising a variable

stiffness coil (coil 100 in figure 1A and column 6, lines 14 to 17) formed from one flexible strand of a shape memory material (column 5, lines 8 to 19), wherein said variable stiffness coil has a primary coil configuration (for example when it is within catheter 210, in figure 7A), has a plurality of segments with reduced stiffness (column 6, lines 10 to 17 and segments 106 and 110 in figure 1A) and can permanently assume a random configuration after introduction into the vasculature (column 4, lines 47 to 51).

The appellant's argument that the device of document D1 comprises a softer material provided as a layer at the surface of the device rather than at segments along the length of the coil cannot be followed. The "outer layer (110)" and "second layer (106)" mentioned in column 6, lines 14 to 17 and depicted in figure 1A actually consist of segments of the coil, which, when in the pre-deployment condition as in figure 7A, are wound along the same axis. The fact that sections 106 and 110 are contiguous is not relevant, since, on the one hand, segments of a section can be arbitrarily defined, and on the other hand, there is a clear change of configuration between sections 106 and 110. Therefore the "outer layer" and the "second layer" are considered segments within the meaning of claim 1.

Document D1 does not disclose "a coil that can permanently deform in a random configuration after introduction into the vasculature". There is no disclosure that, in order to reach the "primary coil configuration" within the deployment catheter or to re-assume the unstressed original shape after deployment, the coil of document D1 undergoes a permanent deformation. Rather, it appears that, upon deployment, the device of document D1 goes back to its

unstressed original shape due to the removal of applied stress having caused elastic deformation necessary to assume the "primary coil configuration".

Furthermore, document D1 does not disclose the claimed Austenite phase finish temperature of the segments of 35°C to 50°C. As a matter of fact, it is this particular Austenite phase finish temperature which triggers the permanent deformation of the coil according to claim 1, upon exposure to the body temperature of a patient and to stresses deriving from the interaction with the boundaries of the place of deployment.

These two differentiating features of the subject-matter of claim 1 have the effect of letting the obstructive device readily conform to the shape and size of the vessel being filled.

Therefore, the Board comes to the conclusion that the objective technical problem is to ensure an effective obstruction of the vessel over long periods of time, as also explained in the original application, page 3, line 26 to page 4, line 1.

Although raising the Austenite phase finish temperature of shape memory alloys with the thermal treatment as mentioned in claim 1 was known from document De (column 5, lines 9 to 36), in said document there is no hint to provide segments with the Austenite phase finish temperature of an occlusive device for use in interventional therapy and vascular surgery as claimed, in order to solve the objective technical problem posed. Document De discloses shape memory stents. Its main point of concern is therefore keeping vessels open. For this reason in itself, the skilled person

wishing to ensure an effective obstruction of a vessel would turn away from document De.

Furthermore, as the appellant submits, document D1 even stresses that an important benefit of its shape memory alloys is that they maintain their shape even when subjected to high stress (column 5, lines 8 to 10). This is exactly what the device according to claim 1 seeks to avoid.

Hence, the subject-matter of claim 1 involves an inventive step in accordance with Article 56 EPC.

Similarly to claim 1, the method according to claim 10, which is for making a variable stiffness occlusive coil comprising a shape memory nickel titanium alloy, includes the feature of artificially aging a plurality of segments to set their Austenite phase finish temperature to 35°C to 50°C. For the same reasons as given above, it also involves an inventive step in accordance with Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of:

   - claims 1 to 11 filed with letter dated 1 November 2013;

   - description pages 2, 4, 7 and 8 filed with letter dated 11 November 2013, pages 5, 6 and 9 filed with letter dated 1 November 2013, and pages 1 and 3 as published; and

   - drawing sheets 1/2 to 2/2 as published.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated