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**Datasheet for the decision
of 1 February 2018**

Case Number: T 1880/14 - 3.2.08

Application Number: 09154935.2

Publication Number: 2074964

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

Stent-valves for valve replacement and associated methods and systems for surgery

Patent Proprietor:

Symetis SA

Opponent:

Kietzmann, Lutz

Headword:

Relevant legal provisions:

EPC Art. 100 (c), 100 (a), 56, 84

Keyword:

Added subject-matter (no)

Inventive step - (yes)

Claims - clarity (yes)

Decisions cited:

Catchword:



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Case Number: T 1880/14 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 1 February 2018

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 30 June 2014
rejecting the opposition filed against European
patent No. 2074964 pursuant to Article 101(2)
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 2014 the Opposition Division rejected the opposition against European patent No. EP-B-2074964.
- II. The appellant (opponent) lodged an appeal against that decision within the prescribed time limit.
- III. Oral proceedings before the Board took place on 1 February 2018. For further details thereof, in particular the issues discussed with the parties and the parties' initial requests, reference is made to the minutes of the oral proceedings.
- IV. The requests ripe for decision either during or at the end of the oral proceedings were as follows:

The appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested that the appeal be held inadmissible, auxiliary that the patent be maintained on the basis of the set of claims filed as auxiliary request 5 on 23 March 2015.

- V. Claim 1 of auxiliary request 5 reads as follows:

"1. A cardiac stent-valve delivery system comprising:

a cardiac stent-valve (2212, 2214) for replacing a failed aortic valve, comprising a stent component (2214) and a valve component (2212), the stent-valve being capable of a collapsed configuration for delivery

and being self-expandable to an expanded configuration for implantation;

a first assembly comprising an outer sheath (2206) and an inner shaft (2204) forming a guide wire tubing, the inner shaft functioning as a lumen for a guide wire; and

a second assembly comprising a stent holder (2222) configured for removable attachment to at least one attachment element (808) of said stent-valve when the stent-valve is positioned over the guide wire tubing of the first assembly in said collapsed configuration;

wherein the first assembly and the second assembly are configured for relative movement with respect to one another in order to transition from a closed position to an open position, such that in the closed position the outer sheath encompasses the stent-valve still attached to the stent holder and thus constrains expansion of the stent-valve, and such that in the open position the outer sheath does not constrain expansion of the stent-valve;

characterized by the delivery system being configured

(i) for trans-apical introduction into a heart to access an implantation site for the stent-valve; and

(ii) such that once the outer sheath is removed and it no longer constrains the attachment elements the stent-valve automatically detaches from the stent holder due to the self-expanding property of the stent-valve and expands to said fully expanded configuration,

wherein the first assembly and the second assembly are configured to transition from the closed position, to a partially-open position, to the open position, wherein in the partially-open position, the stent-valve (2212, 2214) expands partially proximally but does not detach from the stent holder (2222) because the outer sheath (2206) still encompasses the at least one attachment element (808) of the stent-valve and the stent holder, wherein the stent-valve is revertable from the partially expanded configuration to the collapsed configuration by sliding the outer sheath in a proximal direction over a proximal section of the stent valve to recapture the stent valve,

wherein the reverted stent valve is repositionable within the patient's body or removable from the patient's body and wherein a tip (2202) is secured or fastened at the distal end of the inner shaft (2204) and wherein the outer sheath (2206) is secured or fastened to the proximal section of the tip (2202)."

VI. The following documents played a role in the present decision:

D9: US-A-5,980,533;

D14: US-A-2004/0093060.

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

Admissibility of the appeal

As pointed out in the Board's preliminary opinion, the notice of appeal at least implicitly comprised the request that the decision of the Opposition Division be

set aside, thus complying with Rule 99(1)(c) EPC.
Therefore, the appeal was admissible.

Article 100(c) EPC

Several features of claim 1 were not originally disclosed. Primarily, there was no basis for the delivery system being configured for (i) trans-apical introduction into a heart to access an implantation site for the stent-valve. This feature allegedly found basis in a sentence in paragraph [0086], according to which "the heart may be penetrated, for example, trans-apically through a relatively small opening in the patient's body." However, the application as filed consistently disclosed a single stent-valve delivery system applicable for all four cardiac valves and for all approaches. Such a device had to be thinner, more flexible and longer than a typical device configured for trans-apical access. Defining the stent-valve delivery system as being configured for trans-apical introduction thus implied device features which had not been disclosed for the stent-valve delivery system described in the application as originally filed, neither in its general disclosure, nor in a specific example.

Moreover, there was no original disclosure for the stent valve being self-expandable, the first assembly comprising an inner shaft forming a guide wire tubing with the inner shaft functioning as a lumen for a guide wire, and for the stent holder being configured for removable attachment to the at least one attachment element of the stent-valve, when the stent-valve was positioned over the guide wire tubing of the first assembly in the collapsed configuration. For these

objections reference was made to the written proceedings.

Hence, the subject-matter defined in the main request extended beyond the content of the application as filed and of the earlier application as filed.

Article 100(a) EPC

Closest prior art document D14 disclosed a stent-delivery device suitable for retrograde or antegrade aortic stent-valve deployment. When used in the retrograde approach, retraction of the sheath opened the inflow end first, whereas when used in the antegrade approach the outflow end of the stent-valve expanded first. The skilled person would thus be aware of the advantages in placing an aortic valve replacement with the inflow-end opening first. Consequently, from D14 alone, the skilled person would strive at providing said functionality also when working in the antegrade direction. In doing so, he would consider the teaching of D9, which is from the closely related technical field of stent introducers, and from the mechanical features of which it is immediately evident that it frees the inflow end of the stent first. Combining the teaching of D14 and D9 would lead the skilled person in an obvious way to a stent-valve delivery system falling under the definition of claim 1.

The feature according to which the stent valve is revertable from the partially expanded configuration to the collapsed configuration by sliding the outer sheath in the proximal direction over a proximal section of the stent-valve to recapture the stent-valve had been at least implicitly present in the D14 stent-valve

delivery device. It was evident from the valve structure shown in D14, Figures 37 and 38 and from the attachment means - hooks and loops as in the patent - disclosed in paragraphs [103], [0104], that there were no structures impeding re-sheathing and that the valve exterior was sufficiently smooth to be reverted into the sheath. Thus the structure disclosed in D14 implied the functionality claimed, in particular as the functional feature comprised situations wherein the partial expansion to be reverted from was minimal. Moreover, also repositioning the stent required massive force, such that the solidity of the attachment structures had to be considered likewise sufficient for re-sheathing.

Therefore, in combining the teaching of documents D14 and D9, the person skilled in the art would come in an obvious way to a stent valve delivery system having all the features of claim 1, the subject-matter of which did thus not involve an inventive step.

Clarity of the amended features

The amended features introduced method features, which were of unclear scope in a device claim. Furthermore, defining the device by reference to the patient's body, which was not part of the claimed subject-matter, made the claim unclear.

Claim 1 did thus not fulfill the requirements of Article 84 EPC.

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

Admissibility of the appeal

In the notice of appeal, the appellant had requested that the opposition division rectify its decision. However, such a request was impossible in opposition appeal proceedings according to Article 109(1) EPC. Hence, the notice of appeal did not contain a possible request and therefore did not comply with Rule 99(1)c EPC, such that the appeal had to be rejected as inadmissible.

Article 100(c) EPC

Paragraph [0086] and claim 42 of the parent as originally filed (EP application 07818037.9) disclosed delivery of the stent-valve by trans-apical introduction into the heart. Hence, the stent-valve delivery system had to be suitable for trans-apical introduction. Nothing more was defined in feature (i) of claim 1, which was thus clearly and unambiguously disclosed. The suitability implied structural restrictions, such as the orientation of the cardiac stent-valve on the delivery system or a certain maximum diameter of the stent-valve delivery system in accordance with trans-apical introduction. It did, however, not exclude the longer, thinner and more flexible delivery systems used in the retrograde transfemoral approach or in the transseptal antegrade approach, which were likewise suitable for trans-apical introduction.

With respect to the features objected to in the written proceedings, the respondent fully agreed with the provisional opinion expressed in the Board's communication, which endorsed the arguments put forward with the reply to the appeal. In particular, the stent

being self-expandable found basis in paragraphs [0057] and [0090], the inner shaft of the first assembly forming a guide wire tubing was described in consecutive paragraphs [0087] and [0088], and the stent being positioned over the guide wire tubing in a collapsed configuration was disclosed in claim 1 as filed, paragraph [0091] and Figures 22A, 22B and 22C.

The subject-matter of claim 1 was thus clearly and unambiguously disclosed in the application and in the earlier application as originally filed.

Article 100(a) EPC

It was correct that D14 formed the closest prior art. When used in an antegrade approach, such as trans-apical introduction into the heart, bringing the outer sheath of the delivery device shown in Figure 41A towards the open position led to expansion of the stent-valve outflow end first, whereas according to the invention the stent-valve inflow end was to expand first, which had considerable advantages for stent-valve placement. The appellant had argued that a modification of the stent-valve delivery system of D14 towards opening the inflow end of the stent-valve first was obvious in view of document D9. This document was however from the different technical field of PCTA stent delivery and would be considered by the person skilled in the art only in an *ex post-facto* analysis. Even if it were considered, applying its teaching required further adaptations, such as a more distal placement of the attachment structures.

Furthermore, neither D14 nor D9 disclosed the stent valve to be revertable from the partially expanded configuration to the collapsed configuration by sliding

the outer sheath in a proximal direction over a proximal section of the stent-valve to recapture the stent-valve, wherein the reverted stent-valve is repositionable within the patient's body. Paragraph [0012] of D14 - cited by the appellant- mentioned that the prosthetic valve assembly might be partially released and expanded within the body and moved or otherwise adjusted to a final desired location, where the prosthetic valve assembly might be totally released from the catheter and expanded to its fully expanded position. The document was, however, fully silent on re-sheathing of the valve. Nor was it possible to derive from the valve structure shown in D14, Figures 37, 38, a revertibility of said prosthesis. Indeed, cardiac stent-valves were typically designed to have considerable expansive forces, which could only be overcome by specific crimping devices in order to fit them into an introduction sheath. Without explicit teaching, the skilled person would therefore not have considered the delivery device of D14 to be capable of reverting the stent-valve from the partially expanded configuration to the collapsed configuration.

Thus even by combining the teaching of D14 and D9, the skilled person would not have arrived at a stent-valve delivery system having all the features of claim 1. Hence, the subject-matter of claim 1 involved an inventive step.

Clarity of the amendment

The definition of the stent-valve being revertable did not have any influence on the claim category. It merely defined a functionality of which the device was capable. The claim category was thus clear.

Likewise, mentioning the patient's body did not render the claim unclear. The feature according to which the stent valve, once partially or fully recaptured in the sheath was repositionable within or removable from the patient's body only further explained and illustrated what was already intrinsic in the stent-valve being revertable. It thus rather made the claim clearer than unclear.

Reasons for the Decision

1. Admissibility of the appeal

With letter dated 10 September 2014 the appellant requested that "the Opposition Division rectify the decision dated 30 June 2014 to reject the opposition filed against European Patent No. 2 074 964." The appellant argued that such a request was impossible in opposition appeal proceedings according to Article 109(1) EPC. Hence, the notice of appeal did not contain a possible request and therefore did not comply with Rule 99(1)c EPC, such that the appeal had to be rejected as inadmissible.

However, in the present case, the Opposition Division had decided to reject the opposition, thereby maintaining the patent as granted. Requesting rectification of said decision can only be understood as meaning that the decision of the Opposition Division was to be set aside and that the patent not be maintained as granted, i.e. be revoked. The notice of appeal thus contains a request defining the subject of the appeal.

Hence, the requirements of Rule 99(1)(c) EPC are fulfilled and the appeal is admissible.

2. Article 100(c) EPC

2.1 The patent was granted on a divisional application (parent: EP application 07818037.9). The description of the divisional application is identical to the description of the parent application and claims 1-19 of the divisional application are identical to claims 16-34 of the parent application. It thus suffices to examine the original disclosure with respect to the application of the impugned patent as filed. In this respect, reference will be made to the A1 publication.

2.2 Feature (i): "the delivery system being configured... for trans-apical introduction into a heart to access an implantation site for the stent-valve".

Paragraph [0086] explicitly discloses that "the heart may be penetrated, for example, trans-apically through a relatively small opening in the patient's body. For example, to replace a failed aortic valve, the patient's body may be penetrated through an intercostal space..., which is a region between two ribs" (lines 15-21).

The appellant has argued that the term "configured for" implied structural features of a delivery device, such as the device being relatively shorter, stiffer and of larger diameter than a transfemoral retrograde delivery device. Such a device was not disclosed in the application as filed. According to the appellant, the original application documents disclosed one single delivery device suitable for all cardiac valves and for every approach, with no indication whatsoever that the

device was to be specifically "configured for" the transapical approach for the aortic valve. There was clearly no basis for the hardware restrictions of the device which had to be considered implied by feature (i) in view of the wording "configured for".

It is common ground between the parties that devices for the antegrade approach to the aortic valve (i.e. through the femoral vein, the right and left atrium and the ventricle, see D14) are suitable for trans-apical introduction into a heart to access in particular the aortic valve. The appellant himself brought forward with reference to scientific publications that devices for stent valve delivery in the retrograde approach have been used and were thus suitable for the trans-apical approach (the valve direction being of course adapted accordingly).

Stent-valve delivery systems which are longer, thinner and more flexible than those typically used for a trans-apical approach can thus be used for trans-apical introduction into a heart to access the aortic valve without any adaptation of their configuration. This is equivalent to saying that such devices are configured for the trans-apical approach.

The same applies for the delivery device disclosed in the application as originally filed (see in particular Figures 22): Even if it were sufficiently long, thin and flexible for e.g. the retrograde approach (via the femoral artery), it would still be configured as defined in feature (i). In this context it is pointed out that the orientation of the stent-valve as shown in Figures 22A-22D of the application as filed is in accordance with trans-apical insertion of an aortic valve (see in this respect the explanations on page

5-6, point M1a of the board's communication dated 13 November 2017 which have not been challenged by the parties in the oral proceedings).

Hence, the application as originally filed clearly and unambiguously discloses a cardiac stent-valve delivery system for replacing a failed aortic valve "configured for trans-apical introduction into a heart" to access the aortic valve implantation site of the stent-valve.

2.3 Article 100(c) objections brought forward in the written proceedings.

2.3.1 Feature: The stent-valve is capable of a collapsed configuration for delivery and is self-expandable to an expanded configuration for implantation.

According to paragraph [0055], lines 18-21, in the case of a biological valve, expansion of the valve component from a collapsed configuration to an expanded configuration "may require self-expansion of an affixed stent component...". A stent-valve in which the stent component is self-expanding, thereby expanding the biological valve, forms a stent-valve "being self-expandable" as well as a stent-valve having 'self-expanding property'. The feature is thus clearly and unambiguously disclosed.

2.3.2 Feature: The first assembly comprises an inner shaft forming a guide wire tubing, the inner shaft functioning as a lumen for a guide wire.

Claim 1 as filed defines the first assembly to comprise an outer sheath and a guide wire tubing, i.e. a tube / catheter / shaft with a lumen therein for receiving a guide wire. From the term "outer sheath"

it can be derived that the guide wire tubing is "inner" with respect to said "outer sheath". It may thus be called an "inner shaft forming a guide wire tubing" without change of the technical content of the claim.

- 2.3.3 Feature: The stent holder is configured for removable attachment to the at least one attachment element of the stent-valve when the stent-valve is positioned over the guide wire tubing of the first assembly in the collapsed configuration.

Claim 1 as filed defines that in the closed position (of the first and second assembly) the stent-valve is encompassed in the outer sheath and that in this position the stent-valve is (still) attached to the stent holder (claim 1, lines 13-16). With the stent-valve being positioned over the guide wire tubing (claim 1, lines 8, 9), i.e. over the inner shaft functioning as a lumen for a guide wire, the stent is "positioned over the guide wire tubing" at the time when it is in the collapsed configuration. Thus, the stent holder is configured for removable attachment to the at least one attachment element of said stent-valve when the stent-valve is positioned over the guide wire tubing of the first assembly in said collapsed configuration.

- 2.4 To conclude, none of the objections raised by the appellant under Article 100(c) EPC, neither in the written procedure, nor during the oral proceedings prejudices the maintenance of the patent according to the only remaining request (auxiliary request 5).

3. Article 100(a) + 56 EPC

3.1 It is common ground that D14 forms the closest prior art.

3.2 D14 discloses

A cardiac stent-valve delivery system (paragraphs [0101]-[0107]) for replacing a failed aortic valve (either in a retrograde manner through a peripheral artery, e.g. the femoral artery, or through a venous approach and trans-septally, i.e. antegrade see paragraph [0028], last sentence and paragraph [0107], first sentence), comprising a stent component and a valve component (paragraph [0103] refers to the prosthesis assembly of Figures 36, 37), the stent-valve being capable of a collapsed configuration for delivery ("...contracted prosthesis assembly engages the pusher tip...", paragraph [0101]) and being self-expandable to an expanded configuration for implantation (paragraph [0103], "...when the entire prosthesis assembly is advanced beyond the distal end of the outer sheath, the entire prosthesis assembly is permitted to expand...");

a first assembly comprising an outer sheath (Figure 41A, No. 512)

a second assembly comprising a stent holder (No. 520, paragraph [0101], "...pusher tip is sufficiently large so that a contracted prosthesis assembly engages the pusher tip in a frictional fit arrangement.")

configured for removable attachment (via "hooks", No. 522) to at least one attachment element of said stent-valve (loop elements, see paragraph [0104]) when the stent-valve is positioned on the stent holder in said collapsed configuration;

wherein the first assembly and the second assembly are configured for relative movement with respect to one another in order to transition from a closed position to an open position, such that in the closed position the outer sheath encompasses the stent-valve still attached to the stent holder and thus constrains expansion of the stent-valve, and such that in the open position the outer sheath does not constrain expansion of the stent-valve (paragraph [0103]);

wherein the delivery system is configured

(i) for trans-apical introduction into a heart to access an implantation site for the stent-valve (it was common ground between the parties that the stent-valve delivery system of D14, configured for the antegrade approach, i.e. through the femoral vein to the right atrium, then to the left atrium through a transseptal approach and through the left ventricle, see paragraph [0107] and [0028], last sentence, was also configured for trans-apical introduction into a heart to access the aortic valve implantation site for the stent-valve); and

(ii) such that once the outer sheath is removed and it no longer constrains the attachment elements the stent-valve automatically detaches from the stent holder due to the self-expanding property of the stent-valve and expands to said fully expanded configuration (paragraph [0103]),

wherein the first assembly and the second assembly are configured to transition from the closed position, to a partially-open position, to the open position, wherein in the partially-open position, the stent-valve expands partially proximally but does not detach from the stent holder because the outer sheath still encompasses the

at least one attachment element of the stent-valve and the stent holder (paragraph [0012], last three sentences).

3.3 The subject-matter of claim 1 differs from the disclosure of D14 in that

A) the first assembly additionally comprises an inner shaft forming a guide wire tubing, the inner shaft functioning as a lumen for a guide wire; and in that a tip is secured or fastened at the distal end of the inner shaft and the outer sheath is secured or fastened to the proximal section of the tip;

and B) in that

the stent-valve is revertable from the partially expanded configuration to the collapsed configuration by sliding the outer sheath in a proximal direction over a proximal section of the stent-valve to recapture the stent-valve, wherein the reverted stent-valve is repositionable within the patient's body or removable from the patient's body.

3.4 Feature B has the effect to allow recapturing and re-sheathing of the valve, thus solving the problem to allow repositioning or removal of the valve from the body.

D14 discloses that the prosthesis may be partially released and expanded within the body and moved or otherwise adjusted to a final desired location, with the prosthetic valve assembly being totally released from the catheter and expanded to its fully expanded position at the final desired location (paragraph [0012], second half). It does, however, not disclose

that the stent-valve was "revertable from the partially expanded configuration to the collapsed configuration by sliding the outer sheath in the proximal direction over a proximal section of the stent-valve". The appellant was of the opinion, that said functionality was implicit in the D14 stent delivery system, in particular if the stent-valve had only been minimally partially expanded.

It would be highly unusual to describe partial expandability and adjustability before final placement, without mentioning the equally desirable possibility of recapturing and removing the valve. Moreover, holding the valve within the sheath before expansion requires different mechanical properties than pulling an already expanded valve back into the sheath or readjusting its position. Indeed, cardiac stent-valves have considerable expansive forces, such that loading them into a sheathed delivery system typically requires specific crimping devices. It thus cannot be considered implicit that the sheath and inter-engaging hook and loop elements as disclosed in D14 also have the mechanical strength and solidity to allow re-sheathing. Finally, when reading the claim features with the mind willing to understand, it is apparent from both D14 as well as from the specification of the impugned patent that the term "partially-expanded position" does not refer to a minuscule retraction of the sheath, but to a position in which the stent-valve is sufficiently expanded to allow adjustment of the final desired location.

3.5 Since D14 does not implicitly disclose Feature B, even if combining the teaching of documents D14 and D9, the person skilled in the art would not arrive at a stent

delivery system having all the features claimed in claim 1.

Hence, the subject-matter of claim 1 involves an inventive step.

4. Article 84 EPC

The appellant was of the opinion that claim 1 was not clear because it comprised method features in a device claim and it defined the subject-matter by reference to a non-claimed further entity.

The claim defines a device. It uses terms like "revertable", "repositionable" or "removable". These terms, however, define no more than functional properties of that device which correspond to structural features and which cannot be considered features relating to a method or raise doubts as to the category of the claim.

Moreover, the claim explicitly defines the structural features, the interplay of which allows the claimed functionality: the stent-valve, the at least one attachment element of the stent-valve, the stent holder, and the sheath. In particular with respect to the stent-valve and the attachment elements, the disclosure comprises various different designs (see e.g. Figure 8A-16), a more precise description of which would unduly restrict the scope of the invention.

Being "revertable...to the collapsed configuration by sliding the outer sheath in a proximal direction over a proximal section of the stent-valve to recapture the stent-valve" is a directly verifiable property of the claimed stent-valve delivery system as such. That, once

reverted and recaptured, the stent-valve can be repositioned within or removed from the patient's body, is nothing more than an additional explanatory statement which facilitates understanding of the claimed functionality, making explicit what is already implicit in the features quoted above. Hence, mentioning the patient's body in the claim does not render the claim unclear.

Therefore, claim 1 complies with the requirements of Article 84 EPC.

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 with the order to maintain the patent as amended in the following version:
 - Claims 1-22 of the main request which was filed as auxiliary request 5 with letter dated 23 March 2015
 - Description: Pages 2, 3, 12 and 14 as filed during the oral proceedings and pages 4-11 and 13 of the patent specification
 - Figures 1A-28C of the patent specification.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated