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**Datasheet for the decision
of 3 December 2021**

Case Number: T 1039/16 - 3.2.08

Application Number: 11703346.4

Publication Number: 2531141

IPC: A61F2/12

Language of the proceedings: EN

Title of invention:

INFLATABLE PROSTHESES AND METHODS OF MAKING SAME

Applicant:

ALLERGAN, INC.

Headword:

Relevant legal provisions:

EPC Art. 82, 123(2), 56

Keyword:

Unity of invention - (no)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

Catchword:



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 1039/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 3 December 2021

Appellant: ALLERGAN, INC.
(Applicant) 2525 Dupont Drive
Irvine, CA 92612 (US)

Representative: Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 10 December
2015 refusing European patent application No.
11703346.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: A. Björklund
Y. Podbielski

Summary of Facts and Submissions

- I. The appeal was filed by the applicant (appellant) against the decision of the examining division to refuse the patent application in suit (hereinafter "the application").
- II. The examining division decided that claim 1 of the request on file did not fulfil the requirements of Article 84 EPC since it did not comprise all the features which were essential to the definition of the invention.
- III. With letter dated 15 November 2021 the appellant requests that the decision under appeal be set aside and that a patent be granted as a main request on the basis of claims 1 to 15 filed upon entry into the regional phase before the EPO or alternatively on the basis of the first auxiliary request filed with this letter.

No further request is relevant to the decision.

- IV. The independent claims of the main request read as follows:

Claim 1:

"A method of making an inflatable device suitable for implantation in a mammal, the method comprising:
providing a mesh (40);
positioning the mesh (40) on a curved molding surface;
applying a fluid elastomeric material to the molding surface with the mesh (40) positioned thereon;

allowing the elastomeric material to set to form a flexible shell having an open end, the shell including the mesh (40) embedded within the set elastomer (36, 38), and the shell being useful as a component of an inflatable prosthesis(10; 310); and providing a puncture resistant member and sealing the puncture resistant member to the open end of the elastomeric shell to form an inflatable prosthesis (10; 310) having a self-sealing anterior portion (12; 312) and a puncture resistant posterior portion (34)."

Claim 7:

"An inflatable prosthesis (10; 310) comprising: a self-sealing inflatable anterior portion (12; 312) comprising a silicone-based elastomer material (36, 38) and defining a fillable cavity (28; 312a); and a posterior portion (34) substantially opposing the anterior portion (12; 312) and comprising a needle guard assembly (50; 314) including a first composite guard (64; 316) and a second composite guard (66; 318), each composite guard including an arrangement of puncture resistant members (68; 330) and a flexible substrate (62; 332) having a first side on which the puncture resistant members (68; 330) are disposed in a spaced apart fashion, the first composite guard (64; 316) and the second composite guard (66; 318) being positioned such that the arrangement of puncture resistant members (68; 330) of the second composite guard (66; 318) are misaligned with the arrangement of puncture resistant members (68; 330) of the first composite guard (64; 316), and an intermediate layer (26; 324) disposed between and connecting the first composite guard (64; 316) with the second composite guard (66; 318)."

Passages in bold are relevant for the assessment of lack of unity (see point 1 below).

The first auxiliary request comprises only one independent claim which reads as follows:

"A method of making an inflatable prosthesis device suitable for implantation in a mammal, the method comprising:
providing a mesh (40);
positioning the mesh (40) on a curved molding surface;
applying a fluid elastomeric material to the molding surface with the mesh (40) positioned thereon;
allowing the elastomeric material to set to form a flexible shell having an open end, the shell including the mesh (40) embedded within the set elastomer (36, 38), and the shell being useful as a component of an inflatable prosthesis (10; 310); and providing a puncture resistant member and sealing the puncture resistant member to the open end of the elastomeric shell to form an inflatable prosthesis (10; 310) having a self-sealing anterior portion (12; 312) and a puncture resistant posterior portion (34)."

The differences with respect to claim 1 of the main request is underlined.

V. The following documents are relevant for the decision:

- D1 US 5,133,753 A
- D2 US 4,190,040 A
- D3 US 4,428,364 A
- D4 US 4,650,487 A
- D5 US 2009/0099538 A1

- VI. With its communication of 21 October 2020, the Board raised an objection of lack of unity with respect to the main request.
- VII. The appellant filed a new first auxiliary request addressing the objection of lack of unity with letter of 12 March 2021. No arguments regarding the objection of lack of unity were put forward.
- VIII. In a telephone call on 4 November 2021, the Board raised an objection of lack of clarity in claim 1 of the first auxiliary request, due to an inconsistent wording. The claim defined a method of making an inflatable device but then specified that an inflatable prosthesis was formed.
- IX. With letter of 15 November 2021, the appellant filed an amended first auxiliary request addressing the lack of clarity.
- X. The appellant's arguments, as far as relevant to the decision, are essentially the following:

Main request - Article 82 EPC

In the appeal proceedings the appellant did not put forward any arguments regarding the unity of invention of the main request.

First auxiliary request - Article 84 EPC

The amendment made to claim 1 of the first auxiliary request overcame the objection raised by the Board.

First auxiliary request - Articles 54 and 56 EPC

D1 failed to disclose the method step of sealing the puncture resistant member to an open end of an elastomeric shell to form an inflatable prosthesis.

This feature allowed for a particularly efficient and reliable way of providing a prosthesis that has (any) puncture resistant properties.

Furthermore, none of the other documents on file (D2 to D5) disclosed this step.

Reasons for the Decision

1. Main request - Article 82 EPC

The appellant has not put forward any arguments in reply to the objection of lack of unity raised by the Board in its communication of 21 October 2020.

1.1 The features of claims 1 and claims 7 marked in bold are seen as corresponding features of the method of making an inflatable device for implantation of claim 1 and the inflatable prosthesis of claim 7.

At least said corresponding features (highlighted in bold) are disclosed in D1, see e.g. Fig. 11. In D1, the self sealing anterior portion of the shell 12 is shown as being penetrated by the needle 28, and comprises a polydimethylsiloxane (silicone) layer which is self sealing and embedding a mesh 26, see column 4, lines 38 to 56. It is made by applying the elastomer to a mandrel (molding surface) in several layers to embed a mesh, column 4, line 62 to column 5, line 55. Finally, a

needle stop member 40 is positioned inside the shell 12 in a posterior portion substantially opposing the anterior portion (column 6, lines 44-51).

Furthermore, in point 4.1 of the grounds of appeal the appellant acknowledges that the subject-matter of claim 1 differs from the method disclosed in D1 in the method step of sealing the puncture resistant member to the open end of the elastomeric shell to form an inflatable prosthesis.

- 1.2 The features of method claim 1 (the sealing of the puncture resistant member to the open end of the elastomeric shell) and product claim 7 (the features not in bold further defining the needle guard assembly) which define a contribution over the prior art in D1 are special technical features in the sense of Rule 44(1) EPC.

The problem solved by the special technical features of claim 1, i.e. the method step of the sealing of the puncture resistant member to the open end of the elastomeric shell can be considered as the provision of a more efficient method of making a prosthesis that has puncture resistant properties.

The first and second composite guard arrangement defined in claim 7 solves a different technical problem, namely providing an implant which can be readily folded or rolled up, see page 23, penultimate sentence of the published application.

Since the special technical features of claims 1 and 7 address different technical problems, they are not the same or corresponding special technical features in the sense of Rule 44(1) EPC. It follows that the

requirements of unity of invention under Article 82 EPC are not met.

1.3 The main request is thus not allowable.

2. First auxiliary request - Article 123(2) EPC

Claim 1 of the new auxiliary request 1 is based on the combination of claims 1 and 4 as filed. The first line of the claim has been amended so that it defines a method of making an inflatable prosthesis instead of an inflatable device. This amendment is based on the final paragraph on page 5 of the published application.

Dependent claims 2-5 correspond to original claims 2-3 and 5-6.

3. First auxiliary request - Articles 54 and 56 EPC

D1 discloses:

A method of making an inflatable prosthesis suitable for implantation in a mammal, the method comprising:
providing a mesh (column 5, lines 5 to 17);
positioning the mesh (26) on a curved molding surface;
applying a fluid elastomeric material to the molding surface with the mesh (column 5, lines 18 to 24)
positioned thereon;
allowing the elastomeric material to set to form a flexible shell having an open end, the shell including the mesh embedded within the set elastomer (column 5, lines 25 to 51), and the shell being useful as a component of an inflatable prosthesis (e.g Figures 3, 4, 11 or 16); and providing a puncture resistant member (item 40, column 6 lines 4 to 6).

According to column 6, lines 7 to 16, the opening in the shell is covered by patches. It is not disclosed in D1 that the needle guard 40 is sealed to an open end of the shell to form an inflatable prosthesis.

The method of claim 1 thus differs from the method of D1 in that it further comprises sealing the puncture resistant member to the open end of the elastomeric shell to form an inflatable prosthesis having a self-sealing anterior portion and a puncture resistant posterior portion and is therefore novel.

- 3.1 The objective technical problem solved by the differing feature can be seen as the provision of a more efficient and reliable method of making a prosthesis that has puncture resistant properties.
- 3.2 None of the prior art on file D2 to D5 discloses the sealing of an opening of a shell with a puncture resistant member in order to form an inflatable prosthesis.
- 3.3 The claimed solution to the problem posed is therefore not obvious for the skilled person.

The subject-matter of claim 1 of the first auxiliary request thus involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division with the order to grant a patent on the basis of claims 1 to 5 of the first auxiliary request filed with letter of 15 November 2021 and a description to be adapted thereto.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated