

**Internal distribution code:**

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

**Datasheet for the decision  
of 23 February 2017**

**Case Number:** T 1594/13 - 3.3.10

**Application Number:** 08873572.5

**Publication Number:** 2254649

**IPC:** A61L24/00, A61L27/56

**Language of the proceedings:** EN

**Title of invention:**  
DELIVERY SYSTEM ATTACHMENT

**Applicant:**  
Warsaw Orthopedic, Inc.

**Headword:**

**Relevant legal provisions:**  
EPC Art. 123(2), 56

**Keyword:**  
Inventive step - unexpected improvement shown

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 1594/13 - 3.3.10

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.10**  
**of 23 February 2017**

**Appellant:** Warsaw Orthopedic, Inc.  
(Applicant) 2500 Silveus Crossing  
Warsaw, IN 46581 (US)

**Representative:** O'Connell, Maura  
FRKelly  
27 Clyde Road  
Dublin D04 F838 (IE)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 11 February  
2013 refusing European patent application No.  
08873572.5 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** P. Gryczka  
**Members:** J. Mercey  
F. Blumer

## Summary of Facts and Submissions

- I. The appeal lies from the decision of the Examining Division refusing European patent application No. 08 873 572.5.
- II. *Inter alia* the following documents were cited in the examination proceedings:
- (2) EP-A-82621,
  - (7) US-A-2004/220615,
  - (17) WO 2008/013763 and
  - (19) <http://www.orthosupersite.com/images/content/OT/200505/DBM.pdf> (pdf dated May 2005).
- III. In the decision under appeal, the Examining Division found that that the subject-matter of the then pending main request did not fulfil the requirements of Articles 123(2) and 56 EPC. More particularly, it found that claim 1 of said request found a basis in the application as filed, but not the late-filed drawings. With regard to inventive step, a demineralised bone matrix (DBM) of document (19) represented the closest prior art, the subject-matter of said claim not being inventive thereover in the light of documents (2), (7) and/or (17), which taught porous mesh coverings for bone implants.
- IV. With letter dated 23 January 2017, the Appellant (Applicant) submitted a main request and auxiliary requests 1 to 3 and 4a to 4d and withdrew the request made before the Examining Division to insert figures 13a to 13g into the specification. During oral proceedings before the Board, held on 23 February 2017, it filed a new main request, replacing the previous main request.

V. The Appellant submitted that the subject-matter of all requests complied with the requirements of Article 123(2) EPC. By withdrawing the request to insert figures 13a to 13g into the specification, the objections in point 12 of the contested decision under Article 123(2) EPC were overcome. With regard to inventive step, the product Grafton® DBM Crunch of document (19) represented the closest prior art. The declaration of Dr. D. Shimko filed with letter dated 23 January 2017 containing further experimental data comparing a delivery system according to the invention, namely Magnifuse® DBM, with said product, showed a performance improvement for Magnifuse® DBM over Grafton® DBM Crunch. Said improvement was unexpected, since at the date of filing of the present application it would have been counter-intuitive and gone against accepted teachings in this field for the skilled person seeking to promote bone fusion at a grafting site, to provide the bone products with a mesh covering which would act as a barrier between the bone products and the bone, *inter alia* document (23) being cited in this respect:

(23) D. G. Marchesi: "Spinal fusions: bone and bone substitutes", Eur. Spine J., 2000, 9, pages 372 to 378.

The skilled person would not have turned to the teachings of documents (2), (7) and/or (17) when seeking to develop an improved bone void filler product to maximise bone tissue regeneration. The claimed subject-matter was thus inventive.

VI. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request as filed during oral proceedings

before the Board, or, subsidiarily, on the basis of any of the auxiliary requests 1 to 3 and 4a to 4d as filed with letter dated 23 January 2017.

VII. At the end of the oral proceedings, the decision of the Board was announced.

### **Reasons for the Decision**

1. The appeal is admissible.

#### *Main request*

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

2.1 Claim 1 is based on original claims 1, 34, 37, 38 and 60, together with page 36, lines 4 to 6 of the application as filed.

2.2 Dependent claims 2 to 36 are based on original claims 2 to 13, 17, 19, 20, 26, 32, 33, 39, 41 to 46, 53, 57 to 59, 74 to 76 and 89 to 91, respectively.

2.3 Therefore, the amendments made to the claims do not generate subject-matter extending beyond the content of the application as filed and the Board concludes that the requirements of Article 123(2) EPC are satisfied.

2.4 Since the Appellant withdrew the request made before the Examining Division to insert figures 13a to 13g into the specification, the reason for refusing the application under Article 123(2) EPC given in the contested decision (see point 12 thereof), is now moot.

3. *Inventive Step*

3.1 The present invention relates to a delivery system for surface demineralised bone chips and demineralised bone fibres.

3.2 The Examining Division considered document (19) to represent the closest prior art, and the Board sees no reason to depart from this finding. Document (19) discloses the commercially available product Grafton® DBM Crunch, which comprises a blend of demineralised bone fibres and cubes in a glycerol carrier for use in *inter alia* spinal fusions.

3.3 In view of this state of the art, the Appellant submitted that the problem underlying the present application was the provision of a DBM product with improved bone grafting performance.

3.4 As the solution to this problem, claim 1 proposes containing the DBM, which includes surface demineralised chips, in a mesh of synthetic resorbable polymeric material.

3.5 To demonstrate that the claimed system achieves the alleged improvement, the Appellant relied *inter alia* upon test data (see point V above) comparing a delivery system according to the invention, namely Magnifuse® DBM, with Grafton® DBM Crunch of document (19). Magnifuse® DBM differs from Grafton® DBM Crunch by virtue of the specific combination of demineralised bone fibres and surface demineralised bone chips which are provided in a mesh covering made of a synthetic polymeric resorbable material, namely poly(glycolic acid), instead of being mixed with a carrier. The average score in the athymic rat osteoinductivity test,

which evaluates bone grafting performance by measuring new bone formation *in vivo*, is 3.4 for Magnifuse® DBM, which is higher than the score of 1.9 for Grafton® DBM Crunch. Additionally, Magnifuse® DBM shows an athymic rat posterolateral radiographic fusion rate score of 100% versus a score of 88% for Grafton® DBM Crunch, said test evaluating spinal performance *in vivo* by measuring posterolateral fusion of two lumbar vertebrae levels. The Board is therefore satisfied that the technical problem as defined in point 3.3 above has been successfully solved by the claimed delivery system.

- 3.6 It remains to be decided whether or not the proposed solution to this problem is obvious in view of the cited state of the art.
- 3.6.1 There is no suggestion in any of the cited art that a DBM product with improved osteoinductivity and fusion rates could be achieved by containing the DBM, which includes surface demineralised chips, in a mesh of synthetic resorbable polymeric material. Indeed to the contrary, and as outlined in the declaration of Dr. D. Shimko (see point V above), at the priority date of the present application, commercially available bone graft products were granular bone products with a carrier such as glycerol (as in Grafton® DBM Crunch), and it was conventional knowledge in the field of bone grafting at that time that direct contact with a host bone was facilitated by a carrier and impeded by the use of a mesh covering. The skilled person would thus have expected that the polymeric mesh covering would impede apposition and negatively impact new bone formation, document (23), which describes best practices for bone grafting, teaching that "Appropriate osteoconduction is provided by direct apposition



between host bone and implant" (see page 373). It is thus surprising that the synthetic resorbable polymeric mesh in fact gives better results in terms of bone grafting performance.

3.6.2 Documents (2), (7) and (17) cited in the contested decision, do indeed teach porous mesh coverings for bone implants. However, none of these documents suggests that bone grafting performance may be improved by containing the bone implant in such a mesh.

3.6.3 Accordingly, faced with the problem of providing a DBM product with improved bone grafting performance, the skilled person would not have found any suggestion in documents (2), (7) and (17), or in any of the other prior art cited, to contain the bone implant in a mesh of synthetic resorbable polymeric material.

3.7 For these reasons, the Board concludes that the delivery system according to claim 1, together with the subject-matter of dependent claims 2 to 36, involves an inventive step within the meaning of Articles 52(1) and 56 EPC.

## 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 with the order to grant a patent on the basis of claims 1 to 36, filed as main request during oral proceedings before the Board, and a description yet to be adapted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated