PATENTAMTS

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## Datasheet for the decision of 17 September 2012

T 0846/11 - 3.2.08 Case Number:

Application Number: 06701063.7

Publication Number: 1978897

IPC: A61F 2/44

Language of the proceedings: EN

Title of invention:

Total disc replacement device

Applicant:

Synthes GmbH

Headword:

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes, after amendments)"

Decisions cited:

Catchword:



Europäisches Patentamt European Patent Office

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Boards of Appeal

Chambres de recours

Case Number: T 0846/11 - 3.2.08

DECISION
of the Technical Board of Appeal 3.2.08
of 17 September 2012

Appellant: Synthes GmbH (Applicant) Eimattstraße 3

CH-4436 Oberdorf (CH)

Representative: Lusuardi, Werther

Dr. Lusuardi AG Kreuzbühlstraße 8 CH-8008 Zürich (CH)

Decision under appeal: Decision of the Examining Division of the

European Patent Office posted 25 October 2010

refusing European patent application

No. 06701063.7 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: T. Kriner

Members: M. Alvazzi Delfrate

D. T. Keeling

- 1 - T 0846/11

## Summary of Facts and Submissions

I. By decision posted on 25 October 2010 the examining division refused European patent application
No. 06 701 063.7 on the grounds that the subject-matter of claim 1 then on file lacked an inventive step over the combination of

D1: FR -A- 2 863 868 and

D2: US -A- 2005/0154468.

- II. The appellant lodged an appeal against said decision on 24 November 2010, paying the appeal fee on the same day. The statement setting out the grounds for appeal was filed on 11 February 2011.
- III. The appellant requests that the appealed decision be set aside and a patent be granted on the basis of claims 1 to 33 filed with letter dated 30 July 2012.
- IV. Claim 1 reads as follows:

"A total disc replacement device (1) with a central axis (13) comprising

A) a first apposition member (2) with an apposition surface (7) and an intermediate surface (8) both being arranged transversely to said central axis (13);

B) a second apposition member (3) with an apposition surface (9) and an intermediate surface (10); said intermediate surfaces (8;10) of said first and second

apposition members (2;3) facing each other; the device

further comprising

- 2 - T 0846/11

C) an elastic spacer (4) disposed between said intermediate surfaces (8;10) of said first and second apposition members (2;3); whereby

- D) said intermediate surface (8) of said first apposition member (2) is provided with first rigid constraint means (22) and said intermediate surface (10) of said second apposition member (3) is provided with second rigid constraint means (23) interfering with said first constraint means (22) and being configured such that a gap (21) with a width W> 0 is provided at least transversely to the central axis (13) between said first and second constraint means (22;23) in the unloaded state of the total disc replacement device (1); whereby
- E) the elastic spacer (4) is made of a material A having a Young's modulus  $Y_A$  and said first and second apposition members (2;3) are made of a material B having a Young's modulus  $Y_B$  and wherein  $Y_A$  is between 4% and 66% of  $Y_B$ ;
- F) said first and second apposition members (2;3) have an elongated shape with a major axis (27) and a transverse minor axis (28) when viewed parallel to said central axis (13); and
- G) said central axis (13), major axis (27) and transverse minor axis (28) intersect each other and said central axis (13) and transverse minor axis (28) define a middle plane (26) and whereby said first and second apposition members (2;3) have a cross-sectional area orthogonal to said central axis (13) which is essentially oval or elliptical and comprises at least two concavities (29) lying on different sides of said middle plane (26) and on the same side of said major axis (27)."

- 3 - T 0846/11

#### Reasons for the Decision

- 1. The appeal is admissible.
- 2. D1, which represents the most relevant prior art, discloses a total disc replacement device with a central axis comprising
  - A) a first apposition member (10) with an apposition surface and an intermediate surface both being arranged transversely to said central axis (see Figure 2);
  - B) a second apposition member (7) with an apposition surface and an intermediate surface; said intermediate surfaces of said first and second apposition members facing each other; the device further comprising
  - C) an elastic spacer (15) disposed between said intermediate surfaces of said first and second apposition members; whereby
  - D) said intermediate surface of said first apposition member is provided with first rigid constraint means (14) and said intermediate surface of said second apposition member is provided with second rigid constraint means (13) interfering with said first constraint means and being configured such that a gap with a width W > 0 is provided at least transversely to the central axis between said first and second constraint means in the unloaded state of the total disc replacement device (see Figure 2).

- 4 - T 0846/11

However, D1 does not disclose any of the features E, F and G of claim 1.

3. The object underlying the claimed invention starting from D1 can be seen in the provision of a total disc replacement device which can be positioned more easily.

This object is achieved by virtue of features F) and G) according to which the first and second apposition members have an elongated shape with a major axis and a transverse minor axis when viewed parallel to said central axis, and said central axis, major axis and transverse minor axis intersect each other and said central axis and transverse minor axis define a middle plane and whereby said first and second apposition members have a cross-sectional area orthogonal to said central axis which is essentially oval or elliptical and comprises at least two concavities lying on different sides of said middle plane and on the same side of said major axis.

By means of this shape unnecessary material on the first and second apposition plates is removed in order to give special attention to the fact that the bony endplates of the vertebral bodies change their shape at the location where the prosthesis is situated during their degeneration, i.e. they become more undulated over time. Moreover, possible osteophytes on the posterior periphery of the vertebral endplates which the surgeon decides not to remove are taken into consideration, i.e. the intervertebral prosthesis can be more easily positioned because the prosthesis can be manipulated around the undulations (see second paragraph on page 7 of the application as published).

- 5 - T 0846/11

D2 can at best suggest the provision of feature E). The prior art does not render it obvious to achieve the object above in accordance with features F) and G) of claim 1.

#### Order

### For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- The case is remitted to the department of first instance with the order to grant a patent on the basis of the following documents:
  - claims 1 to 33 as filed with letter dated 30 July 2012;
  - description, pages 3, 4, 5, 8, 11 and 13 as published, pages 1,2,3,6 and 7 as filed with letter dated 30 July 2012 and pages 9, 10 and 12 as filed with letter of 29 August 2012;
  - Figures 1 to 8 as published.

The Registrar: The Chairman:

V. Commare T. Kriner