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Datasheet for the decision of 10 May 2016

Case Number: T 0565/13 - 3.3.10

Application Number: 06784588.3

Publication Number: 1896056

IPC: A61K38/39, A61K9/00, A61F2/02

Language of the proceedings: EN

Title of invention:
REINFORCED COLLAGEN SCAFFOLD

Patent Proprietor:
ETHICON, INC.

Opponent:
Covidien

Headword:

Relevant legal provisions:
EPC Art. 100(a), 54(2), 123(2), 123(3)

Keyword:
Grounds for opposition - lack of novelty (yes) - fresh ground for opposition (not admitted)
Novelty - (no) - auxiliary request 1
Auxiliary request 2 - added subject-matter (no), novelty (yes), inventive step (yes)

Decisions cited:

Catchword:

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Case Number: T 0565/13 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 10 May 2016

Appellant: (Opponent)	Covidien 555 Long Wharf Drive Mailstop 8 N-1 New Haven, Connecticut 06511 (US)
Representative:	Maschio, Antonio Maschio & Soames IP Limited 30 Carlton Crescent Southampton SO15 2EW (GB)
Respondent: (Patent Proprietor)	ETHICON, INC. U.S. Route 22 Somerville, NJ 08876-1515 (US)
Representative:	Kirsch, Susan Edith Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 4 January 2013 rejecting the opposition filed against European patent No. 1896056 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón
C. Schmidt

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division to reject the opposition, filed on the ground of lack of novelty and inventive step (Article 100(a) EPC), against European patent No. 1 896 056.

II. The documents filed during the opposition proceedings included the following:

D2 US 6,179,872 B1
D3 WO 96/08277 A1
D5 US 2002/0173448 A1
D6 Experimental report
D10 Oxford Dictionary of Chemistry, third edition, page 317.

III. Claim 1 of the patent as granted, which is the main request in these appeal proceedings, reads as follows:

"A collagen scaffold comprising a collagen matrix having a basic pH, the collagen matrix being interspersed within a reinforcing polymeric fibrous structure."

IV. The opposition division concluded that the claimed collagen scaffold was novel over that of D2, as the latter did not disclose a collagen matrix interspersed within a reinforcing fibrous structure. It further concluded that document D2 was the closest prior art, and that the problem underlying the claimed invention was the provision of a collagen scaffold, for tissue engineering, which facilitated repair or regeneration of diseased or damaged tissues. The solution, which was a scaffold in which a collagen matrix was interspersed

within a reinforcing polymeric fibrous structure, was not obvious having regard to the prior art.

V. With the response to the grounds of appeal, the respondent (patent proprietor) filed auxiliary requests 1 to 8. During the oral proceedings, auxiliary requests 4 and 5 became auxiliary requests 1 and 2. Claim 3 of both requests limits the collagen scaffold of claim 1 of the main request by requiring that it should be

"*obtainable by the method of claim 1*".

Claim 1 of auxiliary request 1 reads as follows:

"*A method for making a collagen scaffold comprising the steps of: i) applying a basic pH collagen solution having a basic pH to a reinforcing polymeric fibrous structure, and ii) drying the solution to form a collagen matrix interspersed within the reinforcing polymeric fibrous structure*".

Lastly, claim 1 of auxiliary request 2 reads as follows:

"*A method for making a collagen scaffold comprising the steps of: i) applying a basic pH collagen solution having a pH of 8 to 12 to a reinforcing polymeric fibrous structure, and ii) drying the solution to form a collagen matrix interspersed within the reinforcing polymeric fibrous structure*".

VI. The arguments of the appellant relevant for the present decision were the following:

Example 1 of document D2 disclosed the preparation of a fibril-gel matt by adjusting a collagen solution to

pH 7.4, mixing the solution obtained for 2 h at 4°C, and pouring over a screen. The matt thus obtained was a collagen scaffold comprising a matrix having a basic pH interspersed within fibril, and fibril was a reinforcing polymeric fibrous structure. Such a matt could be obtained by applying a basic collagen solution to fibril, and drying. For these reasons, the scaffold of claim 1 of the main request and of claim 3 of auxiliary request 1 was not novel.

The invention as claimed in auxiliary request 1 was not sufficiently disclosed for it to be carried out by a person skilled in the art. Although Article 100(b) EPC had not been a ground of opposition, such an objection could be raised since the claims as granted had been amended, creating a new procedural situation.

Claim 1 of auxiliary request 2 required a collagen solution having a pH of 8 to 12. Although this feature could be found on page 6, line 4, of the application as originally filed, it was disclosed therein only in combination with other features, such as the nature of the buffer or its amount, which were not in claim 1. For that reason, claim 1 of auxiliary request 2 contained added subject-matter.

VII. The arguments of the respondent relevant for the present decision were the following:

D2 referred to a collagen solution having a pH of 7.4, which was not a basic pH. In addition, claim 1 of auxiliary request 1, and thus also its claim 3, required a drying step, which affected the structure of the final product. The matt of D2 was not amorphous enough to be a matrix in the sense of claim 1. Further, the fibrils of D2 did not have cavities or interstices,

so the matt could not contain a collagen matrix interspersed within. For these reasons, the subject-matter of claim 1 of the patent as granted and of claim 3 of the first auxiliary request was novel.

The respondent did not agree to the ground of opposition defined in Article 100(b) EPC being examined; it had not been raised during opposition proceedings. As the objection raised by the appellant applied in the same manner to claim 1 of the patent as granted, it could not have originated from the amendments carried out.

Document D2 was the closest prior art for the subject-matter of auxiliary request 2. The scaffold of D2 could not be obtained from a collagen solution having a pH of 8 to 12. The respondent considered that the problem underlying the claimed invention was providing an improved collagen scaffold. If, nevertheless, that problem were to be considered as merely providing an alternative collagen scaffold capable, like that of D2, of retaining growth factors soluble in acid media, the solution, which was a scaffold which could be obtained from a collagen solution having a pH of 8 to 12, was inventive, as there was no indication towards this solution in the cited prior art.

VIII. Oral proceedings before the board of appeal took place on 10 May 2016.

IX. The final requests of the parties were the following:

- The appellant requested that the decision under appeal be set aside and that European patent No. 1 896 056 be revoked.

- The respondent requested that the appeal be dismissed or - alternatively - that the decision under appeal be set aside and that the patent be maintained on the basis of one of the auxiliary requests, filed with letter dated 30 September 2013, in the following order:
  - auxiliary requests 4 to 6 (now auxiliary requests 1 to 3),
  - auxiliary requests 1 to 3 (now auxiliary requests 4 to 6) and
  - auxiliary requests 7 and 8.

X. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Procedural matters

2. Article 100(b) EPC had not been invoked as a ground for opposition in the notice of opposition, and was not raised during opposition proceedings. The appellant, nevertheless, argued during the oral proceedings before the board that the subject-matter of the claims of auxiliary request 1 was not sufficiently disclosed for it to be carried out by a person skilled in the art.

Claim 3 of auxiliary request 1 limits the subject-matter of claim 1 of the patent as granted merely by requiring that the claimed product should be obtainable by the process of claim 1, which is identical to claim 13 as granted. The alleged deficiency was therefore already present in the claims as granted.

Under the present circumstances, such a fresh ground of opposition could only be examined with the consent of the respondent (G10/91, point 3. of the opinion), which has not been given. Thus, this fresh ground cannot be admitted into the proceedings.

3. The appellant relied for the first time during the oral proceedings before the board on example 1 of document D2, having discussed during the written proceedings other passages of said document. The respondent has not raised any formal objection against this new argument.

As the content of document D2 has already been thoroughly discussed in the written proceedings, the content of example 1 is very similar to that in column 9, examined by the opposition division and relied upon in appeal, and the respondent has not raised any objection, the board does not see any reason not to admit this new argument.

Novelty, auxiliary request 1

4. Claim 3 of auxiliary request 1 is directed to a collagen scaffold comprising a collagen matrix having a basic pH, the collagen matrix being interspersed within a reinforcing polymeric fibrous structure.

Said scaffold should be obtainable by the method defined in claim 1, which requires i) applying a basic pH collagen solution to a reinforcing polymeric fibrous structure and ii) drying the solution to form a collagen matrix interspersed within the reinforcing polymeric fibrous structure.

5. Example 1 of document D2 discloses adjusting a collagen solution to pH 7.4, mixing the solution obtained during

2 h at 4°C, and pouring over a screen. A fibril-gel is formed, which is dried to form a matt.

On column 9, lines 22-53, document D2 explains the transformations to the collagen structure due to the process of example 1. Incubation at 4°C with gentle stirring leads to the formation of collagen fibril (lines 30-33). Such fibril "solution" is poured over a porous structure (a 270-mesh stainless steel screel according to example 1), which retains the fibrils. As the fibrils become trapped, their layering becomes dense enough to slow the flow of solution. The remaining solution is allowed to gel to trap the fibrils and form a semi-solid fibril-gel structure (lines 49-51). The amount of gel can be reduced by using NaCl (example 1, lines 30-32; column 9, lines 54-55). The resulting gel-fibril composite is thus a collagen scaffold comprising a collagen matrix (collagen gel) which is at least partially interspersed within a reinforcing polymeric fibrous structure (collagen fibrils).

There is no apparent reason why the matt of example 1 of D2 could not be obtained by the method of claim 1, by applying a basic collagen solution to isolated fibrils, and drying the resulting mixture.

For these reasons, claim 3 of auxiliary request 1 is not novel over example 1 of D2.

5.1 The respondent argued that claim 3 required the collagen scaffold to be obtainable by the method of claim 1, which included drying a collagen solution. Such a method was different from that of D2, in which the product was first allowed to gel, and only then was dried. This different procedure affected the final

structure of the compound obtained and, for that reason, the matt of D2 was not obtainable by the method of claim 1.

However, the respondent has confronted the appellant and the board with a claim drafted in product-by-process form. Such a product could be novel if, as contended, the process features necessarily lead to a different product. However, the respondent has not provided any evidence of that, and nor is it immediately apparent that it is the case.

5.2 The respondent argued that the term "matrix" could have different meanings in different technical fields but, in the context of collagen technology, a matrix referred to an amorphous dispersion obtained from dissolved collagen, once dried.

The respondent relied on documents D5 and D10 in support for that interpretation. On the last sentence of paragraph [0004], D5 defined a matrix as "a solid porous composition having a relative fixed three-dimensional structure". D10 disclosed that, in chemistry, a matrix is "a continuous solid phase in which particles are embedded". The product obtained in D2, which did not use the term matrix, was not amorphous enough to be a matrix in the sense of claim 3, as it was a random array of fibrils (column 7, lines 26-28).

The patent in suit does not contain a definition of the term "matrix". Those provided by the respondent merely prove that there is no generally applicable definition: D5, but not D10, requires a matrix to be porous; D10, but not D5, requires embedded particles,. None of these definitions requires a matrix to be "amorphous", or

limits a collagen matrix beyond a collagen three-dimensional structure.

5.3 The respondent argued that a matrix could only be interspersed within a polymer if the latter had cavities or interstices. However, according to column 9, line 45, the fibrils of example 1 were densely packed and thus lacked cavities. For that reason, the matt disclosed in example 1 of document D2 did not contain a matrix interspersed within a reinforcing polymeric fibrous structure, as required by claim 3.

However, document D2 discloses a mixture of collagen fibrils and collagen gel, obtained by gelling the "remaining solution above the porous structure" (i.e. above the mesh). D2 does not disclose, as argued by the respondent, densely packed fibrils having no interstices. According to D2, the collagen solution is allowed to gel when the fibril layering becomes dense enough to slow the flow of solution through the mesh, at which point of time, collagen solution remains in the interstices of the fibrils. For that reason, contrary to the argument of the respondent, the matt of D2 has collagen gel interspersed within fibril.

5.4 The respondent further argued that 7.4 was not a basic pH, as required by claim 3. Rounded to one significant figure, 7.4 was 7, i.e. neutral. Neutral pH did not define an infinitesimal point but a range and, even though the boundaries of such an interval were not clear, it included a pH of 7.4. Such an interpretation was supported by D2, which disclosed that a pH 7.4 buffer was a "neutralisation buffer" (column 9, line 55). For these reasons, the pH disclosed in document D2 was neutral and not basic.

However, 7.4 is a basic pH in the usual meaning of the term, i.e. pH > 7. The patent in suit does not include any passage indicating that the term should be interpreted otherwise.

5.5 The respondent argued that, as the claimed invention was in the field of collagen scaffolds for tissue engineering, the skilled person understood that neutral pH meant physiological pH, i.e a pH of around, not exactly, 7.

However, nothing in the patent in suit indicates that neutral pH should be interpreted as physiological pH.

5.6 The respondent argued that there was no evidence on file showing that a basic pH corresponded to a pH higher than 7.

However, no such evidence is required, as this is a basic concept in chemistry which is part of the general knowledge of the skilled person.

5.7 The respondent further argued that all dissolved collagen went through the mesh and thus the matt of D2 only contained fibrils. For that reason, the claimed subject-matter differed from that disclosed in D2.

However, document D2 explicitly mentions the formation of collagen gel out of the remaining solution above the porous, mesh structure, which requires dissolved collagen to be still present above it. The gel thus formed is interspersed within fibrils, for the reasons already explained.

6. The scaffold of claim 3 of auxiliary request 1 is thus not novel (Article 54 EPC).

Main request, novelty

7. As claim 1 of the main request includes the subject-matter of claim 3 of auxiliary request 1, it is not novel for the same reasons.

Auxiliary request 2, amendments

8. Claim 1 of auxiliary request 2 differs from that of auxiliary request 1 in that it requires applying a collagen solution having a pH of 8 to 12 to a reinforcing polymeric polymer.

It is the result of combining claim 13 as originally filed and the pH values on page 6, lines 4-5, of the application as originally filed.

The appellant argued that this passage disclosed the pH required by claim 1 only in combination with other features, such as the nature and the concentration of the buffer, which had not been incorporated into claim 1. For that reason, the amendment was an unallowable generalisation.

However, the passage on page 6 is the sole reference to a precise basic pH in the whole application, leaving aside the examples. There is no reason why said pH range could not be seem as applying to the other embodiments of the application as filed.

The sentence referring to the required pH is between two full stops and does not refer back to the information given in the preceding sentences. Further,

there is no technical reason why such a pH could only be achieved at the concentration, or by the type of buffers, disclosed in the preceding paragraph.

The skilled person would therefore consider that the pH of 8 to 12 is independent of the concentration and type of buffer, and combined with the features of claim 13 as originally filed. Claim 1 thus finds the required basis in the application as originally filed.

Auxiliary request 2, novelty

9. The appellant did not raise any objection under Article 54 EPC against the subject-matter of auxiliary request 2.

9.1 None of the documents on file discloses the step of applying a collagen solution having a pH of 8 to 12 to a reinforcing polymeric structure. For that reason, claim 1 is novel over the prior art.

With respect to claim 3, directed to a scaffold obtainable by the process of claim 1, it is considered that the pH of the required collagen solution has an effect on the degree of protonation of the side chains of the collagen. For that reason, the scaffold of claim 3 differs from that of example 1 of D2, which is obtained from a solution having a pH of 7.4.

9.2 During the written proceedings, the appellant argued that document D3 already disclosed the scaffold of claim 1 of the main request. This document concerns collagen scaffolds obtainable from a collagen solution at a pH of 8. Although the appellant has not relied on this argument with respect to the subject-matter of auxiliary request 2, it needs to be examined because

the conclusions should be the same as for the main request.

D3 does however not disclose, in combination, collagen scaffolds obtainable from collagen solutions at a pH of 8 (page 8, lines 12-15) and a reinforcing polymer, as the latter is only mentioned in the examples, in the context of scaffolds obtained from acid collagen solutions. Claim 3 of auxiliary request 2 is thus novel over D3.

Auxiliary request 2, inventive step

10. The appellant did not raise objections with respect to the inventiveness of the subject-matter of auxiliary request 2.

11. Closest prior art

The opposition division and the parties considered that document D2 was the closest prior art. The board sees no reason to differ.

It has not been disputed that document D2 discloses collagen scaffolds which differ from those of claim 3 at least in being obtainable from a less basic collagen solution. The collagen units of the scaffold of claim 3 thus contain more anionic groups.

12. Technical problem underlying the invention

The respondent defined the technical problem underlying the claimed invention as providing a collagen scaffold which makes it possible to improve the ability to retain protein-based growth factors that are highly soluble in acidic solutions, while marginally soluble

under neutral or basic conditions [0017].

The question of whether or not the problem as formulated by the respondent has been solved in all aspects can be left aside, since the board holds that, even if the technical problem is reformulated as merely the provision of an alternative collagen scaffold able, like that of the prior art, to retain that type of growth factors, the proposed solution is not obvious.

13. Solution

The solution to this technical problem is the claimed collagen scaffold, characterised in that it is obtainable by applying a collagen solution having a pH of 8 to 12 to a reinforcing polymeric fibrous structure.

14. Success

Having regard to the data provided in the experimental report D6, the problem mentioned under point 12 above is considered to be successfully solved by the collagen scaffold of claim 3 of auxiliary request 2. These data show that scaffolds obtained, like those claimed, from basic collagen solutions are able to retain growth factors such as GDF-5.

15. It thus remains to be decided whether or not the proposed solution to the objective problem defined above is obvious in view of the state of the art.

Document D2 explictly mentiones that the pH of the collagen solution needs to be carefully adjusted to 7.4. D2 explains that such a pH is essential in order to preserve the natural structure of the collagen

(column 1, line 22).

The skilled person, trying to obtain an alternative scaffold, has no motivation to change the pH of the collagen solution used for preparing the scaffold of D2, let alone to use a more basic pH. In particular, even if the collagen scaffold of D2 has the ability to retain growth factors, neither D2 nor any of the documents cited against the patent in suit refers to the effect of the pH of the collagen solution on such retention. Trying to obtain an alternative scaffold capable of retaining this type of growth factors, the skilled person is given no hint that such an effect would be maintained for scaffolds obtainable from collagen solutions having a more basic pH.

For these reasons, the board concludes that document D2 does not hint at the claimed solution, and hence that the subject-matter of claim 3 of auxiliary request 2 is inventive, as required by Article 56 EPC.

16. Although claim 1 of auxiliary request 2 does not necessarily lead to a product according to claim 3, no objection going beyond those which would also apply to the collagen scaffolds of claim 3 has been raised or is immediately apparent from the cited prior art.

Conclusion

16.1 The collagen scaffold of claim 1 of the main request is not novel, with the consequence that the ground defined in Article 100(a) EPC precludes the maintenance of the patent as granted.

16.2 The collagen scaffold of claim 3 of auxiliary request 1 is not novel and for this reason this request is not

allowable.

16.3 The claims of auxiliary request 2 find a basis in the application as originally filed and define subject-matter novel and inventive over the prior art cited against them.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the second auxiliary request, filed as auxiliary request 5 with letter dated 30 September 2013, and a description to be adapted thereto.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated