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Datasheet for the decision of 30 May 2016

Case Number: T 2593/11 - 3.2.02

Application Number: 98946804.6

Publication Number: 1011469

IPC: A61B17/00, A61F2/01, A61B17/12

Language of the proceedings: EN

Title of invention:
PERCUTANEOUS CATHETER DIRECTED OCCLUSION DEVICES

Applicant:
Aga Medical Corporation

Headword:

Relevant legal provisions:
EPC Art. 123(2), 83

Keyword:
Amendments - added subject-matter (no)

Decisions cited:

Catchword:

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Case Number: T 2593/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 30 May 2016

Appellant: (Applicant)	Aga Medical Corporation 5050 Nathan Lane North Plymouth MN 55442-2204 (US)
Representative:	Potter Clarkson LLP The Belgrave Centre Talbot Street Nottingham NG1 5GG (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 August 2011 refusing European patent application No 98946804.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	D. Ceccarelli

Summary of Facts and Submissions

I. The appeal of the applicant is against the decision of the Examining Division, posted 4 August 2011, refusing the application for non-compliance with Article 123(2) EPC.

The reasoning of the Examining Division was essentially as follows: the subject-matter of claim 1 was not limited to devices made of tubular metal braided metal fabric, but also covered devices made of planar braided metal fabric. However, a device having the main features of claim 1 was at most disclosed as being made from a tubular braided metal fabric and it was not self-evident that such a device, in particular with a cupped expanded diameter portion and means for securing the strands only at the proximal end of the device, was feasible starting from a planar braided metal fabric, because of the higher rigidity of the proximal part. Therefore the requirements of Article 123(2) EPC were not fulfilled.

II. The notice of appeal was filed on 3 October 2011 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 9 December 2011.

III. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, on the basis of one of auxiliary requests 1 to 4, all filed with the statement setting out the grounds of appeal.

IV. The appellant’s arguments are essentially those underlying the reasons of the present decision as set out below.

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

"A collapsible medical device (120), comprising a braided metal fabric having an expanded preset configuration, the ends of the wire strands of the braid being secured in order to prevent the braid from unravelling, wherein said medical device is shaped to create an occlusion of an abnormal opening in a cardiac septal wall, whereby said expanded preset configuration is deformable to a lesser cross-sectional dimension for delivery through a channel in a patient's body, the braided metal fabric having a memory property such that the medical device tends to return to said expanded preset configuration when unconstrained, the expanded preset configuration comprising first and second expanded diameter portions (122, 124) respectively at distal and proximal ends of the device and a reduced diameter portion (126) disposed between the two expanded diameter portions, said reduced diameter portion having a length dimension which approximates a thickness of the septal wall at the abnormal opening, in which at least one of said first and second expanded diameter portions (122, 124) is cupped towards the other of the first and second expanded diameter portions causing, in use, the perimeter edge of the cupped expanded diameter portion to fully engage the sidewall of the septum, characterised in that, the collapsible medical device further comprises a recessed means for securing said strands adapted to be releasably coupled to a delivery device and said braided metal fabric has a recess receiving said means for securing in the expanded diameter portion at the proximal end of the device."

Reasons for the Decision

1. The appeal is admissible.

2. The invention concerns a braided metal fabric structure made to create an obturation of a shunt in a vessel or between two cavities, for instance in the heart. Claim 1 concentrates on a device for occlusion of an abnormal opening in a cardiac septal wall.

3. Added subject-matter

3.1 As regards the wording of claim 1 concerning the critical feature:

Already in its first part, the claim requires generally that "*the ends of the wire strands of the braid being secured in order to prevent the braid from unravelling*". The characterising portion is more precise, in that it requires
that the means for securing the strands is recessed, that the means for securing the strands is adapted to be releasably coupled to a delivery device, and lastly that the means for securing the strands is received in a recess at the proximal end of the braided metal fabric.

These three features are present in several embodiments shown in the figures, and described in the corresponding description parts. The critical issue as regards added subject-matter is that the wording also covers embodiments in which only the proximal end of the device is provided with means for securing the strands, as would be the case if the device was manufactured from a planar braided metal fabric.

3.2 It appears that all embodiments disclosed in the figures are made from a tubular braided metal fabric, hence with the two ends provided with means for securing the strands. Indeed, in relation to the braided metal fabric, the adjective "tubular" is used regularly and the adjective "planar" does not appear even once in the part of the description where the specific embodiments are presented. Further, all the figures show a recess with a means for securing the strands not only at the proximal end but also at the distal end of the device.

All the independent claims (1, 10, 11 and 18) of the application as originally filed recite that the proximal end and distal end have securing means, which also seems to imply that all the devices claimed there are made from a tubular – not a planar - braided metal fabric.

3.3 However, this does not mean that devices made from a planar braided metal fabric were not disclosed. Indeed, the more general part of the description (page 6, line 14 to page 13, line 23) mentions several times that tubular or planar braided metal fabrics can be used, without indicating any specific advantage of the one option over the other (page 6, line 17; page 6, line 19; page 7, line 13; page 8, line 9; page 8, line 12; page 10, line 4; page 11, line 17).

More specifically, for instance, the second paragraph of page 8 describes how the device is manufactured (the issue queried by the Examining Division):

"*When forming a medical device in accordance with the present invention, an appropriately sized piece of tubular or planar metal braided metal fabric is*

inserted into a mold, whereby the fabric deforms to generally conform to the shape of the cavities within the mold. The shape of the cavities are such that the metal braided metal fabric deforms into substantially the shape of the desired medical device. The ends of the wire strands of the tubular or planar metal fabric should be secured to prevent the metal fabric from unraveling. A clamp or welding, as further described below, may be used to secure the ends of the wire strands" (emphasis added).

Therefore, from this general part, the person skilled in the art learns that it makes no fundamental difference whether manufacturing starts from a tubular or planar braided metal fabric; both options are equally suitable or compatible with the devices to be manufactured.

Mechanically it is self-evident that if a planar – as opposed to a tubular - braided metal fabric is used to manufacture the embodiments shown in the figures, only one side of the device has to be provided with a means for securing the wire strands, because on the other side the strands would have no free ends. In other words, for the person skilled in the art, disclosing that the manufacturing process can start from a planar braided metal fabric amounts to disclosing that only one side of the device is provided with means for securing the strands.

In the opinion of the Board, this is enough to comply with Article 123(2) EPC.

3.4 The Examining Division took the view that if a planar braided metal fabric were used, the proximal part of the device would be more rigid because there would be

more braids, and that consequently, because of this increased rigidity, it was not self-evident that devices according to claim 1 could actually be manufactured using such a fabric. It argued that for the person skilled in the art this amounted to non-disclosure of such devices made from a planar braided metal fabric.

The Board does not agree. It would emphasise that the requirements of Article 123(2) EPC differ from those of Article 83 EPC. Article 123(2) EPC aims more particularly to prevent inventors from obtaining protection for inventions they had not thought of at the date of filing, respectively not put into their application as filed. Article 83 EPC aims more particularly to prevent them from obtaining protection for "theoretical" inventions which could not be carried out at the date of filing. While in some specific instances there might be a link between the two, in the present case, as explained above, the manufacturing of the medical device from a planar braided metal fabric is clearly disclosed.

3.5 Therefore, claim 1 of the main request complies with Article 123(2) EPC.

4. To avoid further discussion and delay, the Board would add that it considers the requirements of Article 83 EPC to be fulfilled as well. Manufacture from a planar braided metal fabric requires forming a kind of pocket first before using the mould, but that is the only difference compared to manufacture from a tubular braided metal fabric. The braids have to be shaped in the mould in the same way in either case. The process may have to be adapted to the higher density of braids on one side of the device, but that is part of the

normal adaptation of the process. If making the device from a tubular braided metal fabric, the person skilled in the art also has to choose the right material, thickness, physical properties, etc. of the braids in order to arrive at the desired result. Things are no fundamentally different if he uses a planar braided metal fabric. The presence of some technical difficulties which can be overcome by simple testing is not detrimental to compliance with Article 83 EPC. It must be possible to carry out the invention without undue burden, and that is the case here.

5. The remaining requirements of the EPC have not yet been dealt with by the department of first instance. Accordingly the Board finds it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the department of the first instance for further prosecution.

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