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**Datasheet for the decision
of 7 May 2013**

Case Number: T 1582/08 - 3.3.04

Application Number: 98944836.0

Publication Number: 1017415

IPC: A61K 38/39

Language of the proceedings: EN

Title of invention:

Product for promoting dural or meningeal tissue growth
comprising collagen

Patent Proprietor:

Integra Lifesciences Corporation

Opponent:

CODMAN & SHURTLEFF INC.

Headword:

Collagen/INTEGRA LIFESCIENCES CORP.

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

"All requests - added-matter (yes)"

Decisions cited:

T 0190/99, T 1082/02, T 1408/04

Catchword:

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Case Number: T 1582/08 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 7 May 2013

Appellant: Integra Lifesciences Corporation
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 17 July 2008
revoking European patent No. 1017415 pursuant
to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: M.-B. Tardo-Dino
Members: B. Claes
R. Morawetz

Summary of Facts and Submissions

- I. The appeal was lodged by the patent proprietor (appellant) against the decision of the opposition division, whereby the European patent No. 1 017 415 with the title "*Product for promoting dural or meningeal tissue growth comprising collagen*" and published as international patent application WO 99/013902 was revoked.
- II. The opponent (respondent) had opposed the patent under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Articles 100(b) and 100(c) EPC.
- III. The decision of the opposition division was based on a main request, corresponding to auxiliary request 1 filed with a letter dated 30 May 2008 and auxiliary request 1, corresponding to auxiliary request 2, filed with the same letter. The opposition division decided that both the main request and auxiliary request 1 failed to meet the requirements of Article 123(2) EPC (Article 100(c) EPC).

Claim 1 of the main request before the opposition division read:

"1. Use of a cross-linked matrix for promoting meningeal tissue growth to replace a damaged meningeal tissue, said matrix comprising:

certified collagen prepared by a process **certified** to provide physiologically compatible collagen which is

free of effective amounts of active viruses and prions,
and
pores having a diameter of 10-500 micrometers that
permit growing meningeal tissue to infiltrate said
matrix,

said matrix being substantially free of non-collagenous
proteins and adapted to contact said damaged meningeal
tissue to promote meningeal tissue growth through said
matrix, and to be resorbed, wherein said **certified**
process comprises:

cleaning extraneous matter from a native source of Type
I collagen;
washing said cleaned collagen containing material;
comminuting said washed collagen containing material;
digesting said comminuted collagen containing material
with a proteolytic enzyme to substantially remove
elastin and non-collagenous impurities which can cause
antigenic activity and to swell said collagen;
inactivating said proteolytic enzyme;
washing said enzymatically digested collagen containing
material to substantially remove excess enzyme and non-
collagenous protein impurities;
alkalinizing said collagen containing material to a pH
of about 13 to about 14, at a temperature of about 25°C
to about 30°C for a period of about 35 to about 48
hours, to substantially remove contaminating
glycoproteins and lipids;
neutralizing said alkalinized collagen containing
material with an acid;
washing said neutralized collagen containing material;
acidifying said washed and neutralized collagen
containing material to a pH of about 2 to about 3 to

further swell said material, wherein said acidifying does not employ an acid that causes substantial cross-linking of collagen;
homogenizing said acidified collagen containing material;
filtering said homogenized collagen containing material to remove unswollen, non-collagenous material from collagen fibers; and
collecting said filtered collagen fibers for use in said matrix,

in the manufacture of a medicament for promoting meningeal tissue growth to replace a damaged meningeal tissue." (emphasis added by the board)

Claim 1 of auxiliary request 1 before the opposition division read:

"1. A matrix for promoting meningeal tissue growth to replace a damaged meningeal tissue, said matrix prepared by a process comprising:

providing **certified** collagen fibers which are physiologically compatible and **certified** to be free of effective amounts of active viruses and prions;
providing at least two different volumes of a liquid medium containing said **certified** collagen; and
evaporating said liquid medium from each of said different volumes to provide at least two different members of the group consisting of a film, a sponge, a non-woven and a felt, and

wherein said matrix comprises said at least two different members, said **certified** collagen fibers, and

pores having a diameter of 50-150 μ m adapted to permit growing meningeal tissue to infiltrate said pores, and wherein said matrix is substantially free of non-collagenous proteins, and said matrix is adapted to be resorbed within about three months after implantation, and wherein said **certified** collagen fibers are obtained by a method which comprises:

cleaning extraneous matter from a native source of Type I collagen;

washing said cleaned collagen containing material;

comminuting said washed collagen containing material;

digesting said comminuted collagen containing material with a proteolytic enzyme to substantially remove elastin and non-collagenous impurities which can cause antigenic activity and to swell said collagen;

inactivating said proteolytic enzyme;

washing said enzymatically digested collagen containing material to substantially remove excess enzyme and non-collagenous protein impurities;

alkalinizing said collagen containing material to a pH of about 13 to about 14, at a temperature of about 25°C to about 30°C for a period of about 35 to about 48 hours, to substantially remove contaminating glycoproteins and lipids;

neutralizing said alkalinized collagen containing material with an acid;

washing said neutralized collagen containing material;

acidifying said washed and neutralized collagen containing material to a pH of about 2 to about 3 to further swell said material, wherein said acidifying does not employ an acid that causes substantial cross-linking of collagen;

homogenizing said acidified collagen containing material;
filtering said homogenized collagen containing material to remove unswollen, non-collagenous material from collagen fibers; and
collecting said filtered collagen fibers for use in said matrix." (emphasis added by the board)

- IV. In the statement of grounds of appeal the appellant *inter alia* argued that claims 1 of the main and auxiliary request 1 complied with the requirements of Article 123(2) EPC as the term "certified" when properly construed found a basis in the application as filed and filed a new document (i.e. document (D27), The Oxford English Dictionary, 2nd ed., 1989, page 1053).
- V. In its reply to the statement of grounds of appeal, the respondent endorsed the findings of the opposition division concerning added matter.
- VI. In a further letter dated 4 April 2013, the appellant *inter alia* submitted further arguments on added matter.
- VII. Oral proceedings took place before the board on 7 May 2013. The respondent was not represented as announced in a letter dated 1 February 2013.
- VIII. The appellant requested that the decision under appeal be set aside and the case be remitted to the first instance for further prosecution on the basis of the main request corresponding to former auxiliary request 1 or on the basis of auxiliary request 1

corresponding to former auxiliary request 1, both as filed with the letter dated 30 May 2008.

The respondent requested in writing by letter dated 21 April 2009 that the appeal be dismissed and that the decision of the opposition division to revoke the patent be upheld.

IX. The appellant's arguments concerning added matter (Article 100(c) EPC) in relation to claim 1 of both claim requests can be summarised as follows:

The opposition division had erroneously and improperly constructed the term "certified" holding that the term "certified collagen" had to be taken to mean that the collagen had a certificate which certified that the collagen had certain specifications. This imposed limitations not supported in the patent and failed to consider the ordinary understanding of "certified" which did not require that some governing body issues a certificate.

With reference to Article 69 EPC a skilled person should try, with synthetical propensity, i.e. "building up rather than tearing down", to arrive at an interpretation of the claim which was technically sensible and took into account the whole disclosure of the patent. Furthermore, Article 123(2) EPC did not require that terms added by way of an amendment were expressly present in the specification, but they had to be directly and unambiguously derivable from what was previously presented in the application, including matter which was implicit to a person skilled in the art.

Document (D27) included "assured" as part of the plain and ordinary dictionary meaning of "certified". A process "certified" to achieve a given outcome was thus "assured" to achieve that outcome. While such an assurance could possibly be reflected in a certificate, the concept was by no means limited to assurances that were reflected in a certificate.

Based on the description of the patent the term "certified" meant "assured". Whereas previously used collagen sponges posed health hazards, the invention **ensured** the elimination of such health hazards by focussing on the need for "processing" that provided a "suitable safety margin" to allow for a "mass-marketable" product enabling commercial scale use, i.e. there was a need for "assurances" regarding the safety of the product (see patent paragraphs [0012] and [0013]). The patent provided a dural graft with a "suitable safety margin" to allow for a "mass-marketable" product, including the use of steps that were "recognized" as effective for achieving "a very high safety level" and disclosed multiple methods that assured the safety of the product contemplated (see patent, paragraph [0018]). Methods "recognized" as effective, as a result of research, testing or otherwise, were "assured" to be effective without there necessarily being any actual certificate to that effect.

The patent provided in paragraphs [0018] to [0027] detailed information on two different processes for obtaining collagen that was assured to be physiologically compatible and substantially free of

viruses and prions. It was clear and unambiguous to the skilled person that following the steps of these methods was an assured way to achieve the desired result of obtaining "a very high safety level" collagen sponge with respect to physical compatibility and inactivation of viruses and prions.

The patent did not disclose an additional limitation requiring that some governing body issue a certificate. Accordingly, a construction of the term "certified" in light of the specification, could not inject an unwarranted limitation into the term that was neither compelled by the ordinary meaning nor supported by the specification.

Adding the term "certified", as properly construed, did not provide a technical contribution to the invention as it merely referred to a limitation that was otherwise expressly set forth in the claims, i.e. that a process be utilized to ensure physiological compatibility and substantial inactivation of viruses and prions. Such processes were disclosed in the application as originally filed. If the term "certified" were to be removed, neither the meaning nor the scope of the claims changed, because a process by which the physiologically compatible and virus/prion-free collagen would be obtained was embedded in every independent claim. Thus, in accordance with the EPO Enlarged Board of Appeal decision G 1/93, its recitation in the claims did not offer any unwarranted advantage, and it was not to be considered as subject-matter that extended beyond the content of the application as filed within the meaning of Article 123(2) EPC.

- X. The respondent's arguments in writing concerning added matter (Article 100(c) EPC) in relation to claim 1 of both claim requests can be summarised as follows:

The term "certified" in relation to the collagen used in the matrix and to the process for obtaining the collagen, limited the collagen and/or the process to certain properties. There was however no explicit nor implicit disclosure of the term "certified" in the application as filed. Furthermore, there was no indication what properties "certified" collagen had nor a teaching whether a process used to prepare "certified" collagen was a "certified" process. It was therefore not possible to construe the term in light of the description. Accordingly, it needed to be ascertained with what information a person skilled in the art was presented when reading the granted claims and whether that information was disclosed in the application.

The word "certified" provided a clear, credible technical teaching to a skilled reader which was not disclosed in the application as filed and the description should not be used to give a different meaning to a claim feature which in itself imparted a clear, credible technical teaching to a skilled reader (see decision T 1018/02).

The appellant had cherry-picked the most desirable meaning of the term "certified" from the dictionary definition in document (D27), i.e. "assured". The definition provided however no evidence of what a person skilled in the art would have understood by the

word "certified" in the context of the patent in suit. Furthermore, the dictionary definition made clear that the standard meaning of "certified" indeed involved the provision of a certificate, receipt or guarantee by some official body.

The terms "certified collagen" and "certified process" provided a technical contribution to the claimed subject-matter. The parameter that the collagen was "substantially free of all prion and viral contamination" was present in the claims of the application as filed and was also present in the claims under consideration. Therefore, the addition of "certified" to the claims could not simply be equivalent in meaning to "substantially free of all prion and viral contamination" and had to refer to other additional parameters, for instance those mentioned at page 13, lines 1 to 9 of the application as filed (degree of purity, amount of endotoxins, fat content, hydroxyproline content or ash content). In addition, collagen could also be certified in relation to its nitrogen content, amide content, amino acid analysis, particular amino acid content (such as glycine or hydroxylysine content), heavy metal content, source of the collagen, age of the source, content of non-collagenous proteins *etc.* Consequently, it was clear to a skilled person that the term "certified" related to more than just substantial absence of prions and viruses. Therefore, the term "certified", had to make a technical contribution to the claims.

Reasons for the Decision

1. The appeal is admissible.

*Main request and auxiliary request 1 - claim 1 - added matter
(Article 100(c) EPC)*

2. The opposition division decided that *inter alia* claim 1 of both the main request and auxiliary request 1 before it (which are identical to the main request and auxiliary request in this appeal) failed to meet the requirements of Article 123(2) EPC (Article 100(c) EPC) because the term "certified", qualifying by way of amendment, the collagen and the process of its preparation recited in these claims, constituted subject-matter which extended beyond the content of the application as filed.
3. Article 123(2) EPC provides that a European patent application or a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.
4. It is an accepted principle of the established case law of the Boards of Appeal that, in order to determine whether or not an amendment offends against Article 123(2) EPC, it has to be established whether the amendment results in the introduction into the specification and/or into the claims of technical information which a skilled person would not have objectively and unambiguously derived from the application as filed, when account is taken of matter which is implicit to a person skilled in the art in what has been expressly mentioned. In accordance with

established case law the relevant question to be decided is whether the proposed amendments were directly and unambiguously derivable from the application as filed (see Case Law of the Boards of Appeal of the EPO, 6th Edition, 2010, III.A.7).

5. It is not disputed by the appellant that the application as filed does not contain the term "certified", neither to qualify "collagen" nor to qualify a "process of preparation" therefor.
6. The pivotal question in the present appeal is therefore what the technical information embodied in this feature in the context of claim 1 of both requests is and whether this technical information is clearly and unambiguously derivable from the application as filed, account being taken of matter which is implicit to a skilled person in what is expressly mentioned therein.
7. The appellant has referred to the dictionary definition of "certified" contained in document (D27) which states: "**certified** (...) a. Made certain; assured; certainly informed; attested by certificate; furnished with a certificate. (...)". The board is satisfied that the above dictionary definition reflects the common understanding of the term "certified" and also reflects the understanding of the person skilled in the relevant technical field.
8. The appellant argued that, in the context of the description of the patent and the invention claimed, the skilled person would understand the term "certified" to have the meaning "assured".

9. The board notes that the appropriate reference, in the context of Article 123(2) EPC, is to the application as filed. The passages referred to in the patent are however identical to the corresponding passages in the application as filed. Therefore, for the sake of the appellant's argument in the present case, the board considers the reference to the patent as equivalent to a reference to the application as filed.
10. It was argued by the appellant that, whereas previously used collagen sponges posed health hazards, the invention ensured the elimination of such health hazards and assured the safety of the product (see patent, paragraphs [0012] and [0013]). The patent provided a dural graft with suitable safety margin to allow for a mass-marketable product enabling commercial scale use. The patent, in paragraph [0018], stated that: "*(...) the method for producing the product of the present invention makes use of steps that are **recognized** as the most effective for inactivating viral and prion contamination. This gives the product a very high safety level while eliminating the inflammatory response. That is, the method for producing the product of the invention provides a product that is substantially free of viruses and prions without being physiologically incompatible*" (emphasis added by the board). The subsequent disclosure in paragraph [0018] and paragraphs [0019] to [0027] and [0041] of the patent (in particular paragraph [0022], lines 1 to 6; paragraph [0024], lines 1 to 9 and paragraphs [0027] and [0041]) of the patent provided detailed information on two different processes for obtaining such collagen that was assured to be physiologically compatible and substantially free of viruses and prions. Accordingly,

it was clear and unambiguous to the skilled person that following the steps of these methods was an assured way to achieve the desired result of obtaining a very high safety level collagen sponge with respect to physical compatibility and inactivation of viruses and prions without there necessarily being any actual certificate to that effect. The patent did furthermore not disclose an additional limitation requiring that some governing body issue a certificate.

11. The board agrees with the appellant that the methods as disclosed in the application as filed (and the patent) may "assure" the skilled person that the collagen produced conforms certain safety (e.g. substantially free of viruses and prions) and physiological (e.g. free of inflammatory response) criteria (see paragraph [0018] of the patent). However, it has not been contested by the appellant that the technical field of pharmaceutical products and their production methods - also in the field of neural surgery - is highly regulated and that these products and methods are subject to a multitude of prescribed "good manufacturing practices" and certification schemes ensuring technical compliance. The board therefore considers that a skilled person when confronted with the feature "certified" in the context of the claimed invention would, rather than interpreting the term in the restrictive manner advocated by the appellant, also consider the two meanings disclosed in document (D27) involving a certificate ("attested by certificate" and "furnished with a certificate").

12. It is for the present decision irrelevant what the precise nature of a certification is. However, it is evident, as the respondent has argued that a variety of additional parameters can be considered for certification such as those mentioned in paragraph [0051] of the patent, i.e. degree of purity, amount of endotoxins, fat content, hydroxyproline content or ash content or e.g. concerning the nitrogen content, the amide content, the amino acid analysis, the particular amino acid content (such as glycine or hydroxylysine content), the heavy metal content, the source of the collagen, the age of the source, the content of non-collagenous proteins etc.

13. The board concludes that, in the context of claim 1 and with reference to point 7, above, the feature "certified" conveys in itself technical information to the skilled person, including the reference to a certificate, which goes beyond what results from operating the "recognized" methods referred to in the description and which information is not derivable in a clear and unambiguous manner from the application as filed.

14. In the present circumstances, the board follows the rationale of decision T 1082/02 of 16 October 2007 that "*[a]lthough a claim must not be interpreted in a way which is illogical or does not make any sense, the description cannot be used to give a different meaning to a claim feature which in itself imparts a clear credible technical teaching to the skilled reader. This also applies if the feature has not been initially disclosed in the form appearing in the claim.*" (see point 3.8 of the Reasons).

15. Accordingly, the term "certified" introduces into the claims information which the skilled person could not derive directly and unambiguously from the application as filed. Hence, the amendment constitutes added matter (Article 123(2) EPC; Article 100(c) EPC).

16. The appellant has furthermore argued, with reference to Article 69 EPC, that a skilled person should try, with synthetic propensity, i.e. "building up rather than tearing down", to arrive at an interpretation of the claim which was technically sensible and took into account the whole disclosure of the patent (see Case Law of the Boards of Appeal, 6th Edition, Section II.B.5.1). The board agrees that the claims must be interpreted by a "mind willing to understand" and not by "a mind desirous of misunderstanding". However, this is understood to mean only that technically illogical interpretations should be excluded (see e.g. decision T 190/99 of 6 March 2001 and decision T 1408/04 of 17 November 2006). The board furthermore considers that a "mind willing to understand" does not require that a broad term needs to be interpreted more narrowly, but instead that a broad term should be understood to include all technically logical meanings, which for the present case includes those set out in points 12 and 13, above.

17. In view of the foregoing finding also the appellant's argument that the addition of the term "certified", as properly construed, did not provide a technical contribution to the invention because it merely referred to a limitation that was otherwise expressly set forth in the claims, i.e. that a process be

utilized to ensure physiological compatibility and substantial inactivation of viruses and prions, must fail.

18. In view of the foregoing considerations the board decided that claim 1 of both the main request and auxiliary request 1 do not comply with the requirements of Article 123(2) EPC (Article 100(c) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairperson

P. Cremona

M.-B. Tardo-Dino