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**Datasheet for the decision  
of 17 July 2012**

**Case Number:** T 1916/09 - 3.3.02  
**Application Number:** 03019311.4  
**Publication Number:** 1393749  
**IPC:** A61K 47/48, A61K 47/36,  
A61K 31/728, A61P 17/00  
**Language of the proceedings:** EN

**Title of invention:**

A pharmaceutical preparation in colloidal form useful in the treatment of skin diseases, comprising hyaluronic acid

**Applicant:**

Petrigni, Giuseppe

**Headword:**

Hyaluronic acid/PETRIGNI GIUSEPPE

**Relevant legal provisions:**

EPC Art. 123(2)

**Keyword:**

"Allowability of the amendments - (no)"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 1916/09 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 17 July 2012

**Appellant:** Petrigni, Giuseppe  
(Applicant) Via Fontana, 1  
IT-20123 Milano (IT)

**Representative:** Beneduce, Gianna  
Via Poggibonsi 7  
IT-20146 Milano (IT)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 3 March 2009  
refusing European patent application  
No. 03019311.4 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** A. Lindner  
L. Bühler

## **Summary of Facts and Submissions**

I. European patent application No. 03 019 311.4 was refused by a decision of the examining division dispatched on 3 March 2009 on the basis of Article 97(2) EPC on the grounds that the subject-matter claimed in the main and sole request contained subject-matter that extended beyond the content of the application as originally filed, was not sufficiently disclosed, and lacked clarity, novelty and inventive step.

The examining division came to the conclusion that the feature "... hyaluronic acid fractions mixed each other in a unitary or integer multiple molar ratio in respect to the fraction of the biopolymerized hyaluronic acid having the lowest molecular weight present in the mixture" had no basis in the original application. Moreover, deletion of "molar" would lead to a lack of clarity, as the skilled person would not know whether molar ratios or weight ratios were meant.

II. The applicant (appellant) lodged an appeal against this decision.

III. In the annex to the summons to oral proceedings issued by the board pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), the board in its preliminary opinion concurred with the reasoning of the examining division in the decision under appeal.

IV. With the fax dated 12 July 2012, the appellant requested postponement of the oral proceedings for reasons of illness of the inventor.

- V. With the fax dated 16 July 2012, the board informed the appellant that the oral proceedings would be held as planned.
- VI. Oral proceedings were held on 17 July 2012, in the absence of the duly summoned appellant, in accordance with Rule 115 EPC and Article 15(3) RPBA.
- VII. The independent claims of the main request (request 1) and auxiliary request (request 2) read as follows:

*(i) main request*

"1. The use of a mixture of fractions of different molecular weight biopolymerized hyaluronic acids, in the range from 200kDa to 4,000kDa, being the different molecular weight biopolymerized hyaluronic acid fractions mixed each other in a unitary or integer multiple molar ratio in respect to the fraction of the biopolymerized hyaluronic acid having the lowest molecular weight present in the mixture, for the preparation of medicaments for the treatment of skin pathological diseases such as erythematous and erythema-squamous eruptions, vesicular eruptions, papular eruptions, pustular eruptions, blistered eruptions, ulcerous eruptions, in metabolic diseases, nodular eruptions, skin mycotic diseases, tumoral eruptions, hair and scalp diseases, cutaneous rashes related to systemic diseases, pediatric dermatosis, geriatric dermatosis, dermatological emergencies.

2. The use of a mixture of fractions of different molecular weight biopolymerized hyalurodic acids in the

range from 200kDa to 4,000kDa, being the different molecular weight biopolymerized hyaluronic acid fractions mixed each other in a unitary or integer multiple molar ratio in respect to the fraction of the biopolymerized hyaluronic acid having the lowest molecular weight present in the mixture, together with a dispersing amount of at least one diluent selected from the group consisting of distilled water, saline solution, dimethylsulphoxide, suitable alcoholic solutions and, optionally, other suitable diluents, for the preparation of medicaments in colloidal form for the treatment of skin pathological diseases such as erythematous and erythema-squamous eruptions, vesicular eruptions papular eruptions, pustular eruptions, blistered eruptions, ulcerous eruptions, in metabolic diseases, nodular eruptions, skin mycotic diseases, tumoral eruptions, hair and scalp diseases, cutaneous rashes related to systemic diseases, pediatric dermatosis, geriatric dermatosis, dermatologieal emergencies."

*(ii) Auxiliary request*

"1. The use of a mixture of biopolymerized hyaluronic acid fractions of different molecular weight in the range from 400kDa to 2,000kDa, which are mixed each other in multiple molar ratio in respect to the biopolymerized hyaluronic acid fraction having the lowest molecular weight present in the mixture, for the preparation of medicaments for the treatment of skin pathological diseases such as erythematous and erythema-squamous eruptions, vesicular eruptions, papular eruptions, pustular eruptions, blistered eruptions, ulcerous eruptions, in metabolic diseases,

nodular eruptions, skin mycotic diseases, tumoral eruptions, hair and scalp diseases, cutaneous rashes related to systemic diseases, pediatric dermatosis, geriatric dermatosis, dermatological emergencies.

2. The use of a mixture of biopolymerized hyaluronic acid fractions of different molecular weight, in the range from 400kDa to 2,000kDa, which are mixed each other in multiple molar ratio in respect to the biopolymerized hyaluronic acid fraction having the lowest molecular weight present in the mixture, together with a dispersing amount of at least one diluent selected from the group consisting of distilled water, saline solution, dimethylsulphoxide, suitable alcoholic solutions and, optionally, other suitable diluents, for the preparation of medicaments in colloidal form for the treatment of skin pathological diseases such as erythematous and erythema-squamous eruptions, vesicular eruptions, papular eruptions, pustular eruptions, blistered eruptions, ulcerous eruptions, in metabolic diseases, nodular eruptions, skin mycotic diseases, tumoral eruptions, hair and scalp diseases, cutaneous rashes related to systemic diseases, pediatric dermatosis, geriatric dermatosis, dermatological emergencies."

VIII. The appellant essentially argued as follows:

Regarding the feature "... hyaluronic acid fractions mixed each other in a unitary or integer multiple molar ratio in respect to the fraction of the biopolymerized hyaluronic acid having the lowest molecular weight present in the mixture", it was pointed out that the term "unitary ratio" had a basis in original claim 6

and in paragraph [0016] of the application as published. The introduction of "integer" constituted a limitation rather than a broadening of the claim and was therefore allowable. As far as insertion of the term "molar" was concerned, reference was made to claim 6 as originally filed, which disclosed molecular weight fractions of 400kDa, 800kDa, 1,200kDa, 1,600kDa and 2,000kDa which were mixed in a reciprocal ratio of 1:1:1:1:1. The skilled person would derive from this disclosure that the multiple ratio was expressed as a molar ratio. Moreover, the statement that "such hyaluronic fractions are mixed together in defined ratios depending on their molecular weight" (see paragraph [0016] of the application as published) also led to the conclusion that molar ratios were meant.

- IX. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, of the auxiliary request, submitted with the statement of the grounds of appeal.

### **Reasons for the decision**

1. The appeal is admissible.
2. *Request for adjournment of the oral proceedings*

The representative of the appellant requested that the oral proceedings scheduled for 17 July 2012 be postponed on the ground that her client was seriously ill and therefore not in a position to attend the oral proceedings.

The procedure for adjournment of oral proceedings is set out in the Notice of the Vice-President of Directorate-General 3 of the European Patent Office dated 16 July 2007 concerning oral proceedings before the boards of appeal of the EPO (OJ EPO 2007, Special edition No. 3, 115). However, the serious substantive reasons listed in point 2.1, which include serious illness, are related to impediments concerning the representative and not, as in the present case, the client. As a consequence, the board decided that the oral proceedings scheduled for 17 July 2012 are not postponed.

3. *Claim 1 of the main request - amendments*

3.1 Regarding the feature that the fractions are mixed in a unitary or integer multiple molar ratio in respect to the fraction of the biopolymerized hyaluronic acid having the lowest molecular weight present in the mixture, the board notes that there is no basis in the original application as far as **integer** multiple molar ratios are concerned. The introduction of integer does not, as was correctly pointed out in the statement of the grounds of appeal (see paragraph bridging pages 2 and 3) lead to a broadening of the claims. However, the board wants to emphasise that the introduction of limiting features, which are not disclosed in the original application, is not allowable under Article 123(2) EPC either.

3.2 Moreover, there is no information in the original application as to whether the ratios in which the hyaluronic acid fractions are to be mixed constitute



molar or weight ratios. The fact that original claim 6 as well as paragraph [0016] of the application as published (which corresponds to the passage from page 4, line 18, to page 5, line 3, of the application as originally filed) define several hyaluronic fractions according to their molecular weight does not indicate a preference of molar ratios over weight ratios as was alleged by the appellant. As a consequence, the feature "molar ratio" is not specifically disclosed in the original application, neither by explicit nor by implicit disclosure so that its introduction into claim 1 of the main request is not allowable under Article 123(2) EPC.

4. The reasons given in points 3.1 and 3.2 above for claim 1 of the main request apply *mutatis mutandis* to claim 2 of the main request so that the requirements of Article 123(2) EPC are also not met.
  
5. The reasons given in point 3.2 above for claim 1 of the main request apply *mutatis mutandis* to claims 1 and 2 of the auxiliary request so that the requirements of Article 123(2) EPC are also not met. Consequently, the auxiliary request also fails.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman

N. Maslin

U. Oswald