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Datasheet for the decision of 5 February 2025

Case Number: T 1297/22 - 3.2.01

Application Number: 13735117.7

Publication Number: 2861186

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
REPLACEMENT HEART VALVE

Patent Proprietor:
Boston Scientific Scimed, Inc.

Opponents:
Medtronic Vascular, Inc.
Tendyne Holdings, Inc.

Headword:

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - (no)

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It can be changed at any time and without notice

Decisions cited:

Catchword:

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Case Number: T 1297/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 5 February 2025

Respondent: (Patent Proprietor)	Boston Scientific Scimed, Inc. One Scimed Place Maple Grove, MN 55311-1566 (US)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Straße 3 80331 München (DE)
Appellant: (Opponent 1)	Medtronic Vascular, Inc. 3576 Unocal Place Santa Rosa CA 95403 (US)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Appellant: (Opponent 2)	Tendyne Holdings, Inc. 2825 Fairview Avenue North Roseville, MN 55113 (US)
Representative:	LKGLOBAL Lorenz & Kopf Patentanwalt Attorney at Law PartG mbB Brienner Straße 11 80333 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 17 December 2021 concerning maintenance of the European Patent No. 2861186 in amended form.**

Composition of the Board:

Chairwoman	S. Mangin
Members:	M. Geisenhofer
	S. Fernández de Córdoba

Summary of Facts and Submissions

I. Appeals were filed by the patent proprietor and both opponents against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request 1 (as submitted during oral proceedings before the opposition division), European patent No. EP 2 861 186 met the requirements of the EPC.

II. Oral proceedings were held before the board.

(a) The patent proprietor withdrew its appeal, leaving only the two opponents as the appellants, with the patent proprietor as the respondent to their appeals.

(b) The appellants both requested that the decision under appeal be set aside and that the patent be revoked.

(c) The respondent requested that the appeals be dismissed (i.e. that the patent be maintained on the basis of auxiliary request 1, the request deemed allowable by the opposition division), or, in the alternative, that the patent be maintained in amended form based on one of auxiliary requests 2 - 6 as filed on 19 October 2022, or based on one of auxiliary requests 1a - 6a as filed on 19 December 2024.

III. Independent claim 1 of auxiliary request 1 reads as follows:

"*A replacement heart valve assembly (10) comprising:*

a stent frame (12);
a replacement valve (14), the replacement valve having a plurality of leaflets (20) and a valve frame (22), the valve leaflets attached to the valve frame (22);
a plurality of suspension struts (18) attached to the stent frame (12) and the valve frame (22), wherein the valve frame (22) is suspended within the stent frame (12) via the suspension struts (18); and
a sealing member (24), the sealing member (24) attached to the stent frame (12);
characterized in that the replacement heart valve assembly (10) has a deployed configuration, wherein, in the deployed configuration, the stent frame (12) is elliptical and the valve frame (22) is circular."

Compared with claim 1 of auxiliary request 1, independent claim 1 of auxiliary request 2 additionally requires the valve leaflets to be attached to the valve frame "*by sutures*".

Compared with claim 1 of auxiliary request 1, independent claim 1 of auxiliary request 3 contains the additional feature "*wherein the leaflets are all the same shape*", while independent claim 1 of auxiliary request 4 contains the additional feature "*wherein at least a portion of the sealing member (24) is disposed exteriorly to the stent frame (12)*".

Compared with claim 1 of auxiliary request 1, independent claim 1 of auxiliary request 5 contains the additional feature "*wherein the suspension struts (18) extend radially inwardly from the stent frame (12)*", and independent claim 1 of auxiliary request 6 contains the additional feature "*wherein the suspension struts (18) are configured to deform upon deployment of the stent frame (12) and replacement valve (14) to*

allow the stent frame (12) to take on an elliptical configuration, and match the native valve geometry".

Auxiliary requests 1a - 3a and 6a differ from auxiliary requests 1 - 3 and 6 only in that dependent claims 6 - 15 have been deleted.

In auxiliary request 4a, dependent claims 5 - 14 have been deleted (compared with auxiliary request 4), and in auxiliary request 5a, dependent claims 4 and 6 - 15 have been deleted (compared with auxiliary request 5).

IV. The appellants' arguments, where relevant for the present decision, can be summarised as follows.

The patent in suit did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person for the following reasons.

(a) The geometry of the stent frame in its deployed state depended on the shape of the native-valve opening in which it was installed. An elliptically-shaped stent frame could only be achieved when implanted in particular native valves (e.g. bicuspid aortic valves).

(b) Due to the difference in geometry of the stent frame and the valve frame, a resulting gap between the two frames provided an opening through which blood might leak around the replacement valve. The patent did not provide information on how this gap could be sealed.

V. The respondent's arguments, where relevant for the present decision, can be summarised as follows.

(a) The claimed replacement valve could be used for any heart valve and not just for bicuspid aortic valves since the stent frame could adopt to any geometry.

(b) The skilled person knew from their common general knowledge that any gap apart from the lumen of the replacement valve must be sealed and they were familiar with how to seal such gaps.

Reasons for the Decision

1. The patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person (Article 83 EPC).

1.1 The appellants argued that an elliptically-shaped stent frame in its deployed state could only be achieved when the replacement heart valve assembly was used with an elliptically-shaped opening. This was only the case for bicuspid aortic valves; not for all heart valves. Thus, the claimed replacement heart valve assembly could only be used in very limited situations, but not over the entire scope of the claim.

1.1.1 The opposition division held that the use of the claimed heart valve assembly was not restricted to particular types of heart valve, in particular not to bicuspid aortic valves. On the contrary, paragraph [0004] of the description referred in a general manner to bicuspid valves or bicuspid-like valves, while paragraph [0002] referred even more generally to any valve (section 4.2 of the Reasons for the decision).

1.1.2 During the oral proceedings before the board, the respondent explained that the stent frame would adapt to the native-valve opening in which it was installed. Regardless of its initial geometry in an unrestricted configuration (whether circular or elliptical), in its deployed configuration the stent frame would conform to the geometry of the opening in which it was installed.

1.1.3 The board notes that claim 1 is directed to a replacement heart valve assembly as such and not to the use of such a replacement heart valve assembly or a method of installing one. Claim 1 requires that "*the replacement heart valve assembly has a deployed configuration, wherein, in the deployed configuration, the stent frame is elliptical*".

1.1.4 The patent in suit does not teach how the stent frame of the replacement heart valve assembly of claim 1 can be elliptical in its deployed configuration with any type of heart valve.

(a) If the claimed replacement heart valve assembly is implanted in a native valve having an approximately circular opening (such as a mitral valve), the stent frame will not be elliptical when deployed. Instead, it will be approximately circular as it adapts - as explained by the respondent - to the opening's shape. The same applies to other shapes of native-valve openings, such as a kidney shape, where the stent frame in its deployed configuration will conform to the kidney shape of the opening.

(b) Thus, the patent does not provide sufficient information on how to design the replacement heart valve assembly such that the deployed stent frame will be elliptical with openings of any geometry,

in particular with non-elliptical openings. The patent does not teach how to achieve a stent frame which will always have an elliptical shape in its deployed configuration. The invention therefore cannot be carried out over the whole scope of claim 1.

1.1.5 The respondent argued that the patent in suit disclosed in paragraph [0003] a particular use of the claimed replacement heart valve assembly for bicuspid aortic valves. These valves had an elliptical shape, and therefore at least one way of carrying out the invention was disclosed, which is usually sufficient for inventions in the field of mechanics.

(a) It is not disputed that the patent provides sufficient information for using a replacement heart valve in an elliptically-shaped opening such that the stent frame adopts an elliptical shape when deployed.

(b) However, it is disputed that the replacement heart valve assembly can be inserted and installed into a non-elliptically shaped opening of a native valve with the stent frame being elliptical in its deployed state.

1.1.6 The respondent further alleged that the skilled person knows how to design a stent frame to fit into any kind of native valve, and therefore the application of the claimed valve is not restricted to bicuspid aortic valves.

(a) It is not disputed that the skilled person is aware of techniques for installing a replacement heart

valve assembly within another type of valve (e.g. within a mitral valve).

(b) However, it is disputed that installing a replacement heart valve assembly according to the invention within another type of native valve will inevitably result in a stent frame of the assembly being elliptical, as required by the invention. According to the explanations of the respondent given during the oral proceedings before the board, the stent frame will in any case adapt its geometry to the shape of the opening such that installing the claimed valve within a mitral valve will not necessarily result in a stent frame being elliptical.

1.1.7 Since the invention is not restricted to the use of the claimed replacement heart valve assembly in elliptically-shaped native valves, the subject-matter of claim 1 cannot be carried out over its entire scope and therefore it does not comply with the requirements of Article 83 EPC.

1.2 The appellants further alleged that the patent did not teach the skilled person how to seal the inevitable gap between the elliptical stent frame and the circular valve frame.

1.2.1 The respondent argued that the patent did not mention a gap between the stent frame and the valve frame.

(a) When a circle is inscribed within an ellipse, there will always be a gap on the longer axis of the ellipse.

(b) Furthermore, the inventive concept provides an inner valve frame that is not influenced by the deformation of the exterior stent frame when deploying the replacement heart valve assembly. This is achieved by the inner valve frame being suspended within the outer stent frame via suspension struts, which requires a gap between the two frames, preventing the deformation of the outer stent frame being transferred to the inner valve frame.

(c) The board therefore does not share the respondent's view. Rather, it is convinced that the design of the replacement heart valve assembly results in a gap between the two frames, even though the patent does not mention such a gap.

1.2.2 The respondent further alleged that the skilled person would know that any gap between the valve and the surrounding native tissue needed to be sealed and that they were familiar with suitable sealing means.

(a) It was undisputed between the parties that the skilled person was aware of the general principle that any gap allowing paravalvular leakage must be sealed. However, the appellants argued that the skilled person was not taught by the patent in suit how to seal this particular gap, and this could not form part of the skilled person's common general knowledge either since a circular valve frame suspended within an elliptical stent frame was not known in the prior art.

(b) The patent in suit referred in paragraph [0025] to a sealing member. This sealing member was, in particular, disposed exteriorly to the stent frame

to prevent leakage of blood around the stent frame as shown in the only embodiment falling under the invention and as shown in Figure 3. This sealing member was neither intended nor suitable for sealing the gap between the two frames.

(c) In the board's view, no sealing member is suitable for bridging the gap between the two frames.

Firstly, the gap has a non-uniform width, and therefore the sealing member would have to have an unusual geometry to avoid wrinkling of the sealing tissue.

Secondly, the gap is required to allow relative movement between the stent frame and the valve frame, whereby the stent frame is to be decoupled from the valve frame, i.e. a deformation of the stent frame is not to be transferred to the valve frame. The sealing member must therefore be chosen such that no forces are transmitted from the stent frame to the valve frame.

(d) These additional requirements exceed the common general knowledge of the skilled person and therefore a particular teaching in the patent would be needed on how to provide a sealing member bridging an irregularly-shaped gap for the valve frame's geometry as shown in Figure 3 such that no forces are transmitted from the stent frame to the valve frame upon installation. The prior art does not provide such a teaching applicable to the above three particular conditions either.

1.2.3 Thus, the patent does not contain any teaching as to how the skilled person should seal the gap between the

stent frame and the suspended valve frame, and this is not part of common general knowledge either. For this reason, the skilled person is not able to put the invention into practice, contrary to Article 83 EPC.

2. This deficiency also applies to all of the auxiliary requests as confirmed by the respondent during the oral proceedings before the board.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar: The Chairwoman:

H. Jenney S. Mangin

Decision electronically authenticated