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**Datasheet for the decision  
of 28 May 2025**

**Case Number:** T 2609/22 - 3.2.02

**Application Number:** 19203816.4

**Publication Number:** 3616652

**IPC:** A61F2/24

**Language of the proceedings:** EN

**Title of invention:**

IMPROVEMENTS RELATING TO TRANSCATHETER STENT-VALVES

**Patent Proprietor:**

Symetis SA

**Opponent:**

Abbott Cardiovascular Systems, Inc.

**Headword:**

**Relevant legal provisions:**

EPC Art. 54, 56, 76(1), 83

**Keyword:**

Novelty - (yes)

Inventive step - (yes)

Divisional application - added subject-matter (no)

Sufficiency of disclosure - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 2609/22 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 28 May 2025**

**Appellant:** Symetis SA  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
28 October 2022 concerning maintenance of the  
European Patent No. 3616652 in amended form.**

**Composition of the Board:**

**Chairman** M. Alvazzi Delfrate  
**Members:** S. Böttcher  
Y. Podbielski

## **Summary of Facts and Submissions**

- I. Both the opponent and the patent proprietor filed an appeal against the interlocutory decision of the opposition division that the patent could be maintained on the basis of auxiliary request 1.
- II. Oral proceedings before the Board took place on 28 May 2025 in person.
- III. The appellant-patent proprietor requested that the decision under appeal be set aside and the patent be maintained as granted (main request), or that the patent be maintained on the basis of one of auxiliary requests 1 to 4 filed with the statement setting out the grounds of appeal on 3 March 2023.

The appellant-opponent requested that the decision under appeal be set aside and that the patent be revoked. They further requested to hold the oral proceedings as a videoconference.

- IV. Claim 1 of the patent as granted (main request) reads as follows.

"A stent-valve (10) for transcatheter implantation to replace a cardiac valve, the stent valve being compressible to a compressed state for delivery, and expandable to an operative state for implantation, the stent-valve comprising  
a stent (12) comprising a lattice structure with apertures (112),  
a plurality of leaflets for defining a prosthetic valve (14), and  
a paravalve seal for sealing against surrounding

tissue,  
wherein the paravalve seal comprises a plurality of flexible pockets (110), characterized in that each pocket (110) is associated with a respective aperture (112) of the lattice structure of the stent, wherein the pocket is open on one side facing towards the outlet of the stent (12) and closed in the opposite direction."

Claim 3 of the patent as granted (main request) reads as follows.

"The stent-valve of claim 2, wherein the lower portion (16) has an extremity formed with a zig-zag shape."

Claim 5 of the patent as granted (main request) reads as follows.

"The stent-valve of any of the preceding claims, wherein the stent-valve (10) comprises an inner skirt (30), wherein a wall of the pocket (110) is defined by a portion of the inner skirt (30)."

Claim 8 of the patent as granted (main request) reads as follows.

"The stent-valve of any of the preceding claims, wherein the pockets (110) open under the influence of blood back pressure entering a mouth of the pocket (110) once deployed."

V. Documents referred to in this decision

- P1 WO 2014/139545 A1 (earlier application)
- D2 US 2011/0098802 A1
- D3 WO 2012/048035 A2

D5 WO 2012/177942 A2

- VI. The appellant-patent proprietor's arguments concerning the main request (patent as granted) may be summarised as follows.

*Sufficiency of disclosure*

The term "associated" in claim 1 implied a relationship between each pocket and a respective aperture.

Paragraph [0062] described the claimed embodiment in detail. The opponent's objections were in fact mere clarity objections. The fact that the opponent had been able to draft four embodiments which were covered by claim 1 in the document presented during the oral proceedings before the Board supported that the invention could be carried out by the person skilled in the art.

Paragraph [0062] also disclosed how the pockets could be designed such that they were deployed either under the influence of natural resilience or under the influence of blood back pressure.

Hence, the requirements of Article 83 EPC were met.

*Added subject-matter - claim 1*

The feature that the pockets were associated to the apertures was not inextricably linked to the specific shape and size of the pockets shown in figure 13 of the parent application P1.

The embodiment as described on pages 16 to 17 of P1 was clearly intended to be broader than what was

specifically illustrated in Figure 13. The size and shape of the pockets and the apertures of the lattice as illustrated in Figure 13 was only one example of a lattice structure and associated pockets. Hence, the shape and size of the lattice apertures (and with that the pockets) were optional features.

The omission of features relating to the shape and size of the pockets in claim 1 therefore did not constitute an unallowable intermediate generalisation.

The embodiment of Figure 13 did not require the feature "one or more seals deployable from or through apertures of the lattice". The omission of this feature did not constitute an unallowable intermediate generalisation.

Thus, the subject-matter of claim 1 did not extend beyond the content of the parent application as filed.

*Added subject-matter - claim 3*

In Figure 13 of the parent application as originally filed, there was a direct and unambiguous disclosure of the pockets being at the inflow extremity as well as being distanced from the inflow extremity.

Hence, claim 3 complied with Article 76(1) EPC.

*Added subject-matter - claim 5*

Claim 2, the paragraph bridging pages 16-17 and the second paragraph on page 5 of the parent application as originally filed disclosed both skirts as being optional and independently of each other.

Therefore, claim 5 complied with Art. 76(1) EPC.

*Added subject-matter - claim 8*

An opening up under the influence of blood back pressure as defined in claim 8 was disclosed on page 17, lines 8-10, of P1 in combination with an opening up under the influence of natural resilience as defined in claim 7. Hence, the subject-matter of claim 8 when dependent on claim 7 was disclosed in the parent application as filed.

Therefore, claim 8 complied with Art. 76(1) EPC.

*Novelty in view of D2*

D2 did not disclose the feature "each pocket is associated with a respective aperture of the lattice structure of the stent".

In paragraph [0070] of D2, no details were disclosed for the arrangement of the pockets with respect to the lattice apertures of the stent. It was rather stated that the pockets "can be provided in any number, size, and/or shape". In Figure 10, the feature "each pocket is associated with a respective aperture" was not disclosed either. The pockets were not in any relationship or alignment with the apertures of the stent lattice. The number of cells did not even correspond to the number of pockets. The structure of the stent behind the cuff 285 was not visible in Figure 10.

Thus, claim 1 of the main request was novel in view of D2.

*Inventive step starting from D2*

The pockets in D2 (Figure 10) were attached to a cuff which was then attached to the stent. D2 did not mention or suggest any relationship between the pockets and the apertures of the lattice structure of the stent, neither in terms of the numbers of pockets and apertures nor in terms of any alignment or attachment.

To associate each pocket to a respective aperture allowed to stow the pockets between the stent struts when the stent was crimped during insertion. Hence, this feature solved the technical problem of improving the crimped profile. This problem was not addressed in D2.

Hence, it was not obvious for the person skilled in the art to modify the stent-valve of D2 such that each pocket was associated with a respective aperture. The subject-matter of claim 1 was inventive in view of D2.

*Inventive step starting from D3 in combination with D2*

D3 disclosed a stent-valve having a single pocket associated with multiple apertures of the stent lattice (paragraph [0083], Figures 2 and 43). D3 did not disclose that the para-valve seal comprised a plurality of pockets and that each pocket was associated with a respective aperture of the lattice structure of the stent.

As mentioned in paragraph [0084] of D3, the outer skirt was configured with excess material to cause the outer skirt to bulge outwardly as the frame foreshortens during radial expansion. Thereby the excess material assisted in forming a good fluid-tight seal between the valve and the native annulus. Hence, D3 disclosed a

different concept for providing the seal.

Combining D3 with D2 would result in the replacement of the whole skirt of D3 by the cuff of D2. However, the person skilled in the art would still not be prompted to associate each pocket to a respective aperture of the stent structure.

The subject-matter of claim 1 involved an inventive step when starting from D3 in combination with D2.

