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**Datasheet for the decision  
of 1 March 2011**

**Case Number:** T 0370/10 - 3.3.10

**Application Number:** 95904642.6

**Publication Number:** 0738161

**IPC:** A61L 31/00

**Language of the proceedings:** EN

**Title of invention:**

Use of a collagen membrane for the preparation of an implant  
for guided tissue regeneration

**Patentee:**

ED. GEISTLICH SÖHNE AG

**Opponent:**

GENZYME CORPORATION

**Headword:**

Use of collagen membrane for preparation of an  
implant/GEISTLICH SÖHNE AG

**Relevant legal provisions:**

EPC Art. 100(c), 123(2), 123(3)

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Main and auxiliary request 3: added subject-matter (yes)"  
"Auxiliary requests 1, 2 and 4: extension of protection  
conferred (yes)"

**Decisions cited:**

T 0307/05

**Catchword:**

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Case Number: T 0370/10 - 3.3.10

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.10  
of 1 March 2011

**Appellant:**  
(Patent Proprietor)

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(Opponent)

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**Decision under appeal:**

Decision of the Opposition Division of the  
European Patent Office posted 27 November 2009  
revoking European patent No. 0738161 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** P. Gryczka  
**Members:** J. Mercey  
J.-P. Seitz

## Summary of Facts and Submissions

- I. The Appellant (Proprietor of the Patent) lodged an appeal on 6 February 2010 against the decision of the Opposition Division sent by post on 27 November 2009 revoking European patent No. 738 161.
  
- II. Notice of Opposition had been filed by the Respondent (Opponent) requesting revocation of the patent in its entirety on the grounds of *inter alia* extending the subject-matter of the patent in suit beyond the content of the application as filed (Article 100(c) EPC).
  
- III. The decision under appeal was based on an amended set of fifteen claims, independent claim 1 of which read as follows:

"Use of a physiologically acceptable and resorbable collagen membrane which is obtained by purification of a natural collagen membrane so as substantially to retain its natural collagen structure and which has opposing fibrous and smooth sides for the manufacture of an implant for guided regeneration of bone tissue in the orofacial region of a human or non-human animal body following orofacial or dental surgery, wherein said membrane is for orientation so that said fibrous side will face the area of said body where bone tissue regeneration is required and allow cell growth thereon, and said opposing smooth side will inhibit cell adhesion thereon and act as a barrier to prevent passage of cells through the membrane."

The Opposition Division held that the subject-matter of this claim extended beyond the content of the

application as filed, since there was no disclosure therein of the feature "so as **substantially** to retain its natural collagen structure".

IV. With letter dated 4 April 2010, the Appellant submitted auxiliary requests 1 to 3, and with letter dated 14 February 2011, an auxiliary request 4. During the oral proceedings before the Board on 1 March 2011, the Appellant withdrew auxiliary request 5 which it had filed with letter dated 2 February 2011.

Claim 1 of auxiliary request 1 differed from claim 1 of the main request in that the feature "so as substantially to retain its natural collagen structure" was replaced by the feature "so as to retain as far as possible its natural collagen structure".

Claim 1 of auxiliary request 2 differed from claim 1 of the main request in that the term "substantially" was deleted from the feature "so as substantially to retain its natural collagen structure".

Claim 1 of auxiliary request 3 differed from claim 1 of the main request in that the feature "so as substantially to retain its natural collagen structure" was replaced by the feature "so as to retain more than 95% of its natural collagen structure as determined by the level of amide nitrogen in the membrane having fallen by not more than one half from its original level".

Claim 1 of auxiliary request 4 differed from claim 1 of the main request in that the feature "so as substantially to retain its natural collagen structure"

was replaced by the feature "so as to minimise any alteration to the chemical structure of the collagen and thus to maintain its original native properties" and the resorbable collagen membrane was additionally defined as "consisting of pure, native (not denatured), insoluble collagen".

- V. The Appellant argued that claim 1 of all requests found a basis in the application as filed. With regard to the main request, although the term "substantially" in the feature "so as substantially to retain its natural collagen structure" was not explicitly disclosed in the application as filed, the skilled person could derive said term from the general teaching thereof. The Appellant drew particular attention in this respect to page 4, lines 17 to 20, page 4, line 27 to page 5, line 2, page 5, lines 26 to 31 and the Example on page 12 of the application as filed. Most particularly, in view of the fact that the application taught that the membrane to be used should "preferably consist of pure, native (not denatured), insoluble collagen" and that during purification of such a natural collagen alteration to the chemical structure should be "minimised" so that the natural collagen structure could be retained "as far as possible", the skilled person would understand that after purification, a membrane having more than 95% of the collagen in its native state, i.e. which substantially retained its natural collagen structure, was disclosed by the application as filed.

