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# Datasheet for the decision of 13 August 2018

**Case Number:** T 0084/14 - 3.2.02

**Application Number:** 10005062.4

**Publication Number:** 2228020

**IPC:** A61B17/12, A61B17/00

**Language of the proceedings:** EN

**Title of invention:**
Multi-layer braided structures for occluding vascular defects

**Patent Proprietor:**
AGA Medical Corporation

**Opponent:**
(withdrawn)

**Headword:**

**Relevant legal provisions:**
EPC Art. 76(1), 83, 111(1), 123(2)

**Keyword:**

Divisional application - added subject-matter (no) - after amendment

Sufficiency of disclosure - (yes)

Appeal decision - remittal to the department of first instance (yes)

**Decisions cited:**

T 2593/11

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

**Case Number: T 0084/14 - 3.2.02**

# D E C I S I O N
# of Technical Board of Appeal 3.2.02
# of 13 August 2018

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | AGA Medical Corporation<br>5050 Nathan Lane North<br>Plymouth, MN 55442-2204 (US) |
| **Representative:** | Potter Clarkson LLP<br>The Belgrave Centre<br>Talbot Street<br>Nottingham NG1 5GG (GB) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted on 12 November 2013 revoking European patent No. 2228020 pursuant to Article 101(3)(b) EPC** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | E. Dufrasne |
| **Members:** | D. Ceccarelli |
| | M. Stern |

## Summary of Facts and Submissions

I. The patent proprietor has appealed against the Opposition Division's decision to revoke European patent No. 2 228 020 on the grounds of added subject-matter and insufficiency of disclosure. The decision was despatched on 12 November 2013.

II. The patent was opposed on the grounds of added subject-matter, insufficiency of disclosure, lack of novelty and lack of inventive step.

III. Notice of appeal was filed on 7 January 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 27 February 2014.

IV. The respondent opponent withdrew its opposition by letter dated 27 June 2016. It then ceased to be a party to the present appeal proceedings.

V. Oral proceedings took place on 13 August 2018.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main and auxiliary request 1, both filed with letter dated 9 July 2018.

VI. Claim 1 of the main request reads as follows (amendments to claim 1 of the patent as granted highlighted by the Board):

"A collapsible medical device (10) having proximal and distal ends, the device comprising an outer metal fabric layer (20) surrounding an inner metal fabric layer (22), said outer and inner metal fabric layers

each having a plurality of braided metal strands with an expanded preset configuration, the ends of the braided metal strands being secured to prevent the layers from unravelling and the ends of the plurality of braided strands comprising the inner and outer metal fabric~~s~~ layers being secured together at one end of the device, the medical device being shaped to create an occlusion in the vascular system, said expanded preset configuration being deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, the outer and inner metal fabric layers having a memory property such that the medical device tends to return to said expanded preset configuration when unconstrained."

VII. The appellant's arguments where relevant to the present decision may be summarised as follows:

The amendments carried out in claim 1 of the main request were based on page 9, lines 12 to 21 and page 17, lines 13 to 18 of the application as filed. While the amendments specified that the ends of the metal strands were secured together at one end of the device, they left open whether there were secured strand ends at the other end of the device. This did not add matter, since the application as filed disclosed the manufacture of the medical device from planar fabric layers. In such a case the claimed device would have strand ends at one end of the device only. Secured strand ends at the other end of the device were optional and only present if the device was manufactured from layers of tubular fabric. The manufacture of a device as claimed, from plural layers of planar metal fabric, was sufficiently disclosed in paragraphs [0024], [0031] and [0036] of the opposed patent.

The application as filed included disclosures very similar to those relied upon in case T 2593/11. The issues to be decided in the present case were based on the same grounds of Articles 123(2) and 83 EPC and were essentially the same as those decided on in T 2593/11. For the same reasons as those expressed in T 2593/11 the subject-matter of claim 1 of the main request did not add matter and was sufficiently disclosed.

## Reasons for the Decision

1. The appeal is admissible.

2. The opposed patent is derived from a divisional application of European patent application No. 08075105.0 (hereinafter "the parent"), which is itself a divisional application of European patent application No. 05251472.6 (hereinafter "the grandparent"). All of these applications as originally filed share the same figures and the description up to page 22, line 24.

