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Datasheet for the decision of 3 March 2015

Case Number: T 0626/11 - 3.3.10

Application Number: 05256123.0

Publication Number: 1645298

IPC: A61L27/48, A61L27/56, A61F2/00

Language of the proceedings: EN

Title of invention:
Method of preparation of bioabsorbable porous reinforced tissue implants and implants thereof

Patent Proprietor:
ETHICON, INC.

Opponent:
Tyco Healthcare Group, LP

Headword:
Ethicon / Tyco Healthcare

Relevant legal provisions:
EPC Art. 56, 83, 100(a), 100(b), 100(c), 123(2), 123(3)

Keyword:
Main Request, Auxiliary Request 1: Amendments - extension beyond the content of the application as filed (yes)
Auxiliary Request 2: Inventive step - (yes)

Decisions cited:
T 0288/92, T 0680/93

Catchword:

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Case Number: T 0626/11 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 3 March 2015

Appellant: (Opponent)	Tyco Healthcare Group, LP 60 Middletown Avenue North Haven CT 06473 (US)
Representative:	Niemann, Frédéric Cabinet Plasseraud 52, rue de la Victoire 75440 Paris Cedex 09 (FR)
Respondent: (Patent Proprietor)	ETHICON, INC. U.S. Route 22 Somerville, New Jersey 08876 (US)
Representative:	Fisher, John William Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 January 2011 concerning maintenance of the European Patent No. 1645298 in amended form.**

Composition of the Board:

Chairman P. Gryczka
Members: C. Komenda
D. Rogers

Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal against the interlocutory decision of the Opposition Division, which found that the European patent No. 1 645 298 in the form as amended during opposition proceedings according to the then pending main request met the requirements of the EPC.

II. During opposition the granted patent had been opposed under Article 100(a) EPC *inter alia* for lack of inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC on the ground of extending the subject-matter beyond the content of the application as filed.

Inter alia the following documents were submitted in opposition proceedings:

(1) US-A-2004/175 408,
(3) US-A-5 626 611,
(8) Analytical Letters, Vol. 23, Issue 9, September 1990, pages 1607 to 1619, Abstract, and
(9) US-A-5 108 807.

III. The Opposition Division held that the subject-matter of the patent in suit as amended during the examination phase did not extend beyond the content of the application as filed. In particular, with respect to the amendments made to claim 1 the Opposition Division found that the basis for the reinforcement member comprising "a lactide-rich lactide/glycolide copolymer" was supported by the passage bridging pages 7 and 8 of the original application referring to lactide-rich lactide/glycolide copolymers. Further, the passage on page 17, line 6 disclosed that lactide-rich polymers and

copolymers were of particular utility. With regard to novelty and inventive step the Opposition Division found that the documents cited neither anticipated nor rendered obvious the claimed subject-matter.

IV. As its Main Request the Respondent (Patent Proprietor) defended the maintenance of the patent in suit on the basis of the amended set of claims held to be patentable by the Opposition Division. The wording of independent claims 1 and 36 of this Main Request was identical to the wording of granted claims 1 and 36 and read as follows:

"1. A tissue implant, comprising:
a biocompatible polymeric foam, said foam soluble in a lyophilizing solvent;
a biocompatible polymeric reinforcement member, wherein said reinforcement member is soluble in the lyophilizing solvent and comprises a lactide-rich lactide/glycolide copolymer; and,
a polymeric coating having a thickness applied to the reinforcement member, said coating comprising a coating polymer, wherein said coating polymer is substantially insoluble in said lyophilizing solvent and the thickness of the coating is sufficient to effectively prevent the lyophilizing solvent from contacting the reinforcement member."

"36. A method of manufacturing a biocompatible tissue implant, comprising:
providing a solution comprising a foam forming, biocompatible polymer in a lyophilizing solvent, said solvent having a freezing point;
providing a biocompatible polymeric reinforcement member, said reinforcement member comprising a lactide-rich lactide/glycolide copolymer that is

soluble in the lyophilizing solvent, and, a biocompatible polymeric coating having a thickness applied to said member, wherein said polymeric coating comprises a coating polymer that is substantially insoluble in the lyophilizing solvent and the thickness of the coating is sufficient to effectively prevent the lyophilizing solvent from contacting the reinforcement member;
placing the polymeric reinforcement member in a cavity of a suitable mold;
adding the solution to the cavity of the mold such that at least a part of the cavity is filled with the solution and at least part of the reinforcing member is in contact with the solution; and,
cooling the reinforcement member and solution to below the freezing point of the solvent, and lyophilizing."

Subsidiarily the Respondent defended the maintenance of the patent in suit on the basis of the sets of claims according to Auxiliary Request 1 as submitted under cover of a letter dated 20 October 2011, and Auxiliary Requests 2 and 3, submitted at the oral proceedings held on 3 March 2015 before the Board.

The wording of independent claims 1 and 36 of Auxiliary Request 1 was based on the wording of claims 1 and 36, respectively, of the Main Request, wherein the reinforcement member was further characterized in that it comprises a mesh.

Independent claims 1 and 35 of Auxiliary Request 2 were based on the wording of claims 1 and 36, respectively, of the Main Request, wherein the feature "a lactide-rich lactide/glycolide copolymer" was replaced by "poly(lactide-co-glycolide) at a 95/5 mole ratio".

The set of claims according to Auxiliary Request 3 contained only claims 35 to 52 of Auxiliary Request 2, which were renumbered as claims 1 to 18.

V. With its statement of the grounds for appeal the Appellant argued that the amendments made to the claims during the examination phase did not have a basis in the application as filed, corresponding to an objection under Article 100(c) EPC. The passage bridging pages 7 and 8 of the original application documents referred to compositions of the prior art and cannot, therefore, serve as a basis for the amendment. Further, this passage referred only to "certain lactide-rich lactide/glycolide copolymers", which cannot be generalized to any lactide-rich lactide/glycolide copolymer as defined in claim 1 of the Main Request and of Auxiliary Request 1.

Claim 1 of Auxiliary Request 2 did not comply with the requirements of Article 123(2) EPC, since the incorporation of specific features of one dependent claim into independent claim 1 created new combinations of features for the other dependent claims, which all were only dependent on claim 1.

Further, the Appellant maintained its objection that the subject-matter of claim 1 was not disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person, since the tissue implant was defined by means of the solubility of its components in a lyophilizing solvent, the solvent, however, not being specified at all.

The Appellant further argued that starting from document (1) as closest state of the art the subject-matter of

the claims according to all Requests did not involve an inventive step.

VI. With respect to the issue of added subject-matter, the Respondent argued that although the passage bridging pages 7 and 8 of the original application referred to the description of the prior art, it nevertheless emphasized that the invention focused on these lactide-rich lactide/glycolide copolymers. Further, the passage on page 17, line 6 disclosed the particular utility of lactide-rich polymers and copolymers. Therefore, the amendment made to claim 1 during the examination phase, which restricted the material of the reinforcing member to "lactide-rich lactide/glycolide copolymers" had a basis in the original application documents.

As regards the alleged new combination of features in the claims of Auxiliary Request 2 the Respondent argued that the combination of features was to be found in the description as originally filed, which in several passages and in all examples referred to the poly(lactide-co-glycolide)at a 95/5 mole ratio being the preferred polymer used for the reinforcing member.

The patent in suit contained sufficient information to enable a skilled person to prepare the tissue implants according to claim 1. The objection of the Appellant went into the direction that without any information on the specific lyophilizing solvent a skilled person would not know, whether he was working inside the claims or outside, which clearly was a matter of Article 84 EPC.

With regard to inventive step it argued that starting from document (1) as closest state of the art the problem to be solved was to provide a tissue implant with improved structural integrity and longevity.

Coating the reinforcement member with a coating being insoluble in the lyophilizing solvent in order to solve this problem was not obvious from the prior art.

VII. The Appellant requested that the decision under appeal be set aside and that the European patent No. 1 645 298 be revoked.

The Respondent requested that the appeal be dismissed, or alternatively, that the patent be maintained upon the basis of Auxiliary Requests 1, 2 or 3, Auxiliary Request 1 filed under cover of a letter dated 20 October 2011, and Auxiliary Requests 2 and 3 filed during the oral proceedings before the board.

VIII. 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 100(c) EPC)

2.1 The Respondent opposed the patent in suit on the ground that its subject-matter extended beyond the content of the application as filed.

2.2 Claim 1 of the Main Request, which had the identical wording as granted claim 1 relates to a tissue implant comprising a biocompatible polymeric foam and a reinforcement member. According to the Respondent the feature defining that the reinforcement member comprised a "lactide-rich lactide/glycolide copolymer", introduced

into claim 1 during the examination phase, had no proper basis in the application as filed.

2.3 In order to determine whether or not the subject-matter of a claim in a patent extends beyond the content of the application as filed it has to be examined whether that claim comprises technical information which a skilled person would not have objectively and unambiguously derived from the application as filed (see decisions T 288/92, point 3.1 of the reasons; T 680/93, point 2 of the reasons; neither published in OJ EPO)

2.4 In the present case, amended claim 1 contains the feature that the reinforcement member comprised a "lactide-rich lactide/glycolide copolymer". This wording is disclosed in the original application documents only in the passage bridging pages 7 and 8 (page 7, line 33 to page 8, line 3). However, this passage clearly refers to the description of the prior art and, therefore, cannot form part of the teaching in relation to the invention. Further, this passage states that "certain lactide-rich lactide/glycolide copolymers" can be made into reinforcing elements. Introducing the more general term "lactide-rich lactide/glycolide copolymer" into claim 1 would, however, cover any lactide-rich lactide/glycolide copolymer. Since the application as filed does not contain an indication that any lactide-rich lactide/glycolide copolymer was suitable that amendment is regarded as being an undue generalization and creating embodiments which a skilled person would not have objectively and unambiguously derived from the application as filed.

The Respondent argued that the passage bridging pages 7 and 8 of the original application set out the core problem underlying the invention. Therefore, a skilled

person would have obtained the information that the problem to be solved was that of the solubility of these lactide-rich lactide/glycolide copolymers. This is also supported by original claims 28 and 29 and by the passage on page 17,line 6.

However, original claim 28 merely states that the polymeric reinforcement member comprises a mesh of a copolymerized lactide and glycolide, without any indication that these copolymers are lactide-rich. In claim 29 a particular copolymer is claimed, namely a "poly(lactide-co-glycolide) at a 95/5 mole ratio", which is a lactide-rich copolymer, but with a very specific molar ratio of lactide and glycolide units. Therefore, the original claims 28 and 29 cannot serve as a basis for the amendment made to claim 1.
The passage on page 17, line 6 discloses that of particular utility are "lactide-rich polymers and copolymers". This passage, however, only specifies the lactide being part of the copolymer, but is silent on the other comonomers. In one specific embodiment this passage refers to "a lactide/glycolide copolymer at a 95/5 mole ratio [95/5 poly(lactide-co-glycolide)]", which also cannot form the basis for any "lactide-rich lactide/glycolide copolymer" (page 17, lines 19 to 21).

2.5 For these reasons, the Board concludes that claim 1 of the Main Request extends beyond the content of the application as filed, thus justifying the ground for opposition pursuant to Article 100(c) EPC.

Auxiliary Request 1

3. Amendments (Article 100(c) EPC)

Since claim 1 of Auxiliary Request 1 contains the same feature as claim 1 of the Main Request that the reinforcement member comprised a "lactide-rich lactide/glycolide copolymer" (see paragraph IV *supra*), the arguments and conclusions drawn in paragraphs 2.4 and 2.5 *supra* apply *mutatis mutandis* also to Auxiliary Request 1, i.e. the subject-matter claimed extends beyond the content of the application as filed, thus justifying the ground for opposition pursuant to Article 100(c) EPC.

Auxiliary Request 2

4. Amendments Article 123(2) EPC

4.1 Independent claims 1 and 35 of Auxiliary Request 2 were based on the wording of claims 1 and 36, respectively, of the Main Request, wherein the feature "a lactide-rich lactide/glycolide copolymer" has been replaced by "poly(lactide-co-glycolide) at a 95/5 mole ratio".
A basis for this amendment is *inter alia* to be found in original claim 29.

4.2 The Appellant objected to this amendment as creating combinations of features that were not derivable from the application as filed, since all dependent claims only referred back to claim 1. The incorporation of the specific embodiment of dependent claim 29 into claim 1 created new embodiments for dependent claim 3, which was only dependent on claim 1. As a consequence claim 3 now referred to a tissue implant, wherein the polymer for the polymeric foam is selected from the specific list of original claim 3 combined with a reinforcement member comprised of poly(lactide-co-glycolide) at a 95/5 mole ratio.

4.3 However, the originally filed claims are not the only basis for the amendment to claim 1. The description refers at various passages in general to "poly(lactide-co-glycolide) at a 95/5 mole ratio" as being the preferred copolymer for the reinforcement member (examples 1 to 13, Fig. 10 to 13,). Further, the description gives a list of polymers that are generally suitable for making the porous structure, which list contains the polymers claimed in claim 3 (page 13, lines 24 to 33).

The amendment made to claim 1 does, therefore, not extend beyond the content of the application as filed and restricts the scope of the patent as granted. The Board concludes that the amendments fulfil the requirements of Article 123(2) and (3) EPC.

5. Insufficiency of disclosure (Article 100(b) EPC)

5.1 The Appellant objected to the subject-matter of claim 1 as not being disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person. In particular, the objection related to the polymeric coating applied to the reinforcement member, which was defined as comprising a coating polymer being substantially insoluble in the lyophilizing solvent used for preparing the biocompatible polymeric foam. Claim 1 did, however, not specify the lyophilizing solvent. Since the skilled person knew various solvents that were suitable for use in lyophilization processes, he could, thus, be faced with the situation that the coating material was insoluble in one of these solvents, but soluble in another. Consequently he would not know whether he was working inside or outside the claimed subject-matter.

5.2 In the present case the Appellant conceded that the skilled person could prepare the claimed tissue implants, even by methods other than lyophilization processes. The patent application contains enough information on the kind of materials used for the individual parts of the claimed tissue implant (page 13, last paragraph to page 15, middle; paragraph bridging pages 27 and 28; Examples; claim 32).
Therefore, the objection of the Appellant rather refers to determining the limits of the subject-matter claimed. Accordingly, that objection is related to the question whether the claims clearly define the matter for which protection is sought, which is a matter of Article 84 EPC only.

5.3 For these reasons the Board accepts that the patent in suit discloses the invention as defined in claim 1 of Auxiliary Request 2 in a manner sufficiently clear and complete for it to be carried out by a skilled person.

6. Novelty

Novelty of the then pending broader claimed subject-matter was accepted by the Opposition Division and was not objected to by the Appellant. The Board sees no reason to investigate into this matter on its own motion.

7. Inventive step (Article 56 EPC)

7.1 Claim 1 of Auxiliary Request 2 relates to a tissue implant comprising a reinforcement member and a biocompatible polymeric foam, both being soluble in the lyophilizing solvent. A similar tissue implant is described in document (1), which was accepted by the Opposition Division and by both parties to the appeal

proceedings as representing the closest state of the art.

7.2 Document (1) discloses a biocompatible tissue implant comprising a biocompatible polymeric foam and a biocompatible reinforcement member, wherein both are soluble in a common solvent (claim 1). The tissue implant is prepared according to a lyophilization process, wherein the reinforcement member is composed of an absorbable polymer that is soluble in the lyophilizing solvent. Among the suitable polymers are lactide-rich polymers and copolymers, such as poly(lactide-co-glycolide) at a 95/5 molar ratio (paragraph [0045] and [0059]; Examples; claim 29).

7.3 According to the Respondent the problem to be solved was to provide a biocompatible tissue implant having enhanced structural integrity and longevity.

7.4 As a solution to this problem the invention proposes the tissue implants according to claim 1, wherein a coating substantially insoluble in the lyophilizing solvent was applied to the reinforcement member.

7.5 The Respondent argued that even in the absence of experimental evidence the success of the suggested solution was credible, since document (1) taught that during the lyophilization process the reinforcement member could be dissolved by the lyophilizing solvent. In order to minimize degradation/dissolution of the reinforcement member document (1) suggested various measures: the annealing of the reinforcement member, the quenching of the lyophilizing solution and the reinforcement member in the mold or the use of larger fibre diameters for the reinforcement member. However, the coating of the reinforcement member with a coating

material being insoluble in the lyophilizing solvent, as suggested in the patent in suit completely avoided dissolution of the reinforcement member during the lyophilization process thereby preserving the initial structural integrity of the reinforcement member.

7.5.1 The Appellant argued that document (1) referred in paragraph [0012] to preparation methods other than the lyophilization process, which would not result in any degradation/dissolution of the reinforcement member.

7.5.2 However, the passage cited by the Appellant relates to a description of the prior art. The only method used for preparing the tissue implants of document (1) was the lyophilization process having the disadvantages referred to in paragraph 7.5 *supra*. For this reason the argument of the Appellant cannot succeed.

7.6 Thus, the Board accepts that the tissue implants according to the patent in suit show higher structural integrity and enhanced longevity compared to those of document (1) and the technical problem mentioned in paragraph 7.3 supra is successfully solved.

7.7 According to the Appellant the solution suggested by the patent in suit was, however, not based on an inventive step in view of documents (1), (3), (8) or (9):

7.7.1 When starting from document (1) the skilled person was aware of the problem that the reinforcement member could easily be dissolved during the lyophilization step. Therefore, he would first try to protect the reinforcement structure by appropriate means, such as the application of a protective coating. Document (1) disclosed in paragraph [0047] that the filaments of the reinforcement member may be co-extruded to produce a

sheath/core construction, wherein one or more biocompatible core filaments were surrounded by another biocompatible polymer. Therefore, applying a protective coating to the reinforcement member, was already suggested in document (1).

However, this specific sheath/core structure was suggested to enhance the tissue ingrowth of the tissue implant, but it does not refer to protecting the reinforcement member from dissolution or to improving the structural integrity or longevity of the tissue implant. Moreover, this passage does not specify that the sheath material has to be insoluble in the lyophilizing solvent. The passage cited by the Appellant cannot, therefore, render the claimed subject-matter obvious.

7.7.2 Document (3) related to a bioabsorbable composite material having a core portion of a first bioabsorbable material, such as copolymers of glycolide and lactide, and a shell portion comprising a second bioabsorbable material, such as those specified in the patent in suit for the coating polymers. Preferably, the shell portion having a higher rate of bioabsorbability (column 3, lines 27 to 41 and 59 to 63).

However, the problem related to in document (3) was to provide a material that shows enhanced tissue ingrowth due to the higher rate of bioabsorbability of the shell material (column 4, lines 8 to 10). Therefore, the skilled person would not have consulted this document when looking for a solution to the technical problem mentioned in paragraph 7.3 *supra*. Consequently, this argument of the Appellant is not convincing.

7.7.3 Document (8) related to biosensors comprising enzymes immobilized on a polymeric film. This film was further covered by a thin layer of Nafion to avoid its subsequent dissolution in water.

Document (9) related to multilayer degradable thermoplastic articles, which were used for the preparation of biodegradable bags (abstract). In column 6, lines 30 to 35 it referred to a particular embodiment which comprised outer layers that were less water soluble than the core material in order to protect the more soluble core material from dissolution.

However, documents (8) and (9) relate to a completely different technical field than the patent in suit. A skilled person starting from document (1) as closest state of the art would not consult these documents when looking for a solution to the technical problem of enhancing structural integrity and longevity of tissue implants. Therefore, the teaching of documents (8) and (9) did not lead the skilled person to the claimed invention.

7.8 For these reasons the Board comes to the conclusion that the subject-matter of claim 1 of Auxiliary Request 2 is not obvious when starting from document (1) in combination with either of documents (3), (8) or (9) and is, therefore, regarded as being based on an inventive step (Article 56 EPC).

8. The subject-matter of independent claim 35 concerns the method of manufacturing a biocompatible tissue implant being characterized by the same technical features as in claim 1. Since the tissue implant of claim 1 is regarded as involving an inventive step the same arguments may be applied to its method of manufacture as defined in claim

35 which, as a consequence, is also regarded as involving an inventive step.

The dependent claims 2 to 34 and 36 to 52 are preferred embodiments of independent claims 1 and 35, respectively, and are, therefore, also regarded as involving an inventive step.

9. Since the Board found that the subject-matter of Auxiliary Request 2 was based on an inventive step, a decision on Auxiliary Request 3 was not necessary.

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 maintain the patent with the following claims and a description to be adapted:
Claims Nos. 1 - 52 of Auxiliary Request 2 received during the oral proceedings of 3 March 2015.

The Registrar: The Chairman:

M. Kiehl P. Gryczka

Decision electronically authenticated