The Appellant submitted that the replacement of the term "substantially" by "as far as possible" in auxiliary request 1 and by "so as to minimise any

alteration to the chemical structure of the collagen and thus to maintain its original native properties" in auxiliary request 4, and its complete deletion in auxiliary request 2, did not result in an extension of the protection conferred.

The Appellant further submitted that the feature "so as to retain more than 95% of its natural collagen structure as determined by the level of amide nitrogen in the membrane having fallen by not more than one half from its original level" in auxiliary request 3 found a basis in the passage at page 5, lines 26 to 31 of the application as filed, the skilled person understanding from this passage that it was preferable to use a membrane which consists of more than 95% of its collagen in its native state.

- VI. The Respondent argued that the main request contained subject-matter extending beyond the content of the application as filed, contrary to the requirements of Article 100(c) EPC, since there was no disclosure therein of the feature "so as substantially to retain its natural collagen structure", the term "substantially" not appearing as such in the application as filed at all. It held that this term meant close to 100%, whereas the expression "as far as possible" actually used in the application as filed did not indicate any absolute extent. The value of 95% on page 5 of the application as filed was disclosed only in connection with a method of measuring how much collagen was present in its native state. It further argued that the amendments made to auxiliary requests 1, 2 and 4 offended against the requirements of Article 123(3) EPC, since both deletion of the

restrictive term "substantially" as well as its replacement by the expressions "as far as possible" or "to minimise any alteration to the chemical structure of the collagen", neither of which specified the absolute level of retention of natural collagen structure thereby achieved, led to an extension of the protection conferred. In addition, the amendments made to auxiliary request 3 offended against the requirements of Article 123(2) EPC.

VII. In a communication of the Board dated 10 December 2010, various objections under Article 100(c), 123(2) and/or (3) EPC were raised against claim 1 of each of the requests then on file.

VIII. The Appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request, namely the claims on which the decision under appeal was based, or, subsidiarily, on the basis of any of auxiliary requests 1 to 3 submitted with letter dated 4 April 2010, or on the basis of auxiliary request 4, submitted with letter dated 14 February 2011.

IX. 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. *Article 100(c) EPC*
  - 2.1 In order to determine whether or not an amendment adds subject-matter extending beyond the content of the application as filed, it has to be examined whether technical information has been introduced which a skilled person would not have directly and unambiguously derived from the application as filed, either explicitly or implicitly, implicit disclosure meaning no more than the clear and unambiguous consequence of what is explicitly disclosed.
  - 2.2 In the decision under appeal, the Opposition Division found that the feature "so as substantially to retain its natural collagen structure" of claim 1 was not disclosed. Thus, this feature will hereinafter be examined for its basis in the application as filed.
  - 2.3 Claim 1 is directed to the use of a physiologically acceptable and resorbable collagen membrane which is obtained by purification of a natural collagen membrane so as substantially to retain its natural collagen structure, the term "substantially" thus defining to what extent the natural collagen structure should be retained during purification. Said term, although unclear, is absolute, the Appellant holding that the extent thereby meant was "most" of said structure and

the Respondent holding that "substantially" meant close to 100% of said structure.

2.4 The feature that the membrane is obtained by purification of a natural collagen membrane so as **substantially** to retain its natural collagen structure is not disclosed explicitly in the application as filed. The Appellant submitted, however, that this feature was implicitly disclosed from the application as filed read as a whole, citing in particular the passages at page 4, lines 17 to 20, page 4, line 27 to page 5, line 2, page 5, lines 26 to 31 and the Example on page 12 in this respect.

2.5 The passage at page 4, lines 17 to 20 of the application as filed, on which the Appellant most heavily relies for support for this feature, reads as follows:

"The membrane for use in the present invention may be derived directly from naturally occurring membranes which, **as far as possible**, retain their natural collagen structure" (emphasis added).

However, the expression "as far as possible" is a definition of the level of retention of the natural collagen structure which depends upon the particular purification method by which the membrane is derived from the naturally occurring membrane and the desired level of purification to be achieved, and thus covers **any** level of retention of natural collagen structure, since different purification methods/levels of purification necessarily lead to different "possible" degrees of alteration of the collagen membrane

structure, the Appellant conceding that purification of a naturally occurring collagen inevitably led to an alteration of its chemical structure (see also page 4, line 35 to page 7, line 6 of the application as filed). The aim of the purification is not "to retain the natural collagen structure" but rather to remove substances having undesirable chemical, physical and/or physiological properties (see page 4, lines 29 to 33 and page 5, lines 11 to 16 of the application as filed), changes to the natural collagen structure being an undesired, but inevitable, side reaction of the purification process (see page 5, lines 17 to 25 of the application as filed), which should be avoided "as far as possible". Usually, the greater the degree of purification required (i.e. the desirable changes listed on page 5, lines 11 to 16 of the application as filed), the lower the retention of the natural collagen structure (see the undesirable changes listed on page 5, lines 17 to 25 of the application as filed), since a more rigorous treatment with alkali and acid (see page 6, line 14 to page 7, line 6) is then required. As such there is a tension between these two requirements, the application as filed not teaching the skilled person to sacrifice level of purity for retention of natural collagen structure, the purity requirements being in fact high, since the product must be physiologically acceptable and the quantity of glycosamine and galactosamine after purification is about 1 molecule to 10,000 molecules of amino acids (see page 6, lines 10 to 13 of the application as filed).

However, there is no teaching in this passage of the absolute extent of retention of the natural collagen structure at the end of the purification process, let

alone that it should be "substantially" retained, as required by the term introduced into granted claim 1.

Hence the term "substantially" is neither the same as the expression "as far as possible", nor can it be derived therefrom, the former term defining an absolute extent of retention of the natural collagen structure, the latter merely any extent of retention of the natural collagen structure which may possibly be achieved by any particular, undefined, purification process.

Thus, the passage at page 4, lines 17 to 20 of the application as filed cannot form a basis for the feature "so as substantially to retain its natural collagen structure".

- 2.6 The passage at page 4, line 27 to page 5, line 2 of the application as filed, which the Appellant also uses as a basis for this feature reads as follows:

"The membrane material for use in the present invention should **preferably** consist of pure, **native** (not denatured), insoluble collagen. However, in an animal's body, collagen is accompanied by a number of substances which have undesirable chemical, physical and/or physiological properties. The collagen therefore **has** to be freed from these substances by purification. Since the nature of such substances varies considerably, enzymatic purification is virtually impossible. It is thus preferable to carry out purification chemically, taking care to **minimise** any alteration to the chemical structure of the collagen and thus to maintain its original native properties" (emphasis added).

However, this "pure, native" collagen is merely described in the application as filed as the ideal material for use in the invention. The paragraph continues by indicating that collagen from an animal's body has to be purified, purification, however, leading inevitably to changes in the chemical structure of the collagen (cf. point 2.5 above). It is then indicated that the purification should be carried out taking care "to minimise any alteration to the chemical structure of the collagen and thus to maintain its original native properties" without, however, specifying an absolute extent of retention of natural collagen structure, let alone "substantial" retention, maintenance of original native **properties** additionally not being necessarily synonymous with retention of the natural collagen **structure**. The disclosure level of this passage is thus very similar to that of the passage at page 4, lines 17 to 20, namely the skilled person is merely taught to derive a collagen membrane for use according to the invention from naturally occurring collagen, and during the method (namely purification) of so doing, to "minimise" any alteration to the chemical structure, or in other words, to retain the natural structure "as far as possible", without however, giving any indication of the absolute extent of retention to be achieved (cf. point 2.5 above).

Thus, the passage at page 4, line 27 to page 5, line 2 of the application as filed cannot form a basis for the feature "so as substantially to retain its natural collagen structure".

2.7 The passage at page 5, lines 26 to 31 of the application as filed upon which the Appellant also relies reads:

"The level of amide nitrogen in the membrane serves as an indicator of these changes. For example, it has been found that if the amide nitrogen content falls by about half (ie. from 0.7 mmol/g to 0.35 mmol/g) then more than 95% of the collagen is still present in its native state."

However, leaving aside the question of whether the term "substantially" can be derived from "more than 95%", this passage cannot serve as a basis for any particular extent of retention of natural collagen structure at all, since it merely indicates how to measure the level of collagen which is still present in its native state after purification, but does not specifically disclose a particular collagen membrane having more than 95% of the collagen in its native state *per se*, and certainly not the use of such a membrane for the manufacture of an implant for use in dental surgery.

Thus, the passage at page 5, lines 26 to 31 of the application as filed cannot form a basis for the feature "so as substantially to retain its natural collagen structure".

2.8 The Example on page 12 illustrates the purification of collagen membranes from young calves and the resultant membrane has an amide nitrogen content of 0.47 mMole/g. The Appellant argued that since this value of 0.47 mMole/g was higher than that of 0.35 mMole/g indicated on page 5, line 30 as meaning that more than

95% of the collagen had retained its natural structure, this Example illustrated a natural collagen membrane which had been purified so as substantially to retain its natural collagen structure.