3. The invention

The invention as defined in claim 1 of the main request relates to a collapsible medical device (10) comprising an inner (22) and an outer (20) metal fabric layer. The device is for creating an occlusion in an abnormal opening in a vascular organ, for example for closing an atrial septal defect or a patent foramen ovale. More particularly, the fabric layers are for promoting the formation of an occluding thrombus. The device has an expanded preset configuration, as shown for example in figures 1 and 2 of the patent reproduced below, which

is the configuration that the device reaches once it has been deployed at the treatment site, and a deformed configuration for deployment, in which the device, for example in a longitudinally stretched state, can be inserted in a catheter for delivery to the treatment site. Figure 3 of the patent, reproduced below, shows a device in a somewhat longitudinally stretched state. Once the device has been delivered to the treatment site it will reach the expanded preset configuration due to a memory property of the metal fabric layers.

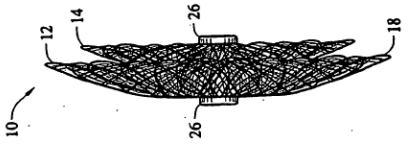


FIG. 1

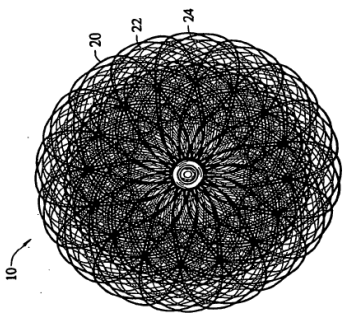


FIG. 2

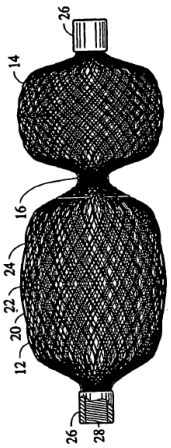


FIG. 3

The metal fabric layers have a plurality of braided metal strands, the ends of which are secured to prevent the layers from unravelling. The inner and the outer metal fabric layers are secured together at one end of

the device.

According to the opposed patent the provision of multiple fabric layers as claimed contributes to the achievement of a rapid occlusion following delivery and placement (column 5, lines 27 to 36).

4. Added subject-matter

The subject-matter of claim 1 of the main request has a general basis in the section "SUMMARY OF THE INVENTION" on page 6, more specifically in lines 3 to 16, of the application as originally filed.

4.1 In the impugned decision, the Opposition Division held that the general definition in claim 1 of the patent as granted, according to which the braided metal strands were secured to prevent the layers from unravelling, added subject-matter because the description as originally filed disclosed such securement only at the ends of the strands (point 1 of the Reasons). This objection is rendered moot by the amendment in claim 1 of the main request which specifies that the ends of the braided metal strands are secured together. The Board notes that for that specific feature there is a basis on page 9, lines 18 to 21, of the application as originally filed, which read:

> "*The ends of the wire strands of the tubular or planar metal fabric layers should be secured to prevent the metal fabrics from unravelling. A clamp or welding, as further described below, may be used to secure the ends of the wire strands*".

4.2 The Opposition Division held further that the feature in claim 1 of the patent as granted reading "the

plurality of braided metal strand comprising the inner and outer metal fabrics being secured together" was an unallowable generalisation (point 2 of the Reasons).

In claim 1 of the main request the following has been specified: "the ends of the plurality of braided strands comprising the inner and outer metal fabric layers being secured together at one end of the device".

The disclosure on page 6, lines 6 to 11, of the application as originally filed reads:

> "*The collapsible medical device has proximal and distal ends each incorporating clamps for securing the plurality of braided strands that comprise the inner and outer metal fabrics together. It is to be understood that each of the several inner layers may have their ends clamped individually and separately from the ends of the strands comprising the outer layer.*"

Compared with this disclosure, the wording of claim 1 of the main request is more general in that the clamps as the securing means are not recited, and the securement is required only at one end of the device.

It has to be established whether this generalisation introduces subject-matter extending beyond the content of the application as originally filed.

4.2.1 As regards the clamps for securing the braided strands together, it is the teaching of the application as originally filed that the specific form of the securing means is merely optional for the claimed invention as long as the ends of the braided metal strands are

secured together. This can be clearly derived from page 9, lines 18 to 21, reproduced in point 4.1 above, page 17, lines 16 and 17, and page 21, lines 9 to 12. In particular, the latter passage, which describes an embodiment of the invention, recites:

> "*It is to be understood that other suitable fastening means may be attached to the ends in other ways, such as by welding, soldering, brazing, use of biocompatible cementious material or in any other suitable fashion.*"

It follows that leaving out the clamps as the specific form of the securing means is a generalisation of the passage on page 6, lines 6 to 11, that does not present the skilled person with information extending beyond the content of the application as originally filed.

4.2.2 As regards the claimed feature of the securement of the ends of the plurality of braided metal strands being required only at one end of the device, the Board notes that the application as originally filed teaches two possibilities of forming the medical device of the invention: starting from planar metal fabrics and starting from tubular metal fabrics (page 7, lines 17 and 18).

In the impugned decision, the Opposition Division correctly noted that in a number of passages of the "DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS" of the application as originally filed it is specified that the fabrics are "secured" or "held together" at "each end" or "both ends" of the device (page 17, lines 13 to 17, and page 21, lines 5 to 7 and 17 to 21). This is in conformity with the general disclosure on page 6, lines 6 to 11, recited under point 4.2 above.

However, all these passages relate to embodiments of the medical device formed from tubular metal fabrics. There is no such disclosure for embodiments formed from planar metal fabrics.

Page 9, lines 18 to 21, of the application as originally filed, recited under point 4.1 above, teaches the technical effect to be achieved by securing the ends of the wire strands of the metal fabrics: to prevent the metal fabrics from unravelling. Clearly, if a tubular metal fabric is used to form the medical device, free ends of the wire strands will be present at each end of the tubular fabric. Under these circumstances, to prevent unravelling, the free ends of the wire strands will have to be secured at both ends of the device.

When the medical device is formed from a planar fabric, the skilled person recognises that one mechanically straightforward possibility is to fold the sides of the planar fabric together and form a pocket. Under those conditions, the device will have free ends of the wire strands at only one of its ends. By consequence, according to the general teaching of page 9, lines 18 to 21, it would be necessary to secure those free ends only at the one end of the device where they are present.

It follows that the skilled person directly and unambiguously recognises that having the plurality of braided strands secured at both the proximal and distal end of the device is an optional feature because, in one embodiment, it is not required.

As a result, leaving out the securement of the

plurality of braided metal strands at the other end of the device is a generalisation of the passage on page 6, lines 6 to 11, that does not present the skilled person with information extending beyond the content of the application as originally filed.

4.2.3 The Board notes that in case T 2593/11, concerning a case similar to the present one, the same conclusions were reached (points 3.1 to 3.3 of the Reasons).

4.3 Since the present, the parent and the grandparent application as originally filed share the description passages referred to in the analysis above, the Board concludes that claim 1 of the main request complies with Articles 76(1) and 123(2) EPC.

5. Insufficient disclosure

The Board is in no doubt that the skilled person, on the basis of the common general knowledge and the patent specification, can carry out the invention as defined in claim 1 of the main request. More particularly the Board refers to the disclosure of metal clamps and the other suitable fastening means in column 17, lines 2 to 22, of the patent and to the definition in the claim that the ends of the plurality of braided strands are secured together at one end of the claimed medical device, which renders moot most of the objections raised by the Opposition Division in relation to Article 100(b) EPC.

It follows that claim 1 of the main request complies with Article 83 EPC.

6. Under Article 111(1) EPC, following the examination as to the allowability of the appeal, the Board retains

the discretion to remit the case to the department which was responsible for the decision appealed for further prosecution.

Since the impugned decision did not deal with the grounds for opposition of lack of novelty and inventive step, the Board decides to remit the case to the Opposition Division for further prosecution, in order to give the appellant the possibility of having those grounds too considered at two instances.

## 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 for further prosecution.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated