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Datasheet for the decision of 29 July 2022

Case Number: T 1581/17 - 3.2.08

Application Number: 11178135.7

Publication Number: 2422750

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
Stent-valve delivery system

Patent Proprietor:
Symetis SA

Opponent:
Schulz Junghans
Patentanwälte PartGmbB

Relevant legal provisions:
EPC Art. 76(1), 83, 54(2), 56

Keyword:
Divisional application - added subject-matter (no)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)

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Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1581/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 29 July 2022

Appellant: (Patent Proprietor)	Symetis SA Chemin de la Venoge 11 1024 Ecublens VD (CH)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Strasse 3 80331 München (DE)
Appellant: (Opponent)	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. 2422750 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. 2422750 in amended form fulfilled the requirements of the EPC.

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

III. Appellant 1 (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed with the grounds of appeal, or on the basis of one of auxiliary requests 1-7 filed with the grounds of appeal, or one of auxiliary requests 8 and 9 filed with the reply to the grounds of appeal.

IV. Appellant 2 (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

V. Oral proceedings took place before the Board on 29 July 2022.

As announced with the letter of 27 December 2021, appellant 2 did not attend the oral proceedings. According to Article 15(3) RPBA 2020 the proceedings were continued without appellant 2.

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

D4 WO 2004/019825 A1
D5 DE 10 2005 003 632 A1

D22 DE 198 57 887 A1

VII. Claim 1 of the current **main request** reads as follows (numbering added):

"A cardiac stent-valve delivery system (2200, 2300, 2400, 2500, 2600), comprising:
1
a delivery device, and
2
a stent—valve comprising a stent component (800, 900, 1000) and a valve component;
3
wherein the stent component (800, 900, 1000) comprises a first section (802), a second section (804) configured for housing the valve component, and a third section (806) having at least one attachment element (808, 814, 902, 1002) configured for removable attachment to the delivery device,
4
wherein the stent component (800, 900, 1000) includes a lattice structure with a plurality of cells,
5
wherein the stent component (800, 900, 1000) and the valve component are capable of a collapsed configuration for delivery and capable of expansion to an expanded configuration after installation,
5a
wherein the stent component is self-expandable to the expanded configuration,
5b
wherein the stent-valve is configured to automatically detach from a stent holder when released from the delivery device, due to the self-expanding property of the stent-valve, and
6

wherein the stent component (800, 900, 1000) further comprises a plurality of independently bendable locking elements (816, 828) generally located at the second section (804) and forming a crown for engaging a failed biological valve or calcified native annulus from the outflow side."

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

Amendments - Article 76(1) EPC

The wording of Feature 6 was disclosed in paragraph [0071] of the parent application as filed (WO 2008/028569 A1). The position of the second section in the middle of the stent component was merely optional, as mentioned in paragraph [0067].

The fixation element 830 did not need to be introduced into the claim, because paragraph [0064] described the locking elements as being alternative to or in addition to the fixation element.

The wording of claim 6 could be derived from paragraph [0086] of the parent application as filed.

Sufficiency of disclosure - Article 83 EPC

The subject-matter of claims 9 and 15 was sufficiently disclosed to be carried out by a skilled person.

Novelty - Article 54(2) EPC

Document D4 did not disclose Feature 4 because the overall structure of the stent component of D4 did not represent a lattice structure.

Document D5 did not disclose a stent component having a lattice structure either.

Inventive Step - Article 56 EPC

When starting from document D4, it was not obvious for a skilled person to provide the stent component with a lattice structure according to Feature 4.

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

Amendments - Article 76(1) EPC

Feature 6 of claim 1 specified a plurality of independently bendable locking elements (816, 828) generally located at the second section (804). In this feature the fact had been omitted that the second section represented a middle section of the stent component. This represented an unallowable generalisation of the disclosure of the parent application as originally filed.

Furthermore, the fixation element 830 shown in Figure 8E had been omitted from feature 6. This represented an intermediate generalisation of the embodiment shown in Figure 8E and described in paragraph [0071] of WO 2008/028569 A1.

Finally the parent application as originally filed did not disclose an "integrated introducer" in the broad sense as specified by claim 6.

Sufficiency of disclosure - Article 83 EPC

The subject-matter of claims 9 and 15 was not disclosed by the patent in a manner sufficiently clear and complete to be carried out by a person skilled in the art.

Novelty - Article 54(2) EPC

The subject-matter of claim 1 lacked novelty over D4 and over D5 which referred back to D4. In particular, the stent component of D4 formed a lattice structure in the sense of Feature 4 of claim 1.

Inventive Step - Article 56 EPC

Appellant 2 did not present any arguments in view of inventive step.

Reasons for the Decision

1. **Added Subject-Matter - Article 76 EPC**

The patent in suit is based on a divisional application of the European patent application no. 09154935.2 which in turn was a divisional application of the European patent application no. 07818037.9, published as WO 2008/028569 A1.

The objections under Article 76(1) EPC of appellant 2 aimed at amendments with respect to the first parent application as originally filed (WO 2008/028569 A1).

1.1 **Location of the second section 804**

Feature 6 of claim 1 requires that "the stent component (800, 900, 1000) further comprises a plurality of independently bendable locking elements (816, 828) generally located at the second section (804), and forming a crown for engaging a failed biological valve or calcified native annulus from the outflow side."

This wording is disclosed in paragraph [0071] (lines 7 - 11) of the parent application as originally filed, which reads: "the stent component shown in Fig. 8E includes a plurality of independently bendable locking elements 828 generally located within the region of the stent component referenced as region 804 in Fig. 8B. Locking elements 828 form a crown that may engage, for example, a failed biological valve or calcified native annulus from the outflow side."

Appellant 2 argued that Figure 8B, which paragraph [0071] refers to, showed the second section 804 as being a middle section. This fact was missing in the claim, contrary to Article 76(1) EPC.

It is true that the section 804 in Figure 8B is shown as a middle section. Figure 8B is more closely described in paragraph [0067]. This paragraph mentions that the stent component includes first section 802 that includes a fixation element, second section 804 housing the valve component, and third section 806 that includes attachment elements 808. However, the description does not suggest that the order given in Figure 8B needs to be adhered to.

So, the text of the description does not require the section 804 to be a middle section of the stent

component. Even if the disclosure of Figure 8B is more specific regarding the order of the sections than the description, it does not restrict the broader disclosure of the description. Hence, paragraph [0067] represents a basis for the generalisation of the location of the second section in Feature 6.

Also the reference to Figure 8B in paragraph [0071] does not lead to the conclusion that the section 804 must be a middle section. The skilled reader would still refer to paragraph [0067] to get the relevant information about Figure 8B.

Additionally, paragraph [0071], lines 13-17 mentions that the location of the bendable locking elements may vary.

Therefore, the omission of the feature according to which the section 804 is a middle section of the stent, does not contravene Article 76(1) EPC.

1.2 **Omission of the fixation element 830**

Appellant 2 argued that when taking Feature 6 from paragraph [0071], the fixation element 830 shown in Figure 8E had been omitted. This represented an unallowable intermediate generalisation of the embodiment shown in Figure 8E and described in paragraph [0071]. In particular, there was a functional link between the locking elements 828 and the fixing element 830 which would not allow such an omission.

Paragraph [0071], however, does not mention any cooperation of the fixing element 830 and the locking elements 828.

Regarding the locking elements, paragraph [0071] refers to Figures 6A and 6B which are more closely described in paragraphs [0063]-[0064] of the parent application as originally filed. There, on page 15, lines 4-7, it is explained that the locking elements are provided "as an alternative to or in addition to [the] fixation element".

Furthermore, paragraph [0066] which introduces the description of Figures 8-16, mentions that "in some embodiments, these stent components may also include a fixation element... for fixing the stent component in place at the implantation site".

From these passages, the Board concludes that the omission of the fixation element 830 from Feature 6 of claim 1 does not contravene Article 76(1) EPC.

1.3 **Claim 6**

Claim 6 specifies the delivery device to comprise an integrated introducer.

This feature can be derived from paragraph [0086], line 19 of the parent application as originally filed. This passage mentions the delivery system 2600 to include an integrated introducer.

It is true that in claim 25 of the parent application as originally filed, in paragraph [0018] and in paragraph [0097], the function of and relation to the delivery device are described more closely. However, the general disclosure of paragraph [0086] forms a sufficient basis for the subject-matter of claim 6.

Therefore, the subject-matter of claim 6 does not contravene Article 76(1) EPC.

2. Sufficiency of disclosure - Article 83 EPC

2.1 Claims 9 and 15

Claim 9 specifies that the delivery device is configured for accessing a patient's body through an intercostal space and penetrating the left ventricle at the apex of the heart. Claim 15 defines that the system is capable of trans-apical penetration of the heart.

Appellant 2 raised an objection under Article 83 EPC, because the patent did not disclose the technical features necessary to enable these ways of insertion.

These features specify, however, a mere suitability of the system for a particular approach, and it is a routine operation for the skilled person to adapt a delivery device (e.g. in view of rigidity, length and thickness) to the approach to be used.

Therefore, the subject-matter of claims 9 and 15 does not contravene Article 83 EPC.

3. **Novelty - Article 54(2) EPC**

3.1 **Document D4**

Document D4 discloses a cardiac stent-valve delivery system comprising:

1

A delivery device (Figures 1-3) and

2

a stent—valve comprising a stent component (1), and a valve component (4);

3

wherein, the stent component comprises a first section (Bügel 3, 7), a second section (Ringträger 5') configured for housing the valve component (page 19, lines 7-12), and a third section (5) having at least one attachment element (9) configured for removable attachment to the delivery device.

D4 further discloses

5

the stent component and the valve component [being] capable of a collapsed configuration for delivery and capable of expansion to an expanded configuration after installation (page 4, lines 20-30),

5a

wherein the stent component is self-expandable to the expanded configuration,

5b

wherein the stent-valve is configured to automatically detach from a stent holder when released from the delivery device, due to the self-expanding property of the stent-valve (Page 20, line 34 - page 21, line 11) and

6

wherein the stent component further comprises a

plurality of independently bendable locking elements (Stützbügel 2) generally located at (here: attached to) the second section (5') (page 19, lines 7-12), and forming a crown (of three hoops) for engaging a failed biological valve (Taschen der natürlichen Herzklappe) from the outflow side.

The structure of the stent component of D4 is essentially formed by the two ring sections (5, 5') and by the three connecting struts (8). This structure results in three cells which are delimited by the ring sections and the connecting struts. When reading document D4, a skilled person would not recognise this structure as "a lattice structure comprising a plurality of cells" (Feature **4**).

It is true that D22 describes in column 3, lines 18-23, a structure similar to that of D4 as a "lattice". However, D22 is a patent application and as such does normally not constitute the basis for interpretation of a specific term. Moreover, it is evident from the context of D22 that the author of D22 regarded it as necessary to explain that such a structure shall be seen as a "lattice". In a reverse conclusion it results that such structure is normally not regarded as a "lattice". Finally, there is no reason why the reader of D4 should use the definition of D22 when interpreting the disclosure of D4.

Therefore, the subject-matter of claim 1 of the main request differs from the disclosure of D4 in Feature 4 according to which "the stent component (800, 900, 1000) includes a lattice structure with a plurality of cells".

3.2 **Document D5**

Referring to D5, appellant 2 only discussed Features 5a and 5b which describe the self-expansion and automatic detachment of the stent from the stent holder.

For the remaining features, D5 refers to D4, describing that the stent of D4 is to be used with the delivery device of D5 (paragraph [0017]).

Therefore, D5, even taking into consideration D4, does not disclose Feature 4 either, and the subject-matter of claim 1 is novel over D5.

3.3 **Inventive Step - Article 56 EPC**

The subject-matter of claim 1 of the main request differs from the disclosure of D4 in Feature 4 according to which "the stent component (800, 900, 1000) includes a lattice structure with a plurality of cells".

The problem to be solved may be regarded as to improve the stability of the fixation of the stent valve.

According to D4, this problem may be solved by additional stabilising hoops (page 9, lines 24-27) or by a support ring (page 11, lines 12-15).

D4 does not suggest to provide the stent with a lattice structure. On the contrary, it teaches away therefrom by suggesting further hoops or support rings.

D4 has a fixation concept for the stent which is based on clamping the natural valve between the support hoops (2) and the commissure hoops (3). The support rings

provide angular stability of the stent. In contrast to that, expandable stents having a lattice structure are normally fixated over the complete outer surface formed by the lattice structure. At the priority date of the patent in suit it was not obvious for the skilled person to combine these two fixation concepts and to provide the stent component of D4 with a lattice structure.

Therefore, the subject-matter of claim 1 of the main request involves an inventive step.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted thereto:

Claims: No. 1-16 according to the main request filed with the statement setting out the grounds of appeal dated 19 September 2017.

The Registrar: The Chairwoman:

C. Spira P. Acton

Decision electronically authenticated