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Attorneys for Plaintiff
Lonza Ltd.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

LONZA LTD.,
a Swiss Corporation

Plaintiff,

v.

NUTRACEUTICAL CORPORATION; NUTRACEUTICAL INTERNATIONAL CORPORATION; NATURAL MAX, INC; AND THE MAKERS OF KAL INC.

Defendants.

JUDGE BATTS

04 CV 01812 DAB

Civil Action No.

COMPLAINT ECF CASE

JURY DEMANDED

Plaintiff Lonza Ltd. ("Lonza") for its Complaint asserts the following:

NATURE OF THIS ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, including 35 U.S.C §§ 271 and 281-285.

THE PARTIES

2. Lonza is a corporation organized under the laws of Switzerland with its principal place of business at Muenchensteinerstrasse 38, CH-4002, Basel, Switzerland.

3. On information and belief, defendant Nutraceutical International Corporation is a Delaware corporation having a principal place of business at 1400 Kearns Blvd., Park City, Utah, 84060.

4. On information and belief, defendant Nutraceutical Corporation is a corporation having a principal place of business 1400 Kearns Blvd., Park City, Utah, 84060.

5. On information and belief, defendant Natural Max, Inc. is a corporation having a principle place of business at 1400 Kearns Blvd, Floor 2, Park City, Utah 84060-7228.

6. On information and belief, defendant The Makers of Kal Inc., a corporation having a principal place of business at 1400 Kearns Blvd., Floor 2, Park City, Utah 84060-7228.

JURISDICTION AND VENUE

7. This Court has jurisdiction over these claims pursuant to 28 U.S.C. §§ 1331 and 1338.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTS COMMON TO ALL COUNTS

A. Plaintiff and its Patented Technology

9. Lonza is one of the leading suppliers of active chemical ingredients, intermediaries and biotechnology solutions to the pharmaceutical and agrochemical industries. It employs 5600 people worldwide and maintains facilities in 8 countries.

10. Among the many products sold by Lonza is L-Carnipure, an oral supplement made from L-carnitine L-tartrate. L-carnitine is a nutrient that is beneficial for weight loss, athletic performance and general cardiovascular health.

11. Lonza is the owner by assignment of all right, title and interest in and to U.S. Patent No. 5,073,376 ("the '376 Patent") entitled "Preparations Containing L-Carnitine." The '376 Patent was duly and legally issued on December 17, 1991, and is currently valid and enforceable. Lonza has the right to sue and recover for past, present and future infringement of the '376 Patent and to obtain the relief sought herein. A copy of the '376 Patent is attached as Exhibit A.

12. The '376 Patent covers the production of solid oral dosage forms, namely, tablets, capsules and other preparation forms, of L-carnitine L-tartrate for enteral administration.

B. Defendants and their Infringing Activity

13. In about October of 2003, Plaintiff became aware that Defendants were selling and offering for sale L-carnitine L-tartrate in the United States in the form of solid oral dosages.

14. On information and belief, Defendants continue to sell and offer for sale in the United States L-carnitine L-tartrate in the form of solid oral dosages.

15. Defendants' activities infringe the '376 Patent.

COUNT I

PATENT INFRINGEMENT

16. Lonza repeats and realleges each of the allegations contained in paragraphs 1 through 15 as though fully set forth herein.

17. Defendants' acts alleged herein constitute infringement of the '376 Patent in violation of the patent laws of the United States, 35 U.S.C. §§ 271 and 281-285.

18. By reason of Defendants' acts alleged herein, Lonza has suffered, is suffering, and will continue to suffer irreparable damage, and unless Defendants are restrained from continuing their wrongful acts, the damage to Lonza will continue.

19. On information and belief, Defendants' infringing activities are deliberate and willful.

20. Lonza has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Lonza demands Judgment and seeks an Order:

1. declaring that Defendants have infringed the '376 Patent;

2. permanently enjoining and restraining Defendants and their agents, attorneys, servants, successors, assigns, employees and all those in privity or in active concert and participation with them, or any of them, from infringing the '376 Patent;

3. requiring Defendants to compensate Lonza adequately for the damages caused by their infringement of the '376 Patent together with interest and costs;

4. increasing the damages award to Lonza up to three times pursuant to 35 U.S.C. § 284;

5. holding that this case is exceptional and awarding plaintiff Lonza its reasonable attorneys' fees and expenses against Defendants pursuant to 35 U.S.C. § 285;

6. assessing costs, other expenses and such other and further relief as the Court may deem just and proper.

Dated: 3/5/04

Respectfully submitted,

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EXHIBIT A

United States Patent [19]

Kohl et al.

[11] **Patent Number: 5,073,376**

[45] **Date of Patent: Dec. 17, 1991**

[54] **PREPARATIONS CONTAINING L-CARNITINE**

[75] Inventors: **Willibald E. Kohl**, Muri bei Bern; **Thomas Scholl**, Visp, both of Switzerland

[73] Assignee: **Lonza Ltd.**, Gampel, Switzerland

[21] Appl. No.: **499,629**

[22] Filed: **Mar. 27, 1990**

[30] **Foreign Application Priority Data**

Dec. 22, 1989 [CH] Switzerland 4633/89

[51] **Int. Cl.**[5] **A61K 9/48**

[52] **U.S. Cl.** **424/451**; 424/464; 514/551; 514/556

[58] **Field of Search** 424/451, 464, 465, 466, 424/440; 514/551, 556

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,810,994	5/1974	Wiegand	424/316
4,255,449	3/1981	Cavazza	424/316
4,537,772	8/1985	Alexander	514/9

FOREIGN PATENT DOCUMENTS

57-126420	1/1981	Japan	514/556

Primary Examiner—Thurman K. Page
Assistant Examiner—D. Gabrielle Phelan
Attorney, Agent, or Firm—Fisher, Christen & Sabol

[57] **ABSTRACT**

Tablets, capsules and other preparation forms for oral administration are produced which contain L-carnitine-L-tartrate. In comparison to preparations made with free L-carnitine, the invention preparations exhibit less hygroscopicity, longer stability and better capacity for being stored.

10 Claims, No Drawings

PREPARATIONS CONTAINING L-CARNITINE

BACKGROUND OF THE INVENTION

1. Field Of The Invention

The invention relates to preparations containing L-carnitine for oral use in the form of tablets, capsules or powder.

2. Background Art

L-carnitine plays an important role in lipometabolism and is used especially in food for athletes, but also for the treatment of diseases with metabolic disorders. Athletic food preparations containing L-carnitine are widely used, since they contribute significantly to supplying the muscles with energy and promote endurance performance. Such preparations have great importance since they improve muscle activity and thereby bring about increased endurance and stress tolerance as well as delaying fatigue and shortening recovery time. However, the use of preparations containing L-carnitine is not limited to food for athletes, as they can also be used for geriatric purposes and as general food additives.

Thus, the application can basically take place both enterally and parenterally. For the preferred enteral, i.e., oral, application, suitable forms of administration, preferably in the form of tablets or capsules, optionally also in the form of powder or granulate, are thus necessary. Here the production takes place according to methods of pharmaceutical technology, independently of whether the form of administration is to serve for food purposes or therapeutic purposes. The production and handling of such forms of administration up to now have been made considerably more difficult because of the high hygroscopicity of L-carnitine. Thus, for example, tablets that contain L-carnitine must be produced with the exclusion of moisture and must be packaged hermetically and individually, since they would begin to liquefy in a short time even with the normal moisture in the air. Moreover, L-carnitine often contains traces of trimethylamine, which, because of its fishy odor, has a repulsive effect on the user.

BROAD DESCRIPTION OF THE INVENTION

The object of the invention is to make available a nonhygroscopic and odorless form of L-carnitine, which contains no physiologically unsafe additives and which is preferably suitable in particular for producing tablets or capsules.

According to the invention, the object is attained by the use of L-carnitine-L-tartrate for producing compositions for oral administration. Herein, L-carnitine-L-tartrate is to be understood as the salt of L-carnitine with L-tartaric acid in the molar ratio of 2:1.

It has been found that L-carnitine-L-tartrate at normal air moisture (≦60 percent relative humidity) is stable in storage and can be processed without special precautions. L-carnitine-L-tartrate forms a crystalline powder which can be easily processed and is particularly suitable for processing with rapidly running machines, since it does not tend to stick together or become lumpy. Moreover, it is completely odorless and because of the bonded tartaric acid it has a refreshing, somewhat acidic taste.

L-carnitine-L-tartrate is used advantageously alone or with additional active ingredients, such as, vitamins, amino acids, trace elements or mineral substances, as well as optionally the adjuvants usual for the respective form of administration. The forms of administration include particularly all kinds of tablets, both those that are swallowed without being chewed, and tablets to be chewed or sucked on, as well as those that are dissolved in a liquid before being taken. The tablet forms include uncoated tablets, in one-layer or multilayer or encased form, effervescent tablets, and coated tablets, such as, film tablets or dragees. Further preferred forms of administration are capsules of soft or hard gelatin. Of these, hard gelatin capsules in the form of hard-shell capsules are particularly preferred. Further, L-carnitine-L-tartrate can be used advantageously as a powder, for example, with gas-producing additives as an effervescent powder, or as granulated powder. Adjuvants are, for example, fillers, binding agents, lubricants and mold release agents, flow-regulating agents and disintegrants for the production of tablets, as well as coloring and flavoring substances. Such adjuvants are known to persons skilled in the art, as well as their use and the technology for producing the above-named forms of administration.

DETAILED DESCRIPTION OF THE INVENTION

The examples below explain the execution of the invention.

EXAMPLE 1

Production of L-carnitine-L-tartrate

L-tartaric acid was dissolved in the required quantity of hot 90 percent aqueous ethanol, the calculated quantity of L-carnitine was added, the salt was brought to crystallization by cooling, filtered and dried. The product showed the following characteristics: colorless crystals

melting point: 169°–175° C.

$[a]_D^{25}$: −10.9°±0.6° (25° C., c=1% in water).

composition: mol ratio of carnitine: tartaric acid is 2:1 (^{1}H-NMR).

water solubility: about 73 g/100 g of solution.

water absorption when air humidity is 32 percent.

After hours	L-carnitine-L-tartrate percent	L-carnitine percent
1	0	1.9
2	0	3.6
4	0	6.3
8	0	8.6
24	0	12.3
water absorption when air humidity is 66 percent		
1	0	6.0
2	0	9.6
4	0	21.6
8	0.1	45.2
24	0.1	67.7

EXAMPLE 2

Sucking Tablets With Orange Flavoring

Sucking tablets weighing individually 2,200 mg were produced according to the following formulation:

L-carnitine-L-tartrate	732 mg
fructose	1,089 mg
orange flavoring	30 mg
quinoline yellow lacquer	4 mg
carboxymethyl cellulose	25 mg
polyvinylpyrrolidone	20 mg
saccharose stearate	100 mg

-continued

talc	160 mg
magnesium stearate	40 mg

The mixture was prepared in the usual manner and pressed into tablets 20 mm in diameter. As a comparison, sucking tablets of the same kind were produced which contained 500 mg of L-carnitine and 232 mg of microcrystalline cellulose (for weight compensation) instead of L-carnitine-L-tartrate. On the crushed tablets the water absorption in each case was determined under constant relativity humidity. When they were stored at a relative humidity of 56 percent the crushed tablets, which contained L-carnitine-L-tartrate, did not take up any water even after 10 days. In comparison to this, tablets that contained L-carnitine showed a water absorption of 12 percent under identical conditions. The use of L-carnitine-L-tartrate according to the invention resulted in tablets that could be stored even under extreme conditions.

EXAMPLE 3

Sucking Tablets With Peppermint Flavoring

Analogously to Example 2 sucking tablets were produced according to the following formulation:

L-carnitine-L-tartrate	732 mg
mannitol	1,100 mg
aspartame	13 mg
peppermint flavoring	10 mg
carboxymethyl cellulose	25 mg
polyvinyl pyrrolidone	20 mg
saccharose stearate	100 mg
talc	160 mg
magnesium stearate	40 mg

As a comparison again as in Example 2, tablets were produced with L-carnitine and microcrystalline cellulose. Also with these tablets, as in Example 2, the water absorption was determined. The use according to the invention of L-carnitine-L-tartrate yielded stable tablets capable of being stored, while tablets on the basis of L-carnitine, after storage for one week, formed a sticky mass because of water absorption.

EXAMPLE 4

Tablets for Swallowing

According to the following formulation 12,000 tablets of 650 mg each were produced:

L-carnitine-L-tartrate	4.392 kg
lactose monohydrate (that can be directly tableted)	2.028 kg
wheat starch	420 g
cellulose, microcrystalline	360 g
silicon dioxide (Aerosil ® 200)	60 g
talc	480 g
magnesium stearate	60 g

The L-carnitine-L-tartrate was homogeneously mixed with the wheat starch and the cellulose and sifted. The lactose was added, uniformly mixed in and the mixture was sifted again. Talc, magnesium stearate and silicon dioxide were thoroughly mixed with one another, sifted and sprinkled into the mixture of active ingredients. The whole mixture was again mixed thoroughly and kept in a hermetically sealed container until it was made into tablets. Circular tablets with a facette edge 13 mm in diameter and about 3.9 mm thick were pressed. The tablets exhibited a resistance to pressure of 60 to 70 N and disintegrated in water of 20° C. within 15 to 17 minutes.

EXAMPLE 5

Capsules for use as Food Supplement

Hard gelatin capsules with L-carnitine-L-tartrate were produced, corresponding to the following composition:

L-carnitine-L-tartrate	366 mg
magnesium stearate	4 mg

Magnesium stearate was sifted with a sieve with 0.5 mm mesh size, L-carnitine-L-tartrate was added, and both components were intensively mixed for 15 minutes. Afterwards the mixture was filled into CONI-SNAP ® capsules of size 1. This resulted in capsules that were capable of being stored even under tropical conditions. 366 mg of L-carnitine-L-tartrate per capsule corresponded to a quantity of 250 mg of L-carnitine.

We claim:

1. A preparation for enteral application comprising at least one tablet composed of the salt of L-carnitine with L-tartaric acid in the molar ratio of 2:1, powder composed of the salt of L-carnitine with L-tartaric acid in the molar ratio of 2:1 or at least one capsule containing the salt of L-carnitine with L-tartaric acid in the molar ratio of 2:1.

2. The preparation as claimed in claim 1 wherein said at least one tablet includes or said powder includes or at least one said capsule also contains at least one member of the group consisting of vitamin, amino acid, trace element, mineral substance, inert edible carrier or filler, gas-producing additive, disintegrant, binding agent, lubricant, mold release agent, flow regulating agent, colorant and flavorant, the at least one capsule being composed of soft or hard gelatin.

3. The preparation as claimed in claim 1 wherein the preparation is said at least one tablet.

4. The preparation as claimed in claim 3 wherein said at least one tablet includes a monosaccharide, a disaccharide, a sugar alcohol or a trisaccharide.

5. The preparation of claim 1 wherein the preparation is said powder.

6. The preparation as claimed in claim 1 wherein the preparation is said at least one capsule.

7. A process comprising preparing a preparation for oral administration, the preparation being composed of L-carnitine-L-tartrate, the L-carnitine-L-tartrate being the salt of L-carnitine with L-tartaric acid in the molar ratio of 2:1.

8. The process as claimed in claim 7 wherein the preparation is at least one tablet composed of L-carnitine-L-tartrate, and said process comprises tableting said L-carnitine-L-tartrate into at least one tablet.

9. The process as claimed in claim 7 wherein the preparation is at least one capsule containing L-carnitine-L-tartrate, and said process comprises placing said L-carnitine-L-tartrate into said at least one capsule.

10. Process comprising enterally consuming the preparation of claim 1 by a human.

* * * * *