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Datasheet for the decision of 16 November 2018

Case Number: T 2092/17 - 3.2.08

Application Number: 10008434.2

Publication Number: 2255753

IPC: A61F2/95

Language of the proceedings: EN

Title of invention:
Heart valve delivery system with valve catheter

Patent Proprietor:
Edwards Lifesciences Corporation

Opponent:
Boston Scientific Corporation

Headword:

Relevant legal provisions:
EPC Art. 100(c), 76(1), 123(2), 84
RPBA Art. 13(1), 13(3)

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

Keyword:
Divisional application - added subject-matter (no) - after amendment
Late-filed auxiliary requests - justification for late filing (yes)

Decisions cited:

Catchword:

This datasheet is not part of the Decision.
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Case Number: T 2092/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 16 November 2018

Appellant: (Patent Proprietor)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
Representative:	Eisenführ Speiser Patentanwälte Rechtsanwälte PartGmbB Postfach 31 02 60 80102 München (DE)
Respondent: (Opponent)	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752-1234 (US)
Representative:	Peterreins Schley Patent- und Rechtsanwälte Hermann-Sack-Strasse 3 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 30 June 2017 revoking European patent No. 2255753 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	P. Acton
Members:	C. Herberhold
	Y. Podbielski

Summary of Facts and Submissions

I. By decision posted on 30 June 2017 the opposition division revoked European patent No. EP-B-2 255 753 because they found that its subject-matter extended beyond the content of the application as filed and beyond the content of the earlier application as filed.

II. The appellant (patent proprietor) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

III. Oral proceedings before the Board of Appeal were held on 16 November 2018.

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

The appellant requested that the decision under appeal be set aside and that
- the patent as granted, or, as an auxiliary measure,
- the patent as amended according to the new auxiliary request 1, filed during the oral proceedings before the Board, or one of auxiliary requests 4-10 filed with letter dated 16 October 2018, is found to meet the requirements of Article 76(1) and 123(2) EPC and the case be remitted to the opposition division for further prosecution.

The respondent (opponent) requested that the appeal be dismissed.

V. The following document plays a part in the present decision:

D1b: WO 2007/04788 (parent application, also referred to as the "earlier application" in the following)

VI. Claim 1 as granted (main request) reads as follows:

"A device for treating a human heart, comprising:
an expandable prosthetic valve (16);
a tubular delivery sleeve (24) having a proximal end;
a lead screw nut (514) coupled to the proximal end of the tubular delivery sleeve (24);
a valve catheter (23) having a distal end coupled to a mop (80) comprising a plurality of flexible extensions (150) configured for releasable attachment to the prosthetic valve (16), wherein the valve catheter (23) and the prosthetic valve (16) are slidably advanceable through the delivery sleeve (24); and
a lead screw (506) coupled to the valve catheter (23);
wherein the lead screw (506) engages the lead screw nut (514) and wherein rotation of the lead screw (506) causes the delivery sleeve (24) to retract relative to the valve catheter (23) and the prosthetic valve (16) for exposing the prosthetic valve (16) and extensions (105) and allowing expansion of the valve (16),
characterized in that
the flexible extensions (105) of the mop (80) allow expansion of the prosthetic valve (16) while maintaining the attachment with the prosthetic valve (16) during adjustment of the prosthetic valve (16) at a native valve site."

Claim 1 of the "**new auxiliary request 1**" reads as follows (differences in respect to the main request emphasised):

"A device for treating a human heart, comprising:
an expandable prosthetic valve (16);

a tubular delivery sleeve (24) having a proximal end;
a lead screw nut (514) coupled to the proximal end of the tubular delivery sleeve (24);
a valve catheter (23) including a multi-lumen shaft (72) and having a distal end coupled to a mop (80) by a collet (76) extending from inside of a central lumen of the multi-lumen shaft (72) and a puck (78), wherein the collet (76) is snapped into the puck (78) and wherein the puck (78) is snapped into the mop (80) such that the mop (80) extends distally from the puck (78), the mop comprising a plurality of flexible extensions (150) configured for releasable attachment to the prosthetic valve (16), wherein the valve catheter (23) and the prosthetic valve (16) are slidably advanceable through the delivery sleeve (24); and
a lead screw (506) coupled to the valve catheter (23);
wherein the lead screw (506) engages the lead screw nut (514) and

[M9] wherein rotation of the lead screw (506) causes the delivery sleeve (24) to retract relative to the valve catheter (23) and the prosthetic valve (16) for exposing the prosthetic valve (16) and extensions (105) and allowing expansion of the valve (16),
wherein ~~characterized in that~~
[M10] the flexible extensions (105) of the mop (80) allow expansion of the prosthetic valve (16) while maintaining the attachment with the prosthetic valve (16) during adjustment of the prosthetic valve (16) at a native valve site."

The feature assignment by the Board is in analogy to the feature assignment in the impugned decision (point 14).

VII. The essential arguments of the respondent can be summarised as follows:

Main request - Article 100(c) EPC

Claim 1 as granted defined the device to comprise a "valve catheter having a distal end coupled to a mop comprising a plurality of flexible extensions...". This feature, which also included embodiments with direct coupling between valve catheter and mop, was not disclosed in the earlier application as filed. Neither the summary section nor the claims did mention the presence of a mop at all. Indeed, the only possible support for the distal end of the valve catheter being coupled to a mop was in paragraph [0047], lines 20-22 of D1b, however in combination with a collet extending from the inside of a central lumen of a multi-lumen shaft of the valve catheter, the collet being snapped into a puck, the puck being snapped into the mop, such that the mop extends distally from the puck. The multi-lumen shaft, the collet and the puck, as well as their interaction with the mop were missing in granted claim 1. These features were, however, not only structurally linked but also cooperated functionally to achieve easy assembly of the valve catheter and a quick coupling between the expandable prosthetic valve held by the mop and the delivery valve catheter. To conclude, claim 1 as granted explicitly defined a coupling between the distal end of the valve catheter and the mop, which was, however, only disclosed in the earlier application via collet and puck. The features disclosed in paragraph [0047] in combination could thus not be omitted without violating Article 76(1) EPC.

Admission of new auxiliary request 1 into the proceedings

The amendments in claim 1 of new auxiliary request 1 aimed at overcoming an unallowable intermediate generalization which the respondent had objected to in basically every submission since the filing of the notice of opposition. The appellant could and should thus have provided a request aiming at solving that particular objection much earlier, be it in opposition or in appeal proceedings. In only reacting to the objection at the oral proceedings before the Board, the appellant had not complied with the requirements of Article 12 RPBA according to which the grounds of appeal shall contain a party's complete case.

New auxiliary request 1 should thus not be admitted.

New auxiliary request 1 - Articles 100(c), 76(1) and 123(2) EPC

Claim 1 of the new auxiliary request 1 extended in several ways beyond the content of the earlier application.

Firstly, the subject-matter claimed in features M9 and M10 had only been disclosed in paragraphs [0099]-[0101] of D1b in a functional context with the simultaneous use of an inflatable balloon. Indeed, as disclosed in paragraphs [0092] and [0093], for dilation of the thickened, hardened and calcified leaflets of a stenotic valve, sufficient pressure for dilation could only be exerted by an expanding balloon and not by a conventional self-expanding valve alone. It was true that paragraph [0105] mentioned a possible use of the

system without the inflatable balloon but with a "prosthetic valve [which] self-expands with sufficient force to firmly implant itself at the treatment site". However, such a valve - due to its much greater expansion force in comparison to a conventional self-expanding valve - could not be held by the flexible extensions of the mop such as to allow expansion of the valve while maintaining attachment during adjustment at a native valve site. Instead, contrary to what was claimed, such a valve would - at a certain degree of delivery sheath retraction - spring open, get into contact with the tissue and not be adjustable at all without causing massive tissue abrasion.

Therefore, for a device as claimed which allows adjustment of the valve at the native valve site, the inflatable balloon formed an essential part of the device and its omission amounted to an unallowable intermediate generalization.

Secondly, the patent had been amended in that the meaning of the term 'valve catheter distal end' had been shifted. Whereas according to the earlier application as filed, the valve catheter extended up to the very end of the flexible extensions, which according to claim 20 of the earlier application were disposed along the distal end of the valve catheter, the valve catheter defined in claim 1 of the new auxiliary request 1 was coupled with its distal end to the mop, with the mop comprising the flexible extensions. The term "valve catheter" according to the earlier application as filed thus comprised all the elements of the terminal end, i.e. the multi-lumen tube, the collet, the puck and the mop with its flexible extensions, whereas the term "valve catheter" according to claim 1 of new auxiliary request 1 defined

a catheter which ended with the distal end of the multi-lumen tube and did not comprise the further elements. In other words, the reference point 'valve catheter distal end' relative to which the further features of the claim were defined, had been changed, resulting in an extension of subject-matter.

Furthermore, even though multi-lumen shaft, collet, puck and their respective interaction now formed part of the subject-matter of claim 1, the further features of the valve catheter, disclosed in combination with the multi-lumen shaft in paragraph [0047], were still missing, namely the stiffener tube around a proximal portion of the valve catheter as well as the wire tube extending proximally from a proximal end of the multi-lumen shaft. Omission of these features resulted in a further unallowable intermediate generalization.

New auxiliary request 1 - Article 123(3) EPC

As discussed before, the wording of claim 1 of the new auxiliary request 1 included a change in the reference point to which the coupling arrangement was connected. This resulted in a change in the meaning of the term valve catheter. Whereas according to the patent as granted, a "valve catheter" had to extend up to the very end of the flexible extensions, a "valve catheter" according to claim 1 of the new auxiliary request 1 had only to comprise a multi-lumen shaft. This shift in meaning resulted in objects now qualifying as a valve catheter which originally did not, thus broadening the scope of the claim, contrary to the requirements of Article 123(3) EPC.

New auxiliary request 1 - Article 84 EPC

Claim 1 as amended comprised the feature of "a valve catheter (23) including a multi-lumen shaft (72) and having a distal end coupled to a mop...". It was, however, not clear whether it was the distal end of the "valve catheter" or the distal end of the "multi-lumen shaft" which was subsequently further defined. Thus, the requirements of Article 84 EPC were not met.

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

Main request - Article 100(c) EPC

The core of the invention was in allowing for an exactly controllable positioning, gradual expansion and finally release of the expandable prosthetic heart valve upon insertion. This task was solved by the spindle drive - formed by lead screw and lead screw nut - and by the flexible extensions configured for releasable attachment to the prosthetic valve, as claimed in claims 16 and 20 of the earlier application as filed. The addition of the "mop" in claim 1 as granted did not alter that technical information. For that reason the puck and the collet were only mentioned in the context of assembling the device, but had never been described as essential for the core of the invention. Consistently, when disclosing the operation of the device, paragraphs [0099] and [0100] of the description mentioned the flexible extensions of the mop, without making any reference to the other elements allegedly required. While it was implicit that the mop with its flexible extensions was in some way coupled to the valve catheter, there was no need to claim the specific details of that coupling. Omitting the

particulars of the multi-lumen shaft, the collet, the puck and their mutual interaction did thus not result in the skilled person being provided with new technical information.

Admission of the new auxiliary request 1 into the proceedings

With the grounds of appeal, the appellant had filed an auxiliary request 3 which - by including the features of the collet, the puck and their respective interaction - aimed at overcoming the alleged unallowable intermediate generalization. Only during the discussion before the Board had it become apparent, that also the multi-lumen shaft was considered to be functionally and structurally linked with these components.

