Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 21 July 2023

Case Number: T 1173/22 - 3.2.01

Application Number: 17206130.1

Publication Number: 3311779

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
STENTS, VALVED-STENTS AND METHODS AND SYSTEMS FOR DELIVERY THEREOF

Applicant:
Boston Scientific Medical Device Limited

Headword:

Relevant legal provisions:
EPC Art. 84, 123(2)
RPBA 2020 Art. 11

Keyword:
Claims - clarity - main request (yes) - functional features (yes)
Amendments - allowable (yes)
Remittal - special reasons for remittal - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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 1173/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 21 July 2023

Appellant: (Applicant)	Boston Scientific Medical Device Limited Ballybrit Business Park Galway (IE)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Straße 3 80331 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 3 November 2021 refusing European patent application No. 17206130.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Geisenhofer
Members:	A. Wagner
	S. Fernández de Córdoba

Summary of Facts and Submissions

I. The appeal was filed by the applicant against the decision of the examining division to refuse the European patent application No. 17206130.1 pursuant to Article 97(2) EPC.

II. In the decision under appeal the examining division held that the main request as well as auxiliary requests 1 to 5, all requests filed on 16 September 2021, contravene the requirements of Article 84 EPC.

III. With the statement of the grounds of appeal the appellant requested to set aside the decision under appeal and to grant a European patent on the basis of the main request, or as an auxiliary measure, to grant a patent on the basis of one of the auxiliary request 1 to 5, all requests as underlying the impugned decision.

IV. After a telephone conversation with the rapporteur of the Board, the appellant submitted a letter dated 11 July 2023, wherein auxiliary request 3 was made the main request and remittal to the first instance was requested in case the Board holds the new main request allowable under Article 84 EPC and Article 123(2) EPC. With the same letter, the former main request and former auxiliary requests 1 and 2 were withdrawn and former auxiliary requests 4 and 5 were renumbered to auxiliary requests 1 and 2.

V. In this decision reference is made to the following documents:

D1: US 2007/213813 A

D2: US 2004/106976 A
D3: WO 2007/054015
D3': US 2008/275540 (family member of D3, used as translation of D3 which is drafted in Chinese)
D7: WO 2004/008941 A2
D8: WO 94/02101
D9: US 2002/169359 A1
D10: US 3,843,974

VI. Claim 1 of the main request reads as follows. The feature numbering is added by the Board, deletions made in claim 1 as originally filed being indicated by the Board in strikethrough and additions made underlined.

1. A replacement valve for use within a human body comprising:

1.1 a valve component comprising mammal pericardium tissue

1.2 a stent component (100) for housing the valve component, and

1.3 an inner fabric skirt (122) covering at least a portion of an outer surface of the valve component,
1.3.1 wherein the inner fabric skirt serves as a sealing member between the stent component and the valve component,
1.3.2 wherein the inner fabric skirt (122) covers between 50% and 90% of the stent,

1.4 an outer fabric skirt (126) covering an outer surface of the stent component,

1.4.1 wherein the outer fabric skirt serves as a sealing member between the stent component and the

native valve, wherein ~~characterized in that~~

1.5.1 the topology of the inner surface of the inner fabric skirt is configured to improve blood flow and
1.5.2 the topology of the outer surface of the outer fabric skirt is configured to improve endothelialization,

1.6 wherein the inner and outer fabric skirt (122, 126) form a double fabric skirt which covers the inflow edge of the stent component (100).

Reasons for the Decision

1. **Article 123(2) EPC**

1.1 The amendments made to the main request do not introduce added subject-matter with regard to the application as originally filed. The references in the following paragraphs refer to the publication EP 3 311 779 A1 of the originally filed application documents.

1.1.1 The amendment made in feature 1.1 is based on claim 11 and paragraph [0026] of the A1-publication of the application as originally filed.

1.1.2 The specification in features 1.3 and 1.4 that the inner and outer skirts are fabric skirts is based on original claim 6.

1.1.3 Paragraph [0049] of the above mentioned A1-publication provides basis for features 1.3.1 and 1.4.1, original claim 7 for feature 1.3.2.

1.1.4 Feature 1.6 is literally disclosed in original claim 7.

1.2 The new main request overcomes the objection under Article 123(2) EPC raised by the examining division in the summons to oral proceedings (point 4). The objection was based on the omission of feature 1.5.1 which was part of original claim 1, omitted during examining proceedings and reintroduced in claim 1 of the main request on file.

2. **Article 84 EPC**

2.1 Claim 1 of the main request meets the requirements of Article 84 EPC.

2.2 The examining division revoked the patent application on the basis of Article 84 EPC, as feature 1.5.2 "*topology [...] configured to improve endothelialization*" was considered not clear. In particular it was not clear which topology the surface of the skirt should have to improve endothelialization and how much the endothelialization should be improved (see grounds for the decision, paragraph 10).

2.3 However, the Board agrees with the appellant (applicant) that feature 1.5.2 is clear in the context of a surface of a fabric used for the skirt of a replacement heart valve.

As argued by the appellant, the surface topology can be roughened for improving endothelialization of implants. As an example only, a coarse textile or a textile with a structured surface can be chosen for the fabric to provide a rough surface which promotes formation of scar tissue.

2.4 This is part of the general knowledge of a skilled person in the field of replacement heart valves which is reflected by several prior art documents cited in the procedure:

2.4.1 Document D2 cited in the search report of the application in suit describes in paragraph [0021] that "*The graft is preferably a biocompatible, fatigue-resistant membrane which is capable of endothelialization, and is attached to the stent body member on at least portions of either or both the lumenal and ablumenal surfaces of the stent body member by suturing to or encapsulating stent struts.*"

D2 does not further elaborate on the capability of endothelialization and hence obviously assumes that the skilled person is able to choose a respective material and to decide if a material is capable of endothelialization or not.

2.4.2 Additionally D1 mentions in paragraph [0028] that for an occluder a "*second material may be coarser than the first material. This may facilitate the formation of scar tissue on the outer portion and speed the heeling process*." No further details are given as it is clear for the skilled person what is meant with "coarser" having in mind the materials commonly used.

2.4.3 Furthermore, as disclosed in documents D7 to D10 filed by the applicant during examination proceedings (see D7, page 18, lines 21-24; D8, page 10, lines 25-27; D9, paragraph [0154]; D10, col. 1, lines 16-32), a woven structure of a fabric skirt or a porous material in general has a surface with a topology that is configured to improve endothelialization.

2.4.4 Therefore, even if feature 1.5.2 is defined in a broad sense, the skilled person has the technical knowledge to identify those surface topologies of a fabric skirt which are configured for improving endothelialization and which are not.

2.5 Feature 1.5.1 "*wherein the topology of the inner surface of the inner fabric skirt is configured to improve blood flow*", is likewise clear for a skilled person. The capability of improved blood flow is opposite to that of endothelialization, i. e. the surface of the fabric is designed to be as smooth as possible. This prevents tissue from growing on the surface.

2.5.1 Support for this conclusion can be found in D3 (D3'). In D3, e.g. figure 1, an inner and outer skirt is provided as "*synthetic sealing membranes 351, 354*" (D3', paragraph [0143]). In D3', paragraph [0144], it is stated that "*elastic synthetic materials, packed on the metal stented line, prevent vascular epithelial unit growing on the metal line, leading to the separation valve from vascular wall for removal once more*". As in D1 or D2, D3' does not further elaborate thereon.

2.5.2 Consequently, for skirts in replacement valves, the skilled person is aware of the materials which have a surface topology that is configured to prevent endothelialization and thus to improve blood flow.

3. Article 11 RPBA 2020

3.1 As requested by the appellant (applicant), the Board remits the case for further prosecution.

3.2 The impugned examining division's decision did not deal with the requirements of Article 52(1) EPC. Furthermore it is not apparent if the examining division found the requirements of Article 76(1) EPC to be met, the present application being a divisional application (originally filed parent application is published as WO 2009/053497 A1).

3.3 Under these circumstances, the Board considers that there are special reasons in the sense of Article 11, first sentence, RPBA 2020 for remitting the case to the examining division.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

A. Voyé M. Geisenhofer

Decision electronically authenticated