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Datasheet for the decision of 23 February 2024

Case Number: T 1026/21 - 3.2.01

Application Number: 09799771.2

Publication Number: 2379322

IPC: B32B15/00, A61F2/04

Language of the proceedings: EN

Title of invention:
SYNTHETIC COMPOSITE STRUCTURES

Patent Proprietor:
Boston Scientific Limited

Opponent:
Edwards Lifesciences Corporation

Headword:

Relevant legal provisions:
EPC Art. 100(b)

Keyword:
Grounds for opposition - insufficiency of disclosure (no)

Decisions cited:

Catchword:

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Case Number: T 1026/21 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 23 February 2024

Appellant: (Patent Proprietor)	Boston Scientific Limited Clarendon House 2 Church Street Hamilton HM11 (BM)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Straße 3 80331 München (DE)
Respondent: (Opponent)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
Representative:	Somerville, Andrew Edward Somerville Associates Dunston Innovation Centre Dunston Road Chesterfield S41 8NG (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 May 2021 revoking European patent No. 2379322 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	G. Pricolo
Members:	M. Geisenhofer
	P. Guntz

Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke the European patent EP 2 379 322.

II. The opposition division held that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and revoked the patent.

III. At the oral proceedings held before the Board,

- the appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request), in the alternative that the patent be maintained in amended form either based on one of auxiliary requests 1 or 2 as filed during the oral proceedings before the opposition division, or on one of auxiliary requests 3 - 17 as filed on 8 January 2021 before that oral proceedings in the opposition procedure;

- the respondent (opponent) requested that the appeal be dismissed.

IV. Independent claim 1 according to the **main request** (patent as granted) reads as follows:

"*A valve frame (1078), comprising:*
a first frame member (1077) including a leaflet connection region (1086), where a distal end (179) of the first frame member (1077) defines a distal cross-sectional area and a proximal end (1081) of the first

frame member (1077) defines a proximal cross-sectional area larger than the distal cross-sectional area;
a second frame member (1083) having a distal end (1085) connected to the proximal end (1081) of the first frame member (1077), where the distal end (1085) of the second frame member (1083) and the proximal end (1081) of the first frame member (I 077) define a circular proximal cross-sectional area; and
a third frame member (1087) connected to a middle portion (1089) of the first frame member (1077), where a proximal end (1091) of the third frame member (1087) defines a circular proximal cross-sectional area approximately equal to the circular proximal cross-sectional area defined by the distal end (1085) of the second frame member (1083) and the proximal end (1081) of the first frame member (1077)."

V. The appellant's arguments can be summarized as follows:

Figure 10 shows one way of carrying out the frame such that the invention according to the main request is disclosed in a manner sufficiently clear and complete for a skilled person to carry it out.

VI. The respondent's arguments can be summarized as follows:

The frame shown in figure 10 cannot be installed within a body lumen such that it falls under the definition given in claim 1, taking into account paragraph [0084] of the description.

Reasons for the Decision

1. The patent as granted (main request) discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

1.1 The opposition division decided that the patent as granted lacked information on how to carry out the invention since it was impossible to configure a valve such that, when inserted in the body, a relative size of different cross sectional areas present in the frame was maintained in the body. The claim in fact defined a valve with three frame members defining circular cross-sections following particular relationships, and the definition of these cross-sectional areas was provided by paragraph [0091] of the patent, specifying that the cross-sectional areas referred to the general shape of the body lumen formed once the valve was implanted. Shown in figure 10 was the only embodiment that allegedly achieved the claimed results, but it was not possible to determine from figure 10 any spatial relationship between the frames. (see reasons 19.1, in particular paragraph bridging pages 9 and 10).

1.2 The Board does not agree. As pointed out by the appellant, claim 1 is directed to a frame as such and does not make any reference to the anatomy. Accordingly, the Board takes the view that the features of the claim may well be read as referring to the frame in an uninstalled state.

Figure 10 discloses a suitable geometry for this frame: This frame has three frame members, each consisting of interconnected struts forming a zig-zag pattern. These struts are arranged on respective imaginary cylinders

having a distal end and a proximal end, these cylinders hence each defining, respectively, a "distal cross-sectional area" and a "proximal cross-sectional area" which can be compared.

It can further be derived from the description of figure 10 starting in paragraph [0084] that

- the proximal cross-sectional area of the first frame member is greater than its distal cross-sectional area (second half of paragraph [0089]);
- the distal cross-sectional areas of first and second frame members are identical; and
- the distal cross-sectional area of the second frame member equals the proximal cross-sectional area of the third frame member (second half of paragraph [0092]).

The patent as granted hence contains at least one way to carry out the invention.

1.3 The respondent argued that the skilled person was unable to derive cross-sectional areas for the first frame member since one could only identify two points at each end (see red circles in the figure provided in the respondent's reply to the statement of grounds of appeal on page 2) forming part of the unknown cross-section. However, two points did not allow to inscribe an imaginary circle determining a cross-sectional area.

1.3.1 The Board disagrees. The frame members shown in figure 10 are three-dimensional structures such that not only the bends of the first frame member can be used to define an inscribed circle representing the cross-sectional area but the three-dimensional structure allows to determine a corresponding imaginary cylinder on which the curved, longitudinal struts of the frame

member are arranged. The sections of this imaginary cylinder at the ends of the first frame member correspond to the distal and proximal cross-sectional areas referred to in claim 1.

1.3.2 Furthermore, the frame shown in figure 10 is arranged symmetrically around a longitudinal axis whereby the centre line of the imaginary cylinder of the first frame member corresponds to this longitudinal axis. As soon as the skilled person determines this central longitudinal axis, one single point is sufficient to define the imaginary cylinder, the distance between the central longitudinal axis and that point corresponding to the radius of the imaginary cylinder.

1.3.3 The skilled person hence has no difficulty to determine a respective imaginary cylinder for the first frame member (and also for the other two frame members) such that it is possible to measure the cross-sectional areas at the respective ends of each frame member and compare these areas.

1.4 The respondent further argued, as did the opposition division, that the various cross-sectional areas were addressed in paragraph [0091], however referring to the installed state ("*implanted at a treatment site*") and not to the state in air, i.e. in the relaxed configuration. The frame of figure 10 implanted in a body lumen, however, would follow an irregular shape and not a perfect circle such that the frame could not have the circular cross-sectional areas required by claim 1. Furthermore, it would be deformed irregularly such that the relationships of the various areas of the different frame members no longer applied.

1.4.1 As already stated above, claim 1 does not refer to the frame in installed state but defines the frame as such. Figure 10 discloses the frame in air such that this embodiment provides disclosure for a way to carry out the frame according to the invention.

1.4.2 However, even under the assumption that claim 1 refers to, or encompasses, the installed state of the frame, the Board does not follow the respondent's argument.

(a) The frame shown in figure 10 can be used as a replacement for a venous valve (see paragraph [0084]). Most veins (e. g. a leg vein such as the femoral vein) have cross-sections that are essentially circular over a significant part of their extension, at least over a length having a longitudinal extension being greater than the length of the frame of figure 10.

(b) When the frame of figure 10 is hence installed in such a part of the venous system, the installed frame will adapt to the surrounding tissue but will still have a shape similar to the shape in air. Since the frame has a substantially cylindrical shape in air and it is installed within a circular vein, the Board fails to see why the installed frame would not have cross-sections with a circular shape anymore.

(c) The frame has a comparatively short extension in longitudinal direction such that it is also likely that the elasticity of the surrounding tissue is not that inhomogeneous such that a relative relationship between areas defined by the frame members in air is substantially different as compared to their installed state, but areas with

larger cross-section will remain areas with larger cross-section also after installation.

1.4.3 The respondent argued that paragraph [0084] also referred to using the frame as replacement for an aortic valve. The annulus of the aortic valve, however, was neither circular, nor homogenous in longitudinal direction such that the frame of claim 1 installed within the annulus of an aortic valve had no longer a circular cross-sectional area and the cross-sectional areas at the different ends of the frame members would no longer comply with the relationships given in claim 1. The skilled person hence was not able to carry out the invention over the whole breadth of the claim (any possible use) but only over a part of it (use as replacement for a venous valve).

(a) The Board does not agree. Claim 1 does not refer to a particular use but leaves it open where the frame is intended to be installed. Thus the claim does not specifically requires the frame to be suitable for a specific placement in a non-circular annulus.

(b) Moreover, the skilled person would exclude embodiments that do not make technical sense, such as frames that would excessively modify the anatomy of the body if they were to provide circular cross-sections.

1.4.4 The respondent finally argued that the frame shown in figure 10 contacted the body lumen only in six points such that its shape, if any, would be hexagonal but not circular.

(a) As set out above, the Board is convinced that the frame does not only provide for punctual contact

with the surrounding tissue at the bends of the frame members but also provides for contact along the entire length of the struts. The body lumen will hence not assume the form of a hexagon but will take an approximately circular form as set out in paragraph [0091].

(b) The skilled person is aware that the term "circular" in the field of medical implants does usually not refer to a perfect circle (as argued by the respondent) but is to be considered as an approximation. The skilled person, however, can distinguish a circular and hence rotationally symmetric shape from an oval or elliptical shape being not rotationally symmetric.

2. In view of the above, the ground for opposition under Article 100(b) EPC is not prejudicial to the maintenance of the patent and therefore the opposition division's decision has to be set aside.

3. The contested decision dealing only with the ground of opposition under Article 100(b) EPC and not with the other grounds of opposition, and considering that both parties requested a remittal, the Board takes the view that there are special reasons in the sense of Article 11 RPBA (see Case Law of the Boards of Appeal, 10th edition, chapter V-A-9.3.2) justifying the remittal of the case to the opposition division for further prosecution.

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 for further prosecution.

The Registrar: The Chairman:

A. Voyé G. Pricolo

Decision electronically authenticated