Appeal Decision

Appeal No. 2013-4177

USA
Appellant THE IAMS COMPANY

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The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2008-506508 "Compositions Comprising Probiotic and Sweetener components" (International Publication No. WO 2006/110406 on October 19, 2006, National Publication of International Patent Application No. 2008-535520 on September 4, 2008) has resulted in the following appeal decision:

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The present application is an application filed on April 4, 2006 as an international filing date (priority claim under the Paris Convention received by the foreign receiving office: April 11, 2005, the US Patent and Trademark Office (USPTO)) and received an examiner's decision of refusal on October 29, 2012. Then, a request for the appeal against the examiner's decision of refusal was filed on March 4, 2013 and simultaneously a written amendment was submitted.

No. 2 Decision to dismiss the amendment on March 4, 2013

[Conclusion of Decision to Dismiss Amendment]

The amendment dated March 4, 2013 (hereinafter, referred to as "the Amendment") shall be dismissed.

[Reason]

1. The invention according to Claim 1 after the Amendment

The amendment amends [Claim 1] of the scope of the invention as follows:

"[Claim 1]

A composition characterized by comprising:

(a) a probiotic component comprising strains isolated from resected and washed

canine or feline gastrointestinal tract, and bacteria of a genus selected from the group consisting of Bifidobacterium, Lactobacillus, and combinations thereof;
and

(b) a sweetener component comprising monosaccharides selected from a group consisting of sorbitol, mannitol, glucose, mannose, fructose, and mixtures thereof, wherein

the sweetener component and the probiotic component are mixed with each other, and

the composition is substantially free of a chewing gum base."

The above amendment deletes the condition "the composition has a shelf life of at least about three months to allow at least 50% of the probiotic microorganisms to be viable after three months" and restricts "a probiotic component," which is a matter required for specifying the invention stated in Claim 1 before amendment, by addition of "comprising strains isolated from resected and washed canine or feline gastrointestinal tract, and bacteria of a genus selected from the group consisting of Bifidobacterium, Lactobacillus, and a combination thereof," and also restricts "monosaccharides" by addition of "sorbitol, mannitol, glucose, mannose, fructose, and mixtures thereof." Furthermore, the inventions stated in Claim 1 before and after the Amendment are identical regarding the field of industrial application and the problems to be solved. The Amendment corresponds to an amendment having an object of restricting the scope of claims in accordance with 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 and also having an object of clarifying an ambiguous statement in accordance with the provision of Article 17-2(4)(iv).

Hereinafter, the invention stated in Claim 1 after the Amendment of the case (hereinafter referred to as the "Amended Invention") will be examined in terms of whether or not the Amended Invention could have been patented independently at the time of the patent application (whether or not it complies with the provision of Article 126(5) of the Patent Act which is applied mutatis mutandis pursuant to 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 publication and the described matters

(1) National Publication of International Patent Application No. 2005-508647, which is a publication cited in the reasons for refusal of the examiner's decision and was distributed before the priority date of the application (hereinafter, referred to as Publication 1) relates to foodstuffs and states the following technical matters together with drawings.

(A) "[Claim 1]

A foodstuff which comprises colostrum, a probiotic, and a prebiotic."

(B) "[0020]

A further ingredient of the foodstuff may be sorbitol. The sugar and/or sorbitol content of the foodstuff may be provided in any amount, preferably from 5-50%, more preferably from 35-45% (weight by weight per cent on a dry matter basis).

(C) "[0029] In particular, preferred probiotic microorganisms include one or more of Lactobacillus acidophilus, Lactobacillus mucosae, Lactobacillus ruminus, Lactobacillus reuteri, Bifidobacterium species, and Bacillus subtilis. In particular, the probiotic may be the Lactobacillus deposited under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purposes of Patent Procedure, accession number NCIMB 41117, on October 10, 2001."

(D) "[0033]

Examples of the prebiotic component of the foodstuff of the present invention include, but are not particularly limited to, glucose, fructose, xylose, galactose, lactose, mannose, ..."

(E) "[0039]

For example, one form of foodstuff according to the present invention is a highly palatable dairy treat. The product incorporates colostrum, a prebiotic, and a probiotic in a palatable delivery format. ... The colostrum, prebiotic, and probiotic may be mixed in to any product, infused into the product, or applied to the outside."

(F) "[0066]

The viability of the probiotic, in a format of a fat-based dairy matrix (such as described in Example 1) was tested. Products were stored at room temperature (in the range of 19-24°C) and samples were tested for the viability of probiotic over a 10 month period. The viability of the probiotic was excellent, with only 1 log order loss over 10 months. This level of loss is within the errors of each viability measurement.

[0067]

The viability of probiotic was also tested when incorporated onto dry pet food kibble. The probiotic was coated onto the kibble in a coating base of vegetable oil and tallow. Products were stored at room temperature (in the range 19-24°C) and samples were tested for the viability of probiotic over 11 months. Viability of the probiotic was, again, excellent, with no losses over 11 months."

(G) "[0071]

Example 1

Dairy Treat

A highly palatable dairy treat was produced. The recipe is as set out below:

TABLE 1

Composition

Ingredient	wt%/wt (dry matter basis)
hydrogenated vegetable fat	30
sucrose	43
colostrum	3
prebiotic	3
probiotic	2
emulsifier and salt	1.6
flavor	0.4
yoghurt powder	5
total	100

[0072]

The probiotic was present at a concentration of approximately 3×10^{10} cfu/g.

[0073]

The product was obtained by mixing the raw materials. The mixture was then

spooned/scraped into molds and placed in a refrigerator to set. The pieces were then demolded.
[0074]
The low water activity matrix was developed using a low heat process to ensure that the active components of colostrum were protected during production and over shelf life. Viability of these active components on incorporation into the product was confirmed."
(H) "[0080]
Example 3
Dual Textured Foodstuff
A dual texture kibble pet foodstuff according to the present invention was made with a shell composed of the ingredients shown in Table 1 and filled with the ingredients shown in Table 2. An outer coating was sprayed onto the shell, the content of which is shown in Table 3.
[0081]
TABLE 1

Ingredient	wt%
Chix + BHA/BHT	29.00
Corn whole, #2 Yellow	39.18
Rice Brewers	17.00
Soybean Meal 44%	13.00
Salt, iodized	0.40
Vitamins and Minerals	0.80
Antioxidant	0.02
Iron Oxide Colorant	0.60

TABLE 2

Ingredient	wt%
Hydrogenated vegetable fat	36.2
Sucrose	45.5
Colostrum	15
Inulin	3
Emulsifier	0.3

TABLE 3

Ingredient	wt%
L. acidophilus (freeze-dried)	0.5
Sunflower oil	95.5"

Based upon Example 1, therefore, Publication 1 can be said to disclose the following invention (hereinafter referred to as "Cited Invention").
"A dairy treat product comprising sucrose, colostrum, a prebiotic, and a probiotic, wherein
the product is obtained by mixing raw materials, spooning/scraping the mixture into molds, placing the mixture in a refrigerator to set, and demolding the resulting pieces."

(2) National Publication of International Patent Application No. 2003-534003

distributed before the priority date of the application (hereinafter, referred to as Publication 2) relates to probiotics for pet food applications and states the following technical matters.

(A) "[Claim 1] Novel isolated strains of lactic acid bacteria having high probiotic activity in pets, selected for their ability to survive and colonize the gastrointestinal tract of pets."

(B) "[Claim 9] Use according to claim 7 or 8, wherein the lactic acid bacteria is selected from the genus Lactobacillus, Bifidobacterium, or Enterococcus.
[Claim 10] The use according to any of claims 7 to 9, in which the strain is selected from the group consisting of Lactobacillus reuteri, Lactobacillus acidophilus, Lactobacillus animalis, Lactobacillus ruminis, Lactobacillus johnsonii, Lactobacillus casei, Lactobacillus paracasei, Lactobacillus rhamnosus, Lactobacillus fermentum, Bifidobacterium sp., Enterocoocus faecium, and Enterococcus sp."

(C) "[Claim 18] Pet food composition intended for the health of the gastrointestinal tract of pets containing at least one isolated strain according to any of claims 1 to 6 and/or a supernatant of its culture and/or a metabolite thereof, associated with an ingestible support or a pharmaceutical matrix."

(D) "[0002]
(Background of the Invention)

The well-being of domestic animals is closely related to their feeding. Correct feeding should result in a fit and healthy pet. In addition to providing nutritional value, food composition influences the intestinal microflora equilibrium and may lead to or prevent gastrointestinal disorders. Therefore, knowledge on the gastrointestinal tract and digestion processes of healthy animals is integral to the understanding of a practical feeding practice. As meat-eaters, cats and dogs are characterized by a short digestive tract and a rapid flow rate of the bolus of food."

(E) "[0003]

Among the constituents of the gastrointestinal microflora of cats and dogs Bacteroides sp., Clostridium sp., Enterobacteriaceae, Bifidobacterium sp., Lactobacillus sp., Streptococcus sp., Staphylococcus sp., and yeasts can be recovered."

(F) "[0062]
Example 14: Dry cat food

A feed mixture is made up of about 58% by weight of corn, about 6% by weight of corn gluten, about 23% by weight of chicken meal, with salts, vitamins, and minerals making up the remainder.

The feed mixture is fed into a preconditioner and moistened. The moistened feed is then fed into an extruder-cooker and gelatinized. The gelatinized matrix leaving the extruder is forced through a die and extruded. The extrudate is cut into pieces suitable for feeding to cats, dried at about 110°C for about 20 minutes, and cooled to form pellets. At this point, a lyophilized powder of one or more strains of the following Lactobacillus species is provided for application to the pellets: Lactobacillus acidophilus NCC2628 (CNCM I-2453), or Enterococcus faecium SF68 (NCIMB 10415)."

3. Comparison between amended invention and cited invention
(1) Corresponding relationship between the two inventions
(a) The "probiotic" of Cited Invention is one exemplified as "In particular, preferred

probiotic microorganisms include one or more of Lactobacillus acidophilus, ... Bifidobacterium species ..." of Stated matter (C) in Publication 1. Thus, it is common with "a probiotic component comprising strains isolated from resected and washed canine or feline gastrointestinal tract, and bacteria of a genus selected from the group consisting of Bifidobacterium, Lactobacillus, and combinations thereof" in the Amended Invention in terms of "a probiotic component comprising bacteria of a genus selected from the group consisting of Bifidobacterium, Lactobacillus."
(b) The "prebiotic" of Cited Invention is exemplified as "Examples of the prebiotic component of the foodstuff of the present invention include, but are not particularly limited to, glucose, fructose, xylose, galactose, lactose, mannose, ..." in Stated Matter (D) of Publication 1. Thus, it corresponds to "a sweetener component comprising monosaccharides selected from a group consisting of" "glucose, mannose, fructose" in the Amended Invention.
(c) The statement "a dairy treat product ..., wherein the product is obtained by mixing raw materials, spooning/scraping the mixture into molds, placing the mixture in a refrigerator to set, and demolding the resulting pieces" in Cited Invention does not include any chewing gum base. Thus, it corresponds to the statement "a composition ... , wherein the sweetener component and the probiotic component are mixed with each other, and the composition is substantially free of a chewing gum base" in the Amended Invention.

(2) Corresponding features between the two inventions
"A composition comprising: (a) a probiotic component comprising bacteria including a genus selected from the group consisting of Bifidobacterium, Lactobacillus; and (b) a sweetener component comprising monosaccharides selected from a group consisting of glucose, mannose, and fructose, wherein

the sweetener component and the probiotic component are mixed with each other, and

the composition is substantially free of a chewing gum base."

(3) Different features between the two inventions
A. The different feature 1

The bacteria "comprising strains isolated from resected and washed canine or feline gastrointestinal tract" is stated in the Amendment Invention but not found in Cited Invention.

4. Examination on easiness to conceive of the Amended Invention
(1) Regarding Different feature 1
(a) In Stated matter (B) in Publication 2, "Lactobacillus" (corresponding to "Lactobacillus" in the Amendment Invention) and "Bifidobacterium" are stated as "novel isolated strains of lactic acid bacteria ... survive ... the gastrointestinal tract of pets."

In addition, as stated in the above "3.(1)(a)," particularly preferred "probiotic" microorganisms in Cited Invention include bacteria of each of Lactobacillus acidophilus and Bifidobacterium species. Thus, a person skilled in the art could easily conceive of using "Lactobacillus" (corresponding to "Lactobacillus" in the Amended Invention) and "Bifidobacterium," which "survive ... the gastrointestinal tract of pets" as "probiotic"

microorganisms in Cited Invention to prevent gastrointestional disorders.
(b) Furthermore, in the present specification, paragraph [0024], there is stated that "As a non-limiting example, strains of Bifidobacterium isolated from resected and washed human gastrointestinal tract as disclosed in WO 00/42168 are preferred. ... Strains isolated from resected and washed canine or feline gastrointestinal tract may be particularly useful." Accordingly, it has been conventionally known that bacterial strains can be isolated from resected and washed gastrointestinal tract. In addition, an operation/working-effect of the bacteria of the Amended Invention including "strains isolated from resected and washed canine or feline gastrointestinal tract" remaining in the above statement "may be particularly useful." Considering that the entire statement of the present specification cannot be grasped as a further remarkable operation/working-effect, when using "Lactobacillus" (corresponding to "Lactobacillus" in the Amended Invention) and "Bifidobacterium," which "survive ... the gastrointestinal tract of pets" stated in Publication 2 as "probiotic" in Cited Invention as stated in the above (a), a person skilled in the art could easily conceive of the configuration regarding to Different feature 1 of the Amended Invention such that the "strain" can be isolated from resected and washed gastrointestinal tract.

(2) Comprehensive consideration

The operation/working-effect of the Amended Invention is within the range that could be predicted by a person skilled in the art from Cited Invention, matters stated in Publication 2 and well-known matters.

Thus, the Amended Invention could be easily made by a person skilled in the art based on Cited Invention, matters stated in Publication 2, and well-known matters.

5. Closing

As stated above, the Amended Invention should not have been patented independently at the time of patent application under the provisions of Article 29(2) of the Patent Act. In addition, the Amendment 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. Thus, the Amendment shall be dismissed under the provisions of Article 53(1) of the Patent Act applied mutatis mutandis by replacing certain terms pursuant to Article 159(1) of the Patent Act.

No. 3 Regarding the Invention

1. The Invention

As the Amendment dated on March, 4, 2013 was dismissed as above, the inventions relating to Claims 1 to 19 of the present application are recognized as those specified by the matters stated in Claims 1 to 19 of the scope of claims for patent in the Written Amendment on March 9, 2011. Among the inventions, the invention relating to Claim 1 (hereinafter referred to as the "the Invention") is as follows:

"[Claim 1]

A composition characterized by comprising:

(a) a probiotic component comprising strains isolated from resected and washed canine or feline gastrointestinal tract; and

(b) a sweetener component comprising monosaccharides, wherein
the sweetener component and the probiotic component are mixed with each other,
the composition is substantially free of a chewing gum base, and
the composition has a shelf life of at least about 3 months so that at least about 50% of the probiotic microorganisms are viable after 3 months."

2. Cited Publication
Publication 1 cited in the reasons for refusal of the examiner's decision and the stated matters therein are as stated in the above "(1)" of "No.2 2."

3. Comparison/Judgment
(1) Corresponding relationship between the two inventions
(a) The "probiotic" of Cited Invention is one exemplified as "In particular, preferred probiotic microorganisms include one or more of Lactobacillus acidophilus, ... Bifidobacterium species ..." of Stated matter (C) in Publication 1. Thus, it is common with "a probiotic component comprising strains isolated from resected and washed canine or feline gastrointestinal tract, and bacteria of a genus selected from the group consisting of Bifidobacterium, Lactobacillus, and combinations thereof" in the Invention in terms of "a probiotic component comprising bacteria of a genus selected from the group consisting of Bifidobacterium, Lactobacillus, and combinations thereof."
(b) The "prebiotic" of Cited Invention is exemplified as "Examples of the prebiotic component of the foodstuff of the present invention include, but are not particularly limited to, glucose, fructose, xylose, galactose, lactose, mannose, ..." in Stated Matter (D) of Publication 1. Thus, it corresponds to "a sweetener component comprising monosaccharides selected from a group consisting of glucose, mannose, and fructose" in the Invention.
(c) The statement "a dairy treat product ..., wherein the product is obtained by mixing raw materials, spooning/scraping the mixture into molds, placing the mixture in a refrigerator to set, and demolding the resulting pieces" in Cited Invention does not include any chewing gum base. Thus, it corresponds to the statement "a composition ... , wherein the sweetener component and the probiotic component are mixed with each other, and the composition is substantially free of a chewing gum base" in the Invention.

(2) Corresponding features between the two inventions
"A composition comprising:
(a) a probiotic component comprising bacteria including a genus selected from the group consisting of Bifidobacterium, Lactobacillus; and
(b) a sweetener component comprising monosaccharides, wherein
the sweetener component and the probiotic component are mixed with each other, and
the composition is substantially free of a chewing gum base."

(3) Different features between the two inventions
A. Different feature 1'
The bacteria "comprising strains isolated from resected and washed canine or feline gastrointestinal tract" is stated in the Invention but not found in Cited Invention.

B. Different feature 2

"The composition has a shelf life of at least about 3 months so that at least about 50% of the probiotic microorganisms are viable after 3 months" is stated in the Invention but is unclear in Cited Invention.

4. Examination on easiness to conceive of the Invention

(1) Regarding Different feature 1'

As stated in the above "4.(1)" of "No.2," Different feature 1' could be easily made by a person skilled in the art based on Cited Invention, matters stated in Publication 2, and well-known matters.

(2) Regarding the different feature 2

In Stated matter (F) in Publication 1, it is stated that "The viability of the probiotic, in a format of a fat-based dairy matrix (such as described in Example 1) was tested. ... As a result, the viability of the probiotic was excellent, with only 1 log order loss over 10 months. ...

The viability of probiotic was also tested when incorporated onto dry pet food kibble. ... Products were stored at room temperature (in the range 19-24°C) and samples were tested for the viability of probiotic over 11 months. Viability of the probiotic was, again, excellent, with no losses over 11 months. ..." Thus, it can be said that Cited Invention is substantially "at least 50% of the probiotic microorganisms to be viable after three months." In addition, it can be also said that dairy treat products of Cited Invention have a shelf life of substantially at least about 3 months.

Therefore, Different feature 2 is not a substantial different feature.

(3) Comprehensive consideration

The operation/working-effect of the Amended Invention is within the range that could be predicted by a person skilled in the art from Cited Invention, matters stated in Publication 2 and well-known matters.

Thus, the Amended Invention could be easily made by a person skilled in the art based on Cited Invention, matters stated in Publication 2, and well-known matters.

5. Closing

As stated above, the appellant should not be granted a patent for the Invention under the provisions of Article 29(2) of the Patent Act.

The present application containing the unpatentable invention should be rejected without examining inventions relating to other claims.

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

July 25, 2014

Chief administrative judge: NAKAGAWA, Shinichi
Administrative judge: SUMIDA, Hidehiro
Administrative judge: TAKEMURA, Shinichiro