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**Datasheet for the decision
of 17 March 2016**

Case Number: T 0442/14 - 3.2.08

Application Number: 08425200.6

Publication Number: 2105110

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

Valve prosthesis for implantation in body channels

Patent Proprietor:

Genomnia S.r.l.

Opponent:

Boston Scientific Corporation

Headword:

Relevant legal provisions:

EPC Art. 100(a), 56

Keyword:

Inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern
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Chambres de recours

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Case Number: T 0442/14 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 17 March 2016

Appellant: Boston Scientific Corporation
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 6 February 2014 rejecting the opposition filed against European patent No. 2105110 pursuant to Article 101(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. By its decision posted on 6 February 2014 the Opposition Division rejected the opposition against European patent EP-B-2105110.
- II. The Opposition Division held that the grounds of opposition under Article 100(c) and 100(a) in combination with Articles 54 and 56 EPC did not prejudice the maintenance of the patent as granted.
- III. The appellant (opponent) lodged an appeal against that decision in the prescribed form and within the prescribed time limits.
- IV. Oral proceedings before the Board of Appeal took place on 17 March 2016. For the course taken by the proceedings, in particular the issues discussed with the parties and the parties' initial requests, reference is made to the minutes of the oral proceedings.
- V. At the end of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that in setting aside the decision under appeal the patent be maintained in amended form on the basis of the set of claims filed as auxiliary request during the oral proceedings.

VI. Independent claims 1 and 13 of the request cited as "auxiliary request" - i.e. of the sole remaining request - read as follows:

Claim 1:

"Valve prosthesis (1; 40; 50; 60) comprising a stent (2) and a valve (3) arranged in said stent (2) and bound thereto in at least one pre-established zone (8) so that it can be deformed between a closed state in which said valve (3) is entirely spread out in the stent (2), thus blocking the passage of a body fluid, and an open state in which said valve (3), due to the pressure of said body fluid, is substantially collapsed on an inner wall of said stent (2), thus permitting the flow of said body fluid, whereby the valve is triangular, **characterized in that** the stent (2) comprises longitudinal rectilinear elements (2a) and crossed transverse elements (2b) having a zig zag extension, said stent being expandable from a compressed state to a state of maximum expansion, and the valve (3) is connected to the stent (2) in said pre-established zone (8) along the longitudinal rectilinear elements (2a) and to the transverse elements to form V-shaped junction lines, wherein said valve (3) has a monocusp sail-like form in its spread out state, with substantially triangular longitudinal section and with rounded corners."

Claim 13

"Method for making a valve prosthesis according to any one of the preceding claims, the method being **characterised in that** it comprises the steps of:
- providing a stent (2) of material expandable from a compressed state to a fully expanded state,
- making a valve (3) of biocompatible synthetic material or providing a biological material valve,

- coupling said valve (3) in at least one pre-established zone (8) of said stent in its fully expanded state so that the valve (3) can be deformed between a closed state in which said valve (3) is fully spread out in the stent (2), thus blocking the passage of a body fluid, and an open state in which said valve (3), due to the pressure of said body fluid, is substantially collapsed on an inner wall of said stent (2), thus permitting the flow of said body fluid, **characterized by** the fact that said valve is triangular, said stent (2) is made crossing longitudinal rectilinear elements (2a) and transverse elements (2b) having a zig zag extension, said stent being expandable from a compressed state to a state of maximum expansion, and the valve (3) is connected to the stent (2) in said pre-established zone (8) along the longitudinal rectilinear elements (2a) and to the transverse elements to form V-shaped junction lines, wherein said valve (3) has monocusp sail-like form in its spread out state, with substantially triangular longitudinal section and with rounded corners."

VII. The following documents are referred to in the present decision:

- D2: US-A-5,358,518;
- D5: US-A-7,267,686;
- D6: US-A-6,503,272;
- D7: US-A-2003/0209835.

VIII. The essential arguments of the appellant can be summarised as follows:

Inventive step

Document D2 was to be considered the closest prior art and disclosed a monocusp triangular valve bound to a cylindrical support with a mesh or weave. The mesh or weave structure implied longitudinal rectilinear elements with crossed transverse elements. As the transverse elements alternately ran above and below those rectilinear elements, they also had a zig zag extension. The subject-matter of claim 1 thus differed from the disclosure of D2 in that the stent was expandable from a compressed state to a state of maximum expansion, and in that the triangular valve had rounded corners. However, no technical effect could be attributed to the rounded corners. The feature was therefore to be disregarded when evaluating inventive step. In view of the remaining difference, the technical problem was therefore to improve the D2 valve so that it was easily implantable into a body lumen. In order to solve the above problem, the person skilled in the art would search for a radially expandable structure, which was known as providing an easy implantation and secure anchoring of a valve, and thus find documents D5, D6 and D7, all disclosing an expandable stent component with longitudinal rectilinear elements and crossed transverse elements having a zigzag extension. Even if the longitudinal rectilinear elements did not further extend to the other side of the respective transverse elements, the transverse elements were to be considered "crossed" in the sense of a T-type crossing. Applying the teaching of documents D5-D7 to the D2 valve prosthesis would in

an obvious way lead to valve prosthesis as claimed in claim 1.

The subject-matter of claim 1 was thus not inventive.

IX. The essential arguments of the respondent can be summarised as follows:

Inventive step

Although document D2 did not disclose a stent component having longitudinal rectilinear elements and crossed transverse elements having a zigzag extension, it could be considered as being the closest prior art. The weave or mesh was, however, only disclosed in Figure 4, which showed a rigid valve according to the second embodiment of D2, and it was moreover nothing more than a soft, pliable tissue without mechanical stability, which clearly did not qualify as a stent. The cylindrical support disclosed in D2 was furthermore not expandable and there was no indication that the valve was fixed along rectilinear elements and to transverse elements to form V-shaped junction lines. All these features cooperated to provide a reliable connection between the monocusp sail like valve and its expandable support, providing a good stop of fluid flow in one direction, while allowing an unrestricted flow in the opposite direction. In this context, documents D5 to D7 were not relevant because they related to a multi-cusp valve and not to a monocusp valve. Even if the person skilled in the art were to consult any of these documents, there was no teaching towards the claimed subject-matter. None of D5 - D7 disclosed a stent comprising longitudinal rectilinear elements and crossed transverse elements having a zig zag extension. There

was furthermore no indication how to connect the triangular monocusp valve to such a stent.

In conclusion, even if the disclosure of document D2 were to be combined with the teaching of documents D5 to D7, the person skilled in the art would not arrive at the subject-matter of claims 1 and 13, which thus involved an inventive step.

Reasons for the Decision

1. During the oral proceedings the appellant stated that they had no objections to admitting the new request into the proceedings, to the requirements pursuant to Articles 83, 84 and 123(2) EPC, and to novelty of the subject-matter of claim 1.

Also the Board saw no reasons to raise any of these issues *ex officio*.

As a consequence, the subject-matter under consideration during the appeal proceedings is limited to the appellant's objection under Article 100 (a) in combination with Article 56 EPC to the allowability of independent claims 1 and 13 according to the respondent's only request filed as auxiliary request during the oral proceedings before the Board.

2. Inventive step
 - 2.1 Document D2 represents the most relevant prior art. It is indeed the only document which discloses a monocusp valve.

2.2 Document D2 discloses:

Valve prosthesis (D2, Figures 1, 2 and column 1, line 60 to column 2, line 61) comprising a stent ("mesh or weave which is more or less tight, thin, with ring-shaped or spiral external reinforcements", column 1, lines 66 - 68) and a valve (Figures 1, 2, no. 3) arranged in said stent and bound thereto in at least one pre-established zone (column 2, line 43-45 and Figure 2) so that it can be deformed between a closed state in which said valve is entirely spread out in the stent (Figure 1B, 2B), thus blocking the passage of a body fluid, and an open state in which said valve, due to the pressure of said body fluid, is substantially collapsed on an inner wall of said stent (Figure 1A, 2A; see also column 2, lines 21-27), thus permitting the flow of said body fluid, whereby the valve is triangular, to form V-shaped junction lines (see Figures 1, 2), wherein said valve has a monocusp sail-like form in its spread out state, with substantially triangular longitudinal section.

The subject-matter of claim 1 differs from this prior art in that:

a) the stent comprises longitudinal rectilinear elements and crossed transverse elements having a zig zag extension, said stent being expandable from a compressed state to a state of maximum expansion, and the valve is connected to the stent in said pre-established zone along the longitudinal rectilinear elements and to the transverse elements,

and in that

b) the triangular valve is provided with rounded corners.

2.3 The appellant was of the opinion that the threads of the weave or mesh disclosed in column 1, line 63-68, would run in the longitudinal or transverse direction. According to them, the longitudinal threads qualified as longitudinal rectilinear elements whereas the transverse threads alternating above and below the longitudinal threads qualified as having zig zag extension.

However, firstly, there is no clear and unambiguous disclosure about the direction in which the threads of the mesh of the first embodiment shown in D2, Figures 1 and 2 extend. In this context, it has to be noted that Figure 4, which shows a mesh with longitudinally and transversally orientated threads, belongs to a different embodiment, which, however, has a rigid and not a collapsible valve.

Secondly, the term stent requires a certain mechanical stability, which the more or less tight, thin mesh or weave does not have. Hence, it needs to be reinforced with ring-shaped or spiral external reinforcements. The structure of the D2, Figure 1,2 embodiment which may be seen as falling under the term "stent" is thus the spiral reinforcement, which however neither has longitudinal rectilinear elements nor crossed transverse elements having zig zag extension.

Thirdly, the smooth alternating bends of e.g. a weft thread running above and below a warp thread do not

exhibit the relatively sharp turns associated with a zigzag pattern.

Therefore, the Board comes to the conclusion that - contrary to the appellant's view - document D2 does not disclose a stent comprising "longitudinal rectilinear elements and crossed transverse elements having a zig zag extension". This implies that the D2 valve is not connected to such zig zag transverse elements along longitudinal rectilinear elements either.

2.4 Feature a) allows the valve to be percutaneously implanted thus solving the problem of providing a valve that is easy to use, less invasive and capable of resisting the recoil forces of the destination blood vessels (see patent, paragraph [0015]).

2.4.1 It is true that documents D5-D7 disclose valves having stent components for percutaneous implantation being expandable from a compressed state to a state of maximum expansion. However - leaving aside the question whether their teaching relating to multi-cusp valves can be transferred to the mono-cusp valve of D2 - none of these documents disclose longitudinal rectilinear elements and crossed transverse elements having a zig zag extension.

D5, Figures 18-20 show short longitudinal rectilinear elements which join transverse elements with zig zag extension in a Y-type junction. Such a junction cannot, however, be interpreted as having "crossed transverse elements", for which one would expect the transverse elements to be indeed "crossed", i.e. one would expect the longitudinal rectilinear element to extend also on the other side of the "crossed transverse element".

It is true that - as put forward by the appellants - the English language knows "T-crossings". However, D5 shows "Y-junctions" and not "T-crossings".

In conclusion, the Y-junctions between rectilinear elements and transverse elements as shown in D5, Figures 18-20 do not qualify as "longitudinal rectilinear elements and crossed transverse elements having zig zag extension" in the sense of claims 1 and 13.

An analogous reasoning applies with respect to the Y- or inverse Y-junctions between longitudinal rectilinear elements and transverse elements shown in D7 (see the Figures).

With respect to D6, firstly, the inclined, short elements no. 114 (see e.g. Figure 4) hardly qualify as longitudinal elements at all, and, secondly - if they did - they also join the transverse elements having zig zag extension in a Y-type junction, there being thus no "crossed transverse elements having a zig zag extension".

Therefore, even the combination of the teaching of document D2 with the disclosure of documents D5 - D7 would not result in a valve prosthesis with feature a).

2.5 Consequently, the subject-matter of claims 1 and 13 involves an inventive step.

2.6 In view of the above analysis, it does not need to be considered whether feature b) can be derived from the prior art in an obvious manner or not.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division with the order to maintain the patent in amended form on the basis of the set of claims filed as auxiliary request during the oral proceedings and a description to be adapted.

The Registrar:

The Chairman:



C. Moser

I. Beckedorf

Decision electronically authenticated