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**Datasheet for the decision
of 8 February 2023**

Case Number: T 0142/20 - 3.2.01

Application Number: 10707703.4

Publication Number: 2400924

IPC: A61F2/24, A61F2/915

Language of the proceedings: EN

Title of invention:
PROSTHETIC HEART VALVE

Patent Proprietor:
St. Jude Medical, Inc.

Opponent:
Boston Scientific Corporation

Headword:

Relevant legal provisions:
EPC Art. 54, 100(a), 123(2)

Keyword:
Main and first to fourth auxiliary requests - Novelty - (no)
Fifth auxiliary request- added subject-matter (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0142/20 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 8 February 2023

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 November 2019 concerning maintenance of the
European Patent No. 2400924 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: S. Mangin
O. Loizou

Summary of Facts and Submissions

- I. The appeals were filed by the appellant 1 / patent proprietor and appellant 2 / opponent against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request IV, the patent in suit (hereinafter "the patent") met the requirements of the EPC.
- II. In particular, the opposition division held that
- (1) the patent, on the basis of auxiliary request IV, disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and
 - (2) the subject-matter of the claims of this request did not extend beyond the content of the application as filed, and
 - (3) the subject-matter of this request was novel and involved an inventive step over D7 (WO 2009029199).
- III. Oral proceedings were held on 8 February 2023 before the Board.
- IV. 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, alternatively the patent be maintained in amended form on the basis of one of the first to third auxiliary requests, or that the appeal of appellant 2 be dismissed (fourth auxiliary request), or that the patent be maintained on the basis of the fifth auxiliary request, all requests as filed with the statement of grounds of appeal.

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

VI. Independent claim 1 of the main request, with feature numbering added, reads as follows:

M0 A prosthetic heart valve, comprising:

M1 a stent (100) having a proximal end, a distal end, an expanded condition and a collapsed condition,

M2 the stent including a plurality of proximal cells (106) at the proximal end and a plurality of distal cells (102) at the distal end, the distal cells being longitudinally spaced apart from the proximal cells;

M3 a plurality of support struts (104), each support strut having a first end connected to one of the proximal cells and a second end connected to one of the distal cells;

M4 at least one support post (108) connected to a multiplicity of the proximal cells,

M5 the support post including a collapsible portion (1660, 1760) having a first configuration when the stent is in the collapsed condition and a second configuration when the stent is in the expanded condition,

M6 the support post having a first length when the collapsible portion is in the first configuration and a second length less than the first length when the collapsible portion is in the second configuration; and

M7 a valve structure connected to the at least one support post.

VII. Independent claim 1 of the first auxiliary request corresponds to the main request with feature M5 being amended to read:

M5 the support post including a collapsible portion (1660, 1760) being positioned at a location along the

length of the at least one support post and having a first configuration when the stent is in the collapsed condition and a second configuration when the stent is in the expanded condition

VIII. Independent claim 1 of the second auxiliary request corresponds to the main request with feature M5 being amended to read:

M5 the support post including a distal portion, a proximal portion and a collapsible portion (1660, 1760) between the distal portion and the proximal portion, the collapsible portion having a first configuration when the stent is in the collapsed condition and a second configuration when the stent is in the expanded condition

IX. Independent claim 1 of the third auxiliary request corresponds to the main request with feature M5 being amended to read:

M5 the support post including a distal end, a proximal end, a middle and a collapsible portion being located between the middle and the proximal end, the collapsible portion (1660, 1760) having a first configuration when the stent is in the collapsed condition and a second configuration when the stent is in the expanded condition,

X. Independent claim 1 of the fourth auxiliary request corresponds to the main request with features M5 and M6 being amended to read:

M5 the support post including a distal end, a proximal end, a middle and a collapsible portion being located between the middle and the proximal end, the collapsible portion (1660, 1760) having a first configuration when the stent is in the collapsed

condition and a second configuration when the stent is in the expanded condition,

M6 the support post having a first length when the collapsible portion is in the first configuration and a second length less than the first length when the collapsible portion is in the second configuration, wherein the collapsible portion has a first end and a second end, the first end (1760a) of the collapsible portion is connected to a portion of the elongated support post close to its middle and the second end (1760b) of the collapsible portion is connected to a portion of the elongated support post near its proximal end; and

XI. Independent claim 1 of the fifth auxiliary request corresponds to the main request with features M4 being amended to read:

M4 at least one support post (108) with a distal end, a proximal end, a middle and a collapsible portion being located between the middle and the proximal end, the support post being connected to a multiplicity of the proximal cells, wherein a first leg of one of the multiplicity of proximal cells is connected to the support post between the distal end and the collapsible portion and wherein a second leg of the one proximal cell is connected to the support post between the proximal end and the collapsible portion,

Reasons for the Decision

1. Fourth auxiliary request - Novelty over D7

The subject-matter of claim 1 is not novel over D7.

- 1.1 Appellant 1 argued that D7 did not disclose features M3, M4, M5 and M6.
 - 1.1.1 Firstly, appellant 1 argued that figure 13 of D7 showed one cell at the top of which a support post 5237 was provided. In their view an interpretation of figure 13, according to which the support post was composed of the elongated part 5237 and two connected legs was contrary to the description of D7. Appellant 1 referred to paragraph [0041], disclosing that the *"stent frame 5010e includes commissure regions that are somewhat post-like, as at reference 5237.(...) Making each prosthetic valve commissure region more like a single upstanding post 5237 may enhance each such commissure region's independent flexibility (i.e. its ability to flex independently of other parts of supporting structure 5010e"*.
 - 1.1.2 Secondly, depending on which part of the stent the aperture 5239 was associated to: the post or the strut, one of the features M3 or M4 was missing:
 - either the aperture was considered part of the post, then the strut was not connected to one of the proximal cells (feature M3)
 - or the aperture was considered part of the strut, then the support post was not connected to a multiplicity of proximal cells (feature M4).
 - 1.1.3 Thirdly, D7 did not disclose directly and unambiguously that the legs of the support post spread apart during expansion of the stent and that the length of the support post changed (features M5 and M6). D7 provided no hint that a collapsing of the support post was intended. The proximal cells between the posts may expand whereas the legs beneath the support post did not spread apart. It was not possible to directly and

unambiguously derive such a functional feature only from schematic drawings while the description lacked corresponding disclosure.

1.1.4 Fourthly, D7 was so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention. The teaching derivable from the embodiments in figures 10 and 13 of D7 was also not even remotely related to any expansion characteristics of the stent, let alone a length adaption of a support post in order to facilitate the stent expansion. These embodiments of D7 rather concerned an adaption of the cell number of the aortic outflow portion with respect to the cell number of the annulus inflow portion. In particular, these embodiments included a stent configuration that facilitates annular expansion of the aortic outflow portion 5100 to a larger diameter than the annulus inflow portion 5200 (see paragraph [0046]). Consequently, document D7 would have been disregarded by the skilled person faced with the problem underlying the claimed invention, because they belonged to a remote technical field and, in addition, their subject-matter would not help to solve the problem.

1.1.5 Fifthly, feature M6 required two portions of the support post between which the collapsible portion was located, wherein these two portions did not belong to the collapsible portion. In D7, the collapsible portion extended to the end of the post. Hence there was no proximal region of the post that was connected to the collapsible portion.

1.2 The Board does not agree.

1.2.1 Firstly, while the terminology used in D7 may be different to the one used in claim 1, the overall structure of the claimed stent is disclosed in figure 13 of D7. In figure 13, the support post comprises the elongated upright part comprising three apertures 5239 and two legs directed down to two lower apertures 5239. This understanding, in line with the opposition division's understanding, is based on document D7 as a whole: In figure 10, the post with reference number 5237 can clearly be recognised as extending between the upper apertures 5239 and the two lower apertures 5239, which are typically used for attaching the valve. The stent of figure 13 is similar to the one of figure 10. The posts having the same reference number 5237 must therefore also be considered by analogy as extending between the upper aperture 5239 and the two lower apertures.

The Board notes that the shape of the support post is not defined in claim 1. Furthermore, support posts are not restricted to rod like structures. Indeed, in figures 1 and 2 of D7, the commissure posts have the shape of an inverted V. This is confirmed by paragraph [0028], *"In the FIG. 2 embodiment, for example, each of the commissure tips 5236 is at the free apex of a V-shaped commissure post structure that extends down from the tip as viewed in FIG. 2"* (paragraph [0028]).

1.2.2 Secondly, the post, the strut and the proximal cell are all connected together at the location of the aperture 5239. Therefore, the support strut and the support post are both connected to the proximal cells. Appellant 1's consideration that depending on which component (cell, support post or support strut) the aperture is associated to changes which component are connected together, is rather artificial.

In any event, the Board notes that in dependent claims 5 and 6 the expression "connected directly" is used as opposed to the term "connected" used in feature M3 and M4 of claim 1. The choice of the term "connected" only without the term "directly" conveys the meaning that an indirect connection also falls under the scope of claim 1.

1.2.3 Thirdly, while figure 13 only shows the stent in a collapsed condition, it is implicit that the stent is meant to be expanded after insertion. It is the essence of such an annular stent for a prosthetic aortic valve. This understanding is confirmed in:

- paragraph [0025] of D7, reading *"All of the many embodiments shown and described in this specification are annularly or circumferentially collapsible to a delivery condition like that generally illustrated by FIG. 1, and then annularly or circumferentially re-expandable to an implanted or deployed condition like that generally illustrated by FIG. 2".* and,
- paragraph [0033] of D7: *"When deployed in a patient, all of the various prosthetic valve embodiments that are shown and described in this specification have outwardly bulging connecting struts 5284 like those shown in FIG. 2, with spacing (e.g., W1 and W2) like that shown in FIG. 2, and with positioning of the struts relative to native valve commissure projections 22 like that shown in FIG. 3".*

While the extension of the stent may not be homogeneous, there will be an expansion of the legs of the posts as can be seen on all the figures in D7 representing the stent in expanded condition (figures 2, 4, 5, 6, 8).

Finally, the spreading of the support post's legs will inevitably reduce the longitudinal length of the

support post. There is no need for any measurements, it is a pure mechanical consequence.

1.2.4 Fourthly, D7 discloses prosthetic aortic heart valves comprising a stent and valve attached to the stent as in the claimed invention. The expansion of the stent is a common feature to all stents, and it is also the case in D7, where the circumferentially expanded valve has different spacing W1 and W2 (see paragraph [0031] and [0033]). This spacing has a direct impact on the length of the support posts. D7 is therefore not remote from the claimed invention.

1.2.5 Fifthly, the support post includes a distal end, a proximal end, a middle and a collapsible portion being located between the middle and the proximal end. In D7, the collapsible portion is connected to a portion of the support post near its proximal end. Claim 1 neither defines the portion of the elongated support near its proximal end, nor its shape, nor its length. Thus, the end of the support post may be considered as a portion of the support post.

2. Main and first to third auxiliary requests - Novelty over D7

The subject-matter of claim 1 of the main request and the first to third auxiliary requests is broader than that of claim 1 of the fourth auxiliary request. This was contested by appellant 1 only as regards auxiliary request 1 but the Board judges it otherwise as explained below. Accordingly, the subject-matter of these requests is not novel over D7 for the same reasons as mentioned above for the fourth auxiliary request.

2.1 Appellant 1 was of the opinion that auxiliary request 1 was novel over D7 as it required *"the support post including a collapsible portion being positioned at a location along the length of the at least one support post"*. In their view the term "length" in this feature referred to the same "length" as in feature M6 (*the support length having a first length when the collapsible portion is in the first configuration and a second length less than the first length when the collapsible position is in the second configuration*). In figure 13 of D7, the collapsible portion was not positioned along the structural length of the post.

2.2 The Board does not agree with the interpretation of the expression "along the length" made by appellant 1. The length of the support post is the longitudinal length of the post from top to bottom (i.e., not following the spread legs). This interpretation is consistent with the patent. In the patent, the length considered is not the structural length of the post, (i.e., the sum of the post regions that are not collapsible and the length of the legs of the collapsible portion. See figures 14A and 14B). Otherwise, there would not be any change in the length of the post.

The Board interprets *"a collapsible portion being positioned at a location along the length of the at least one support post"* in the same manner as the feature of the third and fourth auxiliary requests *"the support post including a distal end, a proximal end, a middle and a collapsible portion being located between the middle and the proximal end"*.

Accordingly, also the third auxiliary request is broader than the fourth auxiliary request and is for the same reasons as mentioned above for the fourth auxiliary request not novel over D7.

3. Fifth Auxiliary request - Added subject-matter -
Article 123(2) EPC

The features added to claim 1 of the fifth auxiliary request result in subject-matter extending beyond the content of the application as filed, whereby this claim does not meet the requirements of Article 123(2) EPC.

3.1 In the fifth auxiliary request, feature M4 was amended to read *"wherein a first leg of one of the multiplicity of proximal cells is connected to the support post between the distal end and the collapsible portion and wherein a second leg of the one proximal cell is connected to the support post between the proximal end and the collapsible portion"*. This feature was according to the appellant 1 based on figures 13-16.

3.2 In their reply to the statement of grounds of appeal under point G.I on page 20, appellant 2 argued that nothing was connected to a position between the distal/proximal ends of the post and the collapsible portion. Instead, the groups of post connections directly connected to the ends of the cells. This was also emphasized in paragraph [0209], which disclosed that the cells 1602 were connected via groups of post connections 1610 to the proximal/distal ends of the support post.

3.3 Appellant 1 counter argued that the legs of the cells were not at the end of the posts but on the side between the ends of the posts and the collapsible portion. Additionally, the function of the added feature could be found in paragraph [0210]: the cells immediately adjacent to the elongated support post were able to expand away from the support post. This

function did not require that the legs of the cells were connected at the end of the posts, but as long as the leg of the cells were between the ends of the posts and the collapsible portion, the function would be achieved. This feature could therefore be extracted without giving rise to an unallowable intermediate generalisation.

3.4 The Board does not agree with appellant 1. None of the figures 13-16 disclose the legs of the proximal cells being connected anywhere else other than on the side of the support posts at its distal and proximal ends. The only disclosure of the cells' connection to the post is in paragraphs [0209]:

"Some of these cells 1602 are connected to the elongated support post 1608 via post connections 1610. One group of post connections 1610 couple two cells 1602 to opposite sides of the distal end 1608a of the elongated support post 1608. Another group of post connections 1610 join two other cells 1602 to opposite sides of the proximal end 1608b of the elongated support post 1608".

While figures 14A, 14B, 15A, 15B, 16A and 16B do not refer to the post connection 1610, the legs of the adjacent proximal cells are connected to the support post at the same location as on figure 13A and 13B, i.e. at the ends of the post and not anywhere between the ends of the post and the collapsible portion. There is thus no direct and unambiguous disclosure of the added feature in claim 1.

The argument of appellant 1 that the function is achieved independently on the location between the end of the support post and the collapsible portion is not convincing. This may be an argument for taking a feature in isolation from other features, in which case it has to be assessed whether the isolated feature is

functionally or structurally related to the other features. But in the present case there is no direct and unambiguous disclosure of the legs of the support post being anywhere else than at the ends of the support post.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated