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Datasheet for the decision of 18 January 2022

Case Number: T 1498/17 - 3.2.08

Application Number: 11178145.6

Publication Number: 2420207

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
Apparatus comprising a stent-valve and a delivery system

Patent Proprietor:
Symetis SA

Opponents:
StJude Med,Inc/Abbott Med GmbH/StJude Med UK Ltd/
SJM Int. Inc/The Corp Trust Comp/SJM Coord Center
BVBA/StJude Med S.C. Inc./StJude Med S.C. Inc.

Schulz Junghans
Patentanwälte PartGmbB

Relevant legal provisions:
EPC Art. 76(1), 123(2), 83, 84, 56

Keyword:

Divisional application - added subject-matter (no)
Amendments - allowable (yes)
Sufficiency of disclosure - (yes)
Claims - clarity (yes)
Inventive step - (yes)

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Case Number: T 1498/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 18 January 2022

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Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Strasse 3 80331 München (DE)
Appellant: (Opponent 1)	StJude Med,Inc/Abbott Med GmbH/StJude Med UK Ltd/ SJM Int. Inc/The Corp Trust Comp/SJM Coord Center BVBA/StJude Med S.C. Inc./StJude Med S.C. Inc. 1 St J Med Dr/Helfmann Pk 7/C House/1 St J Med Dr/1209 Orange St/Da Vincilaan 11/ 6300 B Cave Rd/1 St J Med Dr StPaul 55117/65760 Eschborn/Stratford CV37 7GX StPaul 55117/Wilmington 19801/1935 Zaventem Austin 78746/St Paul 55117 (US)
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Party as of right: (Opponent 2)	Schulz Junghans Patentanwälte PartGmbB Grossbeerenstraße 71 10963 Berlin (DE)
Representative:	Schulz Junghans Patentanwälte PartGmbB Großbeerenstraße 71 10963 Berlin (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 9 May 2017 concerning maintenance of the European Patent No. 2420207 in amended form.**

Composition of the Board:

Chairwoman P. Acton
Members: G. Buchmann
Y. Podbielski

Summary of Facts and Submissions

I. With the decision posted on 9 May 2017 the opposition division decided that European patent No. EP 2 420 207 in amended form fulfilled the requirements of the EPC.

II. The proprietor and opponent 1 filed an appeal against that decision.

III. Oral proceedings took place in form of a videoconference before the Board on 18.01.2022.

At the end of the oral proceedings, the proprietor withdrew it's appeal. In the present decision they have the status of a respondent.

IV. The respondent (patent proprietor) requested that the appeal be dismissed.

V. The appellant (opponent 1) and the party as of right (opponent 2) requested that the decision under appeal be set aside and the patent be revoked. The appellant also requested not to admit auxiliary request 15 which had been filed during the oral proceedings in opposition and formed the basis for maintenance of the patent according to the decision of the opposition division.

VI. In the present decision, reference is made to the following documents:

E1 US 2004/0210304 A1
E2 DE 10 2005 003 632 A1
E3 WO 02/067782 A2
E7 US 6,458,153 B1

E11 US 2005/0240200 A1
E12 US 5,980,533 B
S3 "Transapical Transcatheter Aortic Valve Implantation in Humans", Circulation 2006; 114: 591-596

VII. **Auxiliary request 15** formed the basis for maintenance of the patent according to the opposition decision.

Claim 1 of auxiliary request 15 reads as follows (numbering of the features as suggested by the appellant):

"Apparatus comprising:
M1
an aortic stent-valve
M1.1
comprising a valve component and
M1.2
a stent component (800, 900, 1000);
M1.2.1
the stent component (800, 900, 1000) including a first section (802),
M1.2.2
a second section (804) configured to house the valve component, and
M1.2.3
a third section (806) comprising at least one attachment element (808, 814 902, 1002), wherein the first section (802) is a proximal section, the third section (806) is a distal section, and the second section (804) is disposed in a proximal direction with respect to the third section (806) to be axially between the first (802) and third (806) sections,
M1.2.4
the stent component (800, 900, 1000) and the valve component being capable, of a collapsed configuration

for delivery and an expanded configuration after implantation and

M2
a delivery system (2200, 2300, 2400, 2500, 2600) configured for transapical delivery to which the at least one attachment element (808, 814 902, 1002) of the stent-valve is removably attachable; the delivery system (2200, 2300, 2400, 2500, 2600) comprises

M2.1
a stent holder (2222, 2514) to which the at least one attachment element (808, 814 902, 1002) of the stent-valve is removably attachable and

M2.2
a first assembly with an outer sheath (2206, 2506) and a guide wire tubing, wherein in a closed position the outer sheath (2206, 2506) encompasses the stent-valve still attached to the stent holder (2222, 2514) and thus constrains expansion of the stent-valve,

M2.3
wherein the first assembly (2206, 2506) and the stent holder (2222, 2514) are configured for relative movement with respect to one another in order to transition from the closed position, to a partially-open position, to an open position,

M2.3.1
wherein in the partially-open position,
the stent-valve expands partially but does not detach from the stent holder (2222, 2514) because the outer sheath (2206, 2506) still encompasses the at least one attachment element (808, 814 902, 1002) of the stent-valve and the stent holder (2222, 2514),

M2.3.2
while in the open position the outer sheath (2206, 2506) does not constrain expansion of the stent-valve and thus the stent-valve detaches from the stent holder

(2222, 2514) and expands to the expanded configuration,

M3
wherein the stent-valve is automatically detachable from the delivery system (2200, 2300, 2400, 2500, 2600) by moving the outer sheath (2206, 2506) clear of the attachment element (808, 814 902, 1002) and the stent holder (2222, 2514)

characterized in that
M4
the stent-valve is returnable from the partially expanded configuration to the collapsed configuration within a patient's body, by sliding the outer sheath (2206, 2506) in said proximal direction over the first section (802) of the stent component (800, 900, 1000) to recapture the stent-valve within the outer sheath (2206, 2506)."

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

Admittance of auxiliary request 15

Auxiliary request 15 should not be admitted because it was filed extremely late during the oral proceedings in opposition. Furthermore the opponent 1 had not had sufficient opportunity to prepare a response to the new request.

Clarity

Claim 1 was not clear because the positioning of the proximal and distal sections of the stent-valve was not clear.

Sufficiency of Disclosure

The subject-matter of claim 10 was not sufficiently disclosed to be carried out by a skilled person. While the claim specified a "denser population of lattice cells" in the first section of the stent-valve, the patent did not describe what was meant with a density of a cell population, nor which cells were counted for which section of the stent. Additionally, no method was disclosed for measuring the density of cells.

Added subject-matter

Claim 1 of auxiliary request 15 went beyond the application as filed which disclosed stent-valves in general but no aortic stent-valve as required by claim 1 of auxiliary request 15.
Furthermore, the feature according to which the delivery system was "configured for transapical approach", was not derivable from the application as filed.

Inventive Step

Starting from E11 in combination with E12 and E3

E11 disclosed a delivery system for replacing an aortic valve via a transapical approach. This system was not adapted for implantation of a self-expanding stent-valve.

A first partial problem to be solved was therefore to provide a delivery system for a transapical approach and replacement of an aortic valve which could be used with a self-expandable stent-valve. Such a delivery

system would be taken by a skilled person from E12.

A second partial problem to be solved was to provide a delivery system which provided the possibility to recapture a partially deployed stent-valve. A solution to this problem was shown in E3.

Starting from E2 in combination with S3

The delivery system of E2 deployed a self-expandable stent-valve and allowed recapture of a partially deployed stent-valve in order to re-position it.

The transapical approach was known from S3, and there was no modification necessary to the delivery device in order to make it suitable for a transapical approach.

