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**Datasheet for the decision  
of 29 November 2012**

**Case Number:** T 2384/09 - 3.3.04  
**Application Number:** 06077156.5  
**Publication Number:** 1762247  
**IPC:** A61K 45/00, A61K 45/06  
**Language of the proceedings:** EN

**Title of invention:**

The use of anabolic agents, anti-catabolic agents, antioxidant agents, and analgesics for protection, treatment and repair of connective tissue in humans and animals

**Applicant:**

Nutramax Laboratories, Inc.

**Headword:**

Treatment of connective tissue/NUTRAMAX

**Relevant legal provisions:**

EPC Art. 76(1), 111(1), 123(2)

**Keyword:**

"Main request - extension beyond the content of the earlier and the divisional application as filed (no)"  
"Remittal (yes)"



Case Number: T 2384/09 - 3.3.04

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.04  
of 29 November 2012

**Appellant:** Nutramax Laboratories, Inc.  
(Applicant) 2208 Lakeside Boulevard  
Edgewood, MD 21040 (US)

**Representative:** Sturt, Clifford Mark  
Miller Sturt Kenyon  
9 John Street  
London WC1N 2ES (GB)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 9 July 2009  
refusing European patent application  
No. 06077156.5 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman:** C. Rennie-Smith  
**Members:** G. Alt  
M. Montrone

## **Summary of facts and submissions**

I. This is an appeal against the decision of the examining division refusing the European patent application No. 06 077 156.5. The application is published under No. 1 762 247. It is a divisional application of the European application no. 99 927 137 published under No. 1 083 929.

II. The decision under appeal dealt with a main and an auxiliary request.

Claim 1 of the main request read:

"1. A composition comprising an avocado/soybean unsaponifiable (hereinafter "ASU") and a glycosaminoglycan."

Claim 1 of the auxiliary request read:

"1. A composition comprising an avocado/soybean unsaponifiable (hereinafter "ASU") and a chondroitin or a salt thereof."

III. The examining division took the view that the application contravened the requirements of Articles 76(1) and 123(2) EPC because neither the parent application nor the divisional application as filed clearly and unambiguously disclosed the claimed combination of an avocado/soybean unsaponifiable with either a glycosaminoglycan in general or with the specific glycosaminoglycan chondroitin or its salts.

IV. With the statement of the grounds of appeal the appellant filed a main and an auxiliary request and requested inter alia that oral proceedings be held in case that the board of appeal was "not minded to accede" to either of these requests.

V. The board informed the appellant in a notification dated 18 April 2012 of its preliminary view that several claims of the main request and claim 3 of the auxiliary request contravened the requirements of Articles 76(1) and 123(2) EPC and therefore summoned oral proceedings to take place on 29 November 2012.

VI. With its letter dated 9 November 2012 the appellant filed a new main request. Its five claims read:

"1. A composition comprising avocado/soybean unsaponifiables (hereinafter "ASU") and a chondroitin or a salt thereof.

2. A composition as claimed in claim 1, comprising ASU and chondroitin sulfate.

3. A composition as claimed in any one of the preceding claims which is formulated for administration intramuscularly, intravenously, orally, subcutaneously, rectally, topically, transcutaneously, intranasally, intra-articularly, sublingually or intraperitoneally.

4. A composition as claimed in any one of the preceding claims which is formulated as an extended release dosage form, pills, tablets, capsules, cream, liquid, aerosol or an injectable composition.

5. A composition as claimed in claim 1 or claim 2 for use in the treatment, repair or prevention of damage to connective tissue in humans and other animals."
- VII. The appellant requested in its letter of 9 November 2012 that, if the amended claims were considered to fulfil the requirements of Articles 76(1) and 123(2) EPC, the oral proceedings be cancelled and the application be remitted to the examining division for further prosecution.
- VIII. By a notification dated 23 November 2012 the board informed the appellant that the oral proceedings were cancelled.

### **Reasons for the decision**

1. During the appeal proceedings the appellant has pursued the application on the basis of an amended main request (see section VI above). Given that the sole reason for refusing the present application was that the claims of the main and auxiliary request did not comply with the requirements of both Article 76(1) and 123(2) EPC, the first question to be dealt with in the present decision is whether or not the claims of the amended main request fulfil the requirements of Articles 76(1) and 123(2) EPC.
2. Article 76(1) EPC stipulates that a European divisional application "may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed". Article 123(2) EPC stipulates that "a European patent application may not

be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed".

Hence, it has to be determined whether or not the subject-matter of the five claims of the main request is disclosed in the earlier and the divisional application as filed.

The texts of the two applications are identical. Therefore, the references to pages and lines below are valid for both of them.

3. In its most general form the invention is disclosed on page 8, lines 11 to 13. It is stated that the compositions of the invention *"include combinations of anabolic, anti-catabolic and/or antioxidant agents"*.

Avocado/soybean unsaponifiables (hereinafter "ASU") are an example of such an agent, and it is even one which has two of the mentioned functions. It is stated on page 16, lines 30 to 32:

*"Because they (note added by the board: the fat soluble vitamins present in ASU mixtures) stimulate TGF beta and also decrease degradative enzymes, as explained above, ASU mixtures can be said to have both anabolic and anti-catabolic effects."*

4. It is stated on page 16, last line to page 17, line 11:

*"Although some of the effects of ASUs **overlap the effects of other compounds** in the present invention, ASUs contribute unique properties to the group of*

*compounds and provide very **beneficial effects when used in combination with those other compounds**. For example, while **glucosamine and ASUs** both stimulate anabolic processes in connective tissue cells, these compounds have different cellular mechanisms of action. Glucosamine acts in part through protein kinase C, while the effect of ASUs, as stated above, is through transforming growth factor. **Similarly, chondroitin and ASUs** have inhibitory effects of IL-1. ASUs, however, inhibit the plasmin cascade, while chondroitin decreases activation of the complement cascade. Osteoarthritis is a complex disease involving interplay of many cytokines at the cellular level." (emphasis added by the board).*

The skilled person would derive from the above cited passage that ASUs, which themselves have a dual function (see point 3 above), can advantageously be used in combination with compounds having overlapping functions, such as glucosamine or chondroitin.

Thus, a combination of ASUs and chondroitin is disclosed in the earlier and the divisional application as filed as an embodiment of the invention.

5. It is disclosed on page 7, lines 17 to 20 that one of the components of the compositions of the invention are glycosaminoglycans (GAG). That chondroitin is a specific example of this group of compounds is stated on page 9, lines 3 to 7 where it is also disclosed that the salts of the GAG-compounds may be used according to the invention.

Thus, the earlier and the divisional application as filed disclose also combinations comprising ASUs and salts of chondroitin.

6. Consequently, the subject-matter of claim 1 has a basis in the earlier and the divisional application as filed.

7. The subject-matter of claim 2 relating to a composition as claimed in claim 1 comprising ASU and chondroitin sulfate is derivable from the passages referred to above further combined with the passage on page 9, line 19 where it is stated that "*[c]hondroitin sulfate is a preferred GAG*".

8. The subject-matter of claims 3 to 5 is disclosed in the above-mentioned passages in combination with

page 26, lines 6 to 9: "*The compositions of the present invention may be administered via any route, including but not limited to intramuscularly, intravenously, orally, subcutaneously, rectally, topically, transcutaneously, intranasally, and intra-articularly, sublingually, intraperitoneally.*" ;

page 26, lines 11 to 14: "*In addition, the composition can be given in all common dosage forms including extended release dosage forms, pills, tablets, capsules, creams, liquids, aerosols, extended release forms, injectables, etc.*" ; and

page 1, lines 9 and 10: "*The present invention relates to compositions for the protection, treatment and repair of connective tissues in humans and other animals.*", respectively.



9. Hence, claims 1 to 5 fulfil the requirements of Articles 76(1) and 123(2) EPC and consequently meet the objections on which the decision under appeal relies.
  
10. The appellant requests that, if the amended claims are considered to fulfil the requirements of Articles 76(1) and 123(2) EPC, the oral proceedings be cancelled and the application be remitted to the first instance for further prosecution.

In view of the finding in point 9 above, the oral proceedings were cancelled (see section VIII above).

Since in the decision under appeal only the patentability requirements pursuant to Articles 76(1) and 123(2) EPC were investigated and since moreover the present claims differ from those dealt with in the decision under appeal (and during examination proceedings), the board considers it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the first instance for further prosecution of the application.

Hence, both of the appellant's requests are granted.

**Order**

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

1. The decision under appeal is set aside.
  
2. The case is remitted to the department of first instance for further prosecution on the basis of the claims of the main request filed with the letter of 9 November 2012.

The Registrar:

The Chairman:

P. Cremona

C. Rennie-Smith