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**Datasheet for the decision  
of 17 March 2011**

**Case Number:** T 1333/08 - 3.3.10

**Application Number:** 02257995.7

**Publication Number:** 1312383

**IPC:** A61L 27/24

**Language of the proceedings:** EN

**Title of invention:**

Resorbable extracellular matrix containing collagen I and collagen II for reconstruction of cartilage

**Applicant:**

Ed Geistlich Söhne AG Für Chemische Industrie

**Opponent:**

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**Headword:**

Resorbable collagen matrix/GEISTLICH SÖHNE AG

**Relevant legal provisions:**

EPC Art. 56

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

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**Keyword:**

"Inventive step (no): alleged but unsupported advantages, arbitrary ratio, obvious alternative"

**Decisions cited:**

T 0020/81

**Catchword:**

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Case Number: T 1333/08 - 3.3.10

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.10  
of 17 March 2011

**Appellant:** Ed Geistlich Söhne AG Für Chemische Industrie  
Bahnhofstrasse 40  
CH-6110 Wolhusen (CH)

**Representative:** Matthews, Derek Peter  
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London EC4Y 8JD (GB)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 24 January 2008  
refusing European application No. 02257995.7  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

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

## Summary of Facts and Submissions

- I. The present appeal lies from the decision of the Examining Division posted on 24 January 2008 refusing European patent application No. 02 257 995.7.
- II. The Examining Division held that the subject-matter of the then pending request was not inventive (Article 56 EPC) over the teaching of document (1):

(1) US-A-5 624 463.

More particularly, it held that the only feature distinguishing the claimed resorbable cellular matrix from that of document (1) was the ratio of collagen I to collagen II of 1:19 to 25:75, said ratio, however, not being associated with a technical effect. Thus the problem to be solved could be seen merely as the provision of an alternative material for promoting regeneration of damaged cartilage, variation of the ratio of these two collagens to achieve this aim being obvious.

- III. With the Statement of Grounds of Appeal dated 29 May 2008, the Appellant (Applicant) submitted that the subject-matter of claim 1 underlying the appealed decision was inventive. More particularly, it submitted that in the light of document (1), the problem underlying the present invention consisted in the provision of an implantable matrix which had a more simple and less durable structure and was prepared *via* a less complicated process resulting in significantly lower manufacturing costs. The crucial difference between the claimed product and that of document (1)

was the "product-by-process" feature that the matrix was prepared by thermal crosslinking, which did indeed lead to different physical characteristics of the product *vis-à-vis* the matrix prepared by chemical crosslinking according to Example 11 of document (1). More particularly, thermal crosslinking resulted in a more lightly crosslinked matrix, which was advantageous over the more heavily crosslinked, and hence more durable, and stress-resisting product of document (1), produced by chemical crosslinking.

IV. In a communication annexed to the summons to oral proceedings dated 6 December 2010, the Board indicated that there would appear to be no disclosure in the application as filed (Article 123(2) EPC) for a process for preparing a matrix which did not include a sterilisation step. It further indicated that in the absence of any surprising effect associated with the ratio of collagen I to collagen II of 1:19 to 25:75, said ratio appeared to be merely an arbitrary choice from within document (1) for which an inventive step could not be acknowledged.

V. With letter 17 February 2011, the Appellant submitted a new set of claims, claim 1 of which read as follows:

"A resorbable extracellular matrix for reconstruction of cartilage tissue, said matrix comprising crosslinked collagen material including collagen I and collagen II in a respective ratio of from 1:19 to 25:75, wherein said matrix is prepared by forming a mixture of collagen I and collagen II slurries in an appropriate respective ratio, freezing the mixture, lyophilising the frozen mixture to form a sponge, crosslinking the

sponge by heating to 120-140°C for at least 2 hours, cutting and stamping the sponge to the required thickness and shape and sterilising the sponge."

The Appellant provided no further arguments in support of inventive step.

- VI. The Appellant informed the Board by letter dated 1 March 2011 that it did not intend to attend oral proceedings, that it withdrew its request for oral proceedings, and requested that the procedure be continued in writing.
- VII. In a communication dated 8 March 2011, the Board indicated that the oral proceedings would take place in the absence of the Appellant (Rule 115(2) EPC).
- VIII. The Appellant requested in writing that the decision under appeal be set aside and that the case be remitted to the Examining Division with the order to grant of a patent on the basis of the claims 1 to 6 filed with letter dated 17 February 2011 and claims 7 to 17 underlying the appealed decision.
- IX. At the oral proceedings held on 17 March 2011 in the absence of the Appellant, the Board gave its decision.

## Reasons for the Decision

1. The appeal is admissible.

2. *Amendments (Article 123(2) EPC)*

Claim 1 is based on original claim 1, basis for the ratio of collagen I to collagen II of 25:75 being page 2, line 13 of the application as filed. The method for the preparation of the matrix is disclosed on page 14, lines 5 to 14 of the application as filed.

For these reasons, the Board concludes that amended claim 1 complies with the requirements of Article 123(2) EPC.

3. *Novelty*

The Board has no objections concerning the novelty of the claimed subject-matter. Since the Examining Division also did not raise objections in this respect, the Board sees no need to consider this matter in more detail.

4. *Inventive Step*

4.1 The Board considers, in agreement with the Examining Division and the Appellant, that the closest prior art is the disclosure of document (1).

Document (1) discloses a prosthetic articular cartilage device (see claim 1) comprising type I and type II collagens prepared by dispersing and homogenising these two types of collagen, followed by careful mixing to

form a uniform suspension containing type I and type II collagens (see Example 11), which is then compressed into a mould of specified dimensions, frozen, crosslinked by soaking in a 0.2% glutaraldehyde solution, pH 7.4 for ca. 24 hours, and lyophilized (see Example 6). The step of compressing into a mould of specified dimensions corresponds to the step of cutting and stamping the sponge to the required thickness and shape according to present claim 1.

- 4.2 In view of this state of the art, the Appellant, in its letter dated 29 May 2008, defined the problem underlying the present application as the provision of an implantable matrix which has a more simple and less durable structure and is prepared *via* a less complicated process resulting in significantly lower manufacturing costs.

However, since the claims are directed to a product *per se* and not to a process, the problem underlying the invention cannot be formulated with regard to advantages associated with the process for its manufacture, but solely with regard to advantages lying in the nature of the product *per se*. For this reason, the problem as defined by the Appellant has to be reformulated, namely by deleting "and is prepared *via* a less complicated process resulting in significantly lower manufacturing costs" therefrom.

- 4.3 As the solution to this problem, the application proposes the resorbable extracellular matrix according to claim 1, which is characterised by the ratio of collagen I to collagen II of 1:19 to 25:75, and by two

"product-by-process" features, namely crosslinking by heating to 120 to 140°C and a sterilisation step.

- 4.4 It now needs to be examined whether said problem has been successfully solved. According to the Appellant (see letter dated 29 May 2008 and page 10, lines 13 to 17 of the application as filed), thermal crosslinking resulted in a lightly crosslinked spongiform material which had the advantage of restricting the extent of swelling when the product came into contact with aqueous fluids, e.g. *in vivo*, whilst retaining its ability to be resorbed. In contrast, the matrix according to Example 11 was crosslinked by soaking in glutaraldehyde solution (see Example 6 F)), which, together with the other crosslinking methods disclosed in Examples 7, 9 and 10, were more aggressive crosslinking conditions leading to a more heavily crosslinked, and hence more durable and stress-resisting, product.

However, no evidence has been provided that a product prepared by heating to 120 to 140°C is more lightly crosslinked than a product prepared by soaking in glutaraldehyde solution, let alone that it has any different properties, such as durability, than a product according to document (1). Furthermore, the Appellant did not rely on any advantageous effects linked to the ratio of collagen I to collagen II of 1:19 to 25:75 or the sterilisation step.

According to the jurisprudence of the Boards of Appeal, alleged but unsupported advantages cannot be taken into consideration in respect of the determination of the problem underlying the invention (see e.g. decision



T 20/81, OJ EPO 1982, 217, point 3, last paragraph of the reasons).

4.5 Since in the present case the alleged improvement, namely a product having a more simple and less durable structure, lacks the required experimental support, the technical problem as defined in point 4.2 above has to be reformulated in a less ambitious manner, namely as the provision of an alternative resorbable extracellular matrix.

4.6 Finally, it remains to be decided whether or not the proposed solution to this objective problem is obvious in view of the state of the art.

4.6.1 The ratio of collagen I to collagen II of 1:19 to 25:75 defining the claimed product is neither critical nor a purposive choice for solving the objective problem underlying the application, since no effect has been shown to be associated with this particular ratio. In particular, since the closest prior art document (1) (see col. 7, lines 53 to 56) teaches that the prosthetic articular cartilage may be "constructed mainly of Type II collagen matrix with [...] Type I collagen fibers reinforcing the matrix", without giving any limitation with regard to the ratio of the two collagen types, the arbitrary choice of a ratio of collagen I to collagen II of 1:19 to 25:75 cannot provide the claimed absorbent with any inventive ingenuity.

4.6.2 Sterilising the matrix is a standard procedure for the skilled person, since the matrix is intended for reconstruction of cartilage tissue and thus for

implantation into a mammalian body, it being common general knowledge for the skilled person that a sterilised product is a necessary prerequisite for such a use.

4.6.3 Finally, since the Appellant has not shown that crosslinking the sponge by heating to 120 to 140°C necessarily leads to a different product than that prepared by soaking in a glutaraldehyde solution according to document (1), this "product-by-process" feature cannot qualify as a feature clearly distinguishing the product claimed from the product prepared according to the state of the art, and hence cannot contribute towards inventive step of the product *per se*.

4.7 Therefore, in the Board's judgement, the subject-matter of claim 1 represents an obvious solution to the problem underlying the patent application. As a result, the Appellant's request is not allowable as the subject-matter of claim 1 lacks an inventive step pursuant to Article 56 EPC.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

P. Gryczka