However, the value of 0.35 mMole/g indicated on page 5, line 30 only corresponds to more than 95% of the collagen still being present in its natural state when the amide nitrogen content of the starting natural collagen was 0.7 mMole/g, it being the relative loss of amide nitrogen content that is decisive ("if the amide nitrogen content falls by about half"). No starting value for the amide nitrogen content has been given in the Example on page 12, it not having been contested by the Appellant that different types of naturally occurring collagen have different amide nitrogen contents. Thus in the absence of a starting value, a percentage loss cannot be determined, such that this Example is not suitable for arriving at any conclusion concerning the percentage retention of natural structure, let alone that this be "substantial".

Thus, the Example on page 12 of the application as filed cannot form a basis for the feature "so as substantially to retain its natural collagen structure".

- 2.9 The Appellant submitted that the skilled person would thus understand the passages discussed above, when taken in the context of the description as a whole, and when read in a reasonable manner and not merely as a linguistic exercise, to disclose natural collagen membrane obtained by purification so as to substantially retain its natural collagen structure.

However, the passages cited by the Appellant have been interpreted in the context of the description as a whole, the meanings of the relevant expressions having not been compared with one another in a vacuum. The application as filed thus does not disclose, either in any of the above cited passages alone and/or taken together and/or in the light of the description as a whole, that the collagen membrane is obtained by purification so as "substantially" to retain its natural collagen structure.

- 2.10 For the reasons given above, the Board concludes that there is neither an explicit nor an implicit disclosure in the application as filed of the feature "so as substantially to retain its natural collagen structure", such that claim 1 of the main request extends the subject-matter claimed beyond the content of the application as filed, thus justifying the ground for opposition pursuant to Article 100(c) EPC.

*Auxiliary request 1*

3. *Article 123(3) EPC*

- 3.1 Article 123(3) EPC requires that the claims of a patent as granted may not be amended during opposition/appeal proceedings in such a way as to extend the protection conferred. In order to decide whether or not an amendment of the patent in suit satisfies that requirement, it is necessary to compare the protection conferred by the claims before amendment, i.e. as granted, with that of the claims after amendment. In that respect, it is established Case Law that a very rigorous standard, namely that of "beyond reasonable



doubt" is to be applied when checking the allowability of amendments under Article 123(3) EPC (see, for example, T 307/05, points 3.3 and 3.4 of the reasons, not published in OJ EPO), such that the slightest doubt that the scope of the patent as amended could cover embodiments not covered by the unamended patent would preclude the allowability of the amendment.

- 3.2 Claim 1 is directed to the use of a physiologically acceptable and resorbable collagen membrane which is obtained by purification of a natural collagen membrane so as to retain **as far as possible** its natural collagen structure (emphasis added).

Claim 1 of the patent as granted is directed to the use of a physiologically acceptable and resorbable collagen membrane which is obtained by purification of a natural collagen membrane so as **substantially** to retain its natural collagen structure (emphasis added).

- 3.3 Thus the question to be answered is whether claim 1 of auxiliary request 1 covers the use of a collagen membrane which was not covered by claim 1 as granted. It thus needs to be examined whether the replacement of the term "substantially" by the expression "as far as possible" results in an extension of the protection conferred.

- 3.4 This question has to be answered in the positive, since as reasoned above (cf. point 2.5), the expression "as far as possible" covers the use of a membrane having **any** level of retention of natural collagen structure, whereas claim 1 as granted covers merely the use of a membrane which "**substantially**" retains its natural

collagen structure, the absolute extent required by the term "substantially" in claim 1 as granted no longer being required by the expression "as far as possible".

- 3.5 For these reasons, the Board concludes that claim 1 of auxiliary request 1 is amended in such a way that the extent of the protection conferred has thereby been extended. The Board therefore has to conclude that claim 1 of auxiliary request 1 offends against Article 123(3) EPC and, consequently, this request cannot be allowed.

*Auxiliary request 2*

4. *Article 123(3) EPC*

- 4.1 Claim 1 is directed to the use of a physiologically acceptable and resorbable collagen membrane which is obtained by purification of a natural collagen membrane so as to retain its natural collagen structure.

Claim 1 of the patent as granted is directed to the use of a physiologically acceptable and resorbable collagen membrane which is obtained by purification of a natural collagen membrane so as **substantially** to retain its natural collagen structure (emphasis added).

- 4.2 Thus the question to be answered is whether claim 1 of auxiliary request 2 covers the use of a collagen membrane which was not covered by claim 1 as granted. It thus needs to be examined whether the deletion of the term "substantially" results in an extension of the protection conferred.

4.3 The claim now covers collagen membranes which have been obtained by purification, which, as indicated in point 2.5 above, always results in loss of natural structure, but where the membrane nevertheless, in the words of the Appellant (see page 6 of letter of 4 April 2010), "retains its natural structure to some extent". However, the actual extent is no longer defined, i.e. the purification does not have to result in a membrane which "substantially" retains its natural structure as required by claim 1 as granted, but may result in a membrane with any level of retention of natural collagen structure (cf. point 3.4 above), such that deletion of this restrictive term broadens the claim.

4.4 For these reasons, the Board concludes that claim 1 of auxiliary request 2 is amended in such a way that the extent of the protection conferred has thereby been extended. The Board therefore has to conclude that claim 1 of auxiliary request 2 offends against Article 123(3) EPC and, consequently, this request cannot be allowed.

*Auxiliary request 3*

5. *Article 123(2) EPC*

5.1 Claim 1 is directed to the use of a physiologically acceptable and resorbable collagen membrane which is obtained by purification of a natural collagen membrane so as to retain more than 95% of its natural collagen structure as determined by the level of amide nitrogen in the membrane having fallen by not more than one half from its original level.

- 5.2 The Appellant submitted that basis for the amendment "so as to retain more than 95% of its natural collagen structure as determined by the level of amide nitrogen in the membrane having fallen by not more than one half from its original level" was to be found in the passage at page 5, lines 26 to 31 of the application as filed.
- 5.3 However, as reasoned in point 2.7 above, this passage cannot serve as a basis for any particular extent of retention of natural collagen structure at all, since it merely indicates how to measure the level of collagen which is still present in its native state after purification, but does not specifically disclose a particular collagen membrane having more than 95% of the collagen in its native state *per se*, and certainly not the use of such a membrane for the manufacture of an implant for use in dental surgery.
- 5.4 Thus, the Board concludes that claim 1 of auxiliary request 3 extends the subject-matter claimed beyond the content of the application as filed, contrary to the requirements of Article 123(2) EPC.

*Auxiliary request 4*

6. *Article 123(3) EPC*

- 6.1 Claim 1 is directed to the use of a physiologically acceptable and resorbable collagen membrane consisting of pure, native (not denatured), insoluble collagen which is obtained by purification of a natural collagen membrane so as to **minimise** any alteration to the chemical structure of the collagen and thus to maintain its original native properties (emphasis added).

Claim 1 of the patent as granted is directed to the use of a physiologically acceptable and resorbable collagen membrane which is obtained by purification of a natural collagen membrane so as **substantially** to retain its natural collagen structure (emphasis added).

6.2 Thus the question to be answered is whether claim 1 of auxiliary request 4 covers the use of a collagen membrane which was not covered by claim 1 as granted. It thus needs to be examined whether the replacement of the term "so as substantially to retain its natural collagen structure" by the expression "so as to minimise any alteration to the chemical structure of the collagen and thus to maintain its original native properties" results in an extension of the protection conferred.

6.3 This question has to be answered in the positive, since as reasoned above (cf. point 2.6), the expression "so as to minimise any alteration to the chemical structure of the collagen and thus to maintain its original native properties" does not provide any indication of the absolute extent of retention of the chemical structure of the collagen to be achieved, the expression "to minimise" in this context being comparable with the expression "as far as possible" used in claim 1 of auxiliary request 1. Claim 1 of auxiliary request 4 thus covers the use of a membrane having **any** level of retention of natural collagen structure, whereas claim 1 as granted covers merely the use of a membrane which "**substantially**" retains its natural collagen structure, the absolute extent required by the term "substantially" in claim 1 as

granted no longer being required by the expression "so as to minimise any alteration to the chemical structure of the collagen and thus to maintain its original native properties".

6.4 In addition, the scope of the claim is not restricted by the fact that it is additionally specified that the collagen membrane consists of pure, native (not denatured), insoluble collagen, since the claim also specifies that said membrane is obtained by purification, and as confirmed by the Appellant, the collagen membrane after purification is always denatured to some extent (cf. point 4.3 above), the absolute extent no longer being defined in claim 1 of this auxiliary request (cf. point 6.3 above).

6.5 For these reasons, the Board concludes that claim 1 of auxiliary request 4 is amended in such a way that the extent of the protection conferred has thereby been extended. The Board therefore has to conclude that claim 1 of auxiliary request 4 offends against Article 123(3) EPC and, consequently, this request cannot be allowed.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

P. Gryczka