Starting from E1 in combination with E12

E1 disclosed a system comprising a delivery device configured for transapical introduction into a heart. The release of the proximal stent section first was also known from E1. The problem to be solved was to provide a delivery system for treatment of the aortic valve transapically. A suitable system was suggested by E12.

Starting from E7 in combination with E12

E7 disclosed a delivery system which deployed a self-expandable stent-valve and allowed recapture of a partially deployed stent-valve in order to re-position it. To the skilled person being aware of the desirability of transapical implantation, it was clear that the valve must be oriented differently. The problem to be solved was to find a delivery system

which provided release of the proximal portion of the stent-valve first, if this end was oriented towards the proximal end of the delivery system. A suitable system was suggested by E12.

IX. **The arguments of the respondent can be summarised as follows:**

Admittance of auxiliary request 15

Auxiliary request 15 formed the basis of the opposition decision and had therefore to be considered by the Board.

Clarity

The features "aortic stent-valve" and "transapical delivery" clarified the orientation of the valve with respect to the delivery device.

Sufficiency of Disclosure

The claim wording was sufficiently self-explanatory and the appellant's arguments referred to clarity instead of a lack of disclosure.

Added subject-matter

The additional features of the "aortic stent valve" and "transapical delivery" were disclosed in paragraphs [0007] and [0086] of the application as filed.

Inventive Step

Starting from E11 in combination with E12 and E3

The problem solution approach of the appellant was not based on two partial independent problems. Starting from E11 it solved the first problem. The second partial problem had been formulated based on an apparatus which had resulted from a combination of documents E11 and E12. Such a formulation of partial problems could not be used to support an objection of lack of inventive step.

Starting from E2 in combination with S3

The device of E2 was not suitable for implantation of an aortic valve by the transapical approach. Adapting the device to this approach would require a complete re-design of the delivery system. This was not suggested by S3 which showed only a delivery system for balloon expandable stent-valves.

Starting from E1 in combination with E12

Neither E1 nor E12 disclosed a delivery system which was suitable to recapture a partially deployed stent valve.

Starting from E7 in combination with E12

The combination of E7 with E12 did not lead to the subject-matter of claim 1 because none of E7 and E12 disclosed attachment elements on the stent, automatic detachment from the stent holder by moving the outer sheath, and the suitability for recapture of a

partially deployed stent valve.

Reasons for the Decision

1. **Admittance of auxiliary request 15**

Auxiliary request 15 was filed as "New auxiliary request 2" during the oral proceedings in opposition and was re-numbered in the proprietor's grounds of appeal. The opposition division had admitted the request and based its decision thereon. The request thus does not fall within the ambit of the Board's discretion under Article 12(4) RPBA 2007.

Additionally, it is noted that since the date of the notification of the opposition division's decision, the appellant had sufficient time to prepare a response to auxiliary request 15.

Therefore, auxiliary request 15 forms part of the appeal proceedings and is to be considered by the Board (Article 12(4) RPBA 2007 and 12(2) RPBA 2020).

2. **Clarity - Article 84 EPC**

The appellant argued that claim 1 was not clear because the positioning of the proximal and distal sections of the stent-valve was not clear. Also Figures 22-28 did not unambiguously show the position of the elements of the valve in relation to the outer sheath.

In claim 1 of auxiliary request 15, features have been added according to which the apparatus comprises an aortic stent-valve and is configured for transapical delivery. In the functional context, this indirectly

provides the orientation of the stent-valve in the delivery device, the distal section of the stent-valve being oriented towards the distal end of the delivery device.

Therefore, the orientation of the stent-valve in the system is clear in claim 1 of auxiliary request 15, and it fulfils the requirements of Article 84 EPC.

3. **Sufficiency of Disclosure - Article 83 EPC**

The appellant raised an objection under Article 83 EPC the invention underlying claim 10 was not sufficiently disclosed to be carried out by a skilled person. The claim specified a "denser population of lattice cells" in the first section of the stent-valve. The patent did not describe what was meant with a density of a cell population, nor which cells were counted for which section of the stent. Moreover, in Figure 8B, the section 806 had no (closed) cells at all. Finally, there was no method disclosed for measuring the density of cells.

However, claim 10 refers back to claims 8-9, which specify that the stent has a lattice structure which comprises closed cells. For a skilled person, it does not represent any difficulty to manufacture such a stent. It is also evident that in this context the density of cells means something like the number of cells in a certain area of the stent surface. A skilled person is clearly able to vary this parameter over different sections of a stent. Nothing more is required by claim 10.

Some of the doubts raised by the appellant might fall under Article 84 EPC. This is, however, not to be

examined by the Board since present claim 10 corresponds to claim 11 as granted (G 3/14).

Therefore, auxiliary request 15 fulfils the requirements of Article 83 EPC.

4. **Added Subject-matter - Articles 123(2) EPC**

The appellant argued that claim 1 of auxiliary request 15 went beyond the content of the application as filed which disclosed stent-valves in general but no aortic stent-valve as required by claim 1 of auxiliary request 15. Furthermore, the feature according to which the delivery system was "configured for transapical approach", was not derivable from the application as filed.

Paragraph [0007] of the description of the application as filed mentions that the invention is directed to "systems... applicable to... cardiac-valve therapies including the replacement of failed aortic... valves". Paragraph [0086] describes the delivery systems shown in Figures 22A-26C. It explains that the heart may be penetrated transapically for e.g. the replacement of an aortic valve (lines 13-17). This can be done by a delivery system shown in figures 26A-26C (lines 17-19).

From these passages, it becomes clear to the skilled reader that one embodiment of the delivery system is configured for the transapical approach. Otherwise it could not be used for this approach. In contrast to the appellant’s opinion, for the inserted feature to fulfil Article 123(2) EPC, it is not required that the application as filed discloses specific features which make the system “configured” for the transapical approach. In contrast, it is sufficient that the

application discloses the fact that the system is configured for this specific use.

As regards the disclosure of an aortic stent-valve, it is correct that the description does not explicitly mention the the delivery system to be loaded with an aortic stent-valve. It is, however, implicitly clear for a system which is used and configured for replacement of an aortic valve, and which comprises a stent-valve, that it comprises an aortic stent-valve. Anything else would not make sense. Again it is not required that specific features of this aortic stent-valve are disclosed as long as it is clear that an aortic stent-valve is present.

Therefore, the subject-matter of claim 1 of auxiliary request 15 does not go beyond the application as filed.

5. **Inventive Step - Article 56 EPC**

5.1 **Starting from E11 in combination with E12, or with E12 and E3**

5.1.1 E11 discloses an Apparatus comprising:
An aortic stent-valve (51) comprising a valve component (55) and a stent component (54) which may be regarded as including three sections (Features M1, 1.1, 1.2 and 1.2.1). The stent component and the valve component are capable of a collapsed configuration for delivery and an expanded configuration after implantation (Feature M1.2.4) and the apparatus further comprises a delivery system configured for transapical delivery to which the stent-valve is removably attachable (part of feature M2).

The delivery system of E11 comprises a balloon (41) and

is thus adapted for insertion of balloon-expandable stent-valves. E11 does not disclose a delivery system according to the Features M2-M4. In particular, no attachment elements are disclosed on the stent valve and no attachment/detachment mechanism is described in E11. Paragraph [0037] of E11 mentions indeed that the system may be used to implant, among others, self-expanding stent valves, but it does not describe any delivery device which would work with a self-expanding stent-valve.

Starting from the distinguishing features, the appellant derived a first partial problem, namely to provide a delivery system for a transapical approach and replacement of an aortic valve which could be used with a self-expandable stent-valve.

From paragraph [0048] of E11, the appellant concludes that the skilled person would look for a delivery device which releases the proximal portion of the stent first. This led the skilled person to E12. However, paragraph [0048] of E11 only mentions "the radial expansion (52) of the balloon (41) causing the replacement valve (51) to press against the aortic valve leaflets (24) of the aortic valve (23) against the annulus (25) [sic]". This is information about the location of the balloon-expandable stent-valve. It does not allow any conclusion about the order of deploying the portions of a self-expandable stent. Therefore, E11 does not contain any hint which would motivate the skilled person to consider E12.

Hence, already for this reason the subject-matter of claim 1 involves an inventive activity.

5.1.2 For the sake of argument, it shall nevertheless be assumed that the skilled person would consider E12 in view of the problem posed.

E12 discloses a delivery catheter for coronary stents, comprising a stent holder (126) to which the stent is removably attachable (part of Feature M2.1),
a first assembly with outer sheath (158) and a guide wire tubing (134), wherein in a closed position the outer sheath encompasses the stent still attached to the stent holder and thus constrains expansion of the stent (Figure 1) (Feature M2.2),
wherein the first assembly and the stent holder are configured for relative movement with respect to one another in order to transition from the closed position, to a partially-open position, to an open position (column 4, lines 36-44) (Feature M2.3),
wherein the stent-valve is automatically detachable from the delivery system by moving the outer sheath clear of the attachment element and the stent holder (Figure 3) (Feature M3).

Even if assuming that the skilled person would adapt the coronary stent delivery system of E12 in order to be suitable for an implantation of a stented valve prosthesis, the resulting system would still not comprise the features needed for controlled release and re-capture of the stent: E12 does not disclose attachment elements at the distal portion of the stent which remain attached to the stent holder in a partially open position of the delivery device, thus allowing re-capture of the stent. The bumpers mentioned in column 4, lines 26-29, do not qualify as means for holding any (also not disclosed) attachment elements in the sense of the claim. Firstly, the bumpers are not described in detail by E12, secondly is must be assumed

that they form some kind of abutments which cannot hold the stent in both axial directions of movement. Hence, they cannot serve the purpose to allow re-capture of the stent. The parts called "marker bands 172" are also not suitable to hold the stent once it has been partially deployed.

Hence, even the combination of the delivery system of E12 with the apparatus according to E11 would lead to an apparatus lacking
- the attachment elements on the stent,
- the automatic detachment therefrom by moving the outer sheath, and
- the suitability for recapture of a half deployed stent valve.

From these differences compared to the claimed system, the appellant derives a second partial problem, namely to provide a delivery system which provides the possibility to recapture a partially deployed stent-valve. A solution to this problem was shown in E3 which disclosed a (coronary) stent delivery system wherein the stent comprised attachment elements (82). These attachment elements held the stent on the stent holder (27) until final deployment (page 9, lines 5-29). Also the location of the attachment elements at the distal end of the stent was suggested by E3 (page 13, lines 15-17).

According to the appellant, the skilled person would adapt the system obtained from the combination of E11 and E12, in order to arrive at the subject-matter of claim 1 without performing an inventive step.

However, the problem solution approach as presented by the appellant is not based on two partial independent

problems. In contrast, the second partial problem has been formulated only after the combination of E11 and E12 had been made, i.e. the second partial problem was not formulated based on the closest prior art (E11) but based on an apparatus which had resulted from a combination of documents E11 and E12.

Therefore, the two partial problems are not independent from each other and the problem solution approach cannot be applied in this way.

5.1.3 The appellant argued further that starting from E11, the skilled person would directly take E3 into consideration, since paragraph [0068] of E11 gave an incentive to the skilled person to look for a delivery system which might recapture the stent (i.e. to solve the second partial problem). However, this paragraph describes re-capture of a temporary valve which forms part of the instrumentation but does not replace a native heart valve. Purpose, structure and way of deployment of such a temporary valve are completely different from a prosthetic stent-valve. Therefore, paragraph [0068] does not provide any direct link from E11 to E3.

For the above reasons, the subject-matter of claim 1 involves an inventive step over E11 either in combination with E12 or in combination with E12 and E3.

5.2 **Starting from E2 in combination with S3**

Document E2 discloses an apparatus comprising an aortic stent-valve comprising a valve component and a stent component (10); the stent component including three sections (implicit) and at least one attachment element (Ösen am distalen Endbereich, paragraph [0067]), the

stent component and the valve component being capable of a collapsed configuration for delivery and an expanded configuration after implantation (Features M1-M1.2.3).

The apparatus further comprises a delivery system (1) configured for transaortic delivery comprising a stent holder (6, 8) to which the at least one attachment element of the stent-valve is removably attachable and an outer sheath (7), wherein in a closed position the outer sheath encompasses the stent-valve still attached to the stent holder (6, 8) and thus constrains expansion of the stent-valve (paragraph [0060]), wherein the sheath and the stent holder are configured for relative movement with respect to one another in order to transition from the closed position, to a partially-open position, to an open position, wherein in the partially-open position, the stent-valve expands partially but does not detach from the stent holder (paragraphs [0063]-[0064]) because the outer sheath still encompasses the at least one attachment element of the stent-valve and the stent holder, while in the open position the outer sheath does not constrain expansion of the stent-valve and thus the stent-valve detaches from the stent holder and expands to the expanded configuration (paragraph [0066]), wherein the stent-valve is automatically detachable from the delivery system by moving the outer sheath clear of the attachment element and the stent holder (paragraph [0066], [0088]) wherein the stent-valve is returnable from the partially expanded configuration to the collapsed configuration within a patient's body, by sliding the outer sheath (7) distally over the first section of the stent component to recapture the stent-valve within the outer sheath (paragraph [0065]).

This is a delivery system for a prosthetic heart valve which at first glance fulfils the same functions as the delivery system of claim 1. It deploys a self-expandable stent-valve and allows recapture of a partially deployed stent-valve in order to re-position it.

However, the delivery system of E2 is adapted to the transaortic approach and has in inverted design compared to that of the patent. For deployment of the stent-valve the outer sheath is moved proximally (with respect to the surgeon). This results in deployment of the proximal end (with respect to the blood flow) of the stent first. Re-capture of a partially deployed stent-valve involves a distal movement of the outer sheath.

The appellant argues that a transapical approach was known from S3, and there was no modification necessary to the delivery device in order to make it suitable for a transapical approach.

The device of E2 is, however, not suitable for implantation of an aortic valve by the transapical approach. If used in this way, the stent-valve could only be deployed at the distal end first (with respect to the blood flow and with respect to the surgeon). This is in contradiction to claim 1 which specifies that the attachment elements are located at the distal end of the stent-valve (in both senses) and the proximal end is deployed first and can be re-captured by a proximal movement of the outer sheath.

Therefore, the delivery device of E2 has a functionality different from the system of claim 1, even if used with a transapical approach. An adaptation

to the transapical approach would involve a complete re-design of the delivery device which is not obvious in view of E2 in combination with S3.

5.3 **Starting from E1 in combination with E12**

Document E1 discloses an apparatus comprising:

An aortic stent-valve according to Features M1-M1.2.4 (Figures 13-17, 37, 38), comprising a valve component (312) and a stent component (314, 316, 318); the stent component including a first proximal section (318), a second section (314) configured to house the valve component, and a third distal section (316), the stent component and the valve component being capable of a collapsed configuration for delivery and an expanded configuration after implantation (e.g. paragraph [0133]).

The apparatus of E1 further comprises a delivery system (Figures 41-45) comprising a stent holder (520, 522) to which attachment elements (loops) of the stent-valve are removably attachable (by hooks 522) and an outer sheath (512) wherein in a closed position the outer sheath encompasses the stent-valve still attached to the stent holder and thus constrains expansion of the stent-valve (paragraph [0136]),
wherein the sheath and the stent holder are configured for relative movement with respect to one another in order to transition from the closed position, to a partially-open position, to an open position, (Figures 43-45).

In the partially-open position, the stent-valve expands partially 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 (Figure 44, paragraph [0137]),
while in the open position the outer sheath does not constrain expansion of the stent-valve and thus the stent-valve detaches from the stent holder and expands to the expanded configuration,
wherein the stent-valve is automatically detachable from the delivery system by moving the outer sheath clear of the attachment element and the stent holder (paragraph [0137]).

Similar to E2, the delivery system of E1 has an inverted design compared to that of the patent. When using the delivery system of E1 as claimed, i.e. with an aortic valve and in a transapical approach, the attachment elements are located at the proximal section (318) of the valve (see Figure 45). This is in contrast to Feature M1.2.3.

For deployment of the stent-valve of E1 the outer sheath is moved proximally (with respect to the surgeon). This results in deployment of the distal end (with respect to the blood flow and to the surgeon) of the stent first. Re-capture of a partially deployed stent-valve is not disclosed in E1. Even if it were possible, it would involve a distal movement of the outer sheath, in contrast to Feature M4.

The appellant argued that the release of the proximal section first was known from E1. The problem to be solved was to provide a delivery system for treatment of the aortic valve transapically. However, E1 (Figures 43-45) shows that the distal section of the valve is released first. It is true that E1 gives a vague hint to use a valve attached to the hooks 522 with its distal section (paragraph [0140]). This would result in

the proximal section being released first. It is, however, not a hint to adapt the delivery system but to orient the stent-valve differently. Therefore, there is no indication in E1 which would motivate the skilled person to look for a different system which releases the proximal section first.

Even if the skilled person were to apply the teaching of E12 to the apparatus of E1, the resulting system would not be configured to recapture a partially deployed stent. In E12, no re-capture of the stent is provided. Also E1 does not describe any re-capture of the stent from a partially deployed state. It is correct that paragraph [0141] describes that "in this partially released state, the position of prosthetic valve 310 may be axially adjusted by moving catheter assembly 510 in the proximal or distal direction". From that, however, it can not be concluded that the stent-valve is re-captured from the partially expanded configuration to the collapsed configuration within a patient's body by sliding the outer sheath over the first section of the stent component. The axial adjustment of a partially deployed stent together with the delivery device as described in paragraph [0141] is different from recapture of the stent into the delivery device.

Therefore, the subject-matter of claim 1 is inventive over E1 in combination with E12.

5.4 **Starting from E7 in combination with E12**

E7 discloses a delivery system for a prosthetic heart valve which at first glance fulfils the same functions as the delivery system of claim 1. It deploys a self-expandable stent-valve and allows recapture of a

partially deployed stent-valve in order to re-position it.

However, in the same way as the delivery system of E2, the system of E7 has in inverted design compared to that of the patent. The appellant argued that the skilled person was aware of the desirability of transapical implantation. For this purpose, it was clear that the valve must be oriented differently. The problem to be solved was to find a delivery system which provided release of the proximal portion of the stent-valve first, if this end is oriented towards the proximal end of the delivery system.

Similar to the combination of E2 with E12 which was discussed above, the combination of E7 with E12 does not lead to the subject-matter of claim 1.

None of E7 and E12, discloses
- attachment elements on the stent which are to be attached to the stent holder,
- automatic detachment from the stent holder by moving the outer sheath, and
- the suitability for recapture of a partially deployed stent valve.

Therefore, the subject-matter of claim 1 involves an inventive step with respect to E7 and E12.

6. Request for reimbursement of the appeal fee

As the appeal is to be dismissed one of the conditions for reimbursement of the appeal fee pursuant to Rule 103(1)(a) EPC is not met, and the corresponding request can thus not be granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated