Appeal decision

Appeal No. 2014-16437

USA
Appellant HILL'S PET NUTRITION, INC.

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The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2011-518960, entitled "Compositions and methods for treating osteoarthritis" [International Publication No. WO2010/009474 published on January 21, 2010, and National Publication of International Patent Application No. 2011-528668 published on November 24, 2011] has resulted in the following appeal decision:

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The application was originally filed on July 20, 2009 (priority claim under the Paris Convention: July 18, 2008 (US)) as an International Patent Application, a written amendment dated February 20, 2014 was submitted against notice of reasons for refusal dated October 21, 2013, a decision for refusal dated April 17, 2014 was issued, and an appeal against the examiner's decision of refusal was requested on August 20, 2014.

No. 2 The Invention

The inventions according to claims 1 to 14 are specified by the matters described in claims 1 to 14 in the scope of claims amended by written amendment dated February 20, 2014, and the invention according to claim 1 is as follows (hereinafter referred to as the "Invention").

"A composition comprising,

a) at least one omega-3 fatty acid,

b) at least one glycosaminoglycan,

c) at least one amino sugar selected from the group consisting of galactosamine, glucosamine, sialic acid, and N-acetylglucosamine,

d) at least one antioxidant, and

e) carnitine or acetylcarnitine." (the Invention)

No. 3 Cited Documents and Cited Inventions

(1) Cited Document 1

Japanese Unexamined Patent Application Publication No. 2000-53569 (hereinafter referred to as "Cited Document 1"), which is cited as Cited Document 1 of reasons for refusal stated in the examiner's decision and was distributed before the priority date for the Invention, describes the following matters (the underlines are applied by the body.).

(Indication 1-1)

"[Claim 1] A composition comprising:

a) L-carnitine or an alkanoyl-L-carnitine, wherein the alkanoyl is a straight or branched chain having 2 to 8, preferably 2 to 6, carbon atoms, or a pharmacologically acceptable salt thereof;

b) a glucosaminoglycan and/or glucosaminoglycan component; and

c) a pharmacologically acceptable excipient.

[Claim 2] The composition of claim 1, wherein the weight ratio of (a):(b) is from 1:1 to 1:100.

[Claim 3] The composition of claim 1, wherein the glucosaminoglycan is selected from the group consisting of chondroitin sulphate, jaluronic acid, dermatan sulphate, keratan sulphate, and heparan sulphate.

[Claim 4] The composition of claim 1, wherein the glucosaminoglycan component is selected from the group comprising glucosamine, glucosamine sulphate, N-acetylglucosamine, galactosamine, and N-acetylgalactosamine.

[Claim 5] The composition of claim 3, wherein the chondroitin sulphate is selected from the group consisting of chondroitin-4-sulphate and chondroitin-6-sulphate.

[Claim 6] The composition of any of claims 1 to 5, which comprises L-carnitine, chondroitin sulphate, and glucosamine.

[Claim 7] The composition of claim 6, wherein a weight ratio of L-carnitine, chondroitin sulphate, and glucosamine is from 1:1:1 to 1:10:10.

[Claim 8] The composition of claim 1, wherein the alkanoyl-L-carnitine is selected from the group consisting of acetyl-L-carnitine, propionyl-L-carnitine, butyryl-L-carnitine, valeryl-L-carnitine, and isovaleryl-L-carnitine.

[Claim 9] The composition of any of claims 1 to 8, wherein the pharmacologically acceptable salt of L-carnitine or alkanoyl-L-carnitine is selected from the group consisting of chloride, bromide, iodide, aspartate, acid aspartate, citrate, acid citrate, tartrate, phosphate, acid phosphate, fumarate, acid fumarate, glycerophosphate, glucose phosphate, lactate, maleate, acid maleate, orotate, oxalate, acid oxalate, sulfate, acid sulfate, trichloroacetate, trifluoroacetate, and methanesulfonate.

[Claim 10] The composition of any of claims 1 to 9, which further comprises vitamins, co-enzymes, mineral substances, and antioxidants." (claims 1 to 10 in the scope of claims)"

(Indication 1-2)

"The present invention relates to a composition suitable both for the prevention and the therapeutic treatment of articular disorders. Accordingly, the composition may take the form and exert the activity of a food or dietary supplement or of an actual medicament in the strict sense, depending upon the particular individuals in whom it is to be used and for reasons which will appear evident here below." (paragraph 0001)

(Indication 1-3)

"[Problem to be solved by the invention] There is therefore a perceived need for a preventive/therapeutic agent which, as a result of its substantial lack of toxicity and side effects, can be safely used at the first manifestation of symptoms or even earlier, once the patient has reached the age when, on average, such symptoms tend to manifest themselves. The aims of the prevention and the therapeutic treatment are both to delay the onset of the symptomatological picture and to combat development of the disease therapeutically.

[0006]

[Means for solving the problem] These dual objectives-preventive and strictly therapeutic-are achieved by the composition to the present invention, which, as will be described in detail here below, comprises a new composition containing as its basic ingredients L-carnitine or a C2-C6 lower alkanoyl-L-carnitine, and a glucosaminoglycan and/or glucosaminoglycan component.

[0007] This composition is characterized by an unexpected and surprising anti-inflammatory and cartilage-protecting activity. As a result of these properties, the new composition can be usefully applied in the prevention and therapeutic treatment of inflammatory or degenerative articular disorders mainly related to a metabolic dysfunction of the articular tissues, whether of endogenous or exogenous origin, induced by traumas or drugs. The new composition can also be usefully employed in both the human and veterinary fields." (paragraphs 0005 to 0007)

(Indication 1-4)

"Type II Collagen Arthritis Tests

Type II collagen arthritis was induced according to the technique described by Trentham (Trentham D. R., Townes A. S., Kang A. H., J. Exp. Med., 146, 857, 1977). One group of mice was immunized by means of intradermal injections of natural collagen emulsified in complete Freund's adjuvent (Difco Labs., Detroit, U.S.A.) at the base of the tail. Three weeks later these mice were re-injected intraperitoneally with the same dose of emulsified collagen. L-carnitine (50 mg/kg and 10 mg/kg), glucosamine (100 mg/kg and 200 mg/kg), and chondroitin sulphate (50 mg/kg and 100 mg/kg) were injected alone or in combination from day one after the collagen injection up to the end of the sixth week. One group of mice (control) received no treatment. The assessment of the severity of the oedema was conducted according to its intensity with scores ranging from 1 to 4. The results of the tests demonstrated that, whereas none of L-carnitine, glucosamine, and chondroitin sulphate when administered alone had any inhibitory effect on the development of the typical signs

of arthritis, their use in combination proved highly efficacious. When L-carnitine was combined with either glucosamine or with chondroitin sulphate, an approximate 50% reduction of arthrosis was obtained.

[0031] On combining L-carnitine with both glucosamine and chondroitin sulphate, the reduction in signs of arthrosis reached almost 90-100%, with no sign of arthrosis manifesting itself in the majority of mice treated." (paragraphs 0030 to 0031)

(Indication 1-5)

"[0034] Carragenin Oedema Tests

Carragenin oedema was induced in the rat by injection of 0.1 ml of a 1% carragenin solution (Sigma Chemical) in the subplantar region of the rat's right paw. The volume of the paw was measured by means of a mercury plethysmograph one hour later and over the 5-hour period following carragenin injection. L-carnitine, glucosamine, and chondroitin sulphate were administered one hour prior to carragenin injection, both alone and in combination, at doses of 50, 100 and 200 mg/kg of these compounds. In these tests, too, although to a less marked extent, whereas L-carnitine, glucosamine, and chondroitin sulphate alone failed to modify the severity of the carregenin-induced oedema, their use in combination brought about a significant reduction in oedema, close to 50% (see Table 1), especially during the first few hours of observation.

[0035] The results obtained in the tests described above are surprising and unexpected, inasmuch as the administration of the single compounds alone and not in combination produced no inhibitory effect on the experimentally induced arthrotic and inflammatory forms. The inhibitory effect appears to be marked, however, when the components are administered in combination. The greatest effect is that obtained by the simultaneous administration of L-carnitine, glucosamine, and chondroitin sulphate. A significant result is also observable with the combination of L-carnitine and glucosamine and with that of L-carnitine and chondroitin sulphate.

[0036] The unexpected pharmacological effect observed with the combination of L-carnitine, glucosamine, and chondroitin sulphate enables this combination to be used effectively in the treatment of those forms of osteoarthrosis related to mechanical stress and those related to inflammatory phenomena or due to ageing. The efficacy, good tolerability, and low toxicity of this combination make the use of this treatment preferable to that of NSAIDs, which present a high risk of adverse side effects and toxic reactions, especially in prolonged treatments." (paragraphs 0034 to 0036)

(Indication 1-6)
"[Table 1]

表１
ラットにおけるカルニチン、グルコサミンおよびコンドロイチン硫酸の単独または併用の、カラゲニン誘発浮腫に対する効果

物質	用量	カラゲニン注後の種々の時間における浮腫減少%			
	mg/kg	1	2	3	4
Ｌ－カルニチン	100	－	－	－	－
Ｌ－カルニチン	200	－	10±0.2	5±0.3	－
グルコサミン	100	－	5±0.3	5±0.5	5±0.6
グルコサミン	200	5±0.2	10±0.9	10±1.1	5±0.5
コンドロイチン硫酸	100	10±0.3	10±0.8	5±0.4	5±0.1
コンドロイチン硫酸	200	10±1.9	15±1.1	20±1.8	10±1.2
Ｌ－カルニチン＋グルコサミン＋コンドロイチン硫酸	100 100 100	25±1.9	30±2.1	30±2.7	25±2.4
Ｌ－カルニチン＋グルコサミン＋コンドロイチン硫酸	200 200 200	20±2.1	35±2.9	46±3.5	40±3.1

表１ Table 1
ラットにおけるカルニチン、グルコサミンおよびコンドロイチン硫酸の単独または併用の、カラゲニン誘発浮腫に対する効果
Effects of carnitine, glucosamine, and chondroitin sulphate alone or in combination on carragenin-induced oedema in the rat

物質 Substance
用量 Dose
カラゲニン注後の種々の時間における浮腫減少％
%Reduction of oedema at various hours after carragenin injection

Ｌ－カルニチン L-carnitine
Ｌ－カルニチン L-carnitine
グルコサミン Glucosamine
グルコサミン Glucosamine

コンドロイチン硫酸 Chondroitin sulphate
コンドロイチン硫酸 Chondroitin sulphate
Ｌ－カルニチン L-carnitine
＋グルコサミン +Glucosamine
＋コンドロイチン硫酸 +Chondroitin sulphate
Ｌ－カルニチン L-carnitin
＋グルコサミン +Glucosamine
＋コンドロイチン硫酸 +Chondroitin sulphate

" (paragraph 0037)

In the Indication 1-1, when the invention according to claim 10 dependent on claims 1 and 6 is described without using dependent form, it is recognized that the following invention (hereinafter referred to as the "Cited Invention") is described.

Cited Invention:
"A composition comprising:
a) L-carnitine or an alkanoyl-L-carnitine, wherein the alkanoyl is a straight or branched chain having 2 to 8, preferably 2 to 6, carbon atoms, or a pharmacologically acceptable salt thereof;
b) a glucosaminoglycan and/or glucosaminoglycan component; and
c) a pharmacologically acceptable excipient,
which comprises L-carnitine, chondroitin sulphate, and glucosamine, and further comprises vitamins, co-enzymes, mineral substances, and antioxidants."

(2) Cited Document 2

International Publication No. WO2007/002837 (hereinafter referred to as "Cited Document 2"), which is cited as Cited Document 4 of reasons for refusal stated in the examiner's decision and was distributed before the priority date for the Invention, describes the following matters (the underlines are applied by the body.).

(Indication 2-1)
"1. A composition comprising one or more omega-3 fatty acids, one or more sulfur-containing amino acids, and manganese in amounts sufficient for preventing or treating inflammatory disease in a patient."(page 22 Claim1)

(Indication 2-2)

"Field of the Invention

[0002] This invention relates generally to compositions and methods for combating inflammatory disease and particularly to the use of food compositions for preventing and treating inflammatory disease.

Description of the Prior Art

[0003] Polyunsaturated fatty acids (PUFAs) are compounds reported to be beneficial for treatment of inflammation-related disorders such as arthritis. Omega-3 fatty acids are one type of PUFA that contain more than one double bond. They are called omega-3 fatty acids because the first double bond counting from the methyl end of the fatty acid is located at the third carbon atom."(paragraphs 0002 to 0003)

(Indication 2-3)

"[0005] Omega-3 fatty acids are known to have a wide range of nutritional and health benefits such as reducing inflammation and treating inflammation-related disorders. Omega-3 fatty acids are thought to be important in arthritis, brain function, visual acuity, and normal growth and development. Omega-3 fatty acids have also been reported to act as anti-inflammatory compounds. They are believed to competitively inhibit the conversion of arachidonic acid to pro-inflammatory eicosanoids. Omega-3 fatty acids are also precursors to the synthesis of prostaglandins that regulate inflammation in mammals."(paragraph 0005)

(Indication 2-4)

"[0006] Rheumatism and arthritis are general terms for acute and chronic conditions characterized by inflammation and pain. Rheumatism is a general category of conditions characterized by inflammation and pain in muscles and joints, including arthritis. Arthritis is characterized by inflammation of joints that causes swelling and pain. Types of arthritis include osteoarthritis, rheumatoid arthritis, ankylosing spondylitis (AS), and systemic lupus erythematosus (SLE). Rheumatic conditions include infectious arthritis, rheumatoid arthritis, arthritis due to rheumatic fever, arthritis due to trauma or degenerative joint disease, myositis, neurogenic articular disorders, bursitis, fibromyositis, and hydroarthrosis. The cause of such diseases in not always fully understood but may be the result of other degenerative diseases, trauma, or auto-immune diseases such as SLE. Inflammation also occurs as a defensive response to host invasion by foreign agents and mechanical trauma that

results in an immune response, e.g., microbial agents such as bacterial and viruses, toxins, and neoplasia.

[0007] What these diseases and conditions, both examples of inflammatory diseases, share in common is inflammation and the resulting pain. Prior methods for preventing and treating inflammatory diseases have generally focused on pain-killing and anti-inflammatory drugs. Typical methods have focused on oral medications such as steroidal cortisone derivatives and numerous nonsteroidal anti-inflammatory drugs (NSAIDs). Unfortunately, these drugs almost always exhibit undesirable side effects. Other efforts have focused on joint implants such as the knee or hip implants. These methods are lengthy and complicated surgical procedures that force the patient to undergo costly invasive surgery and a significant recovery period requiring a rigorous and costly regimen of physical therapy. There is, therefore, a need for new methods for preventing and treating inflammatory diseases that avoid the undesirable side effects and costly surgical procedures characteristic of previous methods for preventing and treating inflammatory diseases.

SUMMARY OF THE INVENTION

[0008] It is, therefore, an object of the present invention to provide compositions and methods for preventing and treating inflammatory disease."(paragraphs 0006 to 0008)

(Indication 2-5)

"[0022] In one aspect, the present invention provides a composition for preventing and treating inflammatory disease. The composition comprises one or more omega-3 fatty acids, one or more sulfur containing amino acids, and manganese in amounts sufficient for preventing or treating inflammatory disease. The invention is based upon the novel discovery that the inflammatory response can be altered by administering the composition to a patient and that altering inflammatory response with the composition can prevent or treat inflammatory disease. Without being bound by theory, it is believed that composition is effective in preventing and treating inflammatory disease because it reduces the amount of proinflammatory mediators in a patient."(paragraph 0022)

No. 4 Comparison

Considering the descriptions of claims 3 and 4 in Indication 1-1 and components in the composition of the Cited Invention, it can be said that the Cited Invention is the following invention for the Cited Invention described in "No. 3 Cited Documents and Cited Inventions."

"A composition comprising:
a) L-carnitine;
b) a chondroitin sulphate and glucosamine; and
c) a pharmacologically acceptable excipient,
which additionally comprises vitamins, co-enzymes, mineral substances, and antioxidants."

We will compare the Invention with the Cited Invention described in Cited Document 1.

As "L-carnitine" in the Cited Invention is a kind of carnitine, "L-carnitine" corresponds to the component "e) carnitine or acetylcarnitine" in the Invention.

As it is described in Indication 1-1 (claim 3) of Cited Document 1 and paragraph 0074 in the description of the Invention that "chondroitin sulphate" in the Cited Invention is a kind of glysosaminoglycan, "chondroitin sulphate" corresponds to the component "b) at least one glysosaminoglycan" in the Invention.

"Glucosamine" in the Cited Invention corresponds to the component "c) at least one amino sugar selected from the group consisting of galactosamine, glucosamine, sialic acid, and N-acetylglucosamine" in the Invention.

The "antioxidant" in the Cited Invention corresponds to the component "d) at least one antioxidant" in the Invention.

As the "composition" of the Invention does not preclude inclusion of components other than the components a) to e), the matter that the Cited Invention comprises a pharmacologically acceptable excipient, vitamins, co-enzymes, and mineral substances is not a different feature.

As described above, the corresponding feature and different feature between the Invention and Cited Invention are as follows.

Corresponding feature:
"A composition comprising,
b) at least one glysosaminoglycan,
c) at least one amino sugar selected from the group consisting of galactosamine, glucosamine, sialic acid, and N-acetylglucosamine,
d) at least one antioxidant, and
e) carnitine or acetylcarnitine."

Different feature:

The Invention comprises, as a component, "at least on kind of omega-3 fatty acid". On the other hand, it is not specified that the Cited Invention comprises this component.

No. 5 Judgment by the body

On the basis of the Indications 1-2 and 1-3, in the Cited Document 1, there is a problem to provide a composition suitable for preventing and treating articular disorders, especially inflammatory or degenerative articular disorders mainly related to a metabolic dysfunction of the articular tissues, and with substantial lack of toxicity and side effects. According to the Indications 1-4 to 1-6, it is described that effect for inhibiting inflammation with a combination of L-carnitine, glucosamine, and chondroitin sulphate was actually confirmed using experimental animals.

As described in the Indication 2-2, the Cited Document 2 is a document relating to compositions for combating inflammatory disease and particularly to the use of food compositions for preventing and treating inflammatory disease. According to the Indication 2-4, the inflammatory disease is rheumatism and arthritis for example, and it can be understood that the Cited Document 2 is a document whose problem is to provide new methods for preventing and treating inflammatory diseases that avoids the undesirable side effects and costly surgical procedures characteristic of previous methods for preventing and treating inflammatory diseases. On the basis of these problems, in the Indications 2-1 and 2-5 of the Cited Document 2, there is described a composition comprising at least one kind of ω-3 fatty acid, at least one kind of sulfur-containing amino acid, and manganese. It is obvious that the "ω-3 fatty acid" is the same as "omega-3 fatty acid" in the Invention. Especially, according to the Indication 2-3, it is indicated that since the ω-3 fatty acid has effect for reducing inflammation and treating inflammation-related disorders, and the ω-3 fatty acid is an important factor for arthritis.

Considering that rheumatism and arthritis in the Cited Document 2 are examples of inflammatory articular disorders, both the invention described in the Cited Document 1 and that described in Cited Document 2 are compositions for preventing or treating inflammatory articular disorders and having no side effect, and are common in the technical art and problem. Further, both inventions are compositions

provided as food (Indications 1-2 and 2-2). Considering these matters, it could be easily arrived for a person ordinarily skilled in the art that a component in the composition described in the Cited Document 2; that is to say, at least one kind of ω-3 fatty acid, at least one kind of sulfur-containing amino acid, and manganese, is added in the composition of the Cited Invention for expecting to obtain a composition having excellent effect for preventing and treating inflammatory articular disorders.

Incidentally, we will examine sulfur-containing amino acids and manganese other than ω-3 fatty acid described in the Cited Document 2. According to the descriptions of paragraphs 0077 to 0078 in the description of the Invention and claims 5, 6, and 7, it is recognized that the composition of the Invention is a composition for which it is supposed that manganese etc. as inorganic matter for food and methionine and taurine etc. as essential amino acid are included according to a subject in need. Further, it is described that the Invention "comprises" the components a) to e), and thus it is understood that the Invention does not exclude the inclusion of other components. Therefore, sulfur-containing amino acids and manganese described in Cited Document 2 are not a new different feature between the Invention and the invention described in Cited Document 2.

We will examine effect of the Invention. As any composition described in Cited Documents 1 and 2 has effect for preventing and treating inflammatory articular disorders, it could be predicted by a person ordinarily skilled in the art that the composition of the Invention has effect for treating arthritis. Further, since the composition of the Invention can treat arthritis, it is obvious for a person ordinarily skilled in the art that the composition of the Invention varies the expression of a marker for arthritis gene, and thus this effect is not a particularly distinguishing feature.

As examined above, the Invention could be invented easily by a person ordinarily skilled in the art on the basis of the inventions described in Cited Documents 1 and 2, and thus the appellant should not be granted a patent for the Invention in accordance with the provisions of Article 29(2) of the Patent Act.

No. 6 Summary

As described above, the appellant should not be granted a patent for the invention according to claim 1 in accordance with the provisions of Article 29(2) of

the Patent Act, and the present application should be rejected without examining other claims.

Therefore, the appeal decision shall be made as described in the conclusion.

December 7, 2015

Chief administrative judge:	KURANO, Masaaki
Administrative judge:	SAKU, Takashi
Administrative judge:	MAEDA, Kayoko