The filing of new auxiliary request 1 was thus an adequate and timely reaction to the course of the proceedings, such that said request was to be admitted.

New auxiliary request 1 - Articles 100(c), 76(1) and 123(2) EPC

Claim 1 of the new auxiliary request 1 explicitly defined the details of the coupling between the distal end of the valve catheter and the mop, precisely as disclosed in paragraph [0047]. Contrary to the respondent's view, there was thus no shift in the meaning of the terms "valve catheter" or "valve catheter end". Therefore, the respective objections as to an unallowable intermediate generalization were moot.

Furthermore, there was no need to include into the definition of the valve catheter further details of its proximal end, such as the stiffener tube or the wire tube, which did not play any part in the coupling on the valve catheter's distal end.

There was also no need to include the inflatable balloon as it was only optionally provided. As explicitly disclosed in paragraph [0105] of D1b the system may be used without a balloon catheter, using a self-expandable valve having sufficient force to firmly implant itself at the treatment site. Nevertheless the disclosed mechanism assured also in the case of such a valve a precisely controlled expansion, allowing expansion of the prosthetic valve while maintaining the attachment with the prosthetic valve during adjustment of the valve at the treatment site. This was consistently reflected in the wording of originally filed claims 16 and 20 which defined the spindle mechanism in combination with the flexible extensions configured for releasable attachment, but without the inflatable balloon and without the valve being explicitly self-expanding. Also consistently, throughout the originally filed description of the earlier application repeated reference was made to situations where no inflatable balloon was used, see e.g. page 6, first complete sentence.

The description also disclosed in paragraph [0102] that, if not satisfied with the initial deployment of the valve, the operator can collapse and reorient the valve, by partially or entirely retracting the valve back into the delivery sleeve, such that the prosthetic valve could be redeployed or withdrawn altogether. In this context, the respondent's allegations according to which controlled expansion, collapsing and

reorientation of a self-expandable valve was not possible, were strongly rebutted. This was, indeed, one of the key capabilities of the inventive system and was made possible by the mechanical gain of the spindle gear.

There was thus no need to restrict the claimed subject-matter to self-expandable valves or to a device further comprising an inflatable balloon.

New auxiliary request 1 - Article 123(3) EPC

Claim 1 of new auxiliary request 1 defined additional features of the valve catheter and the coupling between valve catheter distal end and mop, thereby narrowing the scope of the claim. Namely, the valve catheter was defined as including a multi-lumen shaft and the coupling of the mop as being by the particular arrangement comprising the collet and the puck as disclosed in paragraph [0047] of D1b, corresponding to paragraph [0049] of the patent as granted.

The patent was thus not so amended as to extend the protection it confers.

New auxiliary request 1 - Article 84 EPC

The feature "a valve catheter including a multi-lumen shaft and having a distal end" could only be understood in one way, namely in that it was the valve catheter which included the multi-lumen shaft and which also had the distal end. Contrary to the respondent's view, there was no ambiguity or unclarity.

Reasons for the Decision

1. Main request - Article 100(c) EPC

1.1 The application is a divisional application. The text of the parent application has been incorporated into the divisional in full, with the former claims being reformulated as "The present application may also relate to a....", see description as filed page 34ff.

It is thus sufficient to discuss the amendments with respect to the original parent WO publication (D1b).

1.2 Claim 1 of the main request is based on a combination of claims 16 and 20 of the parent application as filed.

However, it further defines the valve catheter to have "a distal end coupled to a mop comprising a plurality of flexible extensions configured for releasable attachment to the prosthetic valve".

While claims 16 and 20 as filed define the device to comprise a plurality of flexible extensions disposed along the distal end of the valve catheter, they are silent on any details of a coupling between the valve catheter and the flexible extensions.

Such a coupling is described in paragraph [0047] which discloses that "the valve catheter 23 includes a multi-lumen shaft 72,..." and that "a collet 76 extends from inside a central lumen of the multi-lumen shaft 72 and is snapped into a puck 78". Furthermore, "the puck 78 is snapped into the mop 80 such that the mop extends distally from the puck".

These features are not only structurally linked but they also cooperate functionally in a 'snap-in' connection, ultimately connecting the flexible extensions to the distal end of the multi-lumen shaft of the valve catheter. Isolating the mop from this functionally and structurally linked ensemble results in an unallowable intermediate generalization.

The appellant has argued that the multi-lumen shaft, the collet and the puck had nothing to do with the core of the invention and thus could be omitted without the skilled person being confronted with new technical information. However, the same holds true for the mop, which is not essential for the "core of the invention" as defined by the appellant. Releasable attachment of the prosthetic valve relies on the flexible extensions being configured accordingly, whether they are provided on a mop or not. Gradual expansion of the prosthetic heart valve is brought about by the flexible extensions and the tubular delivery sleeve being movable relative to each other by the interaction of the lead screw nut and the lead screw. Again, whether the flexible extensions are provided on a mop or not does not play a role. Consistently, original claims 16 and 20 defined the flexible extensions but not the mop.

The mop is, however, as discussed above, disclosed in a functional and structural context. Claiming the distal end of the valve catheter as being coupled to the mop, without the other features to which the mop is structurally and functionally linked thus results in the skilled person being confronted with new technical information, namely that the coupling can also be realised without the collet (extending from inside a central lumen of the multi-lumen shaft) and the puck.

This analysis is not altered by the fact that paragraphs [0099] and [0100] of the description refer to the "extensions of the mop", without mentioning the other elements. Releasable attachment of the prosthetic valve and allowing expansion of the valve while maintaining said attachment during adjustment is the functionality of the flexible attachments, which - in the detailed example covered in paragraphs [0099] and [0100] - are the extensions of the mop. There is no reason to mention the other elements in this part of the description. It still remains the case that, for the claimed coupling between the distal end of the valve catheter and the mop, they cannot be omitted.

Consequently, the subject-matter of claim 1 as granted extends beyond the disclosure of the application as filed and the earlier application as filed.

2. New auxiliary request 1

2.1 Admission into the proceedings

It is true that, while the omission of the collet and the puck had been prominently objected to (see e.g. the respondent's reply to the grounds of appeal, page 8, penultimate paragraph), the omission of the multi-lumen shaft had not been explicitly discussed by the respondent so far in the appeal proceedings.

Likewise, in the Board's communication dated 18 July 2018, it was announced that it would be examined whether claiming the "mop" without the "puck" and the "collet" amounted to an unallowable intermediate generalization. However, the omission of the multi-lumen shaft was not mentioned as possibly problematic.

Thus, the importance of said feature only became apparent during oral proceedings before the Board. Reacting to this course of the proceedings by amending auxiliary request 3 (filed with the grounds of appeal and directed at overcoming objections based on the omission of the puck, the collet and their interrelationship with the mop) is a justified and adequate reaction to the course of the proceedings.

There is thus no violation of the requirements of Article 12(2) RPBA and the Board decided to admit the new auxiliary request 1 into the proceedings, in accordance with Articles 13(1) and (3) RPBA.

2.2 Articles 100(c), 76(1) and 123(2)EPC

2.2.1 The disclosure in paragraph [0047]

Claim 1 of new auxiliary request 1 defines the mop, as well as the collet, the puck and the multi-lumen shaft in their respective functional and structural relationship, as disclosed in paragraph [0047], lines 20 to 22. These are the elements relevant for the coupling between the valve catheter and the flexible extensions at the distal end of the catheter. Conversely, the stiffener tube and the wire tube, both mentioned in paragraph [0047], are located at the proximal end of the catheter and play no part in the coupling. They are thus neither structurally nor functionally inextricably linked with the mop and their omission from the subject-matter of claim 1 does not amount to an unallowable intermediate generalisation.

2.2.2 The terms 'valve catheter' and 'valve catheter distal end'

The respondent further argued that the terms 'valve catheter' and, in particular, 'valve catheter distal end' in claim 1 of new auxiliary request 1 had undergone a shift in meaning with respect to the disclosure of the earlier application, which resulted in the claimed subject-matter extending beyond the original disclosure of the earlier application as filed.

Indeed, in the original use of the term 'valve catheter', the term includes multi-lumen shaft, collet, puck and mop. This is evident from claim 20 of the earlier application as originally filed, which defines the flexible extensions as being disposed along the distal end of the valve catheter. It likewise follows from paragraph [0080], line 15 which makes explicit reference to the "mop 80 portion of the valve catheter".

Conversely, claim 1 of new auxiliary request 1 defines a valve catheter having a distal end coupled to a mop in a specific way by a collet and a puck. From this definition it follows, that the term 'valve catheter' as used in claim 1 of the new auxiliary request 1 comprises the multi-lumen shaft, but does not comprise the collet, the puck and the mop.

However, it is simply a question of nomenclature, whether one decides to consider only the device's elements up to the distal end of the multi-lumen shaft as part of the "valve catheter", or whether one understands the term to further include the collet, the puck and the mop. Such a change in nomenclature does

not present the skilled person with new technical information. To put it differently, the provision of a valve catheter including a multi-lumen shaft but not the collet, the puck and the mop, being however coupled with its distal end, i.e. with the distal end of the multi-lumen shaft, via the collet and the puck to the mop is technically identical with the provision of a valve catheter including multi-lumen shaft, collet, puck and mop and having the multi-lumen shaft distal end coupled via collet and puck with the mop.

As the amendment does not present the skilled person with new technical information, the requirements of Article 123(2) EPC are fulfilled.

The Board notes that the change in nomenclature results in a small inconsistency between the claim wording and the description / the drawings, which is, however, an issue of clarity (Article 84 EPC). As the inconsistency was introduced by the definition of the valve catheter distal end as being coupled to the mop, i.e. by the amendment already present in claim 1 as granted, an objection under Article 84 EPC in this respect cannot, and indeed has not been raised.

2.2.3 Absence of an inflatable balloon in the subject-matter claimed

The respondent was of the opinion that an inflatable balloon was an essential part of the claimed device, in particular in view of the claimed feature of "maintaining the attachment with the prosthetic valve during adjustment of the prosthetic valve at a native valve site" which in paragraphs [0092] and [0093] of D1b was only disclosed in combination with the use of such a balloon. The omission of the inflatable balloon

thus, according to the respondent, resulted in an unallowable intermediate generalization.

However, the inflatable balloon is consistently disclosed as on optional feature throughout the original disclosure. This is true for the originally filed claims, which solely define the inflatable balloon in dependent claims (see earlier application as filed, dependent device claims 6-8 and 17, 18, as well as dependent method claims 13, 14). It is also true for the description, which, on the one hand, in paragraph [00105] of D1b explicitly states that the system may be used without a balloon, and, on the other hand, consistently refers to an inflatable balloon as being present only in some 'variations' of the invention (paragraph [00013]: "When the system includes an inflatable balloon...."; paragraphs [0016] and [0017]: "In one variation, an inflatable balloon is disposed..."). Even for active expansion of a not or not sufficiently self-expandable valve during deployment, an inflatable balloon is not the only option disclosed: an expandable basket may be used instead (paragraph [0013]). That the device need not necessarily comprise an inflatable balloon is thus not new technical information for the skilled person.

Furthermore, "maintaining the attachment with the prosthetic valve during adjustment of the prosthetic valve at a native valve site", is a functional accomplishment of the releasable attachment between flexible extensions and prosthetic valve (claim 20 of the earlier application as originally filed) and of the lead screw / lead screw nut driven relative motion between delivery sleeve and flexible extensions (claim 16 of the earlier application as originally filed). While the inflatable balloon helps enlarging the valve

against resistive forces of e.g. the stenotic valve leaflets, it does not play a part in maintaining the attachment or in restricting the valve's expansion to an intermediate state of enlargement which allows adjustment at a native valve site. It also cannot play a part in collapsing the prosthetic valve as disclosed in paragraph [00102].

To conclude, although the words "while maintaining the attachment with the prosthetic valve during adjustment of the prosthetic valve at a native valve site" originate from paragraph [00100], this paragraph only supplies the wording for a functional accomplishment already brought about by and intrinsic in the technical features present in claims 16 and 20 of the earlier application as originally filed. There is thus no need to take up in the claim the further features disclosed in said paragraph, in particular the presence of an inflatable balloon.

The inflatable balloon as technical necessity for maintaining the attachment of the valve during adjustment at a native valve site.

The respondent has further argued that in case of a truly self-expanding valve, i.e. a valve not in need of assistance by an expansion device when enlarging into the annulus of the stenotic heart valve, the inventive device was not capable of controlling the valve's expansion such as to allow adjustment at a native valve site while maintaining the attachment with the prosthetic valve. The appellant has strongly rebutted that allegation.

As the appellant has disclosed the mechanism underlying the respective functionality, i.e. the lead screw/lead

screw nut driven relative movement of the delivery sleeve and the flexible extensions, the burden of proof for the mechanism being not capable to adjustably hold the attached valve lies with the respondent. In the view of the Board, without support by further verifiable facts, the reasoning put forward by the respondent cannot shed sufficient doubts on the mechanism's capabilities such as to shift the burden of proof on the appellant. In evaluating the evidence before it, the Board thus accepts that the disclosed system is capable of maintaining the attachment with also such a truly self-expandable valve during adjustment at the native valve site. The respondent's arguments based on allegations to the contrary are thus not successful.

2.2.4 To conclude, the subject-matter of claim 1 of new auxiliary request 1 does not extend beyond the content of the application as filed or of the earlier application as filed.

2.3 Article 123(3) EPC

To examine the requirements of Article 123(3) EPC, the subject-matter of the amended claims has to be compared with the subject-matter of the granted claims.

With respect to granted claim 1, the valve catheter has been further defined to "include a multi-lumen shaft". Furthermore, the coupling between the distal end of the valve catheter and the mop has been further specified to be "by a collet extending from inside of a central lumen of the multi-lumen shaft (72) and a puck (78), wherein the collet (76) is snapped into the puck (78) and wherein the puck (78) is snapped into the mop (80)

such that the mop (80) extends distally from the puck (78)".

Both amendments add additional features, further defining and thereby narrowing down features which had already been part of claim 1 as granted. Consequently the subject-matter is further restricted and there is no extension of the protection conferred by the patent.

Whereas it is true that the term "valve catheter" has undergone a slight shift in its meaning (see point 2.2.2 above), this change occurred between claims 16 and 20 as originally filed and claim 1 as granted. From claim 1 as granted to claim 1 of new auxiliary request 1, the meaning of the term has remained unchanged.

Thus, the requirements of Article 123(3) EPC are fulfilled.

2.4 Article 84 EPC

In the view of Board, the wording "a valve catheter including a multi-lumen shaft and having a distal end coupled to a mop" clearly defines that the distal end forms part of the valve catheter. This is because of the two participles "including" and "having" being connected to each other 'on equal footing' by the word "and". If the distal end of the multi-lumen shaft was meant, one would expect the "and" to be omitted.

Consequently, there is no ambiguity and the requirements of Article 84 EPC are fulfilled.

2.5 There were no additional objections under any of Articles 76(1), 123(2), 123(3) or 84 EPC against the dependent claims.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated