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Datasheet for the decision of 10 March 2016

Case Number: T 0106/14 - 3.2.08

Application Number: 07818037.9

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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:
JenaValve Technology, Inc.
Symetis SA

Opponents:
Boston Scientific Scimed, Inc.
Vondrovsky, Gabriel

Headword:

Relevant legal provisions:
EPC Art. 123(2)
RPBA Art. 12(4)

Keyword:
Amendments - added subject-matter (yes)
Late-filed auxiliary requests - admitted (no)

Decisions cited:

Catchword:

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Case Number: T 0106/14 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 10 March 2016

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Appellant: (Patent Proprietor 2)	Symetis SA Avenue du Temple 19 1012 Lausanne (CH)
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Decision under appeal: **Decision of the Opposition Division of the**

Composition of the Board:

Chairman I. Beckedorf
Members: C. Herberhold
M. Foulger

Summary of Facts and Submissions

I. By its decision posted on 9 December 2013 the Opposition Division revoked European patent EP-B-2059192.

II. The Opposition Division held that the then Main Request as well as the then Auxiliary Requests 1 to 3 - all amended during the opposition proceedings over the patent as granted - contained subject-matter which extended beyond the content of the application as filed contrary to the requirements of Article 123(2) EPC.

III. The patent proprietors (hereinafter: the appellants) lodged an appeal against this decision in the prescribed form and within the prescribed time limit.

IV. Oral proceedings before the Board of Appeal were held on 10 March 2016. To assist the parties in preparing for oral proceedings, the Board issued a communication pursuant to Article 15(1) RPBA with preliminary observations. For the course taken by the oral proceedings, in particular the issues discussed with the parties and the parties' initial requests, reference is made to the minutes of the oral proceedings.

As announced in their letter dated 1 March 2016 the appellants did not attend the oral proceedings. In accordance with Rule 115(2) EPC and Article 15(3) RPBA the proceedings were continued in the appellants' absence, the appellants being treated as relying only on their written case.

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

The appellants requested in writing that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of one of the sets of claims filed as Main Request and as Auxiliary Requests 1 to 6 with the statement of grounds of appeal.

The respondents (opponents 1 and 2) requested that the appeal be dismissed.

V. Claim 1 of the Main Request (corresponding to claim 1 according to the Main Request underlying the appealed decision) reads as follows:

Claim 1:
"A replacement valve for use within a human body comprising:
- a valve component (100); and
- a stent component (800, 900, 1000) comprising: a first section (802) including a fixation element for fixing the stent in place at the implantation site, a second section (804) for housing the valve component (100), and a third section (806), wherein the third section (806) comprises at least one attachment element (808, 814, 836, 902, 1002) configured for removable attachment to a delivery device (2300, 2400, 2500, 2600),
wherein the stent component (800, 900, 1000) includes a lattice structure, wherein the first section (802) has a denser population of lattice cells than the second section (804) and/or the third section (806)

characterized in that

the stent component (800) includes compensation element (826) for accommodating elongation mismatch — if any — within the stent component (800) during manufacturing and/or crimping."

VI. Auxiliary Request 1

Claim 1 of Auxiliary Request 1 filed with the grounds of appeal corresponds to claim 1 of Auxiliary Request 1 underlying the impugned decision.

The subject-matter of claim 1 of Auxiliary Request 1 is based on the subject-matter of claim 1 of the Main Request with the following addition:

"the stent component (800) includes compensation element (826) including a triangular wave portion and two elongate arms for accommodating elongation mismatch..."

VII. Auxiliary Request 2

Claim 1 of Auxiliary Request 2 filed with the grounds of appeal corresponds essentially to claim 1 of Auxiliary Request 2 underlying the impugned decision.

(There is a minor change in wording: "wherein the annular groove is the fixation element" was changed to "wherein the fixation element is an annular groove").

The subject-matter of claim 1 of Auxiliary Request 2 is based on the subject-matter of claim 1 of the Main Request with the following addition:

"wherein the first section (802) includes a plurality of independent bendable elements (816), each bendable element (816) including a single, closed cell of the lattice cells of the first section (802),

wherein the fixation element is an annular groove, wherein the annular groove is formed from the plurality of independently bendable elements (816), wherein each bendable element (816) comprises a bending deformation, the location of which being determined by the lengths (822) of an attached pair of struts (818, 820)."

VIII. Auxiliary Request 3

Claim 1 of Auxiliary Request 3 filed with the grounds of appeal corresponds essentially to claim 1 of Auxiliary Request 3 underlying the impugned decision.

Claim 1 of Auxiliary Request 3 combines the amendments introduced in claim 1 of Auxiliary Requests 1 and 2.

IX. Auxiliary Request 4:

This request was newly filed in the appeal proceedings. It abandons the feature of the "compensation element" (which was present in all requests underlying the impugned decision and in the Main Request and Auxiliary Requests 1-3) and turns to a different feature, namely that "an inflow end of the stent component (800, 900, 1000) is covered on its inner side with a cloth".

Claim 1 of Auxiliary Request 4 is thus here reproduced in full (further additions with respect to claim 1 of the Main Request are underlined, omissions are indicated by ~~strike through~~):

"A replacement valve for use within a human body comprising:

a valve component (100); and
a stent component (800, 900, 1000) comprising: a first section (802) including a fixation element for fixing the stent component (800, 900, 1000) in place at the implantation side, a second section (804) for housing the valve component (100), and a third section (806), wherein the third section (806) comprises at least one attachment element (808, 814, 836, 902, 1002) configured for removable attachment to a delivery device (2300, 2400, 2500, 2600),

wherein the stent component (800, 900, 1000) includes a lattice structure,
wherein the first section (802) has a denser population of lattice cells than the second section (804) and/or the third section (806), wherein the first section (802) includes a plurality of independent bendable elements (816), each bendable element (816) including a single, closed cell of the lattice cells of the first section (802), and

wherein the fixation element comprises an annular groove,

characterized in that

~~the stent component (800) includes compensation element (826) for accommodating elongation mismatch – if any – within the stent component (800) during manufacturing and/or crimping;~~

an inflow end of the stent component (800, 900, 1000) is covered on its inner side with a cloth."

X. Auxiliary Request 5:

The subject-matter of claim 1 of Auxiliary Request 5 is based on claim 1 of Auxiliary Request 4 with the following addition:

"the cloth and the valve component (100) are sutured to the stent component (800) along the border between the first and second sections (802, 804)."

XI. Auxiliary Request 6:

The subject-matter of claim 1 of Auxiliary Request 6 is based on claim 1 of Auxiliary Request 5 with the following addition:

"excess cloth on the inflow end of the stent component (800) is folded over onto the exterior side of the stent component (800) and sutured together with the valve component (100) in the vicinity of the previous suturing location."

XII. The essential arguments of the appellants can be summarised as follows.

Article 123(2) EPC - Main Request, Auxiliary Requests 1-3

Firstly, as could be unambiguously derived from paragraph [0066] of the specification, Figures 8 to 16 of the original application showed exemplary embodiments of a stent design according to a second aspect of the invention disclosed in the opposed patent.

As could be seen from the pictures provided on pages 7 and 8 of the statement setting out the grounds of appeal, which corresponded to Figures 8B, 8D, 9B and 10B of the opposed patent, the stent designs shown in these pictures were all single stents including a first proximal section that included a fixation element, a second section that may follow the contour of the valve component to be housed therein and a third section that included one or more attachment elements. Even if the different sections of the stent component were only indicated with reference numerals in Figure 8B, this could not be regarded as being limited to the specific embodiment shown therein. Rather, from a structural point of view, the stents shown in Figures 8 to 16 were quite similar and all of the stents were provided with such first, second and third sections.

Another common feature of these embodiments was that the stent component included a lattice structure, where the proximal section of the stent component had denser population of lattice cells than the distal section or the second section of the stent component. This particular lattice structure was unambiguously and directly derivable from Figures 8 to 16.

Still another common feature of these embodiments was a compensation element for accommodating elongation mismatch – if any – within the stent component during manufacturing and/or crimping. In this regard it was to be noted that the exact structure of the compensation element was irrelevant for accommodating elongation mismatch. In the embodiments depicted in Figures 8B, 10B and 11 to 16, for example, the compensation element included an undulated wave portion. By contrast, the compensation element utilised in the exemplary embodiment of the stent depicted in Figure 8D included a triangular wave portion. It was thus evident that all of the stent designs according to the second aspect of the invention, i.e. according to the exemplary embodiments depicted in Figures 8 to 16, were provided with the specific feature of the compensation element for accommodating elongation mismatch.

The subject-matter of claim 1 of the Main Request and the Auxiliary Requests 1-3 did thus not extend beyond the disclosure of the application as originally filed.

Admissibility - Auxiliary Requests 4-6

These requests, although only filed together with the statement setting out the grounds of appeal, aimed at overcoming the objections under Article 123(2) EPC by removal of the disputed feature. They were thus an appropriate reaction to the opposition division's decision and should therefore be admitted into the appeal proceedings.

XIII. The essential arguments of the respondents can be summarised as follows:

Article 123(2) EPC - Main request, Auxiliary Requests 1-3

The respective independent claims of the Main Request and Auxiliary Requests 1 to 3 defined a compensation element for accommodating elongation mismatch – if any – within the stent component during manufacturing and/or crimping. Such a compensation element was, however, not disclosed in general, but only in the context of the specific embodiment disclosed in Figure 8D and described on page 17, last sentence of the description as originally filed.

The independent claim combined the compensation element with a particular lattice structure comprising first, second and third sections wherein the first section had a denser population of lattice cells than the second section and/or the third section. Such a lattice structure was only disclosed for the particular embodiment of figure 8A, 8B. The description made it quite clear that Figures 8A, 8B and 8D related to different embodiments. Indeed there was no link to any other embodiment.

There was furthermore no clear and unambiguous disclosure, that the Figure 8D embodiment exhibited the particular lattice structure claimed, nor was it disclosed how – if at all – the first, second and third sections were to be assigned in that case. The assignment performed by the appellants on page 7 - lower drawing - of the statement setting out the grounds of appeal was completely arbitrary in that it assigned the annular groove fixation element partly to the first and

partly to the second section. Moreover, Figure 8D did not indicate the position of the valve, such that a second section for housing the valve component could not be identified. If one were to assume that the valve was connected to a lattice section structurally comparable to the one shown in Figure 8B, no. 804, one had to conclude that the second section included the uppermost row of closed cells shown in Figure 8D, which however meant that there was no first section at all. If, on the other hand, one assigned the first fixation section - in analogy to Figure 8D - to the uppermost row of cells, which indeed included the annular groove forming the fixation element, there would be no sufficiently stable lattice structure left in the lower part of the stent component to which the valve could be connected. It also remained unclear how the density of the population of lattice cells was to be determined for such an open structure hardly comprising any cells at all.

Starting, on the other hand from the embodiment shown in Figures 8A and 8B - which showed the particular lattice structure claimed, there was no disclosure of a compensation element. Contrary to the appellants' view, the wavy part in stem no. 812 could not be considered a compensation element. Firstly, there was no indication whatsoever in the specification that a compensating functionality was associated with that part. On the contrary, no. 812 was explicitly called a commissural post. It was thus the structure to which the delicate valve tissue was connected and which thus needed to be stiff in order to prevent damage of the valve. Secondly, the compensation element as disclosed in the Figure 8D embodiment did not only have a triangular wave portion but also two elongate arms. There was no indication for the skilled person that the wavy structure shown in

Figure 8A, 8B alone - which did not comprise any such elongate arms - had a compensating effect.

In conclusion, the combination of the particular lattice structure and the compensation element as claimed in the independent claim of the Main Request and Auxiliary Requests 1 to 3 was not clearly and unambiguously disclosed in the application as filed and was thus in violation of the requirements of Article 123(2) EPC.

Admissibility - Auxiliary Requests 4-6

Auxiliary Requests 4 to 6 were late filed and should for this reason not be admitted into the appeal proceedings. Furthermore, these requests did not comprise the additional feature relating to the compensation element and thus were not related to any of the main issues of the first instance proceedings. Instead, a different feature was introduced. Therefore, these request should be held inadmissible since they could and should have been presented in first instance opposition proceedings, see Article 12(4) RPBA.

Reasons for the Decision

1. Main Request - Article 123(2)

1.1 The subject-matter claimed

According to claim 1 of the Main Request the stent component includes

i) a lattice structure, wherein the first section (802) has a denser population of lattice cells than the second section (804) and/or the third section (806) and

ii) compensation element for accommodating elongation mismatch – if any – within the stent component during manufacturing and/or crimping.

Due to the and/or combination, feature i) in particular includes feature

i*) a lattice structure wherein the first section has a denser population of lattice cells than the second section and the third section.

Hence, for the requirements of Article 123(2) EPC to be fulfilled, among others, the combination of features i*) and ii) needs to be clearly and unambiguously disclosed in the application as filed.

1.2 Feature i*)

The only disclosure of this feature is in paragraph [0011], third sentence and in paragraph [0067], page 16, lines 3 to 5. The latter explicitly relates to the embodiments shown in Figures 8A and 8B (see the first 2 sentences of paragraph [0067]), the respective sections 802, 804 and 806 being illustrated in Figures 8A and 8B. Feature i*) is thus clearly and unambiguously disclosed in the context of the Figure 8A, 8B embodiment.

However, the situation is different with respect to the embodiment disclosed in Figure 8D - the only embodiment in the context of which there is explicit mentioning of a compensation element (see point 1.3 below).

1.2.1 Firstly, neither paragraph [0011] nor paragraph [0067] have any explicit link to the embodiment of Figure 8D and the corresponding paragraph [0070]. These paragraphs

thus cannot suggest that the three sections as defined in feature i*) were present in Figure 8D.

In this context the Board remarks that the appellants' argument according to which all of the embodiments shown in Figures 8-11 exhibited a combination of a compensation element and the particular lattice structure (feature i) is not convincing: Figures 8E and 8F (and Figure 8C - as far as may be seen given the low image quality) do not show a compensation element. Furthermore, in the context of Figure 8F, even the term "lattice structure" appears inappropriate. The Board thus agrees with the respondents that the embodiments of Figures 8-11 do not clearly exhibit a common "second aspect" of the invention but have to be seen as individual embodiments as is also suggested by the introductory phrases of the respective paragraphs, which each refer to "(yet) another embodiment of a stent component".

1.2.2 Secondly, Figure 8D itself (contrary to Figure 8B) does not indicate any sections. It thus cannot provide guidance on how the respective sections are to be assigned. It does also not show the valve component, thus that the "second section for housing the valve component" cannot be clearly and unambiguously identified.

1.2.3 Thirdly, the assignment of the three different sections to the Figure 8D stent component is not unambiguous, as will be shown in the following.

For ease of understanding, Figures 8D and 8B are reproduced below (with some references added to figure 8D):

FIG. 8D

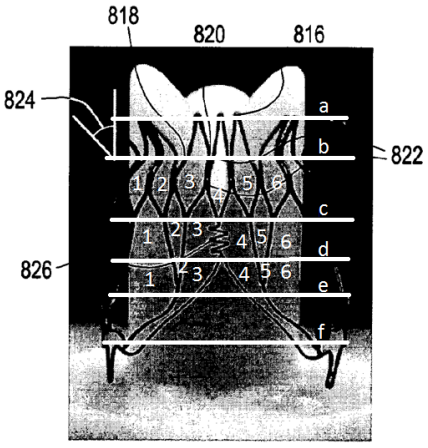
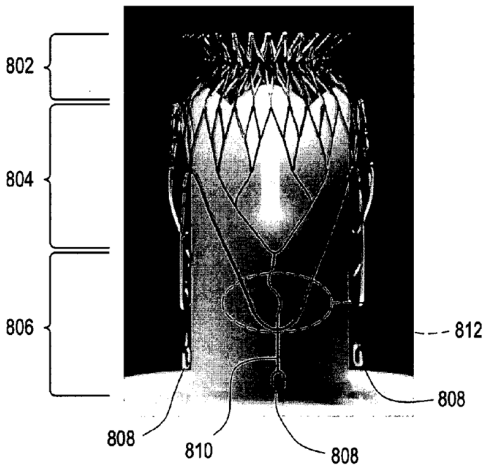


FIG. 8B



According to the appellants, the first section and the second section were separated by line b) (see page 7 of the statement of grounds, lower drawing). However, line b) extends through the bottom of the annular groove collectively formed by the bendable elements 816. As fixation is achieved not only by one of the two side walls but by both side walls of the annular groove, the first section as identified by the appellants does not include the "fixation element for fixing the stent in place at the implantation site". Hence, the assignment performed by the appellant does not result in a first section as defined in the claim.

The respondents have argued that the only part of the 8D stent which was structurally similar to the second section (no. 804) indicated in Figure 8B and which could thus house the valve, was the part extending between lines a) and e). Only there were there sufficient cells to anchor the valve. This would however leave no parts of the stent to which the first section may be assigned.

In a further attempt to identify the sections defined in the claim, the skilled person may try to assign the first section to the cells forming the fixation annular groove, i.e. to the part between lines a) and c) - an assignment which is in accordance with section no. 802 as identified in Figure 8B. With that assumption, it remains to identify the second and third sections. Assuming that the lines separating the second and third sections are in some way related to physical structures of the stent component (rather than being drawn arbitrarily through it), separators d) (at the lower end of the triangular wave part of the compensation element), e) (at the confluence of the wires of cells 2 and 5) or f) (next to the attachment elements) appear reasonable choices.

Line f) would, however, result in a third section without any cells (the attachment elements cannot equally be cells). Furthermore, as can be seen from the added numbers, no matter whether line d) or e) is chosen, the so defined second section would have the same number of cells as the first section, hence feature i*) would not be fulfilled.

1.2.4 In conclusion, there is no clear and unambiguous disclosure that the Figure 8D embodiment includes a lattice structure having the three sections as claimed, wherein the first section has a denser population of lattice cells than the second section and the third section.

1.3 Feature ii)

The only explicit disclosure of feature ii) is in Figure 8D and the corresponding part of the description (paragraph [0070], page 17, line 30 - page 18, line 1)

of the application as filed. None of the other embodiments mentions a compensation element.

The appellants were of the opinion that the person skilled in the art would clearly and unambiguously recognize the wavy elements shown in particular in Figures 8A, 8B (at reference no. 812) as "compensation element". However, the structure labelled no. 812 is explicitly referred to as "a stem" (page 19, line 13-15). In the sentence immediately before, the very similar stem no. 906 (see Figure 9B) is said to be for example a commissural post. From this disclosure the person skilled in the art would derive that stem no. 812 or 906 is the structure to which the valve structures are attached, which implies a certain stiffness to prevent damage to the valve structures.

The wavy structure is furthermore structurally different from the compensation element disclosed on page 17, lines 30ff, which not only comprises a triangular wave form but also two extended arms, a direct "same structure - same function"- argument thus not being valid.

Hence, there is no clear and unambiguous disclosure that the wavy parts shown in Figures 8A, 8B, 9-16 are indeed a "compensation element for accommodating mismatch - if any - within the stent component during manufacturing and / or crimping".

1.4 It results from the above that the combination of features ii) and i*) is not clearly and unambiguously disclosed in the application as originally filed. Therefore, the requirements of Article 123(2) EPC are not fulfilled.

2. Auxiliary Requests 1-3

The independent claims of these requests equally comprise the combination of features ii) and i*). Thus, they are not allowable under Article 123(2) EPC for the reasons detailed in point 1 above.

3. Auxiliary Requests 4-6 - Admission into the proceedings

3.1 Auxiliary Requests 4-6 have been filed for the first time with the statement setting out the grounds of appeal. According to the appellant, the amendments to claim 1 are occasioned by the Article 123(2) EPC objection.

However, the Opposition Division had raised this objection already with the summons to oral proceedings. Therefore, the appellants could and should have filed the respective requests in preparation of or during the oral proceedings in the opposition procedure. In this context the Board notes that during the oral proceedings before the Opposition Division the appellants, when asked by the chairwomen, had explicitly declared to have no further requests (point 16 of the minutes).

3.2 In accordance with Article 12(4) RPBA, the Board has the power to hold inadmissible requests which could have been presented in the preceding instance proceedings.

In the present case, the feature of the "compensation element" - which was present in all requests dealt with in the decision of the Opposition Division - has been removed, and a new feature ("cloth") has been added from the description. The amendments thus result in a fresh case which has not been discussed before the Opposition Division. The Board would thus have to either decide

about these new issues for the first time in opposition appeal proceedings or to remit the case. In this situation the Board decided to exercise its power according to Article 12(4) RPBA and not admit Auxiliary Requests 4-6 into the proceedings.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chairman:

C. Moser I. Beckedorf

Decision electronically authenticated