Appeal decision

Appeal No. 2010-9107

Israel
Appellant LYCORED LTD.

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The case of appeal against the examiner's decision of refusal Japanese Patent Application No. 2007-538605 "a method for fortifying food stuff with phytonutrients and food products obtained thereby" [international publication on May 4, 2006 (International Publication No. WO 2006/046222), national publication of the translated version (of PCT application) on May 29, 2008 (National Publication of International Patent Application No. 2008-517618)] 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 filed on October 26, 2004 as an international filing date, a notice of reasons for refusal was issued on May 25, 2009, and the written amendment was filed on December 1, 2009. However, a decision of refusal was issued on December 21, 2009. Against this, appeal against the examiner's decision of refusal was requested and the written amendment was filed on April 28, 2010.

No. 2 Decision to dismiss amendment dated April 28, 2010

[Conclusion of decision to dismiss amendment]

The amendment dated April 28, 2010 shall be dismissed.

[Reason]

1 The Invention after amendment

The amendment dated April 28, 2010 was the amendment of the scope of claims, and Claim 1 of the scope of claims in the written amendment dated December 1, 2009, "A method for fortifying food stuff with an effective health-beneficial amount of tomato phytonutrients comprising of adding to food stuff tomato oleoresin or tomato components thereof in an amount wherein the flavor of said food stuff are not substantially affected by said oleoresin or tomato component.", was amended to "A method for fortifying food stuff with an effective health-beneficial amount of tomato phytonutrients comprising of adding to food stuff tomato oleoresin in an amount wherein the flavor of said food stuff are not substantially affected by said oleoresin in the process of preparing said food stuff." (hereinafter referred to as "the Amended Invention").

In the above amendment, "tomato components" are deleted from tomato phytonutrients stated in Claim 1 before amendment, the tomato phytonutrients are limited to "tomato oleoresin", and the time when a step of adding to food stuff the phytonutrients is performed is limited to "in the process of preparing said food stuff". Therefore, the above amendment corresponds to restriction of the scope of claims of the provisions of Article 17-2(4)(ii) of the Patent Act before revision by the Act No. 55 of 2006, of which the provisions then in force shall remain applicable according to revision supplement Article 3(1) of the Act No. 55 of 2006.

It will be examined below whether the appellant should be granted a patent for the Amended Invention independently at the time of patent application (whether it falls under the provisions of Article 126(5) of the Patent Act which is applied mutatis

mutandis pursuant to the provisions of Article 17-2(5) of the Patent Act before revision by the Act No. 55 of 2006, of which the provisions then in force shall remain applicable according to revision supplement Article 3(1) of the Act No. 55 of 2006).

2 Cited publications and described matters therein

Publication 1 which was cited in the examiner's decision and distributed before the filing date, describes the following matters.

Publication 1: Japanese Unexamined Patent Application Publication No. 2000-103733 (Publication 1 of the examiner's decision)

Publications 2 to 4 distributed before the filing date, describe the following matters.

Publication 2: U.S. Unexamined Patent Application Publication No. 2003/0203072

Publication 3: National Publication of International Patent Application No. 2002-543819

Publication 4: Japanese Unexamined Patent Application Publication No. H11-98972

(1) Described matters in Publication 1

[1a] "[0002] Lycopene, which belongs to the carotenoids class of substances, occurs widely in nature. Thus tomatoes having a lycopene content of about 20 mg/kg of tomato form the most important natural source of this red pigment.

[0003] Epidemiological studies have shown that a more frequent and regular consumption of tomatoes or tomato products decreases the risk of chronic disorders, inter alia cardiac and circulatory disorders, and exerts a positive effect on the prevention of cancer. This protective function of lycopene is seen in its action as a very effective antioxidant.

[0004] Both for the food stuffs and feedstuffs industry and for pharmaceutical technology, lycopene, for example as a substitute for artificial colorants, represents an important coloring material and is moreover of interest for the reasons mentioned at the outset as a food stuff additive for healthcare.

[0005][Prior Art] The synthesis of lycopene is described, inter alia, in European Unexamined Patent Application Publication No. 382067 and European Unexamined Patent Application Publication No. 000140. International Publication No. WO 97/48287 describes the extraction of lycopene as a natural carotenoid from tomatoes.

[0006] Like all carotenoids, lycopene is also insoluble in water, while in fats and oils a solubility which, however, is only slight is found. This limited solubility and the

high sensitivity to oxidation stand in the way of direct use of the relatively coarse-grain crystalline lycopene in the coloration of food stuffs and feedstuffs, since the pure substance is too unstable in coarse-crystalline form, is only inadequately absorbed and thus yields only poor coloring results.

[0007] Only by means of specifically prepared formulations in which the active compounds are present in finely divided form, and if appropriate protected against oxidation by protective colloids, can improved color yields be achieved in the direct coloring of food stuffs.

[0008] In view of the particularly low stability to oxidation, in comparison with other carotenoids, and the low color stability and storage stability of lycopene also connected therewith, particularly high demands are placed on these formulations.

[0009] For carotenoids generally, a large number of formulations and processes for their preparation are described.

[0010] Thus lycopene, for example, is obtainable under the name Lyc-O-Mato (registered trademark) (Fa. LycoRed, Israel) as a 6% strength oily dispersion. It is extracted from tomatoes as a natural carotenoid according to International Publication No. WO 97/48287. On account of the high phospholipid content in the Lyco-O-Mato (registered trademark), combined with a high viscosity of the oily dispersion, the application properties of this formulation, inter alia the water dispersibility, are not satisfactory."

(2) Described matters in Publication 2

[2a] "[0005] The present invention discloses a good tasting rehydration beverage that when consumed during exercise, provides proper hydration and the correct isotonic concentration to maintain optimum performance and good health. The beverage of the present invention also provides the consumer with electrolytes, nutrients, and energy that may be lost during physical exertion, or to those lacking these vital nutrients. The beverage offers a cleaner taste than known isotonic beverages and has no negative aftertaste".

[2b] "[0018] It should be understood that the present invention may be fortified with additional vitamins, minerals, amino acids and neutriceuticals. ...Moreover, the present invention may also include other neutriceutical ingredients such as... lycopene (a tomato pigment known for its prevention of breast and prostate cancers and commercially available under the trade name Lyc-o-Mato),...."

(3) Described matters in Publication 3

[3a] "[0033]

The extract according to the present invention may contain about 1 % to about 10 % by weight based on dry matter of carotenoids and about 0.05 % to about 0.5 % by weight based on dry matter of other anti-oxidants.

[0034] In a preferred embodiment, said extract may be a tomato extract, which can contain lycopene and other anti-oxidants, such as β-carotene, α-tocopherol, β-tocopherol, δ-tocopherol, γ-tocopherol, vitamin C and folic acid. Such a complex has synergistic properties due to lycopene associated to α-tocopherol, for example, on the inhibition of prostate carcinoma cell proliferation (Pastori et al. "Biological and biophysical research communications.", 582-585, 250, 3, 1998).

...

[0039] Extract containing lycopene can be used in an amount of 0.1 g to 2 g / 100 g of food product composition."

[3b] "[0047]

Example 7: Fermented milk enriched in lycopene

A traditional fermented milk with 1 to 4 % fats was prepared as follow: After standardizing whole milk, low fat milk or a mixture of both, 0.5 % by weight of lycopene extract as prepared in Example 1 are added. The whole was pasteurized in a plate exchanger, the liquid was cooled to the fermentation temperature, a thermophilic or mesophilic lactic ferment was added and incubation was carried out until a pH of <5 was obtained.

The subsequent operations of filling and sealing pots took place in a conventional manner. This fermented milk has an excellent nutritional profile particularly due to its balanced array of anti-oxidants, including carotenoids, flavonoids and vitamins."

(4) Described matters in Publication 4

[4a] "[Scope of claims]

[Claim 1] A nutritional composition for infants, having action for improving stool, which comprises lycopene."

[4b] "[0012]

[Example 1]

Preparing modified milk powder containing lycopene

1.58 kg of whey protein concentrate (WPC) and 9.24 kg of lactose were added and

dissolved in 50.4 kg of skim milk. Further, 75 g of a mixture of water-soluble vitamins (vitamins B1, B2, B6, B12 and C, niacin, folic acid, pantothenic acid, choline, and inositol) and 75 g of a mixture of minerals (calcium carbonate, potassium chloride, magnesium sulfate, sodium ferrous citrate, copper sulfate, and zinc sulfate) were respectively added and dissolved, and a mixture of fat-soluble vitamins (vitamins A, D, E and K) and 5.78 kg of modified fat in which 0.03 g of 5% lycopene solution (Makhteshim Chemical Works Ltd.) was dissolved were added and blended. After homogenization and sterilization by a conventional method, 21 kg of modified milk powder was obtained by concentrating and drying. The lycopene content in the obtained modified milk powder was 7.0 μg / 100 g of milk powder form.

[0013]

[Example 2]

Preparing proteolysis milk powder containing lycopene and β-carotene

7 kg of casein powder was dissolved in 93 kg of hot water, and after the pH was adjusted to 3.9, protease M (Amano Pharmaceutical Co., Ltd) having 560,000 units was added and the mixed solution was stirred at 46°C for 6 hours. After adjusting pH of this solution to 6.1, peptidase R (Amano Pharmaceutical Co., Ltd) having 30,000,000 units was added and the mixed solution was stirred at 46°C for 16 hours. In 100 kg of this solution subjected to hydrolysis treatment, 6 kg of tapioca starch, 30 kg of dextrin, 2.5 kg of sucrose, and 0.18 kg of the mixture of water-soluble vitamins and 0.18 kg of the mixture of minerals same as those in Example 1, were added and dissolved. Further, 5 kg of safflower oil in which 80 mg of a suspension of palm oil carotene (Lion Corporation) was added and fat-soluble vitamins same as those in Example 1 was dissolved was mixed. After homogenization and sterilization by a conventional method, 50 kg of proteolysis milk powder was obtained by concentrating and drying. The lycopene content in the obtained proteolysis milk powder was 2.3 μg / 100 g of the total solid of milk powder form, and the β-carotene content is 30.4 μg / 100 g.

[0014]

[Example 3]

Preparing yogurt

10 kg of skim milk powder was dissolved in 50 kg of hot water, 1 kg of milk cream in which 1 g of 5% lycopene solution was added and mixed was added, and the solution was sterilized after homogenization by a conventional method. Lactobacillus bulgaricus and Streptococcus thermophilus as starters were inoculated

in the sterilized solution, the solution was dispensed in a container of 500 mL, and yogurt was prepared by a conventional method. The lycopene content in the obtained yogurt was 5.0 μg / 100 g of the total solid of product form."

3. Comparison/judgment

(1) Invention described in Publication 1

Although, in [0010] of [1a] above, it is described that the water dispersibility of lycopene is not satisfactory, it is described in [0004] that lycopene is a food stuff additive for healthcare, and it is not denied that lycopene is added to food stuff even though the water dispersibility of lycopene is not satisfactory, taking into consideration addition to oily food. Therefore, in Publication 1, it is recognized that the following invention (hereinafter referred to as "the Invention described in Publication 1") is described.

"A method of adding lycopene as a food stuff additive to food stuff for healthcare, wherein the lycopene is extracted from tomato as natural carotenoid, is obtainable under the name Lyc-O-Mato (registered trademark) as a 6% strength oily dispersion."

(2) Comparison between Amended Invention and Invention described in Publication 1

A With respect to "tomato oleoresin" relating to the Amended Invention, it is stated in [0013] of the description, "Throughout the description the term tomato oleoresin refers to the lipid fraction of the tomato which contains tomato phytonutrients which are not substantially soluble in water.", in [0014] of the description, "Tomato oleoresin and tomato components which are substantially insoluble in water contain relatively high concentrations of phytonutrients, e.g. lycopene, β-carotene, phytoene, phytofluene, tocopherols, phospholipids and phytosterols.", and in [0019] of the description, "Oleoresin suitable for use in the presently described invention may be obtained from tomatoes or tomato products. An example of commercially available tomato oleoresin is Lyc-O-Mato (registered trademark) by Lycored Natural Products Industries Ltd."

Taking into consideration above definition, "tomato oleoresin" relating to the Amended Invention is the lipid fraction containing tomato phytonutrients which are insoluble in water, such as lycopene, and the preferable example is "Lyc-O-Mato (registered trademark)".

Since "the name Lyc-O-Mato (registered trademark)" of the Invention described in Publication 1 is a product in which lycopene extracted from tomato as natural

carotenoid is prepared as a 6% strength oily dispersion, in terms of kinds of product and blended components, "the name Lyc-O-Mato (registered trademark)" corresponds to "tomato oleoresin" which is "tomato phytonutrients" of the Amended Invention.

B Taking into consideration that it is technical common sense that the food stuff additive is added in the process of preparing food stuff, "a method of adding lycopene as a food stuff additive to food for healthcare" relating to the Invention described in Publication 1 is common with "a method for fortifying food stuff with an effective health-beneficial amount of tomato phytonutrients", "tomato oleoresin to food stuff in the process of preparing said food stuff", and "comprising of adding" of the Amended Invention, in the point that a method of comprising of adding tomato oleoresin to food stuff, in the process of preparing said food stuff.

Therefore, both invention are common in the point of "A method comprising of adding tomato oleoresin as tomato phytonutrients to food stuff in the process of preparing said food stuff.", and have following different features.

(Different feature 1)

In the Amended Invention, the blending amount of tomato oleoresin is "an amount wherein the flavor of said food stuff are not substantially affected by said oleoresin", on the other hand, it is not specified in the Invention described in Publication 1.

(Different feature 2)

With respect to a method comprising of adding tomato oleoresin as tomato phytonutrients to food stuff in the process of preparing said food stuff, the Amended Invention is "a method for fortifying food stuff with an effective health-beneficial amount of tomato phytonutrients", on the other hand, the Invention described in Publication 1 is a method of adding to food stuff for healthcare.

(3) Examination on Different Features

(Different Feature 1)

As described in Publications 2 to 4, lycopene including Lyc-O-Mato above has been widely used as a food stuff additive in various food stuff (especially see [2b], [3b], [4b]. "Lycopene" described in Publication 1 is the same compound as "lycopene" described in Publications 3 to 4.), and especially, the above lycopene is added to food stuff in which the flavor of tomato is not required, for example, "rehydration beverage" in Publication 2, "fermented milk" in Publication 3, and "modified milk powder", "proteolysis milk powder" and "yogurt" in Publication 4.

Further, it is described in [2a] of Publication 2 that the rehydration beverage is good tasting.

Therefore, in the Invention described in Publication 1, using the above Lyc-O-Mato as a food stuff additive is a matter that a person skilled in the art can perform as appropriate since the addition amount is described in [0039] of [3a], and adjusting the addition amount to the extent that "the flavor of said food stuff are not substantially affected by said oleoresin" while considering the flavor of said food stuff itself can be easily implemented by a person skilled in the art.

(Different Feature 2)

The invention described in Publication 1 is "a method of adding" lycopene "to food stuff for healthcare", and it is described in [0003] of [1a] of Publication 1 that consumption of tomatoes decreases the risk of chronic disorders and exerts a positive effect on the prevention of cancer, and "This protective function of lycopene is seen in its action as a very effective antioxidant."

Further, it is disclosed in [2b] of Publication 2 that Lyc-O-Mato is known for its prevention of breast and prostate cancers, and added to rehydration beverage as "neutriceutical ingredients".

Accordingly, "adding" lycopene "for healthcare" of the Invention described in Publication 1 and "fortifying food stuff with an effective health-beneficial amount of tomato phytonutrients" are not substantially different.

Even if they are different, "fortifying food stuff with an effective health-beneficial amount of tomato phytonutrients" instead of "adding for healthcare" could have easily arrived for a person skilled in the art.

Examining the effect of the Invention, the effect that the flavor of food stuff is not substantially effected by the tomato phytonutrients, which is stated in [0006] to [0007] of the detailed explanation of the Invention, is naturally obtained by adjusting the addition amount of tomato oleoresin, and thus the effect could only be predicted from matters described in Publication 1 and well-known arts.

In request for appeal dated April 28, 2010, it is alleged that Publication 1 describes that the water dispersibility of tomato oleoresin is not satisfactory and tomato oleoresin is not suitable as a food stuff additive to food stuff, however, it is thought that this point is solved by selecting food stuff suitable for addition, such as oily food. Further, the example that tomato oleoresin was blended in margarine being oily food is stated in Examples 1 and 7, and the allegation about Publication 1 cannot be

adopted.

We will examine draft amendment described in response letter dated March 6, 2012.

The appellant presents the draft amendment of "A method for fortifying food stuff with an effective health-beneficial amount of tomato phytonutrients comprising of adding to food stuff tomato oleoresin in an amount wherein the flavor of said food stuff are not substantially affected by said oleoresin, and said phytonutrients is added to the food stuff in the process of preparing said food stuff, and said tomato oleoresin is added in the form of a microemulsion, emulsion, beadlets, encapsulated form or is included in tomato fibers, in order to impart stability to the oleoresin.", which is limited with respect to the Amended Invention.

However, since the property that Lyc-O-Mato is oily dispersion and the problem relating to water dispersibility thereof are disclosed in Publication 1, properly changing the form of Lyc-O-Mato in order to improve the stability and usability of Lyc-O-Mato as a food stuff additive could be easily performed by a person skilled in the art, and the effect could only be predicted.

(4) Summary

Consequently, the Amended Invention could be provided easily by a person skilled in the art according to the matters described in Publication 1 and the well-known arts, thus, the appellant should not be granted a patent for the Amended Invention independently at the time of patent application in accordance with the provisions of Article 29(2) of the Patent Act.

4 Conclusion

As described above, since the Amendment of the case violates the provisions of Article 126(5) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 17-2(5) of the Patent Act before revision by the Act No. 55 of 2006, of which the provisions then in force shall remain applicable according to revision supplement Article 3(1) of the Act No. 55 of 2006, the Amendment of the case should be dismissed in accordance with the provisions of Article 53(1) of the Patent Act to be applied mutatis mutandis in Article 159(1) of the Patent Act.

No. 3 The Invention

1 The Invention

The amendment dated April 28, 2010 was dismissed as above, the Inventions

claimed in Claims 1 to 7 are specified by matters stated in Claims 1 to 7 of the scope of claims amended by the written amendment dated December 1, 2009, and the Invention claimed in Claim 1 (hereinafter, referred to the invention described in the claim as "the Invention"), is specified by the following matters: "A method for fortifying food stuff with an effective health-beneficial amount of tomato phytonutrients comprising of adding to food stuff tomato oleoresin or tomato components thereof in an amount wherein the flavor of said food stuff are not substantially affected by said oleoresin or tomato component."

2. Cited Publications and Described Matters therein

Cited publications cited in the reasons for refusal of the examiner's decision, and described matters therein are described in "No. 2　2" above.

3. Comparison/judgment

The Invention, with the Amended Invention examined in "No. 2" above, expands tomato phytonutrients from "tomato oleoresin" to "tomato oleoresin or tomato components", and releases the limitation of time when the phytonutrients are added.

In that case, since the Amended Invention which includes all constituent components of the Invention and in which other constituent components are added, as described "No. 2　3" above, could be provided easily by a person skilled in the art according to the matters described in Publication 1 and the well-known arts, the Invention could be provided easily by a person skilled in the art according to the matters described in Publication 1 and the well-known arts, on the basis of similar reasons.

4 Conclusion

As described above, the Invention could be provided easily by a person skilled in the art according to the matters described in Publication 1 and the well-known arts, 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.

There is no need to judge other claimed inventions, and the present application should be rejected.

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

July 23, 2012

Chief administrative judge:　AKIZUKI, Mikiko

Administrative judge: TAKAOKA, Hiromi
Administrative judge: SAITO, Mayumi