*Inventive step starting from D3 in combination with D5*

D5 did not disclose any details about the partitions in the skirt 163 (Figures 2F2-A and 2F2-B) mentioned in paragraph [0209] and nothing about their arrangement with respect to the lattice. Hence, D5 did not prompt the person skilled in the art to provide pockets each of which was associated with respective apertures of the lattice structure of the stent. Thus, a combination of D3 with D5 did not result in the subject-matter of claim 1.

The subject-matter of claim 1 involved an inventive step when starting from D3 in combination with D5.

*Request to conduct oral proceedings as a videoconference*

The format of the present oral proceedings should not be changed as, according to G 1/21, an in-person hearing was still considered as the "gold standard".

VII. The appellant-opponent's arguments concerning the main request (patent as granted) may be summarised as follows.

*Sufficiency of disclosure*

The patent did not disclose how the pockets were attached to the stent in such a way that para-valve leakage was mitigated without substantially hindering the compressibility of a stent-valve. The description in paragraph [0062] of the patent allowed to draft four different embodiments as shown in the document filed during the oral proceedings before the Board.

The patent did not disclose how the pockets were deployed. Furthermore, the patent did not disclose a one-to-one correlation between the pockets and the apertures of the lattice structure. The embodiment of Figure 13, which did not disclose an inner or outer skirt, did not solve the problem of allowing flat folding as indicated in paragraph [0062]. In addition, it was questionable whether the patent disclosed how to ensure that the problem mentioned in paragraph [0005] of the description was solved.

Hence, claim 1 did not meet the requirements of Article 83 EPC.

*Added subject-matter - claim 1*

The subject-matter of claim 1 was not based on Figure 13 of P1 and could not be literally disclosed in the paragraph bridging pages 16 and 17 as the claim was directed to a stent-valve and the paragraph bridging pages 16 and 17 concerned the features of a para-valve seal.

Claim 1 omitted "one or more seals deployable from or through apertures of the lattice" as described on page

6, last sentence of P1. This constituted an unallowable intermediate generalisation.

Hence, claim 1 did not meet the requirements of Article 76(1) EPC.

*Added subject-matter - claim 3*

The combination of features of claim 1 and claim 3 had been disclosed in P1 only in combination with a para-valve seal that was positioned towards one extremity and spaced from that extremity.

Hence, claim 3 did not meet the requirements of Article 76(1) EPC.

*Added subject-matter - claim 5*

The subject matter of claim 5, which recited that "a wall of the pocket is defined by a portion of the inner skirt" had only been disclosed in combination with a wall of the pocket that was defined by a portion of the outer skirt, as recited in claim 4 in P1.

Hence, claim 5 did not meet the requirements of Article 76(1) EPC.

*Added subject-matter - claim 8*

Claim 8 was not disclosed when being dependent on claim 7, since the features of claims 7 and 8 had been presented as alternatives in the first paragraph on page 17 of the description of P1.

Hence, claim 8 did not meet the requirements of Article 76(1) EPC.

*Novelty in view of D2*

In Figure 10 of D2, each of the plurality of pockets 220 was associated with a respective aperture of the stent 30 located at the upper right-hand side or at the upper left-hand side of each pocket. There was therefore a specific arrangement or link between the pockets and the apertures.

Each of the pockets could also be regarded to be associated to one of the small apertures directly above the cuff.

Hence, D2 disclosed the feature "each pocket is associated with a respective aperture of the lattice structure of the stent". The subject-matter of claim 1 lacked novelty in view of D2.

*Inventive step starting from D2*

To arrange the pockets such that each pocket was associated with a respective aperture of the stent structure did not involve any technical effect.

Paragraph [0070] of D2 stated that "the pockets can be provided in any number, size, and/or shape". Thus, it would have been obvious to a person skilled in the art to provide a para-valve seal with a number of pockets that corresponded to the number of apertures around the circumference of the stent body. This was merely an obvious alternative to the embodiment of Figure 10.

Hence, the subject-matter of claim 1 did not involve an inventive step when starting from D2.

*Inventive step starting from D3 in combination with D2*

D3 did not disclose the features "wherein the para-valve seal comprises a plurality of flexible pockets" and "each pocket is associated with a respective aperture of the lattice structure of the stent" of claim 1.

The objective technical problem solved by these features would be to provide an alternative para-valve seal.

The outer skirt 18 and the inner skirt 16 of D3 were joined together and were therefore equivalent to the cuff 85 of D2. Paragraph [0070] of D2 would prompt the person skilled in the art to provide multiple pockets in the outer skirt 18 of D3, such that the number of pockets would correspond to the number of notches 166 in Figure 43 of D3.

Hence, the subject-matter of claim 1 did not involve an inventive step.

*Inventive step starting from D3 in combination with D5*

D5 disclosed a skirt 163 including internal partitions which could be regarded as pockets (paragraph [0209]). The last sentence of this paragraph should not be read in combination with the preceding sentences. Therefore, D5 did not disclose that the purpose of the internal partitions was to limit the radial expansion of the skirt.

It would further be a straightforward design option for the person skilled in the art to attach internal partitions to the stent of Figure 43 of D3 such that

each pocket would be associated with a respective aperture of the stent.

Hence, the subject-matter of claim 1 did not involve an inventive step.

*Request to conduct oral proceedings as a videoconference*

The oral proceedings should be held by videoconference in order to contribute towards reaching the United Nations Sustainable Development Goals, in particular goal 13: Climate Action, by 2030.

## **Reasons for the Decision**

### 1. Subject-matter of the patent

The patent relates to a stent valve for transcatheter implantation to replace a cardiac valve.

Transcatheter valve implantation is a technology for replacement valve therapy. In such a technique, a stent-valve is compressed and loaded into a delivery catheter. The delivery catheter is introduced to the desired site of implantation at the heart via a percutaneous route or via minimally invasive surgery. The stent-valve is deployed into the implantation position from or by the delivery catheter, and the delivery catheter is then withdrawn.

One technological challenge involved with this technique is preventing leakage of blood around the stent-valve (so called para-valve leakage). The stents

form a friction fit with the native anatomy to anchor the stent-valve in position, and are round in cross-section. However the native anatomy in which the stent is implanted is often off-round and is different for each person. Moreover, heavy calcification of the native anatomy may obstruct full deployment of any stent, and make the native anatomy even more irregular. It can sometimes be difficult to provide a perfectly sealing fit between the stent-valve and the surrounding anatomy.

In order to address para-valve leakage, it is known to incorporate an external skirt or cover as part of the stent-valve.

According to claim 1 of the patent as granted, the stent-valve includes a para-valve seal comprising a plurality of flexible pockets (Figure 13). Each pocket is associated with a respective aperture of the lattice structure of the stent and each pocket is open on one side facing towards the outlet of the stent and closed in the opposite direction.

The one or more pockets shall fill with blood in response to blood flow in the reverse direction, such that the pockets distend outwardly. Distension of the pockets can fill a gap between the stent-valve and the surrounding anatomy, to obstruct the reverse flow of blood past the pocket.

2. Main request - sufficiency of disclosure

Claim 1 requires that "each pocket is associated with a respective aperture of the lattice structure of the stent". However, the pockets do not have to be attached to the stent in order to be associated to an aperture.

Hence, the patent does not need to disclose how the pockets are attached to the stent.

Paragraph [0062] and Figure 13 of the patent disclose how the pockets can be designed such that they are deployed either under the influence of natural resilience or under the influence of blood back pressure. Apparently, based on the description in paragraph [0062], the opponent was able to draw sketches of different embodiments of claim 1 in the document submitted during the oral proceedings before the Board.

As to the one-to-one correlation, the Board does not agree with the opponent that paragraph [0062] discloses that one pocket can be associated with a plurality of pockets. It is rather mentioned that the respective aperture can be either in the lower portion 16 of the stent or in the upper crown 18, and there can be pockets in the lower portion and other pockets in the upper crown.

As to the technical effect mentioned in paragraph [0005] of the patent, it is noted that according to the boards' settled case law, a technical effect is to be taken into account in assessing enablement only if it is explicitly claimed. Since it is not claimed in the present case, it is irrelevant for enablement whether or not it is actually achieved.

Therefore, the invention as claimed in claim 1 is sufficiently disclosed to be carried out by the person skilled in the art.

3. Main request - added subject-matter

3.1 The present patent is based on a divisional application of the earlier application P1 (also referred to as D1a by the opposition division).

3.2 Claim 1

The feature that the pockets are associated to the apertures is not inextricably linked to the specific shape and size of the pockets shown in Figure 13 of the parent application P1.

The size and shape of the pockets and the apertures of the lattice as illustrated in Figure 13 are only one example of a lattice structure and associated pockets. Furthermore, the description of P1 does not disclose any details about the shape or size of the pockets at all.

The paragraph bridging pages 16 and 17 of P1 concerns the features of a para-valve seal comprising a plurality of pockets. As mentioned on page 12, penultimate passage, this is a seal configuration that may be used with the stent-valve as defined in claim 1. Hence, contrary to the opponent's view, the paragraph bridging pages 16 and 17 can be regarded as a basis for claim 1.

The last sentence on page 6 states that "in some embodiments" the stent-valve further comprises one or more seals deployable from or through apertures of the lattice. This sentence does not refer to the specific embodiment of claim 1, comprising pockets associated to the apertures of the lattice structure, as shown in Figure 13. Hence, the omission of the feature mentioned in that sentence does not constitute an unallowable intermediate generalisation.

Hence, the omission of the specific shape and size of the pockets of Figure 13 in claim 1 does not constitute an unallowable intermediate generalisation. Claim 1 meets the requirements of Article 76(1) EPC.

### 3.3 Claim 3

Contrary to the opponent's view, P1 does not disclose the combination of features of claim 1 and claim 3 only in combination with a para-valve seal that was positioned towards one extremity and spaced from that extremity.

The last paragraph on page 11 discloses the zig-zag shape of the extremity of the stent without any restriction concerning the position of the para-valve seal. It is rather mentioned that "in some embodiments" the lower portion of the stent may have such a shape.

Hence, the omission of the features relating to the position of the seal in claim 3 does not constitute an unallowable intermediate generalisation. Claim 3 meets the requirements of Article 76(1) EPC.

### 3.4 Claim 5

Contrary to the opponent's view, claim 5 was not only disclosed when being dependent on claim 4.

As correctly concluded by the opposition division, both claim 2 and the description of P1 disclose the inner and the outer skirt independently. The reference to "another wall" on page 17 of the description (lines 1 to 2) merely means that the wall of the pocket that may be defined by a portion of the inner skirt is not the

same as the wall that may be defined by a portion of the outer skirt.

Hence, claim 5 does not include added subject-matter.

3.5 Claim 8

Contrary to the opponent's view, the subject-matter of claim 8 is also disclosed when being dependent on claim 7.

The last sentence of the first paragraph on page 17 of the description of P1 discloses the combination of natural resilience and blood back pressure as the pocket distends due to its natural resilience. The sentence further states that the back pressure further obstructs leakage of blood, i.e. in addition to the seal provided by the natural resilience mentioned in the previous sentence. Hence, the features of claims 7 and 8 have not been presented as alternatives in that paragraph.

Claim 8 therefore does not include added subject-matter.

4. Main request - novelty in view of D2

4.1 D2 discloses in Figure 10 a prosthetic heart valve including a cuff 285 defining multiple pockets 220 (paragraph [0070]). The cuff is arranged around the annulus region 30 of a stent body.

4.2 Contrary to the opponent's view, Figure 10 of D2 does not disclose that each of the plurality of pockets 220 is associated with a respective aperture of the stent. The stent structure behind the cuff is not completely

visible in Figure 10. It cannot be derived that there are apertures of a lattice structure the number of which corresponds to the number of pockets. If anything, the schematic drawing of Figure 10 seems to show that the small apertures above the cuff are not aligned with the pockets and could thus be different in number. In particular, the pockets are not in any relationship or alignment (that would qualify as "associated") with the structure of the stent lattice.

4.3 In paragraph [0070] of D2, no details are disclosed for the arrangement of the pockets with respect to the lattice structure of the stent. It is rather stated that the pockets "can be provided in any number, size, and/or shape".

4.4 Thus, the subject-matter of claim 1 of the main request is novel in view of D2.

5. Main request - inventive step when starting from D2

5.1 The pockets in D2 (Figure 10) are attached to a cuff which is then attached to the stent. D2 does not mention or suggest any relationship between the pockets and the apertures of the lattice structure of the stent. Hence, D2 does not disclose the feature "each pocket is associated with a respective aperture of the lattice structure of the stent"

5.2 This feature allows to stow the pockets between the stent struts when the stent is crimped during insertion. Hence, this feature solves the technical problem of improving the crimped profile. This problem is not addressed in D2, which does not provide any hint towards the claimed configuration.

5.3 Hence, the person skilled in the art would not be prompted to modify the stent-valve of D2 such that each pocket is associated with a respective aperture. The subject-matter of claim 1 involves an inventive step when starting from D2.

6. Main request - inventive step when starting from D3 in combination with D2

6.1 D3 (paragraph [0083], Figures 2 and 43) discloses a stent-valve having a single pocket formed by the outer skirt 18 and the inner skirt 16. The outer skirt is associated with multiple apertures of the lattice structure of the stent. D3 does not disclose that the para-valve seal comprises a plurality of pockets and that each pocket is associated with a respective aperture of the lattice structure of the stent.

6.2 However, D2 does not prompt the person skilled in the art to provide partitions between the inner and the outer skirt at the projections 164 to build multiple pockets.

In D2, the pockets 220 have a half-cylindrical shape and are provided on the outside of the cuff 285 without being associated with the apertures of the stent structure. Hence, the person skilled in the art would at most be prompted to replace the outer skirt of D3 with an outer cuff to which pockets are attached. In any case, D2 does not motivate the person skilled in the art to provide the pockets such that each of them would be associated with a respective aperture of the lattice structure of the stent. A combination of the teaching of D2 with that of D3 would therefore not result in the claimed subject-matter.

- 6.3 Thus, the subject-matter of claim 1 involves an inventive step in view of a combination of D3 with D2.
7. Main request - inventive step when starting from D3 in combination with D5
- 7.1 D5 discloses a skirt 163 including internal partitions (paragraph [0209], last sentence) which are regarded as pockets. However, the person skilled in the art would not consider the combination of D5 with D3 as the purpose of the partitions in D5 (to limit the radial expansion of the skirt) is not relevant for the stent-valve of D3.
- 7.2 Furthermore, D5 does not disclose any details about the partitions and nothing about their arrangement with respect to the lattice. Hence, the combination of the teaching of D3 with that of D5 does not lead to the claimed subject-matter since D5 does not prompt the person skilled in the art to associate each partition (pocket) to a respective aperture of the stent.
- 7.3 Hence, the subject-matter of claim 1 involves an inventive step in view of a combination of D3 with D5.
8. Request to conduct the oral proceedings as a videoconference

The appellant-opponent had requested that the oral proceedings be conducted as a videoconference. Their request was thus not only to be allowed to participate via videoconference but also that the appellant-patent proprietor participated in the same way. The appellant-patent proprietor objected to this request. Whether or not to grant the appellant-opponent's request was a discretionary decision of the Board (Article 15a(1))

RPBA, G 1/21, point 50. of the reasons).

In G 1/21, points 46-50, the Enlarged Board explained that since the holding of oral proceedings is seen as serving the interests of the parties the choice of format for participating to the oral proceedings can be made by the party who requested them, unless good reasons, based on circumstances specific to the case, justify a different format. Where a party requests oral proceedings in person, there ought be circumstances specific to the case which justify a different format.

The reasons advanced by the appellant-opponent (the United Nations Sustainable Development Goals) are not based on circumstances specific to the case.

Hence, the Board could not see any good reason to force the proprietor to attend the oral proceedings via videoconference. As a consequence, the request to hold the oral proceedings via videoconference was rejected.

## **Order**

### **For these reasons it is decided that:**

The decision under appeal is set aside.

The patent is maintained as granted.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated