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**D E C I S I O N**  
of 7 November 2001

**Case Number:** T 1045/00 - 3.3.2

**Application Number:** 91113242.1

**Publication Number:** 0475077

**IPC:** A61L 31/00

**Language of the proceedings:** EN

**Title of invention:**  
Bone regeneration membrane

**Patentee:**  
Synthes AG, Chur

**Opponent:**  
Deutsche Institute für Textil- und Faserforschung Stuttgart

**Headword:**  
Bone regeneration membrane/SYNTHES

**Relevant legal provisions:**  
EPC Art. 54, 56

**Keyword:**  
"Novelty - yes: generic term does not anticipate a specific type of drug"  
"Inventive step - no: predictable improvement"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 1045/00 - 3.3.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 7 November 2001

**Appellant:**  
(Proprietor of the patent)      Synthes AG, Chur  
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**Representative:**  
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**Respondent:**  
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**Decision under appeal:**      Decision of the Opposition Division of the  
European Patent Office posted 30 August 2000  
revoking European patent No. 0 475 077 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:**      P. A. M. Lançon  
**Members:**      J. Riolo  
                     S. U. Hoffmann

## Summary of Facts and Submissions

- I. European patent No 0 475 077 based on application No. 91 113 242.1 was granted on the basis of 23 claims.

Independent claim 1 as granted read as follows:

"1. A bone regeneration membrane comprising resorbable or degradable polymeric and/or polymeric-ceramic material, characterized in that

(A) said polymeric material comprises polyhydroxyacids, polysaccharides, polyamines, polyaminoacids, polyorthoesters, polyanhydrides, collagen or composites thereof with tricalcium phosphate and/or hydroxyapatite;

(B) at least 90 weight percent of said polymeric and/or polymeric-ceramic material has a molecular weight in the range of 5'000 to 1'000'000;

(C) said polymeric and/or polymeric-ceramic material has a molecular weight distribution in the range of 1,2 to 100,0;

(D) the glass transition temperature of said polymeric and/or polymeric-ceramic material is in the range of -30° to +200°C; and

(E) said membrane is provided with micropores."

- II. Notice of opposition was filed against the granted patent by the opponent (respondent).

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step.

The following documents *inter alia* were cited during the proceedings:

- (1) Colloid & Polymer Sci., 261, 477-484, 1983
- (3) Polymer, 23, 1587-1593, 1982
- (6) Polymer Science U.S.S.R., 25 (6), 1491-1497, 1983.

III. The decision of the Opposition Division revoked the patent under Article 102(1) EPC.

The Opposition Division took the view that the patent in suit did not meet the requirements of the EPC.

In its opinion, document (1) anticipated the subject-matter of the main request, as it disclosed the features (A) to (E) of the bone regeneration membrane according to claim 1 of the patent in suit.

The first auxiliary request was considered to contravene Article 123(2) EPC, as the newly introduced feature of claim 1, ie "produced by evaporation of a liquid", was not disclosed in the application as originally filed.

The Opposition Division also considered that the second auxiliary request could not be allowed as the appellant did not file a set of claims with the suggested amendments. It nevertheless expressed the opinion that such a set of claims would in any case also contravene Article 123(2) EPC, as it would also contain the undisclosed feature mentioned above.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. Oral proceedings were held before the Board on 7 November 2001. At the beginning of the oral proceedings, the appellant defined the set of claims of its sole request as being based on claims 1 and 2 filed on 4 October 2001 and claims 3 to 13 filed on 26 October 2000.

Independent claim 1 of this set of claims corresponds to independent claim 1 as granted with the additional features of dependent claims 23, 13 to 14 and 3 as granted, specifying respectively that the molecular weight distribution of the membrane material is in the range of 1,9 to 2,5 (feature (E)), that the bone regeneration membrane contains osteoinductive and/or osteoconductive agents (feature (F)) and that at least 90 percent of the micropores in the membrane have a diameter below 500  $\mu\text{m}$  (feature (G)). Features (D) and (E) of independent claim 1 as granted are moreover now referred to as (C) and (D) respectively, and feature (D) recites that the micropores are interconnected, as disclosed in claim 4 of the patent application as originally filed.

VI. The appellant submitted that, since neither document (1) nor the other available prior art documents disclosed or suggested the features (C) and (E) to (F), this set of claims was novel and inventive, since only the claimed combination of features provided for an efficient bone regeneration membrane.

VII. The respondent contested the novelty of the amended set of claims with respect to the disclosure in document (1), taking into account document (3) and common general knowledge as illustrated by document (6).

It also expressed the view that the amended subject-matter did not involve an inventive step, as it was well-known in the art to provide porous structures for implants with various drugs as apparent from document (1). Moreover, since the contested patent itself acknowledged in the introductory part relating to the prior art the type of drugs useful for treating bone defects, the respondent concluded that it was obvious for the skilled person to add such drugs to the membrane disclosed in document (1) in order to provide an efficient bone regeneration membrane.

VIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained with the set of claims 1 and 2 filed on 4 October 2001 and claims 3 to 13 filed on 26 October 2000.

The respondent requested that the appeal be dismissed.

### **Reasons for the Decision**

1. The appeal is admissible.

2. *Articles 123 and 84 EPC*

No objection under Articles 123 and 84 EPC was raised by the respondent with respect to the set of claims under consideration, and the Board sees no reason to differ.

3 *Novelty*

3.1 Document (1) has been cited under Article 54 EPC as prejudicial to the novelty of the subject-matter of the patent in suit.

Document (1) describes a regeneration structure comprising resorbable or degradable polymeric and/or polymeric-ceramic material wherein

(A) said polymeric material comprises polyhydroxyacids, polysaccharides, polyamines, polyaminoacids, polyorthoesters, polyanhydrides, collagen or composites thereof with tricalcium phosphate and/or hydroxyapatite (ie poly(L-lactide), also referred to as PLLA);

(B) at least 90 weight percent of said polymeric and/or polymeric-ceramic material has a molecular weight in the range of 5'000 to 1'000'000 (ie  $6,0 \times 10^5$ );

(D) said membrane is provided with interconnected micropores;

(G) at least 90 percent of said micropores have a diameter below 500  $\mu\text{m}$  (ie 2 to 5  $\mu\text{m}$ ), (see (1), title, lines 9 and 10 of the abstract, line 2 in Material and techniques, lines 6 and 7 in results and discussion).

Document (1) does not mention *expressis verbis* that

(C) the glass transition temperature of said polymeric and/or polymeric-ceramic material is in the range of  $-30^\circ\text{C}$  to  $+200^\circ\text{C}$ ;

(E) said polymeric and/or polymeric-ceramic material has a molecular weight distribution in the range of 1,9 to 2,5;

(F) said membrane further contains osteoinductive and/or osteoconductive agents of autogenic, allogenic, xenogenic, or synthetic origin.

It must therefore be decided whether the skilled person would nevertheless consider these features (C), (E) and (F) implicitly contained in this document.

In that respect the Board notes that document (1) refers specifically to the document "Polymer, 23, 1587-1593, 1982" (ie document (3)) in the section relating to "Materials and techniques" for details concerning the polymer preparation.

This document discloses that the glass transition temperature of the obtained polymer is around 55°C (page 1587, right column, line 1).

Accordingly, the Board has no reason to doubt that the glass transition temperature of the polymeric material described in document (1) is indeed in the range of -30°C to +200°C.

Documents (1) and (3) are however silent about the molecular weight distribution of the polymeric material and about the presence of osteoinductive and/or osteoconductive agents in the polymeric material.

Therefore, the Board concludes that the subject-matter of claim 1 of the main request is novel under Article 54 EPC.

- 3.2 The respondent emphasized that, having regard to document (6), for instance, it would be clear for the skilled person that a molecular weight distribution in the range of 1,9 to 2,5 could not be regarded as a novel feature, since this was a common range for PLLA polymers.



In that respect, the Board notices that document (6) discloses molecular weight distribution in the range of 1,1 to 5,2 (page 1496, table 2). The Board considers therefore that not any PLLA polymer *inevitably* has a molecular weight distribution in the range of 1,9 to 2,5. Accordingly, said range in relation with the other features of claim 1 must be regarded as novel over the available prior art.

Contrary to the appellant's submission, the Board also considers that the disclosure in document (1) that the porous PLLA structure is a reservoir for drug delivery in general does not anticipate the specific drugs mentioned in claim 1 of the patent in suit, namely the osteoinductive and osteoconductive agents (see (1), page 477, right column, last paragraph).

In view of the above, the Board concludes that the subject-matter of claim 1 fulfils the requirements of novelty under Article 54 EPC.

Accordingly, the subject-matter of its dependent claims 2 to 13 is also novel.

4. *Inventive step*

4.1 The patent provides for a bone regeneration membrane containing resorbable or degradable polymeric material (page 2, left column, lines 5 to 8).

Document (1) relates to resorbable structure containing resorbable polymeric material (PLLA) to produce tubular prostheses.

The Board agrees with the parties that document (1) represents the closest prior art.

4.2 As is apparent from the above assessment of novelty, document (1) does not disclose the features (E) and (F) of the claimed regeneration membrane. Nor does it expressly mention the membrane's specific use for the regeneration of bones.

Having regard to the contested patent, it was moreover found advantageous to incorporate bone conductive and bone inductive substances (page 2, left column, line 56 - right column, line 4).

Accordingly, the problem to be solved as against document (1) can be seen as the provision of an improved regeneration membrane for a specific use, namely for bone regeneration.

4.3 This problem is solved by the subject-matter of claim 1 and, in the light of the working examples 1 and 2 of the patent in suit, the Board is satisfied that the problem has been plausibly solved.

4.4 Thus, the question to be answered is whether the proposed solution, ie the specific application for bones and the additional features (E) and (F), was obvious to the skilled person in the light of the prior art.

As regards the skilled person, both parties agreed that in the present case, the skilled person was in fact a team composed of chemists specialized in polymer chemistry and bone surgeons.

Accordingly, concerning the first aspect of the problem to be solved, namely the specific use for bones, the Board is convinced that such a team would be aware of the scientific publication (1), as this document

mentions bone ingrowth and orthopaedic surgery (page 477, left column, lines 14 to 16 and right column last paragraph).

Therefore, the specific use for bone regeneration cannot provide for an inventive step *per se*.

Concerning the improvement achieved by adding osteoinductive and osteoconductive agents to the membrane, the appellant pointed out, in reply to a remark by the Board about the absence of definition for these agents in the contested patent, that both substances were well-known in the art as being substances promoting the bone growth. This was moreover confirmed by the disclosure in the contested patent itself as far as osteoinductive agents are concerned (page 1, left column, line 20).

The Board can therefore only conclude that it would be obvious to the skilled person faced with the problem of improving the efficacy of a bone regeneration membrane to add to it substances known for having precisely this desired effect.

As to the molecular weight distribution, in the absence of any particular effect linked to it, the range of 1,9 to 2,5 mentioned in claim 1 of the patent in suit represents merely an arbitrary choice devoid of inventive activity.

- 4.5 The main arguments raised by the appellant were that the subject-matter of claim 1 was inventive over document (1) firstly because it achieved an improved efficacy and secondly because, contrary to the structure disclosed in document (1), the claimed membrane did not contain undesirable remaining additives, as the process for its preparation was different from the process of this document.

4.6 The Board cannot share the opinion of the appellant.

It is indeed true that the combination of the polymeric membrane with osteoinductive and/or osteoconductive agents improves the efficacy of the regeneration. However, in the absence of any element showing that this improvement is not merely the expected result of the addition of the effects of the membrane plus the effect of the agents, no inventive step can be acknowledged.

As to the second argument, the Board notes that it concerns elements linked to the process of preparation of the polymeric membrane which are not reflected in the claim under consideration and which therefore cannot be taken into account for the assessment of the inventive step of this set of claims.

In view of the foregoing the Board judges that the subject-matter of claim 1 does not involve an inventive step as required by Article 56 EPC.

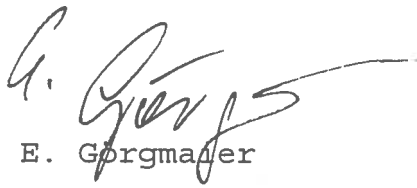
Since claim 1 of the only set of claims under consideration is not allowable, there is no need for the Board to consider the remaining claims.

**Order**

**For these reasons it is decided that:**

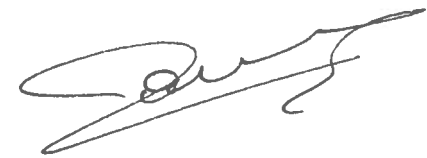
The appeal is dismissed.

The Registrar:



E. Gorgmaier

The Chairman:



P. Lançon

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