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Datasheet for the decision of 28 March 2023

Case Number: T 0379/20 - 3.2.01

Application Number: 10727584.4

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IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
STENTED PROSTHETIC HEART VALVES

Patent Proprietor:
Medtronic Inc.

Opponent:
Boston Scientific Corporation

Headword:

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

Keyword:
Amendments - allowable (no)

Decisions cited:

Catchword:

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Boards of Appeal

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 0379/20 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 28 March 2023

Appellant: (Patent Proprietor)	Medtronic Inc. 8200 Coral Sea Street N.E. Mounds View, MN 55112 (US)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Respondent: (Opponent)	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752-1234 (US)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Straße 3 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 3 December 2019 revoking European patent No. 2437687 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	G. Pricolo
Members:	S. Mangin
	A. Jimenez

Summary of Facts and Submissions

I. The appeal was filed by the appellant (patent proprietor) against the decision of the opposition division to revoke the patent in suit (hereinafter "the patent").

II. The opposition division held that the subject-matter of claim 1 extended beyond the content of the application as originally filed:

- There was no clear and unambiguous disclosure in the WO-publication (WO 2010/141626) of at least two commissure extensions *"secured to the V-shaped structure of the stent structure with attachment material that is slidable along the V-shaped structures of the stent to allow for free movement of the valve relative to the stent structure along its longitudinal axis",* having regard to claim 1 as filed and the embodiment of figures 8/9 and paragraphs [0040] and [0041].
- The attachment of each of the commissure extensions to a V-shaped structure disclosed in paragraph [0056] was inextricably linked to one V-shaped structure corresponding to each of the scalloped areas of the bioprosthesis, which was also functionally related to the longitudinal movement of the attachment.

The opposition division further held that auxiliary requests 1-7 extended beyond the content of the application as filed for the same reasons as for the main request.

III. Oral proceedings were held before the Board by videoconference on 28 March 2023.

IV. **The appellant (patent proprietor)** requested that the decision under appeal be set aside and that the patent be maintained as granted, or in the alternative that the patent be maintained on the basis of auxiliary requests 1-7 filed with the statement of grounds of appeal.

The respondent (opponent) requested that the appeal be dismissed. Should one of the main or auxiliary requests be found to comply with Article 100(c) EPC, the respondent requested the remittal of the case to the opposition division for further prosecution.

V. Claim 1 of the main request reads:

"A stented valve (60) comprising:
a compressible and expandable stent structure comprising a generally tubular body portion having an interior area and a longitudinal axis (104) and V-shaped structures (54) that extend longitudinally along the length of the stent, wherein
the stent structure comprises a series of wires arranged in a generally tubular shape that includes multiple diamond-shaped structures (52) extending around the perimeter at an inflow end (42), and wherein the V-shaped structures (54) each have an end that generally extends from the peaks of the diamond-shaped structures (52); and
a bioprosthetic valve positioned at least partially within the interior area of the tubular body portion of the stent structure and comprising:
an outer tubular portion comprising at least two commissure extensions (44) and an inner wall from which a plurality of leaflets extend; and
at least one scalloped portion extending between adjacent commissure extensions (44);

wherein the at least two commissure extensions (44) are secured to the V-shaped structures (54) of the stent structure with attachment material that is slideable along the V-shaped structures (54) of the stent structure to allow for free movement of the valve relative to the stent structure along its longitudinal axis, wherein each of the commissure extensions (44) is attached to a V-shaped structure (54) with stitches that are spaced apart from each other and extend along the both sides and the peak of each V-shaped structure (54).”

VI. Claim 1 of the first auxiliary request is identical to claim 1 of the main request.

VII. Claim 1 of the second auxiliary request corresponds to claim 1 of the main request with the addition of the following feature:
"and wherein an inflow end of the bioprosthetic valve is secured to the stent structure by suturing the tubular portion to the diamond-shaped structures (52) along the lower portion or edge of the diamond-shaped structures (52)”.

VIII. Claim 1 of the third auxiliary request corresponds to claim 1 of the second auxiliary request with the addition that the inflow end of the bioprosthetic valve is secured to the stent structure by suturing the tubular portion to the diamond-shaped structures (52) also:
"along the upper portion or edge of the diamond-shaped structures (52)".

IX. Claim 1 of the fourth auxiliary request corresponds to claim 1 of the second auxiliary request with the addition of the following feature:

"wherein the stitches are performed using a standard suture material which has a first end that terminates at one end of each V-shaped structure (54) and a second end that terminates at the other end of each V-shaped structure".

X. Claim 1 of the fifth auxiliary request corresponds to claim 1 of the third auxiliary request with the addition of the following feature:
"wherein the bioprosthetic valve further includes a material (48) that covers at least a portion of the inflow end (42) of the bioprosthetic valve".

XI. Claim 1 of the sixth auxiliary request corresponds to claim 1 of the main request with the addition of the following feature:
"the bioprosthetic valve further includes a material (48) that covers at least a portion of the inflow end (42) of the bioprosthetic valve, and wherein an inflow end (42) of the bioprosthetic valve is secured to the stent structure by suturing the material (48) and the tubular portion to the diamond-shaped structures (52) along the lower portion or edge of the diamond-shaped structures (52) and along the upper portion or edge of the diamond-shaped structures (52)".

XII. Claim 1 of the seventh auxiliary request corresponds to claim 1 of the main request with the addition of the following features:
"the bioprosthetic valve further includes a material (48) that covers at least a portion of the inflow end (42) of the bioprosthetic valve, and wherein an inflow end (42) of the bioprosthetic valve is secured to the stent structure by suturing the material (48) and the tubular portion to the diamond-shaped structures (52) along the lower portion or edge of the diamond-shaped

structures (52) and along the upper portion or edge of the diamond-shaped structures (52), and wherein the stitches are performed using a standard suture material which has a first end that terminates at one end of each V-shaped structure (54) and a second end that terminates at the other end of each V-shaped structure".

Reasons for the Decision

1. Main request - Added subject-matter - Article 100(c) EPC

The subject-matter of claim 1 extends beyond the content of the application as originally filed.

1.1 The appellant submitted that claim 1 as granted was a combination of the features of claim 1 as filed with further features of the embodiment of figures 8/9.

They argued that claim 1 as originally filed was not solely related to the embodiment of figures 16/17, but also covered the embodiment of figures 8/9, such that the combination of claim 1 as filed with the added features relating to the embodiment of figure 8/9 did not extend beyond the content of the application as originally filed.

1.1.1 Firstly, while the functional feature, *"wherein the at least two commissure extensions are secured to the V-shaped structures of the stent structure with attachment material that is slideable along the V-shaped structures (54) of the stent structure to allow for free movement of the valve relative to the stent structure along its longitudinal axis"*

was only described in the description in detail in the context of the embodiment of figures 16/17, this did not limit claim 1 to said embodiment. There was no teaching in the original disclosure that would contradict the presence of the above functional feature of original claim 1 in the embodiment of figures 8/9. In fact, the embodiment of figures 8/9 showed each structural feature of claim 1 as originally filed, including the specific V-shaped structures and the attachment material, which was required to realise the functional feature that the attachment material was *"slidable along the stent structure to allow for free movement of the valve relative to the stent structure along its longitudinal axis"*.

1.1.2 Secondly, the embodiment of figures 8/9 was the first embodiment *"in accordance with the invention"* that was presented in the description (see paragraphs [0020], [0040]). An unbiased skilled reader would expect this very first embodiment of the invention to be covered by at least one claim of the application as originally filed, if not by the first claim of the application as originally filed (this assumption was supported by Rule 43(3) EPC). However, the second original independent claim 9 required a *"tubular tissue material… extending beyond the outflow end of the stent"*, which was not realised in the embodiment of figures 8/9. Thus, if claim 1 would not also relate to the embodiment of figures 8/9, then this very first embodiment of the application that was *"in accordance with the invention"* would not be covered by any of the original claims. While this situation may theoretically not be excluded, it was highly unlikely. The appellant re-emphasised that it was possible to realise all features, in particular also that of a slidable attachment material, in the embodiment of figures 8/9.

The fact that the scalloped areas of the prosthesis were not attached in figures 8/9 and the fact that the prosthesis was attached at the inflow end did not affect in any way the attachments of the stitches at the V-shaped structures. There was no teaching in the application as filed that would contradict to realise the stitches at the V-shaped structures of figures 8/9 the same way as in figures 16/17.

1.1.3 Thirdly, paragraph [0010] disclosed the invention namely: *"A bioprosthesis can be attached to the wires of this stent in certain, predetermined locations and preferably will be sewn to the wires in such a way that the material from which the bioprosthesis is made will not be damaged during compression and/or expansion of the stent and attached bioprosthesis"*. The invention lied in the at least two commissure extensions secured to the V-shaped structure of the stent with attachment material that is slideable to allow for free movement of the valve relative to the stent structure along its longitudinal axis. The skilled person would understand that this also applied to the embodiment of figures 8/9.

Furthermore the skilled reader was even explicitly taught in paragraph [0050] of the application as originally filed that the attachment systems described in subsequent paragraphs (which included paragraph [0056] directed to the embodiment of figures 16/17) could be used with the stent configurations described in the preceding paragraphs (which included paragraphs [0040] and [0041], and thus the embodiment of figures 8/9).

1.1.4 Summarising the above, even though the slidable attachment was not again recited in the context of the embodiment of figures 8/9, there was no teaching that

contradicted the presence of said feature in this embodiment, it was technically possible in this embodiment, the same beneficial effect would be achieved, and only in this interpretation would the embodiment of figures 8/9 be covered by any of the original claims.

1.2 The Board does not agree. Claim 1 is a combination of features from the embodiment of figures 8/9 and from the embodiment of figures 16/17 that could not be derived directly and unambiguously by the skilled person, using common general knowledge from the application as filed.

1.2.1 The Board notes that the slidable stitches along the V-shaped structures to allow for free movement of the valve relative to the stent structure along its longitudinal axis, defined in independent claim 1, is only explicitly disclosed in paragraph [0056] of the WO application relative to the embodiment of figures 16/17. In this embodiment both the scalloped openings and the commissure extensions are attached to the stent. The stitches are slidable along the V-shaped structures to minimise stress on the stitches when the stent expands.

The embodiment of figures 8/9 is designed differently, the commissure extensions of the bioprosthesis are stitched to the V-shaped structure while the scalloped openings are not stitched to the stent. The bioprosthesis 40 further includes material 48 that covers at least a portion of the inflow end 42 of the bioprosthesis. The material 48 extends over the edge or end of the bioprosthesis and into the interior tubular surface. The stent comprises a series of wires arranged in a generally tubular shape including multiple

diamond-shaped structures 52 at its inflow side to which the bioprosthesis is secured by suturing the covering material and/or tubing material in a zigzag pattern.

There is no direct and unambiguous disclosure in the application relative to the embodiment of figures 8/9 that the commissure extensions are secured to V-shaped structures of the stent *"with attachment material that is slideable along the V-shaped structure of the stent structure to allow free movement of the valve relative to the stent structure along its longitudinal axis"*.

1.2.2 Firstly there is no explicit disclosure in paragraph [0040] and [0041] relative to the embodiment of figures 8/9 of the above-mentioned functional feature.

1.2.3 Secondly paragraph [00010], under "summary" of the WO application, does not disclose that slidable attachment of the commissure extensions to the V-shaped structure is the solution to the problem to be solved as alleged by the appellant. Paragraph [00010] discloses that the attachments of the bioprosthesis should be made at predetermined locations and in such a way that the material of the bioprosthesis will not be damaged during compression and/or expansion of the stent. Paragraph [00010] then specifies that *"the stent includes three commissure attachment areas, where each of these areas is used as connection location for one of the commissure extensions of a bioprosthesis".* In view of paragraph [00010], the skilled person would not derive that all the embodiments described in the application use slidable stitches to attach the commissure extensions of the bioprosthesis to the stent.

1.2.4 Thirdly paragraph [0050] reads: *"A number of systems, components, and devices are described below for attachment of valve material (e.g., tissue leaflets) within the interior area of a stent structure. It is understood that the systems that are shown and described herein for this purpose can be used with stent configurations described above and/or other stent constructions".*
This paragraph is very broad and does not specify that the slidable attachment of the embodiment of figures 16/17 applies to the embodiment of figures 8/9. No indication is given as to which feature from which embodiment is to be used with other embodiments. Paragraph [00050] is, similar to paragraphs [0008] and [00060] of the application, a general statement that features of different embodiments can be combined. From these paragraphs the skilled person cannot derive any direct and unambiguous teaching.

1.2.5 Fourthly the question whether the skilled person would have an incentive to secure the commissure extension in a slidable manner to the stent structure of figures 8 and 9 is not a criterion for assessing added subject-matter. The criterion is whether the skilled person would derive the combination of features of claim 1 directly and unambiguously, using common general knowledge, from the whole of the documents as filed. While it may be possible technically to secure the commissure extensions to the V-shaped structure with attachment material that is slidable along the V-shaped structures to allow for a free movement of the valve relative to the stent structure along its longitudinal axis, there is not teaching to do so for the embodiment of figures 8/9. Furthermore, should the skilled person want to reduce damages of the bioprosthesis material

when the stent to which it is attached undergoes compression and/or expansion, various technical solutions exist such as for example attaching the valve to the stent in a loosen/slacking manner.

1.2.6 Fifthly there is no reason to assume that the claims of the application as filed cover all the embodiments of the invention. For example, an applicant may choose to disclose embodiments without any corresponding claim in the application as filed and file at a later stage a divisional application regarding these embodiments. Furthermore, it is not because an embodiment is disclosed as being "in accordance with the invention" that it is necessarily claimed.
The appellant makes reference to Rule 43(3) EPC. However, Rule 43(3) EPC deals with the form and content of the claims and does not support the assumption made by the appellant that the claims as originally filed cover all the embodiments disclosed in the application as filed.

1.2.7 To conclude there is no direct and unambiguous disclosure of the stitches being slidable along the V-shaped structures for the embodiment depicted on figures 8/9 (corresponding to paragraph [0040] and [0041]) and the skilled reader would not consider that slidable stitches disclosed with the embodiment of figures 16/17 would implicitly apply for the embodiment of figures 8/9.

2. First to seventh auxiliary requests - Added subject-matter - Article 123(2) EPC

The subject-matter of claim 1 of the first to the seventh auxiliary requests extends beyond the content of the application as filed for the same reasons as for

the main request and therefore does not fulfill the requirements of article 123(2) EPC.

Claim 1 of the first auxiliary request corresponds to claim 1 of the main request. As to claim 1 of the second to the seventh auxiliary requests, they all comprise additional features relating to the embodiment of figures 8/9 compared to claim 1 of the main request. However the features relating to the embodiment of figures 16/17 remains in claim 1, such that the subject-matter of claim 1 is a combination of two embodiments that was not disclosed in the application as filed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Vottner G. Pricolo

Decision electronically authenticated