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**Datasheet for the decision  
of 9 February 2012**

**Case Number:** T 0182/09 - 3.3.10

**Application Number:** 01310843.6

**Publication Number:** 1216718

**IPC:** A61L 27/58, A61L 27/56,  
A61L 27/54, A61L 27/44,  
A61L 27/24, A61L 27/22,  
A61L 27/18, A61L 27/16,  
A61L 2/02

**Language of the proceedings:** EN

**Title of invention:**  
Reinforced foam implants for soft tissue repair and  
regeneration

**Patentee:**  
ETHICON, INC.

**Opponent:**  
Lepère, Marc

**Headword:**  
Reinforced foam implants/ETHICON

**Relevant legal provisions:**  
EPC Art. 54, 111(1), 114(2)  
RPBA Art. 13(1), 13(3)

**Keyword:**  
"Late filed document - admitted"  
"Remittal to the first instance - no"  
"Main Request and auxiliary request 1: Novelty - no"  
"Late filed auxiliary request 2 - not admitted"

**Decisions cited:**  
R 0002/08, T 0506/91

**Catchword:**

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Case Number: T 0182/09 - 3.3.10

**DECISION**  
of the Technical Board of Appeal 3.3.10  
of 9 February 2012

**Appellant:** Lepère, Marc  
(Opponent) 25 Allée Picasso  
F-85000 La Roche sur Yon (FR)

**Representative:** Cabinet Plasseraud  
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**Respondent:** ETHICON, INC.  
(Patent Proprietor) U.S. Route 22  
Somerville  
NJ 08876 (US)

**Representative:** Mercer, Christopher Paul  
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London WC1B 5HA (GB)

**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 19 November 2008  
rejecting the opposition filed against European  
patent No. 1216718 pursuant to Article 101(2)  
EPC.

**Composition of the Board:**

**Chairman:** P. Gryczka  
**Members:** J.-C. Schmid  
F. Blumer

## Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal against the decision of the Opposition Division rejecting the opposition against European patent No. 1 216 718, independent claim 1 thereof reading as follows:

"1. A biocompatible tissue repair stimulating implant, comprising:

a bioabsorbable polymeric foam component having pores with an open cell pore structure;

a reinforcing component formed of a biocompatible, mesh-containing material having a mesh density in the range of 12 to 80%, wherein the foam component is integrated with the reinforcing component such that the pores of the foam component penetrate the mesh of the reinforcing component and interlock with the reinforcing component; and

at least one biological component in association with the implant."

II. The Appellant's notice of opposition requested revocation of the patent in suit in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC), and of extending the subject-matter of the patent in suit beyond the content of the application as filed (Article 100(c) EPC).

III. In the decision under appeal, the Opposition Division considered that the claims as granted satisfied the requirement of Article 123(2) EPC and that their subject-matter was novel and inventive over the cited documents. Furthermore, the Opposition Division refused

to introduce insufficiency of disclosure of the invention (Article 100(b) EPC) as a ground for opposition in the proceedings since it was late filed and lacked relevance *prima facie*.

IV. The Appellant filed an appeal on 19 January 2009 and filed on 27 March 2009 the statement of grounds of appeal contesting the decision of the Opposition Division. On support to its argumentation it relied on new documents. With a letter dated 2 December 2009, the Appellant filed document

(14) Chen G. *et al.* "A hybrid network of synthetic polymer mesh and collagen sponge" *Chem. Commun.*, 2000, pages 1505 to 1506 (published on 19 July 2000),

and submitted that this document was *prima facie* highly relevant since it was clearly novelty destroying for the claimed subject-matter.

V. With a letter dated 28 February 2011 the Respondent (Proprietor of the patent-in-suit) requested the Board to remit the case to the Opposition Division and to make an award of costs against the Appellant. If the case was not remitted to the Opposition Division, the late filed documents should be excluded from the proceedings, *i.e.* among others document (14). The Respondent did not take position on the disclosure of document (14).

VI. In the communication accompanying the summons to oral proceedings dated 25 October 2011, the Board indicated that it was inclined to admit document (14) in the

appeal proceeding in view of its relevance for the issue of novelty and invited the parties to be prepared to handle all the litigious issues during the oral proceedings to be held on 9 February 2012.

VII. On 9 January 2012, the Respondent filed a set of claims as auxiliary request and maintained all its previous procedural requests.

VIII. During the oral proceedings before the Board, the Respondent defended the maintenance of the patent in suit on the basis of the claims of the main request (claims as granted), and subsidiarily on the basis of auxiliary requests 1 and 2 filed during these oral proceedings.

Claim 1 of auxiliary request 1 differed from claim 1 as granted by the addition of the feature requesting that "an aliphatic polyester, a poly(amino acid), a copoly(ether-ester), a polyalkyleneoxalate, a polyamide, a tyrosine derived polycarbonate, a poly(iminocarbonate), a polyorthoester, a polyoxaester, a polyamidoester, a polyoxaester containing amine groups, a polyanhydride, a polyphosphazene or a blend thereof is used to make the foam component."

Claim 1 of auxiliary request 2 differed from claim 1 as granted in that "the bioabsorbable polymeric foam component is formed from an elastomeric copolymer of:  $\epsilon$ -caprolactone and glycolide with a mole ratio of  $\epsilon$ -caprolactone to glycolide of from 35:65 to 65:35;  $\epsilon$ -caprolactone and lactide with a mole ratio of  $\epsilon$ -caprolactone to lactide of from 35:65 to 65:35;

p-dioxanone and lactide with a mole ratio of p-dioxanone to lactide of from 40:60 to 60:40;  
ε-caprolactone and p-dioxanone with a mole ratio of ε-caprolactone to p-dioxanone of from 30:70 to 70:30;  
p-dioxanone and trimethylene carbonate with a mole ratio of p-dioxanone to trimethylene carbonate of from 30:70 to 70:30;  
trimethylene carbonate and glycolide with a mole ratio of trimethylene carbonate to glycolide of from 30:70 to 70:30;  
trimethylene carbonate and lactide with a mole ratio of trimethylene carbonate to lactide of from 30:70 to 70:30; or  
a blend thereof."

IX. According to the Appellant document (14) was clearly novelty destroying for claim 1 of the patent-in-suit. This document had been brought to the Appellant's attention from proceedings in the United States and was consequently filed as soon as possible. Document (14) should be admitted to the proceedings. A remittal of the case to the first instance was not appropriate since document (14) was not a complex document and the Respondent had sufficient time to prepare its defence, the document being known to him since December 2009, i.e. more than two years before the oral proceedings before the Board. The subject-matter of claim 1 of the auxiliary request 1 also lacked novelty with respect to document (14) since collagen disclosed therein as the foam component was a poly (amino acid). Auxiliary request 2 should not be admitted to the proceedings since it was filed at a very late stage of the proceedings and claim 1 thereof took up features from the description.

X. The Respondent requested the Board to exclude document (14) from the appeal proceedings. Document (14), which was a article from a well known scientific journal, could have been found in due time. There was absolutely no difficulty to search documents disclosing implants having the claimed characteristics. Hence, the late filing of document (14) was due to the negligence of the Appellant which did not carry out a comprehensive search. Document (14) should not be admitted into the appeal proceedings without considering its relevance. There was no need for the Patentee to invest time and money to respond on the substance to such a late filed document before the Board had decided on its admissibility to the proceedings. Otherwise the late filing of documents would be an inextricable trap for the Patentee. If the Patentee filed comments and/or auxiliary requests in response to this late filed document, it would support the relevance of document (14) and, hence, its admission into the proceedings.

Additionally, document (14) was *prima facie* not relevant because there was no disclosure therein of a reinforcing material having the claimed mesh density and no disclosure of the feature that foam component was integrated with the reinforcing component such that the pores of the component interlocked with the reinforcing component. The subject-matter of claim 1 as granted was therefore novel over document (14).

If document (14) were admitted to the proceedings, the Board should remit the case to the department of first instance, or subsidiarily, the proceedings should be continued in writing and a new deadline should be set



in order for the Respondent to respond in substance to document (14).

According to the description of the patent-in-suit, collagen was a biopolymer and thus was not encompassed within the term poly(amino acid) which meant only homopolymer of amino acids, thus excluding collagen. Therefore the subject-matter of claim 1 of the auxiliary request 1 was novel.

Auxiliary request 2 corresponded to the auxiliary request filed on 9 January 2012 in response of the communication of the Board indicating that the board was minded to admit document (14) in the proceedings. The amendment in both auxiliary requests 1 and 2 were made in order to delimit the claimed subject-matter from document (14). The foam component was specified according to the paragraph bridging pages 8 and 9 of the application as filed. Accordingly auxiliary request 2 should be admitted into the appeal proceedings.

XI. The Appellant requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent requested that the appeal be dismissed and the patent be maintained as granted or, subsidiarily, that the patent be maintained on the basis of one of the auxiliary requests 1 and 2, both requests as filed during the oral proceedings before the Board.

XII. At the end of the oral proceedings held on 9 February 2012 the decision of the Board was announced.

## Reasons for the Decision

1. The appeal is admissible
2. *Admissibility of document (14) into the proceedings*

Document (14) was filed by the Appellant with the letter dated 2 December 2009, i.e. after filing its statement of the grounds for appeal. The Respondent objected to its introduction into the appeal proceedings for the sole reason that it was filed at a late stage of the proceedings.

According to Article 114(2) EPC the EPO may disregard facts or evidence which are not submitted in due time by the Parties concerned. Thus, any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view of *inter alia* the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy (Article 13(1) RPBA).

In addition, as respects admissibility of late-filed documents, it is established jurisprudence of the boards of appeal that a crucial criteria to be taken into account is whether the document is *prima facie* relevant and whether there is proper justification for its late filing to forestall tactical abuse.

2.1 Document (14) is a two-page document titled "a hybrid network of synthetic polymer mesh and collagen sponge". This network is prepared by forming collagen sponges with interconnected microporous structures in the interstices of the synthetic polymer mesh (see heading of the article, first page, top of the left-hand column). This hybrid network is associated with skin fibroblasts, which are biological components (see figure 2; paragraph bridging pages 1505 and 1506). The mesh made from a biocompatible polymer is shown in figure 1a. Figures 1b and 1c shown the collagen sponges having pores with an open cell pore structure interconnected in the interstice of the reinforcing component.

It therefore appears immediately that the structure shown in figure 2 of this document is novelty-destroying for claim 1 of the main request.

2.2 The Respondent argued that document (14) was *prima facie* not relevant since the mesh density was not disclosed. Furthermore the foam component was not integrated with the reinforcing component such that the pores of the component interlock with the reinforcing component, figure 1c of document (14) showing even that the collagen was only on the top face of the mesh.

However, the mesh density of the structure can be determined from figure 1a of document (14)

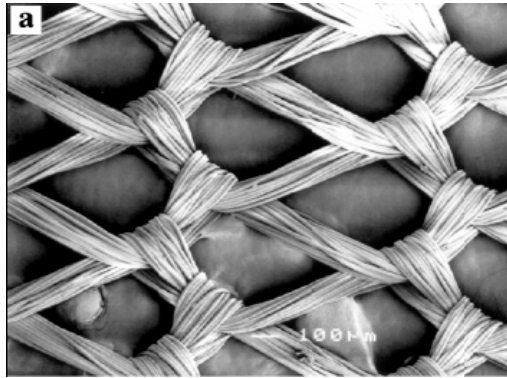
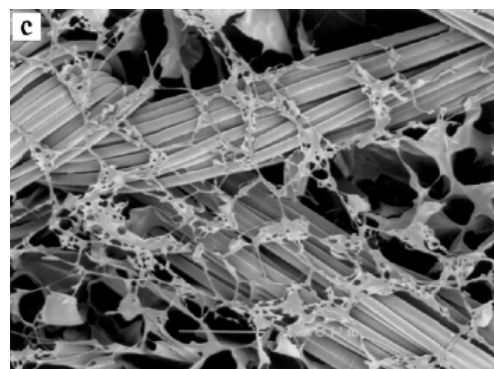
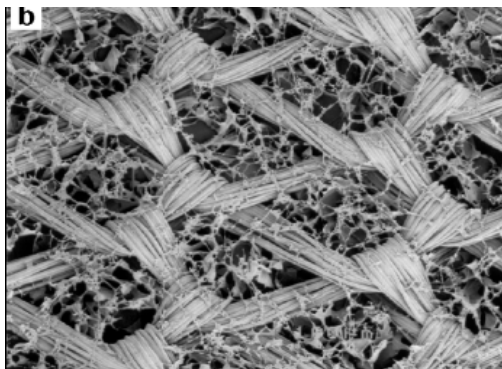


Fig 1a

which reveals that it clearly falls within the broad claimed range of 12 to 80%.

Figures 1b and 1c of document (14)



clearly show that the collagen sponge is located on both faces of the polymer mesh and is integrated with it such that the spores of the sponge penetrate the polymer mesh and interlock with it. Moreover, it is indicated on page 1505, bottom of the left-hand column, that the polymer mesh was embedded in the collagen sponge sheet so that the fibre bundles of polymer mesh and the collagen sponges were alternately chained.

2.3 Accordingly, document (14) is highly relevant since it unambiguously discloses the subject-matter of claim 1 of the patent as granted.

2.4 In addition, the Board is not aware of any facts indicating that the filing of document (14) was

deliberately delayed for tactical reasons. According to the Appellant, this document was filed promptly after it was brought to its attention from proceedings before the United States Patent Office. Furthermore, the Appellant explained that it had no interest at all in delaying the proceedings, what the Respondent did not challenge. Therefore, the Board is not convinced that the late filing of document (14) was caused by tactical reasons as alleged by the Respondent.

- 2.5 The Respondent further argued that since this document was published by the Royal Chemical Society, it was easily retrievable by a simple search. Thus, the late filing of the document was due to the Appellant's negligence to carry out a comprehensive search during the opposition period. Also for this reason, document (14) should not be admitted into the proceedings, independently of its relevance.

However, whether a document can be easily retrieved by search cannot be objectively assessed and therefore cannot be a significant criterion for its admissibility into the proceedings. In this respect, the Board notes that, despite of its relevance (see points 2.2 and 2.3 above), document (14) was not cited in the application as filed, nor in the EPO Search report, and the Respondent was apparently not aware of it.

- 2.6 The Board decides consequently to admit document (14) into the proceedings.

3. *Request to postpone oral proceedings and to set a new deadline for filing substantive comments*

The Respondent argued that the Board should first decide on the admissibility of the late filed document (14) into the proceedings and then set a new deadline for the Respondent to consider the substantive content of the document.

However, since the relevance of a late filed document is an essential criterion for deciding on its admissibility into the proceedings and since any decisive issues constituting the decision may only be based on grounds or evidence on which the Parties concerned have had an opportunity to present their comment (Article 113(1) EPC), the relevance of document (14) must have been considered by all Parties to the proceedings, i.e. including the Respondent, before the Board decides on its admissibility. Accordingly, the Respondent cannot request to consider the relevance of a late filed document only after its admission into the proceedings has been decided.

The Respondent requested a new deadline to file its substantive response to the Appellant's objections based on document (14), or the arrangement of second oral proceedings to discuss these substantive issues, since it did not know before the oral proceedings the Board's opinion on the admissibility of document (14) into the appeal proceedings.

However, a Party which wants a decision in its favour must play a full part in proceedings and submit arguments in support of its case on its own initiative

and at the appropriate time (see R 2/08, points 8.5 and 9.10 of the reasons). It is part of the professional task of representatives to decide independently - that is, without assistance from the Board - how to pursue their cases (see T 506/91, point 2.3 of the reasons; not published in OJ EPO).

In the present case, the Respondent has deliberately chosen not to comment on the substance of document (14) and not to respond to the Appellant's objection of lack of novelty based on document (14), although this objection was known to him for more than two years. In the communication accompanying the summons to oral proceedings, the Board indicated that document (14) was highly relevant and could even be considered as novelty-destroying and that the Parties should be prepared to handle all the litigious issues during these oral proceedings. The Respondent had sufficient time before the oral proceedings to consider the objection of lack of novelty based on document (14) raised by the Appellant.

Under these circumstances, the Respondent's requests to continue the appeal proceedings in writing, to set a new deadline for filing substantive comments or to postpone the oral proceedings are refused.

4. *Request for remittal to the department of first instance*

4.1 The Respondent requested that the Board remit the case to the first instance since the admission of document (14) into the proceedings created a fresh case. The document should be examined at two levels of

jurisdiction, so that the Respondent is not deprived of the possibility of subsequent review.

Pursuant to Article 111(1) EPC the Board may exercise any power within the competence of the first instance or remit the case to that department. However, Article 111(1) EPC establishes no absolute right for Parties to have matters raised in appeal proceedings examined by two successive instances; on the contrary, it leaves the Board of Appeal to decide upon a remittal in the light of the circumstances. Having arrived at the present stage of the appeal proceedings, the Board should therefore assess the appropriateness of a remittal.

In the present case, examination as to the requirement of novelty is made in respect of a two-pages document which was filed two years before the date of the oral proceedings before the Board. The Respondent made no comment about the objection of lack of novelty raised by the Appellant until the oral proceedings before the Board although there was no ambiguity in the disclosure of the document, which immediately appeared novelty-destroying for claim 1 of the patent-in-suit.

Under the present circumstances, the Board exercises its discretion not to remit the case to the first instance, with the consequence that the conditional request of apportionment of the costs if the case is remitted does not apply.



*Main request: claims as granted*

5. *Novelty*

Claim 1 as granted lacks novelty with respect to the implant disclosed in figure 2 of document (14) (see points 2.1 and 2.2 above).

*Auxiliary request 1*

6. *Admissibility*

This request is based on the auxiliary request filed by the Respondent on 19 October 2009 with the letter of reply to the statement of grounds of appeal. The Appellant has not objected to the admissibility of this request into the proceedings.

7. *Modifications (Article 123(2) and (3) EPC)*

Claim 1 of auxiliary request 1 comprises the new feature that "an aliphatic polyester, a poly(amino acid), a copoly(ether-ester), a polyalkyleneoxalate, a polyamide, a tyrosine derived polycarbonate, a poly(iminocarbonate), a polyorthoester, a polyoxaester, a polyamidoester, a polyoxaester containing amine groups, a polyanhydride, a polyphosphazene or a blend thereof is used to make the foam component" according to page 6, lines 17 to 24 of the application as filed. The amendments made to the claims were not objected to by the Appellant, nor does the Board see any reason to question their allowability under Article 123(2) and (3) EPC of its own motion.

8. *Novelty*

8.1 The foam component of the implant of document (14) is made of collagen (see title, and figures 1a and 1b). Collagen is a protein which is a biochemical compound consisting of one or more polypeptides which are polymers of amino acids. Therefore, the amendment to claim 1 requiring that the foam component is made *inter alia* of poly(amino acid) does not restore novelty with respect to the implant disclosed in document (14). Claim 1 of the auxiliary request 1 lacks therefore novelty for the same reasons as claim 1 of the main request.

8.2 The Respondent argued that a poly(amino acid) in the meaning of the patent-in-suit was restricted to homopolymers of amino acids, thus excluding the biopolymer, such as collagen.

The claims define the subject-matter of the patent in suit for which protection is sought. The definition of a poly(aminoacid) is clear and unambiguous in the art, thereby leaving no room for any other interpretation than a polymer made with amino acids. Notwithstanding this finding, the description provides no indication that the poly(aminoacid) in the sense of the invention should be given a definition different from that which it normally has in the relevant art. The Respondent's argument based on a construction of the claim giving to the feature "poly(aminoacid)" a restrictive meaning, namely that biopolymer are excluded, must therefore be rejected.

*Auxiliary request 2*

9. Admissibility

Auxiliary request 2 was filed at a very late stage of the appeal proceedings. It corresponds to the request filed as auxiliary request on 9 January 2012, i.e. one month before the oral proceedings before the Board. The Appellant challenged the admissibility of this request on the grounds that it was late filed.

According to the Rules of Procedure of the Boards of Appeal (RPBA) any amendment to a party's case after it has filed its grounds of appeal may be admitted and considered at the Board's discretion and is not a matter as of right (Article 13(1) RPBA). Amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party cannot reasonably be expected to deal with without adjournment of the oral proceedings (Article 13(3) RPBA).

The Respondent submitted that this new request was filed in reaction to the Appellant's late filed document (14) and the communication of the Board indicating that it was minded to admit document (14) to the proceedings. If document (14) were admitted to the proceedings then auxiliary request 2 should be admitted to the proceedings too. The amendment made to claim 1 of auxiliary request 2 takes up features from the description, namely that the bioabsorbable polymeric foam component is formed from specific copolymers in order to provide novelty of the claimed subject-matter over document (1).

The Board takes the view that the Respondent could have filed the auxiliary request 2 earlier, in response to the filing of document (14), i.e. more than two years before the oral proceedings before the Board. By choosing to wait until short before the oral proceedings to file this request, the Respondent put the Board and the Appellant in a position where they could not deal with it without adjournment of the oral proceedings, the Appellant and the Board being both confronted with a new request that needs to be carefully analyzed. Under these circumstances Article 13(3) RPBA requires that the amendments to the Respondent's case not be admitted.

Under these circumstances, the auxiliary request 2 is not admitted into the proceedings pursuant to Article 13(3) RPBA.

**Order**

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

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar

The Chairman

C. Rodríguez Rodríguez

P. Gryczka