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Datasheet for the decision of 17 September 2015

Case Number: T 1137/13 - 3.2.08

Application Number: 01204926.8

Publication Number: 1210919

IPC: A61F2/06, B21F45/00

Language of the proceedings: EN

Title of invention:
Method of forming medical devices: intravascular occlusion devices

Patent Proprietor:
AGA Medical Corporation

Opponents:
Occlutech GmbH
Lifetech Scientific (Shenzhen) Co. Ltd.

Headword:

Relevant legal provisions:
EPC Art. 107, 108, 100(c), 100(a), 56
EPC R. 99

Keyword:
Admissibility of appeal - statement of grounds
Grounds for opposition - added subject-matter (yes) - main request
Inventive step - auxiliary request 1 and 2 (no)
Inventive step - technically independent partial problems

Decisions cited:
T 0298/97

Catchword:

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Case Number: T 1137/13 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 17 September 2015

Appellant: (Patent Proprietor)	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)
Appellant: (Opponent 1)	Occlutech GmbH Wildenbruchstrasse 15 07745 Jena (DE)
Representative:	Krahbichler, Erik Krahbichler Intellectual Property Advisors AB - KIPA P.O. Box 1065 251 10 Helsingborg (SE)
Party as of right: (Opponent 2)	Lifetech Scientific (Shenzhen) Co. Ltd. Langshan 2nd Road South Hi-tech Industrial Park (North Area) Nanshan District Shenzhen 518057 (CN)
Representative:	Prinz & Partner mbB Patent- und Rechtsanwälte Rundfunkplatz 2 80335 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 April 2013 concerning maintenance of the European Patent No. 1210919 in amended form.**

Composition of the Board:

Chairman	T. Kriner
Members:	C. Herberhold
	D. T. Keeling

Summary of Facts and Submissions

I. By its decision posted on 2 April 2013 the Opposition Division decided that European patent No. 1210919 in amended form according to auxiliary request 8 then on file and the invention to which it related met the requirements of the EPC.

II. The patent proprietor (referred to as appellant 1 in the following) lodged an appeal against that decision on 14 May 2013, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 2 July 2013.

Furthermore, opponent 1 (referred to as appellant 2 in the following) lodged an appeal against the decision on 31 May 2013, paying the appeal fee on that same day. The respective statement setting out the grounds of appeal was filed on 12 August 2013.

Opponent 2 did not file an appeal, thus being party as of right.

III. Oral proceedings before the Board of Appeal took place on 17 September 2015. As announced in its letter dated 3 August 2015 the party as of right did not attend. In accordance with Rule 115(2) EPC and Rule 15(3) RPBA the oral proceedings were held in that party's absence.

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

Appellant 1 requested that the decision under appeal be set aside and the patent maintained as granted (main request) or, in the alternative, that the patent be maintained on the basis of the claims of auxiliary

request 1, filed during the oral proceedings before the Board, or on the basis of the claims of auxiliary request 2, filed by letter of 17 March 2015. Appellant 1 further requested that the appeal filed by appellant 2 be rejected as inadmissible.

Appellant 2 requested that the appeal filed by appellant 1 be rejected as inadmissible and that the decision under appeal be set aside and the patent revoked.

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

"A medical device (80) for occluding an opening in a vascular system, the device comprising a metal fabric (10) formed from a plurality of metal strands (14, 14'), a clamp(90) affixed to the ends of the metal strands at one end of the device to prevent the strands from unraveling, whereby stretching of the device reduces the cross-sectional dimension of the device for deployment of the device through a catheter, the device returning to a preset shape when a constraining force is removed
in which the clamp (90) is threaded for releasable threaded attachment to a delivery device."

The independent method claim 4 did not play a part in the present proceedings.

V. Claim 1 of **auxiliary request 1** reads as follows (additions in respect of the main request are underlined)

"A medical device (80) for occluding an opening in a vascular system, the opening being any one of a shunt between two vessels, a channel, a PDA defect, and the

lumen of a vessel, the device comprising a metal fabric (10) formed from a plurality of metal strands (14, 14'), a clamp (90) affixed to the ends of the metal strands at one end of the device to prevent the strands from unraveling, whereby stretching of the device reduces the cross-sectional dimension of the device for deployment of the device through a catheter, the device returning to a preset shape when a constraining force is removed
in which the clamp (90) is threaded for releasable threaded attachment to a delivery device and in which the metal strands (14, 14') of the metal fabric (10) are heat-treated in a deformed state to set the preset shape of the device, wherein the metal strands (14,14') comprise a shape memory alloy, wherein the shape memory alloy is an NiTi alloy, optionally Nitinol."

VI. Auxiliary request 2 differs from auxiliary request 1 in that the definition that the shunt is "between two vessels" is missing and in that it is further defined that the (threaded) "clamp has a threaded outer surface for releasable threaded attachment to a delivery device".

VII. The following documents played a role for the present decision:

O1.E1: DE-G-9205797.7 U1;
O1.E7: T. Schmitz-Rode, H. Timmermanns, B. Uchida, K.Kichikawa, N. Nishida, R. Günther, J.Rösch: "Self-expandable Spindle for Transcatheter Vascular Occlusion: In Vivo Experiments", Radiology 1993; 188: 95-100 (1993);
O1.E6: WO-A-94/12136;
O2.E7: V. Saveliev, V. Prokubovski, S. Kolody, S. Saveliev, V. Verin: "Patent Ductus Arteriosus:

Transcatheter Closure with a Transvenous Technique", Radiology 1992; 184: 341-344.

VIII. The essential arguments of appellant 1 can be summarised as follows:

Admissibility of the appeals

The appeal of appellant 1

In the decision of the opposition division, only Article 100(c) EPC had been found to prejudice the maintenance of the patent as granted. Appellant 1 had properly dealt with this point of the decision by referring explicitly to the response of 28 January 2011 of the Opposition proceedings, setting out the compliance of the claims of the main request with the requirements of the EPC.

The appeal against the opposition division's decision to consider the maintenance of the patent as granted prejudiced by the opposition ground under Article 100(c) EPC was thus well founded.

The appeal of appellant 2

While the notice of appeal had been filed in the name of "Occlutech GmbH", the grounds of appeal were filed in the name of "Occlutech GmbH and Occlutech Holding AG". The latter was not an adversely affected party to the decision dated 2 April 2013, such that - in analogy to case T298/97 - the appeal could not be held admissible.

Main request - Article 100(c) EPC

Although the term "opening in a vascular system" had not been explicitly used in the parent application as filed, the term "opening" defined nothing more than something through which a fluid is flowing, which was to be occluded by the inventive occlusion device. The description disclosed, see e.g. paragraph [0055] of the A2 publication, to adapt the device to a wide range of different applications extending well beyond the explicitly disclosed examples. The skilled person would recognise that the term "for occluding an opening in a vascular system" accurately described these different applications, without extending the scope beyond the subject-matter of the parent application as filed.

Auxiliary request 1 - Articles 100(a) and 56 EPC

Starting from O1.E1 as closest prior art, it had first to be taken into account that the document was silent on the occlusion device's material. Furthermore, it did neither disclose a threaded clamp for releasable threaded attachment to a delivery device, nor metal strands which were heat treated in a deformed state to set the preset shape of the device, the metal strands comprising a shape memory alloy, the shape memory alloy being a NiTi alloy.

The document O1.E1 already disclosed means to deploy and retract the occlusion device. The person skilled in the art thus had no reason to modify the delivery means.

Moreover, the NiTi material in combination with the improved connection to the delivery device allowed for easy deployment and accurate placement of the device in a vessel, thus solving the problem to provide a reliable and controllable embolisation device as stated in paragraph [0007] of the patent specification. Therefore, the choice of the material and the modification of the connection to the delivery device could not be seen as separate partial problems: as described in paragraph [0065] of the patent specification, the placement of a NiTi alloy with its superelastic spring-back properties required stringent control, and only stringent control allowed to use the specific NiTi alloys, thus benefiting from its advantageous unfolding properties. In order to come to the claimed solution, the skilled person would thus have to combine knowledge from documents O1.E1, O1.E7, O2.E7 and O1.E6 to solve a single combined problem, an exercise clearly requiring inventive activity.

Furthermore, even if one assumed that the skilled person would look for an alternative material, none of the available documents or the patent specification gave any evidence of NiTi-alloys having been used for an intravascular occluding device. Moreover, O2.E7 disclosed the specific threaded holder only for use in a totally different type of manipulation, using differently sized sheaths, such that its teaching could not be transferred to the O1.E1 device.

For all these reasons, claim 1 of auxiliary request 1 was inventive.

Auxiliary request 2 - Articles 100(a) and 56 EPC

Claim 1 of auxiliary request 2 was inventive for the same reasons as detailed above.

IX. The essential arguments of appellant 2 can be summarised as follows:

Admissibility of the appeals

The appeal of appellant 1

In points 33.3.3 and 33.3.4 of the impugned decision, the Opposition Division had found that independent method claim 3 of auxiliary request 3 then on file extended over the teaching of the application as originally filed. This objection implicitly applied to the current and then main request, because its independent method claim - claim 4 of the main request - was identical in wording to independent method claim 3 of former auxiliary request 3. This finding had not been contested by appellant 1 in their appeal, appellant 1 thus having failed to specify in the statement of grounds of appeal the legal and factual reasons why the impugned decision should be set aside. Therefore, the appeal was to be rejected as inadmissible.

The appeal of appellant 2

The notice of appeal named Occlutech GmbH as the appellant. There can therefore be no doubt who is the appellant. The grounds of appeal were submitted by Occlutech Holding AG and Occlutech GmbH, which are two distinct companies. Consequently, the unambiguously identified appellant filed the grounds of appeal in the

prescribed form and within the prescribed time limit, the appeal thus being admissible.

Main request - Article 100(c) EPC

The parent application as filed did not disclose a medical device for occluding an "opening in a vascular system". As could be seen e.g. from the title, the invention related to an "intravascular" device. In fact, all examples consistently showed a device to be placed within a structure having a certain longitudinal extent defining an axis to which - see paragraph [0052] of the application as filed - the axis of the device coincides. The term opening on the other hand was much broader, including thin tears with basically no wall extension available for anchoring the device, a situation with which the devices of the invention could not cope.

Therefore, the subject-matter of the European patent extended beyond the content of the parent application as filed, Article 100(c) EPC thus prejudicing the maintenance of the patent as granted.

Auxiliary request 1 - Articles 100(a) and 56 EPC

Documents O1.E7 and O1.E1 could both be considered to be the closest prior art. The subject-matter of claim 1 of auxiliary request 1 differed from prior art O1.E1 in that the metal material used was a NiTi shape memory alloy and in that the clamp was a threaded clamp. These differences addressed two unrelated partial problems: Firstly, to provide an alternative material capable to return to a preset configuration after having been compressed to a reduced diameter configuration upon

insertion, and secondly, to provide alternative means for connecting and disconnecting to a delivery device. Indeed, the tendency to urge itself forward beyond the end of the catheter was present in any type of self-expandable device, independent of the particular material, and it was also present in the O1.E1 device. The choice of the NiTi material did thus make no difference with respect to the problem to provide alternative means for connecting and disconnecting to the delivery device.

Moreover, the solution to both partial problems was obvious. As also confirmed by the patent specification paragraph [0020], NiTi alloys were well known in the art and used in intravascular devices such as stents as an obvious alternative to shape memorizing stainless steel, see O1.E6, page 15, lines 5-8 and page 23, lines 20-24. Furthermore, document O2.E7 disclosed to manipulate and control the delivery of a self-expanding patent ductus arteriosus occluder by connecting the thrust catheter to an external thread on a clamp connected to the proximal part of the occluder.

With the solution to the two independent partial problems being obvious, so was the subject-matter of claim 1 of auxiliary request 1. Thus, Article 100 (a) in combination with Article 56 EPC prejudiced the maintenance of the patent in the amended form of auxiliary request 1.

Auxiliary request 2 - Articles 100(a) and 56 EPC

The alternative connection between delivery device and occlusion device disclosed in O2.E7 comprises the provision of an external thread on the clamp. The

reasoning advanced with respect to auxiliary request 1 thus applied *mutatis mutandis* to auxiliary request 2.

Reasons for the Decision

1. Admissibility of the appeals

1.1 The appeal of appellant 1

Uncontestedly, appellant 1 in his statement setting out the grounds of appeal dealt with the opposition ground under Article 100(c) EPC, the only ground of opposition mentioned in the impugned decision as prejudicing the maintenance of the patent as granted. The Board is thus satisfied that appellant 1 has sufficiently addressed the only reason given in the contested decision with respect to the main request.

It is true – as pointed out by appellant 2 – that the objections discussed in the contested decision against independent method claim 3 of then auxiliary request 3 would seem to also apply to independent method claim 4 of the then and present main request, for the simple fact that these method claims are essentially identical in wording.

It can however not be incumbent on appellant 1 to filter out particular objections possibly applying to, but never actually decided with respect to the main request further pursued in appeal in order to meet the requirements of admissibility of the appeal. What has to be addressed, are the main reasons given for the contested decision, a criterion which is fulfilled in the present case, the appeal of appellant 1 thus being admissible.

1.2 The appeal of appellant 2

As required by Rule 99(1)(a) EPC, the name of the appellant - Occlutech GmbH - was provided with the notice of appeal. However, the statement setting out the grounds of appeal was submitted in the name of "Occlutech GmbH and Occlutech Holding AG", which – according to appellant 1 – in analogy to the case of joint applicants had to be seen as joint appellants, constituting a party which was not adversely affected by the decision under appeal and thus could not validly submit a statement of grounds. In accordance with the reasoning in decision T298/97 (OJ 2002, 83) the appeal thus should be held inadmissible.

However, as pointed out by appellant 2 and as verified by a quick check of the online "Handelsregister", Occlutech GmbH and Occlutech Holding AG are two different, distinct legal entities. There is no company having the combined name of "Occlutech GmbH and Occlutech Holding AG". The situation is thus different from the one in T298/97. In the present case the company "Occlutech GmbH", which was entitled to appeal and which had filed the notice of appeal, also submitted the statement of grounds of appeal in time. Their appeal is thus admissible.

On the other hand, a second company - Occlutech Holding AG -, which is not entitled to appeal, filed the grounds of appeal together with Occlutech GmbH. This second company cannot acquire the status of an appellant, *inter alia* because it was not negatively affected by the opposition division's decision. Consequently, the fact that the grounds of appeal were

also submitted in the name of Occlutech Holding AG has no relevance for the present case.

2. Main request - Article 100(c) EPC

Claim 1 of the main request defines a "medical device (80) for occluding an opening in a vascular system".

Although the term "for occluding an opening in a vascular system" has been used in the application as filed, it had not been in the parent application (WO-A-96/01599).

Indeed, the earlier application discloses an intravascular device (see e.g. the title or the field of invention section of the parent application). Also the examples cited by appellant 1 only concern conditions, wherein the occluding device remains within the vascular system. This is true also for the disclosure on page 14, 3d paragraph (corresponding to paragraph [0055] of the application as filed), which suggests dimensional adaptation of the device if deployed "in a different channel in a patient's body".

The term "for occluding an opening in a vascular system", on the other hand, includes lesions like tears in a vessel, which are open to the outside of the vascular system, and situations wherein the device has to be placed within such an opening and thus partly exterior of the vessel, subject-matter extending over the content of the earlier application as originally filed.

Thus, Article 100(c) EPC prejudices the maintenance of the patent as granted, i.e. according to the main request.

3. Auxiliary request 1 - Articles 100(a) and 56 EPC

3.1 Both O1.E1 and O1.E7 disclose self-expanding intravascular occlusion devices suited for delivery through a catheter or the like to a remote deployment location in a patient's vascular system or in analogous vessels within a patient's body. O1.E1 is structurally closer to the subject-matter of claim 1 of auxiliary request 1 in that it has a clamp ("Hülse", see O1.E1, page 3, line 7) affixed to one end to prevent the strands from unraveling whereas the strands of the O1.E7 device are held by solder. Thus, O1.E1 is the closest prior art.

Document O1.E1 discloses:
A medical device (Figure 1-3) for occluding an opening in a vascular system (page 2, lines 2-4), the opening being any one of a shunt between two vessels, a channel, a PDA defect, and the lumen of a vessel, the device comprising a metal fabric formed from a plurality of metal strands (page 3, lines 2-5), a clamp ("Hülse", page 3, lines 6, 7) affixed to the ends of the metal strands at one end of the device to prevent the strands from unraveling, whereby stretching of the device reduces the cross-sectional dimension of the device for deployment of the device through a catheter (page 3, lines 9-12), the device returning to a preset shape when a constraining force is removed (page 3, lines 16-19 and Figures 2 => 3).

Appellant 1 was of the opinion that O1.E1 did not indicate any particular material to be used for the fabric. However, the disclosure relates to solder, welding or clamping (page 3, lines 6, 7) as equivalent means for fixation of the wire strand ends, with solder

and welding implying for the skilled person that the wires ("Drähte", page 3, line 3) making up the fabric are metal wires.

3.2 The subject-matter of claim 1 of auxiliary request 1 differs from prior art O1.E1 in the following features:

a) the clamp is threaded for releasable threaded attachment to a delivery device;

b) the metal strands of the metal fabric are heat-treated in a deformed state to set the preset shape of the device, wherein the metal strands comprise a shape memory alloy, wherein the shape memory alloy is an NiTi alloy, optionally Nitinol.

3.3 Feature a) allows for a threaded attachment to the delivery means and thus to control the manner in which the device is deployed out of the distal end of the catheter. As discussed in paragraph [0065] of the granted patent, this solves the problem that, when the device exits the catheter it will tend to resiliently return to a preferred expanded shape, thus acting against the distal end of the catheter and effectively urging itself forward beyond the end of the catheter, which may result in improper positioning of the device. Thanks to the threaded attachment, the device is easy to deploy and can be accurately placed in a vessel thus solving the problem posed in paragraph [0007] of the patent specification.

The tendency to spring back to the expanded form is, however, not limited to devices made from NiTi alloys, but is typical of elastically self-expanding devices, such as the device disclosed in O1.E1. The problem

formulated above is thus independent from the particular choice of self-expanding material.

Also when placing the O1.E1 self-expandable device with the pusher wire ("Schubdraht") the person skilled in the art will be faced with the problem of the device urging itself forward to a possibly unwanted location and will thus look into the prior art in order to solve the problem to easily deploy and accurately place the device.

When looking for a solution to said problem, the person skilled in the art would consider document O2.E7, which equally relates to the field of self-expanding intravascular occlusion devices for delivery through a catheter to a remote location in a patient's vascular system.

As the O1.E1 device, the O2.E7 occluder "springs open, assuming its original conical shape", when being extruded from the introducer sheath (page 341, "Materials and Methods", first paragraph). The device is then retracted into the patent ductus arteriosus (see Figure 5). The person skilled in the art will realize that also in O2.E7 the problem to easily deploy and accurately place the device arises and will thus consider its solution, namely to provide the proximal clamp on the deployable self-expanding device with an outer thread, such as to allow secure connection to the delivery device.

Appellant 1 has argued that the deployment of the O2.E7 device was considerably different and that the purpose of the threaded connection was rather to allow retraction of the device for positioning than control of a spring-out tendency. It is, however, evident to

the skilled person that also uncontrolled opening of the O1.E7 device into the aorta cannot be permitted. Moreover, the person skilled in the art immediately understands that the thread connection disclosed in O1.E7 prevents unwanted movement of the device relative to the delivery device, be it to retract the device or be it to prevent unwanted springing out.

As the O1.E1 occluder already has a proximal clamp ("Hülse"), the provision of a thread on its outer surface does not pose particular difficulties and does not require further modifications of the device. Scaling the thread to the clamp used in O1.E1 is well within the capabilities of the skilled person, such that the difference in diameter pointed out by appellant 1 is no obstacle.

Therefore, it is obvious to provide the O1.E1 device with a thread on the outer surface of the clamp in order to solve the problem to provide a reliable embolization device which is both easy to deploy and can be accurately placed in a vessel.

3.4 Feature b) relates to the choice of a NiTi shape memory metal for the metal fabric. The metal is heat treated in a deformed state to set the preset shape of the device, then elastically deformed into a reduced cross-sectional dimension, self-expanding to the preset shape when the constraining force is removed. As discussed in paragraph [0046] of the patent, the NiTi alloy, in particular Nitinol tends to be "very elastic", the very elastic phase being frequently referred to as a "superelastic" or "pseudoelastic" phase. In the super-elastic phase, great strains can be reached with relatively minor increase in stress and without plastic deformation. The technical effect of feature b) is thus

to allow a "better" elastic behaviour of the device, solving the problem to allow greater elastic deformation. The device is however still self-expanding and has the tendency to "spring forward" upon deployment. In this respect there is no difference with the O1.E1 device, which also has a preset deployed form, is elastically deformed into a catheter for placement and equally - due to its elastic deformation - springs forward upon deployment. Therefore, there is no interrelation between the problems posed by features a) and b) and these can be considered unrelated partial problems.

As also acknowledged in the patent specification (see paragraphs [0020], [[0047]), NiTi alloys were well known in the art at the time of filing. It can be seen from O1.E6 that their use was not limited to the guide wire tips mentioned in the patent, but included application in elastically self-expanding intravascular devices such as stents (O1.E6, page 23, line 20-24). As further mentioned in O1.E6, the material is chosen so that even the fairly severe deformation to compact the stent into the delivery system did not exceed the elastic limit. The person skilled in the art would realize that the use of Nitinol with its superelastic properties is thus a solution to the problem posed above, in that it allows greater elastic deformation thus facilitating the compaction of the device into the delivery system.

It is, therefore, obvious for the skilled person to use Nitinol for the manufacture of the O1.E1 occluder in order to solve the problem posed.

While it is true - as pointed out by appellant 1 - that the O1.E6 stent is deformed by "winding it up", this

does not prevent the skilled person to use Nitinol for the O1.E1 fabric. The skilled person knows that the superelastic behaviour is not limited to wound up structures, but is a material property of NiTi alloys, in particular Nitinol.

With the solution to both independent partial problems being obvious, the subject-matter of claim 1 of auxiliary request 1 is not inventive over the prior art.

4. Auxiliary request 2 - Articles 100(a) and 56 EPC

The subject-matter of claim 1 of auxiliary request 2 further defines the clamp to have a threaded outer surface. As explained above, the provision of an outer threaded surface on the O1.E1 clamp cannot be considered inventive in view of the teaching of O2.E7.

The subject-matter of claim 1 of auxiliary request 2 is thus also not inventive for the reasons discussed in point 3 above.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

V. Commare T. Kriner

Decision electronically authenticated