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Datasheet for the decision of 9 July 2015

Case Number: T 0651/10 - 3.3.02

Application Number: 99927137.2

Publication Number: 1083929

IPC: A61K45/06, A01N37/00, A01N43/04, A01N43/50, A01N43/46, A01N65/00

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 TISSUES IN HUMANS AND ANIMALS

Patent Proprietor:

NUTRAMAX LABORATORIES, INC.

Opponent:

Laboratoires Expanscience

Headword:

Pharmaceutical composition comprising an avocado/soybean unsaponifiable together with an aminosugar/NUTRAMAX

Relevant legal provisions:

EPC Art. 100(b), 100(c), 104(1)
RPBA Art. 16

Keyword:
Main request - added subject-matter (yes)
Auxiliary request 2 - insufficiency of disclosure (yes)
Auxiliary requests 2a, 3, 6, 7, 10, 11, 13, 16 and 17 - prima facie not allowable, admission (no)
Apportionment of costs - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
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Case Number: T 0651/10 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 9 July 2015

Appellant: (Opponent)	Laboratoires Expanscience 10, Avenue de l'Arche 92419 Courbevoie Cedex (FR)
Representative:	Regimbeau 20, rue de Chazelles 75847 Paris Cedex 17 (FR)
Respondent: (Patent Proprietor)	NUTRAMAX LABORATORIES, INC. 2208 Lakeside Boulevard Edgewood, MD 21040 (US)
Representative:	Sturt, Clifford Mark Miller Sturt Kenyon 9 John Street London WC1N 2ES (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 January 2010 concerning maintenance of European Patent No. 1083929 in amended form.**

Composition of the Board:

Chairman	U. Oswald
Members:	M. C. Ortega Plaza
	R. Cramer

Summary of Facts and Submissions

I. European patent EP 1083929, based on European patent application No. 99927137.2, which was filed as an international patent application published as WO 99/62459 (application as filed), was granted with eight claims.

Claim 1 as granted reads as follows:

"1. A pharmaceutical composition comprising an avocado/soybean unsaponifiable (hereinafter "ASU") together with an aminosugar or a salt thereof."

II. Opposition was filed and revocation of the patent in its entirety was requested on grounds pursuant to Article 100(a) EPC, lack of novelty and inventive step, Article 100(b) EPC, insufficiency of disclosure, and Article 100(c) EPC, added subject-matter.

III. The following documents and evidence were cited *inter alia* in the opposition and appeal proceedings:

D1 A. Karleskind, Manuel des corps gras, Technique et Documentation - Lavoisier 1992, Volume I, pages 136 and 240

D9 L. Lipiello et al., "Metabolic Effects of Avocado/Soy Insaponifiables on Articular Chondrocytes", eCam Advanced Access 2007, 1-7 (doi:10.1093/ecam/nem132)

D17 Internet excerpt 2009 "401 Fats and fixed oils", pages 1 and 16-18

D21 Declaration of P. Msika dated 3 June 2010 with technical data

D22 Bailey's Industrial Oil and Fat Products, vol. 2, 115

D24 European Pharmacopoeia 6.0, page 139, point 2.5.7

D26 P. Msika at al., "Avocado/soybean unsaponifiables, ASU EXPANSCIENCE™, are strictly different from the nutraceutical products claiming ASU appellation", Osteoarthritis and Cartilage 2008 (doi:10.1016/j.joca.2008.02.017)

D32 Y. Henrotin, "Avocado/soybean unsaponifiable (ASU) to treat osteoarthritis: a clarification" Osteoarthritis and Cartilage 2008 (doi:10.1016/j.joca.2008.01.010)

D41 D.M. Mello et al., "Comparison of inhibitory effects of glucosamine and mannosamine on bovine articular cartilage degradation in vitro" AJVR 65(10), 2004, 1440-1445

D42 M.Z. Ilic et al., "Effects of long-term exposure to glucosamine and mannosamine on aggrecan degradation in articular cartilage" Osteoarthritis and Cartilage 11, 2003, 613-622

D43 P. Patwari et al., "Mannosamine inhibits aggrecanase-mediated changes in the physical properties and biochemical composition of articular cartilage" Archives of Biochemistry and Biophysics 374(1), 2000, 79-85

A I.1 C. Kut et al., "Morphometric analysis of human gingival elastic fibres degradation by human leukocyte elastase protective effect of avocado and soybean unsaponifiables (ASU)", Path Biol 46(7), 1998, 571-576

A I.2 M.T. Khayyal et al., "The possible "chondroprotective" effect of the unsaponifiable constituents of avocado and soya *in vivo*", Drugs Explt. Clin. Res XXIV(1), 1998, 41-50

A I.3 F. Blotman et al., "Efficacy and safety of avocado/soybean unsaponifiables in the treatment of symptomatic osteoarthritis of the knee and hip", Rev. Rhum. 64(12), 1997, 825-834

A I.4 E. Maheu et al., "Symptomatic efficacy of avocado/soybean unsaponifiables in the treatment of osteoarthritis of the knee and hip", Arthritis and Rheumatism 41(1), 1998, 81-91

A I.5 Y.E. Henrotin et al., "Effects of three avocado/soybean unsaponifiable mixtures on metalloproteinases, cytokines and prostaglandin E_2 production by human articular chondrocytes", Clin Rheumatol 17, 1998, 31-39

A I.6 K. Boumediene et al., "Avocado/soya unsaponifiables enhance the expression of transforming growth factor β_1 and β_2 in cultured articular chondrocytes", Arthritis and Rheumatism 42(1), 1999, 148-156

A I.7 E. Lamaud at al., "Activité des insaponifiables de soja et d'avocat administrés par voie percutanée sur le tissu conjonctif chez le rat", Labo-Pharma – Problèmes et Techniques 275, 1978, 326-329

A I.8 M.H. Thiers, "Les insaponifiables d'huile de soja et d'avocat; Traitement de certaines modalités de la douleur arthrosique", Le journal de Médecine de Lyon, 1972, 1-4

IV. The present appeal lies from an interlocutory decision of the opposition division maintaining the patent in amended form on the basis of the main request filed at the oral proceedings before the opposition division on 15 December 2009 (Articles 101(3) and 106(2) EPC).

The opposition division considered that the claims of the main request did not contain added subject-matter (Articles 100(c) and 123(2) EPC) and that the claimed invention was sufficiently disclosed (Article 100(b) EPC). Moreover, it was also of the opinion that the subject-matter claimed in the main request was novel and inventive over the cited prior art (Article 100(a) EPC).

The opposition division admitted the documents submitted by the patentee on the last day of the deadline for filing submissions for the oral proceedings before the opposition division into the proceedings for being filed within the time limit set in accordance with Rule 116(1) EPC.

The opposition division also admitted the documents filed after the time limit set under Rule 116(1) EPC, since they were submitted by the opponent as a response to the documents filed by the patentee on the last day of the deadline.

V. The opponent (appellant) lodged an appeal against said decision and filed grounds therefor, together with additional documents. With its statement of grounds of appeal the appellant requested that the decision under appeal be set aside and the patent be revoked in its entirety.

VI. Following an extension of the time limit for response to the grounds of appeal, which was granted by the board, the patentee (respondent) filed its response to the grounds of appeal. The respondent maintained its main request before the opposition division and filed three auxiliary requests (first, second and third auxiliary requests). It also filed further documents.

The respondent requested that the appeal be dismissed and that the documents filed with the grounds of appeal not be admitted into the proceedings. Alternatively, it requested apportionment of costs in favour of the patentee if those documents were found admissible.

VII. With its letter of 7 January 2013 the appellant filed arguments against the respondent's requests filed with the response to the grounds of appeal. It also filed a further document.

VIII. With its letter of 28 August 2013 the respondent filed a reply to the appellant's letter dated 7 January 2013. It requested that all documents filed by the appellant during appeal proceedings not be admitted into the proceedings; in the alternative it maintained its request for apportionment of costs.

IX. The board sent a communication on 29 September 2014 pursuant to Article 15(1) RPBA as an annex to the summons to oral proceedings to be held on 9 February 2015.

In said communication the board expressed a negative preliminary opinion with respect to added subject-matter (Article 100(c) EPC) for the main request (i.e. the main request before the opposition division) and gave reasons therefor. Furthermore, with respect to the first auxiliary request filed with the response to the grounds of appeal, the board analysed the claims' construction and stated why the admissibility of this request had to be assessed.

The board also expressed its preliminary view about the discussion concerning the expression "an avocado/ soybean unsaponifiable".

Additionally, the board gave a preliminary opinion on the respondent's request for apportionment of costs.

X. The respondent filed a response to the board's communication with a letter dated 9 December 2014. With said letter the respondent maintained its main request (it re-filed a copy) and filed seventeen auxiliary requests. It also filed a further document. The respondent also stated that it did not dispute the finding that the claimed subject-matter was entitled to the priority date of 23 March 1999 (third priority date).

XI. With a letter dated 12 January 2015 the appellant contested the admission of the seventeen auxiliary requests filed with letter of 9 December 2014.

XII. Oral proceedings scheduled for 9 February 2015 had to be cancelled and on 16 April 2015 the board sent a summons to oral proceedings to be held on 9 July 2015.

XIII. Oral proceedings took place on 9 July 2015.
In the course of the oral proceedings the respondent withdrew auxiliary requests 1, 4, 5, 8, 9, 12, 14 and 15. It filed auxiliary request 2A, containing an amendment to the description, wherein on page 7, lines 2 to 8 were deleted. The claims of auxiliary request 2 were maintained in auxiliary request 2A.

XIV. Claim 1 of the main request is identical to claim 1 as granted.

Claim 1 of auxiliary request 2 reads as follows:

"1. A pharmaceutical composition comprising an avocado/soybean unsaponifiable (hereinafter "ASU") together with **glucosamine or a salt thereof.**" (emphasis added)

Claim 1 of auxiliary request 6 reads as follows:

"1. A pharmaceutical composition comprising an avocado/soybean unsaponifiable (hereinafter "ASU") **obtained from avocado (genus Persea) and soybean (Glycine max)** together with glucosamine or a salt thereof." (emphasis added)

Claim 1 of auxiliary request 10 reads as follows:

"1. A pharmaceutical composition comprising an avocado/soybean unsaponifiable (hereinafter "ASU") together with glucosamine or a salt thereof, **wherein the ASU comprises unsaponifiable extracts which have been extracted from avocado (genus Persea) and soybean (Glycine max).**" (emphasis added)

Claim 1 of auxiliary request 13 reads as follows:

"1. A pharmaceutical composition comprising an avocado/soybean unsaponifiable (hereinafter "ASU") **mixture** together with glucosamine or a salt thereof, wherein the ASU mixture comprises unsaponifiable lipid extracts which have been extracted from avocado (genus Persea) and the soybean (Glycine max)." (emphasis added)

Claim 1 of auxiliary request 16 reads as follows:

"1. A pharmaceutical composition **for use in the treatment, repair or prevention of damage to connective tissue in humans or animals** comprising an avocado/

soybean unsaponifiable (hereinafter "ASU") together with glucosamine or a salt thereof." (emphasis added)

Claim 1 of auxiliary requests 3, 7, 11 and 17 derives from claim 1 of the auxiliary requests 2, 6, 10 and 16, respectively in that the term "avocado/soybean unsaponifiable (hereinafter "ASU")", i.e. in **singular form**, has been replaced by "avocado/soybean **unsaponifiables** (hereinafter "ASU"), i.e. in **plural form**. (emphasis added)

XV. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows:

Main request; added matter

The application as filed (reference was made to international publication WO 99/62459) described compositions comprising one or more compounds from a list of possible compounds including *inter alia* ASU and an aminosugar. However, the application did not provide a direct and unambiguous disclosure of a composition comprising an ASU and an aminosugar, since, starting from the generic disclosure of the application as filed, multiple selections were necessary to arrive at the specific combination claimed. Example 6, a composition comprising ASU, glucosamine and S-adenosylmethionine, hence a ternary composition, could not support the binary composition comprising an ASU and an aminosugar. Moreover, the disclosed specific aminosugar glucosamine could not be generalised to any possible aminosugar.

Meaning of the expression avocado/soybean unsaponifiable (ASU), insufficiency of disclosure

The expression ASU had to be read in the light of the description, which according to paragraph [0029] could "...include any or all unsaponifiable lipids and/or combinations thereof, regardless of origin...". Thus, the expression ASU encompassed not necessarily the whole fraction of unsaponifiables of avocado and soybean, but also only a compound or a class of compounds. The expression ASU, as defined in the patent, included products differing in their composition of compounds or classes of compounds and the amounts thereof, as no method of extraction was disclosed, in contrast to the marketed product Piascledine®, which was produced by a standardised method of extraction. Depending on the preparation and extraction method, the obtained product would have different constituents in different proportions.

In this context the appellant referred to the post-published document D9 and the chromatogram in Figure 1 showing the different preparations, which did not show the same peaks. The appellant submitted that the method of extraction was essential for constitution of the resulting product, and ultimately for its pharmacological activity. The patent, however, did not disclose the method of preparation and/or extraction of the unsaponifiable fraction to be employed. Thus, there was a lack of sufficient disclosure.

Admission of auxiliary requests 2A, 3, 6, 7, 10, 11, 13, 16 and 17

The appellant objected to the admission of auxiliary requests 2A, 3, 6, 7, 10, 11, 13, 16 and 17 for the following reasons:

Auxiliary request 2A did not overcome the objection of insufficiency of disclosure, and instead merely dealt with a clarity issue. Moreover, it was filed very late.

Auxiliary request 3 was late filed and did not *prima facie* overcome the objection of insufficiency of disclosure.

Auxiliary requests 6, 7, 10 and 11 were late filed and did not *prima facie* overcome the objection of insufficiency of disclosure. Moreover, these requests introduced new issues under Article 123(2) EPC.

Auxiliary request 13 was late filed, intended to overcome a clarity issue, and did not *prima facie* overcome the objection of insufficiency of disclosure. Moreover, the request introduced new issues under Article 123(2) EPC.

Auxiliary requests 16 and 17 were late filed and introduced new issues under Article 84 EPC, especially the question of the category of claim 1 and its scope of protection.

Apportionment of costs

The appellant submitted that the patentee had filed documents and experimental data on the last day under Rule 116(1) EPC in opposition proceedings and that these documents were admitted into the proceedings by the opposition division. Therefore, the documents subsequently filed by the opponent with its grounds of appeal were submitted in response thereto and were necessary for its argumentation. Furthermore, they were reasonable in number and filed in one of the official languages. Moreover, the respondent (patentee) had had

enough time to deal with their content. Thus, there was no reason for apportionment of costs in favour of the patentee.

XVI. The respondent's arguments, as far as relevant for the present decision, may be summarised as follows.

Main request; added matter

The application as filed described a combination of an avocado/soybean unsaponifiable (hereinafter "ASU") and glucosamine in the paragraph bridging pages 16 and 17, on page 24, line 11 and in the table on page 25. It was further stated on page 17, lines 10 to 11 that, because the different compounds acted via different mechanisms of action, they would have synergistic effects. Moreover, page 8, line 20 to page 9, line 2 characterized glucosamine as an example of an aminosugar and outlined further suitable aminosugars of the invention such as natural, synthetic or semi-synthetic aminosugars, provided they retained their function. Other aminosugars, such as mannosamine, had similar activity to glucosamine and therefore synergistic effects found for ASU together with glucosamine could reasonably be expected for ASU together with other aminosugars. In this context the respondent cited the post-published documents D41 to D43.

The application as originally filed was not restricted to glucosamine, since the claims as filed defined compositions comprising one or more compounds from a list containing aminosugars in general. Hence, the application as originally filed provided a direct and unambiguous disclosure, at least implicitly, for a combination of ASU and aminosugar based on the explicit

disclosure of a combination of ASU and glucosamine and the disclosure that glucosamine was only an example of a suitable aminosugar. Moreover, example 6 of the application described a combination of ASU, glucosamine and S-adenosylmethionine.

Meaning of the expression avocado/soybean unsaponifiable (ASU); insufficiency of disclosure

The respondent submitted that the invention, which concerned a synergistic combination of an ASU and glucosamine, was sufficiently disclosed.
The expressions ASU and ASUs were commonly and indistinctly used in the general prior art, as supported by documents A I.1 to A I.8. Moreover, a standard method of extraction was known in the art (documents D22 and D24), comprising a first step of saponification with alcoholic potassium hydroxide and a second step of extraction of the unsaponifiable fraction with ether. In this regard, the respondent also cited document D17, which albeit a document from the Internet, confirmed the existence of a standard method for preparing the unsaponifiable matter in oils and fats.

The respondent further submitted that a person skilled in the art understood ASU to mean the total unsaponifiable fraction of avocado and soybean oils representing a complex mixture of compounds, however without exactly knowing which compounds of this mixture were responsible for the pharmacological effects (it cited *inter alia* A I.4). Moreover, document D1 disclosed the components of the unsaponifiable fraction of soybean on page 136, table 20 and the components of the unsaponifiable fraction of avocado on page 240, table 17. The content of ASU, regardless of whether it

was used in singular or in plural form, might vary, and hence different ASU extracts as well as a mixture of different ASU extracts were encompassed by the expression used in the claims, but a single compound or a single compound class were not.

Document D21 referred to document D1 for the definition of the terms "unsaponifiable" or "unsaponifiable fraction" (page 3, first and second paragraph under point 1, "*La connaissance des produits*").

The respondent further submitted that the definition of ASU given in the patent in paragraphs [0024], [0025], [0028] and [0029] was in accordance with the meaning of the expression in the art. The terms "any number" used in paragraph [0024] and "any or all" or "any of a number" used in paragraph [0029] would be understood by a person skilled in the art as meaning that many components of an unknown number were contained in the ASU. Additionally, the patent specified in paragraph [0029] that the unsaponifiable components may also be derived from other plant or animal sources, provided that these components were found in the unsaponifiable fraction of avocado and soybean oils.

The respondent also submitted that the commercial product Piascledine® (Document D26, right-hand column, first paragraph) was different from common natural ASU. Document D21 showed that, due to a purification step, said commercial product did not contain the whole unsaponifiable matter from avocado and soybean oils, but only a fraction thereof. Moreover, the content of Piascledine® had changed over the years in that the furanic components, deriving from the avocado unsaponifiable fraction, had been increased.

Furthermore, the respondent stated that paragraph [0028] lines 47 to 50 and lines 53 to 54 of the patent made it plausible that the combination of ASU with glucosamine or a salt thereof had synergistic effects owing to their different mechanisms of action.
In this context the respondent also cited the two post-published documents D9 and D32, namely page 2, right-hand column, first paragraph, and page 4, Figure 1 of D9 and right-hand column, second paragraph of D32, in order to support the view that different ASU formulations including different ratios of avocado/ soybean in the ASU extracts (it cited document A I.5) showed comparable activities within some degree of variation. It submitted that any ASU or ASUs would be suitable for providing a synergistic combination with glucosamine.

Admission of auxiliary requests 2A, 3, 6, 7, 10, 11, 13, 16 and 17

These auxiliary requests should be admitted into the proceedings for the following reasons:

Auxiliary request 2A overcame the objection of insufficiency of disclosure based on the interpretation of the expression ASU and did thus not merely deal with a clarity issue. The amendment was not complex, it was easy to understand, and it did not cause new issues to be dealt with. Moreover, this request could not have been filed earlier.

Auxiliary request 3 only differed from auxiliary request 2 in that the expression "ASU" was in plural form ("unsaponifiables") in order to exclude a single compound or fraction from the meaning of the expression "ASU". The request was filed in December 2014 and was

similar to the first auxiliary request filed in opposition proceedings, except for the term "aminosugar" being replaced by "glucosamine or a salt thereof". Moreover, this request did not give rise to any new issues to be dealt with.

Auxiliary requests 6 and 7 were filed in response to the objection of insufficiency of disclosure, defining that ASU (or ASUs) was "obtained from avocado (genus Persea) and soybean (Glycine max)", thereby explicitly restricting ASU to the whole extract of unsaponifiables from avocado and soybean. Page 15, lines 12 to 14 of the application as filed provided the basis for the amendment. The requests were filed in December 2014 and were similar to the second auxiliary request filed in opposition proceedings, except for aminosugar being replaced by glucosamine or a salt thereof. Moreover, these requests did not give rise to any new issues to be dealt with.

Auxiliary requests 10 and 11 were filed in an attempt to overcome the objection of insufficiency of disclosure by further specifying the expression ASU. The subject-matter of the requests had a low complexity and was easy to deal with. The basis for the amendments, representing a limitation, was found on page 15, lines 12 to 16 of the application as filed. The requests did not invoke new issues to be dealt with and were *prima facie* allowable under Article 123(2) and (3) EPC.

Auxiliary request 13 was filed in response to the objection of insufficiency of disclosure in an attempt to clarify the meaning of the expression ASU. The subject-matter of the request was not complex, it was easy to deal with and did not give rise to any new

issues. The respondent cited page 16, lines 29 and 31, page 17, first paragraph and page 17, lines 28 to 30 of the application as filed as the basis for the amendment.

Auxiliary requests 16 and 17 were filed as a fall-back position in response to an objection under Article 100(c) EPC by the appellant. Claim 1 of these requests related to a first medical use claim for the combination of an ASU with glucosamine, given the fact that Article 54(5) EPC 2000 did not apply to the patent.

Apportionment of costs

The respondent no longer contested the admission of the documents filed by the appellant during appeal proceedings. However, it maintained its request for apportionment of costs in its favour, owing to the large number of documents and the lateness of their filing.

XVII. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed (i.e. the patent be maintained in amended form on the basis of the main request before the opposition division) or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 2, 3, 6, 7, 10, 11, 13, 16 or 17 filed with the letter of 9 December 2014 or auxiliary request 2A filed during the oral proceedings.

The respondent maintained its request for an apportionment of costs in its favour.

Reasons for the Decision

1. The appeal is admissible.

2. Main request; added matter

2.1 Claim 1 of the main request is identical to claim 1 as granted. Article 100(c) EPC is a ground for opposition within the framework of the present appeal.

2.2 The application as filed does not explicitly disclose a pharmaceutical composition comprising the specific combination of components in claim 1 of the main request, i.e. an avocado/soybean unsaponifiable ("ASU") together with an aminosugar or a salt thereof.

The application as filed discloses a composition "comprising one or more avocado/soybean unsaponifiables and one or more compounds selected from the group consisting of aminosugars, GAGs, GAG-like compounds, pentosan, SAMe, SOD, L-ergothionine, collagen type II, diacerin *[sic]*, arachadonic *[sic]* acid, and tetracycline compounds, wherein each such avocado/ soybean unsaponifiable and each such compound may be naturally, semi-synthetically or synthetically derived" (claim 1 as originally filed).

The general description under the heading "Summary of the Invention" of the application as filed (see page 7, lines 17-27) discloses that it is an object of the invention to provide compositions [of] "any or all of anabolic, anti-catabolic, anti-oxidant and/or analgesic agents selected from the group consisting of

aminosugar, S-adenosylmethionine (SAMe), arachidonic acid (AA), GAG, pentosan sulfate, collagen type II, tetracyclines, diacerin *[sic]*, super oxide dismutase (SOD), L-ergothionine, one or more avocado/soybean unsaponifiables (ASUs), hydroxyproline and analgesics, such as acetaminophen"; and that "it is a further object of the invention to provide compositions (to repair, treat and prevent damage to connective tissue in humans and animals) that contain "one or more of the elements selected from the group consisting of aminosugar, SAMe, arachidonic acid, GAG, pentosan sulfate, collagen type II, tetracyclines, diacerin *[sic]*, SOD, L-ergothionine, one or more ASUs, hydroxyproline and analgesics, e.g,*[sic]* acetaminophen".

Moreover, under the heading "Detailed Description of the Invention" (page 8, lines 14 to 19 of the application as filed), it is generally stated that "Ingredients of preferred embodiments include compositions selected from the group consisting of aminosugars, SAMe, AA, GAGs, including pentosan, collagen type II, tetracyclines, diacerin *[sic]*, SOD, L-ergothionine, and one or more ASUs".

Starting on page 15, line 12 of the application as filed, the background knowledge about lipid extracts, nonsaponifiable or unsaponifiable, in particular in relation to extracts of avocado/soybean unsaponifiables, is analysed. Within this context it is acknowledged that the effects of avocado/soybean unsaponifiables on metalloproteinases, cytokines and prostaglandin E2 production by human articular chondrocytes had already been tested in the prior art (see page 16, lines 10-11). Then, the effects of certain polypeptidecytokines (TG beta 1 and 2) and

proteinases (stromelysins) are explained (page 16, lines 13 to 28 of application as filed). The statements about "ASU mixtures" (containing a plurality of different components, such as, for instance, fat-soluble vitamins) to have both anabolic and anti-catabolic effects (paragraph bridging pages 16 and 17) have to be understood in this context. Thus, it is disclosed in said paragraph that "the fat-soluble vitamins present in ASU mixtures are necessary for growth, and augment the anabolic effects of TGF-beta... ASUs contribute unique properties to the group of compounds and provide very beneficial effects when used with those other compounds". Thereafter it is stated "For example, while glucosamine and ASUs both stimulate anabolic processes in connective tissue cells, these compounds have different cellular mechanisms of actions. Glucosamine acts in part through protein kinase C, while the effect of ASUs, as stated above, is through transforming growth factor".

Independently from the fact that the definition generally given by the skilled person in the prior art to the expression "an avocado/soybean unsaponifiable", be it in plural or singular form (ASU or ASUs), does not correspond to the broader definition given on page 17, lines 19 to 24 of the application as filed, the application as filed does not directly and unambiguously disclose the binary combination in a pharmaceutical composition of an avocado/soybean unsaponifiable (be it in plural or singular form) with an aminosugar.

The definition for "the aminosugar component of the compositions of the present invention" on page 8, lines 25 to 30 of the application as filed comprises "natural, synthetic, semi-synthetic aminosugars

including but not limited to salts of glucosamine...", and includes as well "aminosugars that may have been chemically modified yet retain their function".

Therefore, it cannot be directly and unambiguously derived from the application as filed that the term "glucosamine", which is acknowledged to be "naturally formed in the body from glucose" on page 8, line 20 to 21, is an immediate and unambiguous synonym for any aminosugar, synthetic and/or semi-synthetic. Additionally, in the absence of any reference to a particular testing method in respect of the biological "function" to be retained by the aminosugar, the application as filed does not disclose which (if any) aminosugar could be considered as equivalent to glucosamine in fulfilling the function in the stimulation of anabolic processes in connective tissues (as mentioned on page 17, lines 3 to 4 of the application as filed).

Additionally, the sentence on page 17, lines 10-11, "Because the different compounds of the present invention act on different cytokines, they will have synergistic effects when used in appropriate combinations", is of a general nature and does not give any hint as to the actual nature of the components to be selected for said combinations.

Moreover, the application as filed generally discloses that the "present invention comprises novel combinations of anabolic agents, anti-catabolic agents and antioxidant agents that maximize beneficial, anabolic effects (healing) and minimize potential negative effects" (page 22, second full paragraph of application as filed). However, this general information does not provide sufficient disclosure for

allowing the selection undertaken in the claims according to the main request. Moreover, the generic compound class ASUs may simultaneously qualify for two of these definitions, namely as anabolic agents and as anti-catabolic agents (page 22, third full paragraph of the application as filed). The paragraph bridging pages 22 and 23 discloses that "the present invention consists of various combinations of **two or more** of the following agents: AA, glucosamine, chondroitin sulfate, pentosan, diacerin [sic], S-adenosylmethionine, superoxide dismutase, L-ergothionein *[sic]*, collagen type II, tetracycline-like compounds, one or more ASUs, hydroxyproline, and optionally, one or more analgesics" (emphasis added). Hence, the combination of an ASU (or ASUs) with an aminosugar (in its generic meaning) is not singled out on page 23.

Furthermore, the table on page 25 is to be understood within the context of the explanations given on pages 23 and 24 as representing a matrix showing possible combinations. The table contains compositions including one or more ASUs plus glucosamine (see also page 24, lines 10 and 11). However, this information does not allow a generalisation leading to the combination of an ASU (or ASUs) with an aminosugar.

Moreover, none of the specific examples illustrates the compositions with the binary combination in claim 1 of the main request.

Example 6 discloses the treatment of a 5-year-old Jersey dairy cow with ASU 900mg, SAMe 600mg and glucosamine 500mg daily. There are three active ingredients, which may or may be not administered from separate preparations. Thus, example 6 does not clearly disclose a pharmaceutical composition simultaneously

comprising an ASU and an aminosugar. Apart from that, example 6 mentions that: "The combined effect of the **three compounds** is to reduce inflammation and pain, to support normal function, and to stimulate healing of connective tissues" (emphasis added). As example 6 relates to a combination of three active components having a functional relationship, it cannot serve as an allowable basis for the combination of only two of the active components.

Therefore, the subject-matter claimed in the main request is neither explicitly disclosed nor directly and unambiguously derivable from the application as filed.

As regards post-published documents D41 to D43 cited by the respondent, their content cannot be invoked as forming part of the general knowledge of the skilled person at the effective filing date of the patent. Moreover, the teaching of these documents is very specific, since all three documents relate to mannosamine, which is an epimer of glucosamine. Thus, these documents do not support the generalisation leading to the broader term "aminosugar".

Consequently, the main request contains added subject-matter (Article 100(c) EPC).

3. Auxiliary request 2; sufficiency of disclosure

The ground for opposition pursuant to Article 100(b) EPC concerns sufficiency of disclosure. In order to be maintained, a European patent must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The content of the whole patent, in particular the description (including the examples), has to be investigated by the skilled person in the light of the knowledge of the technical field involved, without making use of inventive skills. The relevant date to be considered for the requirements of sufficiency of disclosure is that of the effective filing date of the application.

Additionally, it is the claimed "invention" reflected by the subject-matter of the claims which has to be investigated. As a general principle, the skilled person should be able to reproduce the invention in the breadth claimed without undue burden.

As for the amount of technical detail needed for a sufficient disclosure, this is a matter which depends on an assessment of the facts of each individual case, such as the character of the technical field, and the actual technical detail disclosed.

The subject-matter of claim 1 of auxiliary request 2 concerns a pharmaceutical composition comprising an avocado/soybean unsaponifiable (ASU) together with glucosamine or a salt thereof.

The "invention" claimed in auxiliary request 2 relies on the synergistic combination of an avocado/soybean unsaponifiable (ASU) with glucosamine or a salt thereof. Paragraph [0028] of the patent refers to the combination of glucosamine with ASUs (avocado/soybean unsaponifiables) and discloses that "although some effects of ASUs overlap the effects of other compounds of 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". Paragraph [0028] further discloses that "because the different compounds of the present invention act on different cytokines, they will have synergistic effects when used in appropriate combinations". There is however, no further information about how to choose the combinations so that they are appropriate for attaining a synergistic effect.

Generally known avocado and soybean unsaponifiables concern a multitude of different components (compounds and compound classes). In general terms these components are unsaponifiable constituents of avocado and soybean oils.

According to the patent in suit, the unsaponifiable compounds from plant lipids (as for instance unsaponifiable constituents of avocado and soybean oils) may be extracted from different plants or even from other organisms such as algae (paragraph [0024]). If derived from lipid extracts, paragraph [0024] defines the unsaponifiables as "that part of the plant lipids that do not undergo saponification, i.e. they do not react with alkali to form a soap". This general definition would imply a treatment with alkali before separation, but leaves it open as to when and how the treatment with alkali should be done and how to prepare the lipid extracts or lipid fractions. There is also no mention of any method for separation and/or solvent extraction for obtaining those constituents or mixtures

of constituents falling under the generic terms "ASU" or "ASUs". In fact, the patent as a whole is silent about a protocol of extraction or a preparation process, and the only example in it does not identify which ASU is employed (either its origins or its preparation).

Paragraph [0024] confirms that there are many such (unsaponifiable) compounds and that "any particular avocado extract may contain any number".
Paragraph [0024] further gives examples of compound classes which may be present in unsaponifiable extracts and/or unsaponifiable fractions from plant lipids. Those examples "include fat soluble vitamins, steroids (e.g. phytoestrogens), sterols (e.g. bioflavonoids) and volatile essential oils (terpenes such as menthol, camphor, lycopene, gibberellic acid, limonene, cinnamaldehyde, carotenoids and ubiquinone)". However, this passage does not explicitly mention which of these components are to be present in the combination ASU with glucosamine claimed, and in which proportions. Therefore, the skilled person is not instructed in respect to what avocado and/or soybean unsaponifiables should be taken together with glucosamine for preparing a binary synergistic combination.

Moreover, asked by the board about the extent to which a compound such as gibberellic acid meets the definition "which does not react with alkali...", the respondent replied that, although the acid residue may react forming an alkali salt, gibberellic acid would only be present in trace amounts in the unsaponifiable extracts.

Paragraph [0025] of the patent acknowledges that commercial products sold under the trade name

Piascledine and containing unsaponifiable fractions of the avocado and soybean oils had been used in Europe for treating *inter alia* osteoarthritis and other forms of arthritis. This paragraph also mentions that "ASUs decrease the effects of IL-1, and thereby reduce chondrocyte and synoviocyte production of collagenase", and cites in this context the prior art document A I.5 by Henrotin. Document A I.5 is entitled "Effects of three avocado/soybean unsaponifiable mixtures on metalloproteinases, cytokines and prostaglandin E_2 production by human articular chondrocytes". It states that "avocado and soybean unsaponifiable residues were mixed in three ratios: **1:2, 2:1 or 1:1**" (abstract). Moreover, it teaches that "the unsaponifiable part of avocado (A) and soybean (S) oils **mixed in a ratio of 1:2** (A1S2, Piascledine..." had been used "to treat connective tissue diseases for several years" (page 31, paragraph under the heading "Introduction") (emphasis added).

Document A I.5 further teaches the particular preparation methodology as follows: "After concentration by molecular distillation and saponification by hydroxide in ethanol, the unsaponifiable part of avocado and soybean oils is extracted on a counter-current column using ethylene dichloride". It also establishes which are the main components of the ASUs products so prepared and their relative amounts expressed as percentages. In the main fraction (up to 50%) of the avocado unsaponifiable prepared in this way, the following is mentioned: "a furyl nucleus is substituted in position 2 by an aliphatic, mono- or polyunsaturated chain. The chain length varies from 13 to 17 carbon atoms, always an odd number". This component is not mentioned for the soybean unsaponifiable in document A I.5. The

respective constituents of the avocado and soybean unsaponifiables prepared according to the method in A I.5 and their relative proportions are different (also in relation to the amounts relative to sterols).

The preparation method in document A I.5 does not form part of the disclosure of the patent in suit, which leaves it open to the skilled person to employ any conceivable preparation and/or extraction method for obtaining avocado/soybean unsaponifiables (fraction extracts or mixtures thereof). In fact, the patent does not refer to document A I.5 as disclosing a preparation method for obtaining an avocado/soybean unsaponifiable (ASU) suitable as constituent for the claimed synergistic combination of an ASU with glucosamine.

Furthermore, the patent is silent as regards the actual ratio for the mixture of components deriving from avocado and soybean, respectively, and does not state that the commercial product Piascledine can be successfully used for the claimed synergistic combination with glucosamine.

There is a lack of information in the patent about the preparation and/or obtention of the ASU ingredient (be it a mixture of unsaponifiable extracts from avocado or soybean oils or a mixture of the total unsaponifiable fractions) necessary for the binary combination claimed. Nor is the skilled person told how to characterise such an ASU product (as for instance with respect to its main components together with their relative amounts expressed as percentages).

The only example in the patent in suit corresponds to example 6 of the application as filed. As already mentioned, it discloses the treatment of a 5-year-old

Jersey dairy cow with "ASU 900 mg, SAMe 600 mg and glucosamine 500 mg daily". Apart from the fact that the example discloses a ternary combination and "the combined effect of the three compounds", it is silent about the origin, preparation and constitution of the "ASU" employed.

Paragraph [0029] of the patent acknowledges that ASUs had been shown to be effective in reducing symptoms of osteoarthritis in the prior art.

Paragraph [0029] further states that "because the active unsaponifiable components found in avocados and soybeans may also be present in other plants and indeed other organisms, ASUs as used in this invention can include any or all unsaponifiable lipids and/or combinations thereof, regardless of origin, whether from plants or other organisms, or whether semi-synthetically or synthetically derived" (page 7, lines 2 to 5).

Additionally, paragraph [0029] of the patent teaches as follows: "Examples of components of ASUs include but are not limited to: limonene, beta carotene, phylloquinone, and gibberellic acid. As explained above, ASUs can include any of a number of classes of compounds including but not limited to fat soluble vitamins, steroids, sterols and volatile essentials oils, or any combinations thereof. The invention includes, moreover, compositions which contain one avocado/soybean extract (ASU) or mixtures or combinations of such extracts (more than one ASU). There are many such combinations and all are intended to be included within the present invention" (page 7, lines 5 to 10).

Even if, for the sake of argument, the skilled person were to ignore the description in paragraph [0029], lines 2 to 8, and its extremely broad definition for products qualifying as ASU or ASUs, and were to begin an attempt to reproduce the claimed invention with naturally occurring avocado and soybean plant unsaponifiables, there is no guidance in the whole patent as to how to proceed in order to get combinations of avocado/soybean oils unsaponifiable components with glucosamine which work synergistic. The lack of at least one detailed way to reproduce the claimed invention causes in the present case a major problem of insufficiency of disclosure for the scope claimed.

The respondent contended that the expressions "unsaponifiable" and "unsaponifiables" and the short terms "ASU" and "ASUs" had been indistinguishably used not only in the patent in suit but also in the prior art forming part of the common general knowledge of the skilled person in the field (*inter alia* A I.1 to A I.8). Moreover, it stated that the expression "ASU" must be understood as concerning the whole content of an unsaponifiable extract or mixture of unsaponifiable extracts of avocado and soybean, and that any ASU (or ASUs) would be suitable for providing a synergistic combination with glucosamine.

However, the respondent's arguments do not hold for the following reasons. In the light of the content of the patent in suit it is not technically well founded to argue that the skilled person would expect any feasible combination of an avocado and soybean unsaponifiable (be it understood in singular form as ASU or in plural as ASUs) together with glucosamine to show synergism, since, as explained throughout the patent, the

constituents of that part of the plant lipids which fall under the expression "unsaponifiable" (be it in singular or plural form) are manifold and belong to very different compound classes. Synergism of biological activities for a binary combination ASU (be it in singular or plural form) with glucosamine remains a wishful target in the patent in suit, since the patent does not teach at least a detailed mode of putting it into practice. The skilled person faces a lack of knowledge regarding the true constitution of the avocado/soybean unsaponifiable(s) to be used (be it a mixture of some extracts from avocado and soybean oils or a mixture of their total unsaponifiable fractions), which will depend on the method of preparation and/or extraction, as well as on the choice of an appropriate mixture of different extracts or fractions deriving from avocado and soybean oils. Additionally, the skilled person would also need to determine, without any specific guidance given in the patent, which is or are (and how to prepare) an adequate mixture or mixtures of avocado and soybean unsaponifiable fractions (or extracts) to be combined with glucosamine in order to successfully put into practice the claimed invention.

Document D1, which is a manual about lipids (*"corps gras"*), shows in Table 20 on page 136 a composition of the unsaponifiable part ("*partie insaponifiable*") of soybean oil (representing 0.5 to 1.6% of the row oil "*huile brute*" and between 0.6 to 0.7% of purified or refined oil), with amounts expressed in mg/100 mg, and in Table 17 on page 240 a composition for the unsaponifiable part (1.0 to 12%) of avocado oil. However, the document states that the data about the composition of the unsaponifiable part disclosed in the primary literature in the field vary extremely (in

relation to content and relative amounts of components) and depend *inter alia* on the plant varieties used, the method of obtaining the oil (e.g. extraction or any other process), the nature of the raw oil or purified/ refined oil, and the method of preparation of the unsaponifiable (page 240). Therefore, the skilled person faces a major lack of information in the patent concerning the adequate mixture of unsaponifiable fractions from avocado and soybean oils to be used for reproducing the invention.

The respondent contended that the preparation process of the unsaponifiable fractions of avocado and soybean oils was a standard procedure and cited document D17, which generally defines the expression "unsaponifiable matter" and a procedure for preparing unsaponifiable matter in oils and fats. However, document D17 is a document downloaded from the Internet in 2009. Its exact publication date could not be established, and the effective filing date of the application underlying the patent in suit is 1999. Therefore, it cannot be accepted that the information in document D17 appertains to the common general knowledge of the skilled person in 1999. Apart from that, the preparation process in document D17 relates to the treatment with alkali (potassium hydroxide in alcohol/ water solution), heating step (reflux during one hour), extraction with ether, etc. There is no indication whatsoever in the patent in suit that the preparation process disclosed in D17 serves the purpose of the invention claimed. The definition of unsaponifiable matter given in document D17 is as follows: "the term "unsaponifiable matter" in oils and fats refers to those substances that are not saponifiable by alkali hydroxides but are soluble in the ordinary fat solvents, and to products of saponification that are

soluble in such solvents". It has also to be mentioned that the extraction step disclosed in document A I.5 (which is one of the documents cited by the respondent as representing the general knowledge in the art) is performed with ethylene dichloride and not with ether (in document D22 ether or hexane are suggested). Therefore, the existence of a standard process for obtaining the unsaponifiable fraction is doubtful. The definition given in document D22 for unsaponifiable matter is as follows: "unsaponifiable matter is the ether or hexane soluble components extracted after a fat sample is refluxed with alcoholic potassium hydroxide", whereas document D24 refers to the term "unsaponifiable matter" as applying to "the substances **non-volatile at 100-105°C** obtained by extraction with an organic solvent from the substance to be examined after it has been saponified. The result is to be calculated as per cent *m/m*" (emphasis added).

There is no doubt that the skilled person would be able to prepare a certain avocado and/or soybean unsaponifiable fraction, extract or mixture. However, the skilled person does not have sufficient information in the patent as to how to prepare a binary combination of an avocado/soybean unsaponifiable with glucosamine that is synergistic, and more particularly, as to which unsaponifiable components deriving from avocado and soybean oils are essential in order to meet this target.

As regards the expert declaration D21 filed by the appellant, the respondent cited it to show that the appellant had acknowledged that the term "unsaponifiable" was well known in the art and that the definition was a standard definition. However, document D21 refers to document D1. As already said, document D1

states that the unsaponifiable part of plant oils (avocado and soybean oils being cited) varies in its constitution and in the relative contents of its components, depending on several factors, none of which has been defined or determined in the patent, leaving a gap that cannot be filled with the general knowledge of the skilled person trying to reproduce the claimed invention. At the same time, the respondent also contended that the unsaponifiables prepared according to declaration D21 were singular and different from the natural ASU (or ASUs) and cited the post-published document D26. However, the patent in suit neither excludes nor includes concentration, extraction or saponification processes such as those mentioned in declaration D21 for preparing an ASU (or ASUs). Moreover, the patent does not contain sufficient information as to whether or not the commercial ASUs (such as Piascledine products) are suitable for the claimed synergistic binary combination with glucosamine.

The board cannot follow the respondent's argument that the total unsaponifiable fraction is meant when using the terms ASU or ASUs. These terms correspond to undetermined mixtures of avocado unsaponifiables and soybean unsaponifiables, which are not required to simultaneously include all the unsaponifiable components of both avocado and soybean oils. Paragraph [0029], lines 8 to 11 of the patent states that *"The invention includes, moreover, compositions which contain one avocado/soybean extract (ASU) or mixtures or combinations of such extracts (more than one ASU)."* There is no mention or definition in the patent of a "total unsaponifiable fraction" or of a method for its obtention.

Consequently, the invention claimed in auxiliary request 2 is not sufficiently disclosed in the patent (Article 100(b) EPC).

4. *Auxiliary request 2A*

After the discussion about sufficiency of disclosure of auxiliary request 2 had taken place at the oral proceedings, the respondent filed auxiliary request 2A, maintaining the set of claims of auxiliary request 2 and amending paragraph [0029] of the patent (deletion of the text beginning with "Because" on page 7, line 2 and ending with "thereof" in line 8).

The deletion of this passage in paragraph [0029] of the patent relates to an attempt to introduce an implicit disclaimer in claim 1 in order to exclude from the definition of ASU those unsaponifiables, initially disclosed, which derive from origins other than avocado or soybean. This deletion does not, however, overcome the lack of guidance in the patent for at least one way to put into practice the binary synergistic combination claimed.

Correspondingly, auxiliary request 2A was not admitted into the proceedings since it is *prima facie* not allowable.

5. *Auxiliary requests 3, 6, 7, 10, 11, 13, 16 and 17; admission*

Auxiliary requests 3, 6, 7, 10, 11, 13, 16 and 17 had been filed with the letter of 9 December 2014.

5.1 Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 only in that the term

"unsaponifiable" has been put in its plural form "unsaponifiables". The reasons given for auxiliary request 2 in relation to lack of sufficiency of disclosure apply in an analogous manner. Therefore, auxiliary request 3 is *prima facie* not allowable and was not admitted into the proceedings.

5.2 Claim 1 of auxiliary request 6 differs from claim 1 of auxiliary request 2 in that the following has been added after the expression "an avocado/soybean unsaponifiable (hereinafter "ASU")": "obtained from avocado (genus Persea) and soybean (Glycine max)".

The amendment to claim 1 of auxiliary request 6 relates to an attempt to define the avocado/soybean unsaponifiable by means of a product-by-process feature. However, in the absence in the patent of a process for preparation of the oil extracts, their saponification, and the mixture of extracts including their characterisation and their proportions in the mixture, the mere statement that the unsaponifiable derives from plants belonging to genus Persea and Glycine max does not overcome all the objections against sufficiency of disclosure of the invention claimed.

Moreover, the amendment gives rise to new issues for discussion, at a late stage of the appeal proceedings, which concern the possible support and meaning of the introduced feature as a limitation of the product claimed (Articles 123(2) and 84 EPC). The respondent's argument that the "product-by-process" feature makes it immediately clear that all the extracts and all the components left behind after saponification are meant to be present cannot succeed, since the true constitution of the "unsaponifiable" (be it in singular

or plural form) in respect of its actual components and their relative amounts would be dependent on the preparation and/or extraction methodology, which is not disclosed in the patent.

Consequently, auxiliary request 6 was not admitted into the proceedings.

5.3 Claim 1 of auxiliary request 7 differs from claim 1 of auxiliary request 6 in that the plural form "unsaponifiables" is used. Therefore, the reasons given for the non-admission of auxiliary request 6 apply *mutatis mutandis* to auxiliary request 7.

Correspondingly, auxiliary request 7 was not admitted into the proceedings.

5.4 Claim 1 of auxiliary request 10 differs from claim 1 of auxiliary request 2 in that the following has been added at the end of the claim: "wherein the ASU comprises unsaponifiable extracts which have been extracted from avocado (genus Persea) and soybean (Glycine max)".

The amendment does not overcome all the objections against sufficiency of disclosure of auxiliary request 2 and introduces new deficiencies regarding the requirements of Article 123(2) EPC.

Therefore, auxiliary request 10 was not admitted into the proceedings.

5.5 Claim 1 of auxiliary request 11 differs from claim 1 of auxiliary request 10 in that the term "unsaponifiable" is in its plural form, "unsaponifiables". Therefore,

the reasons given for the non-admission of auxiliary request 10 apply here too.

Consequently, auxiliary request 11 was not admitted into the proceedings.

5.6 Claim 1 of auxiliary request 13 differs from claim 1 of auxiliary request 11 in that the word "mixture" has been introduced after the expression "an avocado/ soybean unsaponifiable (hereinafter "ASU")".

Analogous reasons to those given for the non-admission of auxiliary requests 10 and 11 apply to auxiliary request 13. There is a lack of disclosure in the patent and in the application as filed (Article 83 EPC) with respect to the composition of a binary combination of any particular mixture of an avocado and soybean unsaponifiable together with glucosamine. Additionally, the amended wording introduces *prima facie* new deficiencies with respect to Article 123(2) EPC.

Therefore, auxiliary request 13 was not admitted into the proceedings.

5.7 Claim 1 of auxiliary request 16 is a purpose-related product claim which relates to a "pharmaceutical composition for use in the treatment, repair or prevention of damage to connective tissue in humans or animals". Thus, the claim's wording defines a product for its use in a specific method of medical treatment.

As mentioned in the board's communication sent on 29 September 2014, according to Article 1 of the Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November

2000, Article 54(5) EPC 2000 does not apply to the patent in suit, since the date of publication and mention of the grant of the patent is 14 February 2007, i.e. before the entry into force of the revised EPC 2000 (13 December 2007).

Therefore, a purpose-limited product claim seeking protection within the meaning of Article 54(5) EPC 2000 for further specific medical uses cannot be allowed, since, as mentioned above, Article 54(5) EPC 2000 does not apply to the patent in suit.

The respondent submitted that claim 1 of auxiliary request 16 should then be read as a first medical use claim for the combination of an ASU with glucosamine, the case being that claim 5 relates to a second medical use claim in the Swiss-type form.

However, the replacement of a product "*per se*" claim by a purpose-related product claim cannot overcome the objections with respect to insufficiency of disclosure for the product, which relates to a synergistic combination of an ASU with glucosamine, as it is the case of the product claimed in auxiliary request 2.

Consequently, auxiliary request 16 was not admitted into the proceedings.

5.8 Claim 1 of auxiliary request 17 merely differs from claim 1 of auxiliary request 16 in that the term "unsaponifiable" is in its plural form, "unsaponifiables". Therefore, the reasons given for the non-admission of auxiliary request 16 apply here too.

Consequently, auxiliary request 17 was not admitted into the proceedings.

6. Request for apportionment of costs

During the written proceedings, the respondent's request for apportionment of costs had been made conditional on the admission of the documents filed by the appellant with the grounds of appeal and with its letter dated 7 January 2013.

In the board's communication sent on 29 September 2014, the board expressed the preliminary opinion that there was not a situation of abuse of proceedings by the appellant (Article 16(e) RPBA), since the appellant filed some documents with its grounds of appeal in an attempt to reply to the filing by the patentee of additional documents and experimental data, which had been admitted by the opposition division into the proceedings, although they were filed the last day under Rule 116(1) EPC. Moreover, the respondent was granted an exceptional extension of the time limit for response to the grounds of appeal, and was able to file counterarguments and further documents in response.

At the oral proceedings before the board the respondent withdrew its objection to the admission of the documents filed during appeal proceedings, but maintained its request for an apportionment of costs in its favour. When asked by the board about the specific legal basis for this request, the respondent remained silent.

Article 16 RPBA stipulates that "subject to Article 104, paragraph 1, EPC, the board may on request order a party to pay some or all of another party's costs" and enumerates some of the situations which may justify a request for apportionment of costs. In view

of the circumstances of the present case, the board sees no reason to deviate from the normal situation, in which each party to opposition and opposition appeal proceedings must bear the costs it has incurred.

Therefore, the request for apportionment of costs is rejected.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.
3. The request for apportionment of costs is rejected.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated