

## Appeal decision

Appeal No. 2015-20055

USA

Appellant HILL'S PET NUTRITION, INC.

Osaka, Japan

Patent Attorney MURAI, Koji

With respect to the case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2013-113901, entitled "High Protein, Low Carbohydrate Pet Food Composition Having Non-Fermentable Fiber" (Japanese Patent Publication No. 2013-188225, published on September 26, 2013), a decision is made as follows.

### Conclusion

The appeal of the case was groundless.

### Reason

#### 1 History of the procedures

The present application is a divisional application filed on May 30, 2013, divided from JP Patent Application No. 2006-515127 (hereinafter referred to as "Original application") derived from an International Application filed on June 3, 2004, with priority under the Paris Convention (Priority Date: June 3, 2003 (US)). A Notice of Reasons for Rejection was issued on September 9, 2014, and an Argument was filed on December 10, 2014 in response to the Notice, and then a Decision of Final Rejection was issued on July 3, 2015. An appeal against an Examiner's Decision was demanded on November 9, 2015, simultaneously with filing an Amendment.

Incidentally, in the Amendment dated November 9, 2015, claim 1 prior to amendment was cancelled; and claim 13 prior to amendment, which refers to claim 12 prior to amendment, which in turn refers to claim 1 prior to amendment, was claimed as new claim 1. Therefore, this amendment is intended to cancel claim 1 prior to

amendment, and thus corresponds to the amendment of "cancellation of a claim or claims" prescribed in Article 17bis, paragraph 5, item 1 of the Patent Law, and is appropriate.

## 2 The Invention

The invention is specified by the matters described in claims 1-26 of an amendment filed on November 9, 2015, and the invention of claim 1 (claim 13 prior to amendment) (hereinafter referred to as "the Invention") is as follows:

"A food composition comprising high protein in an amount of 25 wt% to 70 wt%, high fat in an amount of 10 wt% to 60 wt%, low carbohydrate in an amount of 12 wt% to 20 wt%, and non-fermentable fibers selected from cellulose, hemicellulose, lignin, and mixtures thereof in an amount of 8 to 15 wt%, for use by cats which are in need of weight management and have a temporary abnormal carbohydrate metabolism."

Incidentally, it is deemed that "25 wt% to 70 wt%," "10 wt% to 60 wt%," "12 wt% to 20 wt%," and "8 to 15 wt%," are weight % on a dry matter basis, given that the nutrients are analyzed on "100% DM basis" (see Tables 1, 3, and 6 of the specification).

## 3 Invention described in publications

### (1) Invention described in Publication 1

U.S. Patent No. 6,203,825 (hereinafter referred to as "Publication 1"), which has been cited as Cited Document 1 in the reasons for refusal stated in the examiner's decision, and which was published before the priority date of the Original application, describes the following matters. (Underlines are provided by the body. )

#### A "FIELD OF THE INVENTION

The present invention relates to a method to protect obligate carnivores from a disease of abnormal carbohydrate metabolism, such as diabetes or obesity. In particular, such animals are protected by feeding them a nutritionally balanced diet that includes a high protein content, moderate fat content, and low carbohydrate content." (column 1, lines 15-21)

B "The current invention relates to the surprising discovery that feeding a cat a diet including low carbohydrate content, high protein content, and moderate fat content

improves that cat's health, or well-being. Such a diet is very similar to the natural diet that obligate carnivores, such as cats, have evolved to eat. This invention addresses all obligate carnivores, including all species from the Feloidae family and obligatory carnivores from the Canoidae family. Since an obligate carnivore is not adapted to carbohydrate in its diet, and furthermore has an inability to regulate its hepatic enzymes as omnivores do, without being bound by theory, the inventor believes that the intake of dietary carbohydrate at levels seen in commercial cat foods would actually be harmful to an animal, causing depletion and/or suppression of insulin, and ultimately causing those most sensitive to these effects to become clinically diabetic. The inventor also believes that obesity in an obligate carnivore, such as the cat, is caused, at least in part, by a high carbohydrate intake. High intake of carbohydrate by an animal adapted to almost exclusive intake of fat and protein appears to cause abnormal regulation of the hormones and enzymes that signal the fed and unfed state to the body. Further, this consumption of carbohydrates with the concomitant increase in circulating insulin causes the energy of the diet to be stored as fat." (column 4, lines 3-26)

C "The present invention includes a method to protect an obligate carnivore from a disease of abnormal carbohydrate metabolism. The method includes the step of feeding the carnivore a nutritionally balanced diet that includes a low carbohydrate content; a high protein content, preferably animal source protein; and a moderate fat content. In one embodiment, such a diet maintains the health, or well-being, of an obligate carnivore that is in good health. A preferred nutritionally balanced diet comprises a protein content of about 25% to about 60% on a dry matter basis, a fat content of about 15% to about 60% on a dry matter basis, and a carbohydrate content of not more than about 12% on a dry matter basis. Another preferred nutritionally balanced diet comprises a protein content of about 30% to about 70% on a dry matter basis, a fat content of about 10% to about 40% on a dry matter basis, and a carbohydrate content of not more than about 12% on a dry matter basis. Another preferred nutritionally balanced diet includes animal meat wherein the balance of nutrients in the animal meat approximates the balance of nutrients in a total animal carcass." (column 4, lines 27-47)

D "The present invention also includes a method to protect an obligate carnivore from a disease of abnormal carbohydrate metabolism that includes the following steps: (a) producing a nutritionally balanced diet comprising a protein content of about 25% to about 60% on a dry matter basis, a fat content of about 15% to about 60% on a dry

matter basis, and a carbohydrate content of not more than about 12% on a dry matter basis; and (b) feeding such a diet to the obligate carnivore. The present invention also includes a method to protect an obligate carnivore from a disease of abnormal carbohydrate metabolism that includes the following steps: (a) producing a nutritionally balanced diet comprising a protein content of about 30% to about 70% on a dry matter basis, a fat content of about 10% to about 40% on a dry matter basis, and a carbohydrate content of not more than about 12% on a dry matter basis; and (b) feeding such a diet to the obligate carnivore. (column 4, lines 48-64)

E "Rather, the diets positioned as "diabetes diets" for cats have a high-fiber, moderate protein, moderate carbohydrate, and low fat profile that mimics the diets used to manage diabetes mellitus in dogs. In fact, no definitive research has been conducted on the unique characteristics of feline diabetes and the resulting dietary implications. Rather, what is believed and known about management of canine diabetes has been applied to cats, despite vast differences in the metabolism of obligate carnivores, such as cats, and omnivores, such as dogs. Thus, the invention of using a low carbohydrate diet with high protein and moderate fat to manage, cure, and prevent a disease of abnormal carbohydrate metabolism is different and new." (column 7, line 3 to column 8, line 34)

F "One embodiment of the present invention is a method to protect an obligate carnivore from a disease of abnormal carbohydrate metabolism by feeding the obligate carnivore a nutritionally balanced diet that includes a low carbohydrate, high protein and moderate fat content. As used herein, to protect from a disease means to prevent, control, cure, ameliorate, or reduce the severity of said disease. In accordance with the present invention, to protect also includes to maintain the health; i.e., well-being, of an animal." (column 8, lines 35-44)

G "Other ingredients may be added in this composition as desired; such additives include flavoring agents, coloring agents, inorganic compounds, and fillers. A filler, or bulking agent, is defined as an ingredient that by addition to the composition, brings the composition to a one hundred percent composition. A filler or bulking agent comprises a non-digestible component, examples of which include, but are not limited to, non-digestible proteins, non-digestible fats, or non-digestible carbohydrates. Non-digestible carbohydrate is also known as fiber, examples of which include, but are not limited to, cellulose, peanut hulls, and soy fiber." (column 9, lines 17-28)

H "Examples of diseases of abnormal carbohydrate metabolism include, but are not limited to, diabetes and obesity." (column 9, lines 46-48)

I "The amount of carbohydrate present in a nutritionally balanced diet of the present invention is of key importance and should be sufficiently low so as not to cause, or lead to, a disease of abnormal carbohydrate metabolism in the fed animal. In one embodiment, the amount of carbohydrate in an obligate carnivore's diet, and preferably in a cat's diet, on a dry matter basis, preferably is less than about 20% carbohydrate. More preferred is a concentration less than about 15% carbohydrate, even more preferred is a concentration of less than about 12% carbohydrate, even more preferred is a concentration of less than about 10% carbohydrate, even more preferred is a concentration of less than about 8% carbohydrate, even more preferred is a concentration of less than about 6% carbohydrate, even more preferred is a concentration of less than about 5% carbohydrate, even more preferred is a concentration of less than about 4% carbohydrate, and even more preferred is a concentration of about 2% or less carbohydrate. In one embodiment, no carbohydrate is added to the cat's diet." (column 9, lines 49-67)

J "The present invention also includes a method to protect an obligate carnivore from a disease of abnormal carbohydrate metabolism that includes the step of feeding the obligate carnivore a nutritionally balanced food composition that comprises a percentage of carbohydrate on a dry matter basis that is not more than the highest percentage of carbohydrate on a dry matter basis that will protect said obligate carnivore from said disease of abnormal carbohydrate metabolism. In one embodiment, the method includes a food composition that has a similar protective effect as a food composition comprising animal meat wherein the balance of nutrients in said animal meat approximates the balance of nutrients in a total animal carcass. The present invention also includes a method to maintain the health of a healthy obligate carnivore that includes the step of feeding the carnivore a nutritionally balanced food composition that comprises a percentage of carbohydrate on a dry matter basis that is not more than the highest percentage of carbohydrate on a dry matter basis that will maintain the health of said healthy obligate carnivore. In one embodiment, the method includes a nutritionally balanced food composition that has a similar health maintenance effect as a food composition comprising animal meat wherein the balance of nutrients in said animal meat approximates the balance of nutrients in a total animal carcass." (column

12, lines 1-26)

K "Example 3

This example demonstrates the ability to produce a dry food formulation of a nutritionally balanced diet of the present invention.

A dry nutritionally balanced diet, defined as 4.77% carbohydrate, 32.4% fat, and 44.98% protein with the remainder of the composition being 5.51% ash, 10.94% moisture, and 1.4% fiber, was prepared as follows. A sample of DIET 1 was slowly dried and baked such that a starting moisture content of 25% to 35% was reduced to a moisture content of about 10%." (column 15, lines 6-17)

In view of the above summarized matters, it is deemed that Publication 1 describes the following invention (hereinafter referred to as "Invention of Publication 1").

"A diet for a cat, comprising a protein content of about 25% to about 60% on a dry matter basis, a fat content of about 15% to about 60% on a dry matter basis, and a carbohydrate content of no more than about 12% on a dry matter basis."

(2) Matters Described in Publication 2

JP H08-191668 (hereinafter referred to as "Publication 2"), which has been cited as Cited Document 2 in the reasons for refusal stated in the examiner's decision, and which was published before the priority date of the Original application, describes the following matters.

A "[0001]

[Industrial Applicability] The invention relates to a pet food with high safety for preventing or improving obesity in pets.

[0002]

[Prior Art and Problems to be Solved by the Invention] Recently, the incidence of obesity in dogs and cats is high, 30 to 40%, and as pets are treated as a companion animal like a member of the family, the interest of keepers regarding preventing obesity in pets is increasing.

[0003] In the past, as a method for preventing obesity in pets, a dietary therapy using a diet food, in which fat is strongly limited, and fibers are significantly increased, was generally employed. However, although it is necessary to limit an amount of supply in the dietary therapy, keepers could not limit the amount of supply against pets which feel hungry, and therefore the pets frequently failed to lose weight. In addition, losing

weight due to extreme limitation of supply causes, for example, fatty liver, and, if anything, has an adverse effect on health, and therefore the development of a dietary therapy with no necessity for food restriction has been expected."

B "[0007] Hereinafter, the invention will be described in more detail. A pet food according to the invention comprises an unsaturated fatty acid having a cis/trans ratio of 0001-0.3, and 0.2-30 wt% dietary fibers as a dry component, as well as a kind, or two or more kinds, selected from galenicals selected from a group consisting of hardy rubber tree, geranium thunbergii, gardenia fruit, plantain, poria sclerotium, senna tea, chameleon plant, senna leaf, rhubarb, ephedra herb, carrot, coix seed, hop, chile pepper, oolong tea, plantago ovata, and gymnema sylvestre, and solvent extracts thereof."

C "[0009] In addition, dietary fibers as used herein collectively refer to heavy components such as hemicellulose, cellulose, pectin, lignin, and a dietary fiber content is an amount of dietary fiber quantified by AOAC method (an enzymatic-gravimetric method by Prosky). The blending content of dietary fibers is preferably 2-30 wt%, particularly preferably 5-15 wt% on the dry matter basis of pet food, in view of preventing obesity and palatability to pets."

D Table 1 shows compositions of experimental diets A, B, C, D, E, F, and G; and foods A, B, and C, respectively, comprise 0.0, 2.0, and 5.0 cellulose, 24.5, 22.5, 19.5 dextrin, and equal amount of the other components; i.e., bulk powder of hardy rubber tree, soybean oil, beef tallow, lard, vitamin-free casein, sucrose, glucose, gelatin, DL-methionine, DL-tryptophan, vitamin, mineral, being respectively, 0.0, 3.0, 0.0, 2.0, 15.0, 16.0, 23.0, 15.0, 0.3, 0.2, 0.2, and 0.8.

E "[0024] [Example 3] A purified diet for cats was prepared using hardy rubber tree, an aqueous extract of hardy rubber tree, geranium thunbergii, gardenia fruit, plantain, poria sclerotium, senna tea, chameleon plant, senna leaf, rhubarb, ephedra herb, carrot, a 30% extract of carrot in ethanol, or coix seed, as galenicals for a test diet shown in Table 5, and cats were subjected to feeding test. The feeding test was carried out for five Japanese Bobtails of about 1 year birth per group, and they received control food and the respective foods ad libitum for two months, and were evaluated for weight change and healthy condition.

...

[0026] The results are shown in Table 6. In test groups in which a test diet having the

composition of a pet food according to the invention was given, weight gain in the cats was clearly reduced compared to a control group which does not comprise the galenicals. Incidentally, no health abnormality in the cats of both the test group and the control group was observed for the test period."

F Table 5 shows the mixing amount (wt%) of galenicals and cellulose in the control diet and test diet, and the amount of the galenicals is 0.0 for the former, while it is 0.05 for the latter, and the amount of cellulose is 0.5 for both.

### (3) Matters Described in Publication 3

JP S60-153762 (hereinafter referred to as "Publication 3"), which has been cited as Cited Document 3 in the reasons for refusal stated in the examiner's decision, and which was published before the priority date of the Original application, describes the following matters.

A "The invention relates to a diet for domestic animals or domestic chickens." (page 1, left lower column, line 11)

B "It is accepted that dietary fibers mainly consisting of cellulose, hemicellulose, lignin, etc., correlate with control of increase or decrease in serum cholesterol, prevention of obesity, diabetes mellitus, appendicitis, carcinoma of the colon and rectum, facilitation of exclusion of toxins in food, or the like." (page 2, left lower column, lines 13-17)

### 4 Comparison

The invention will be compared with the Invention of Publication 1.

(1) Since "comprising" "a protein content of about 25 wt% to about 60 wt% on the dry matter basis" in Invention of Publication 1 is included in the numerical range of "25 wt% to 70 wt%," of the feature "comprising" "an amount of 25 wt% to 70 wt% high protein" in the Invention, it corresponds to "comprising" "a high protein content of 25 wt% to 70 wt% "; and "comprising" "a fat content of about 15 wt% to about 60 wt% on the dry matter basis" corresponds to "comprising" "a high fat content of 10 wt% to 60 wt%."

(2) The feature "comprising a carbohydrate content of not more than about 12% on a

dry matter basis" in the Invention of Publication 1 is common to "comprising" "a low carbohydrate content of 12 wt% to 20 wt% on a dry matter basis" in the Invention, in view of "comprising a low carbohydrate."

(3) The subject matter "diet for a cat" in the Invention of Publication 1 corresponds to "food composition for use by cats" in the Invention.

(4) Therefore, the Invention is identical to the Invention of Publication 1, in "food composition for use in cats, comprising "a high protein content of 25 wt% to 60 wt%," "a high fat content of 15 wt% to 60 wt%," and "a low carbohydrate," while the former differs from the latter in the following points.

[Different Feature 1]: Regarding a "low carbohydrate" content, it is "an amount of 12 wt% to 20 wt%" in the Invention, while it is "not more than about 12% on a dry matter basis" in the Invention of Publication-1.

[Different Feature 2]: Regarding the composition of "food composition for use by cats," the Invention "comprises non-fermentable fibers selected from cellulose, hemicellulose, lignin and mixtures thereof, in an amount of 8 to 15 wt%," while Invention of Publication-1 does not specify such matter.

[Different Feature 3]: Regarding "a cat," the subject which "uses" "food composition," in the Invention, it is one which is in need of weight management and has temporary abnormal carbohydrate, "while Invention of Publication-1 does not specify such matter.

## 5 Judgment

### (1) Regarding Different Feature 1

A Since what content of "carbohydrate" within the range of "not more than about 12%" should be contained in the diet in the Invention of Publication-1 is a matter which could have been appropriately conceived by a person skilled in the art, a person skilled in the art could have easily determined the content of 12%.

In addition, in such a case, the content of carbohydrate falls within the scope of the constitution of the Invention regarding Different Feature 1

B In addition, since Publication 1 suggests that about 20% carbohydrate may be contained; i.e., "in an embodiment, ... comprises preferably less than about 20% carbohydrate in a cat food on the dry matter basis," (see 3(1), I), a person skilled in the art could have easily conceived of determining a carbohydrate content as about 12 wt% to about 20 wt% in the Invention of Publication 1.

C For the above reasons, a person skilled in the art could have easily conceived of employing the constitution of the Invention regarding Different Feature 1 in the Invention of Publication 1.

(2) Regarding Different Feature 2

A Applying technique described in Publication 2 to the Invention of Publication 1

(A) Based on the above 3(2), A to C, Publication 2 describes that "dietary fibers, such as hemicellulose, cellulose, lignin, in an amount of 5 to 15 wt% are contained in a pet food on the dry matter basis in view of preventing obesity of a pet including a cat" (hereinafter referred to as "Technique of Publication 2"). Incidentally, hemicellulose, cellulose, and lignin are non-fermentable fibers.

(B) Invention of Publication 1 is intended to protect animals from obesity (see the above 3(1), A and B), and suggests that fibers such as "cellulose," as a filler or bulking agent, may be contained in a diet (see the above 3(1), G), and therefore a person skilled in the art could have appropriately applied Technique of Publication 2 to the Invention of Publication 1, to comprise non-fermentable fibers such as hemicellulose, cellulose, or lignin in the diet.

In addition, based on the descriptions of the specification, it is not deemed that there is critical significance in the numerical limitation of the Invention regarding Different Feature 2, and employing such numerical range is merely a matter which could have appropriately been determined by a person skilled in the art, for example, in view of the numerical range of Technique of Publication 2.

B Applying well-known technique to the Invention of Publication 1

(A) It is well-known technique that dietary fibers such as hemicellulose, cellulose, lignin, are contained in a diet for animals in view of preventing obesity (if necessary, see Publications 2 and 3). Incidentally, hemicellulose, cellulose and lignin are non-fermentable fibers.

(B) The Invention of Publication 1 is intended to protect animals from obesity (see the above 3(1), A to C), and suggests that fibers such as "cellulose" as a filler or bulking agent may be contained in food (see the above 3(1), G), and therefore a person skilled in the art could have appropriately applied the above well-known technique to the Invention of Publication 1, to comprise non-fermentable fibers such as hemicellulose, cellulose, and lignin.

In addition, based on the descriptions of the specification, it is not deemed that there is critical significance in the numerical limitation of the Invention regarding Different Feature 2, and employing such numerical range is merely a matter which could have appropriately been determined by a person skilled in the art.

C For the above reasons, in the Invention of Publication 1, a person skilled in the art could have easily conceived of employing the constitution of the Invention regarding Different Feature 2 based on techniques described in Publication 2 or well known techniques.

### (3) Regarding Different Feature 3

A Regarding animals to which a diet should be provided, according to the Invention of Publication 1, Publication 1 describes that "The inventor also believes that obesity in an obligate carnivore, such as a cat, is caused, at least in part, by a high carbohydrate intake. High intake of carbohydrate appears to cause abnormal regulation of the hormones and enzymes that signal the fed and unfed state to the body. Further, this consumption of carbohydrates with the concomitant increase in circulating insulin causes the energy of the diet to be stored as fat." (see the above 3(1), B).

B Considering that "High intake of carbohydrates by an animal adapted to almost exclusive intake of fat and protein may result in an abnormal regulation of hormones and enzymes that signal the fed and unfed state to the body. This may result in temporary abnormal carbohydrate metabolism, wherein the normal carbohydrate metabolic state returns to the animal once the carbohydrate levels in the food have been altered." in paragraph [0020] of the specification, it is understood that "High intake of carbohydrate appears to cause abnormal regulation of the hormones and enzymes that signal the fed and unfed state to the body," of the above A in Publication 1, means the case where animals have a temporary abnormal carbohydrate metabolism.

In addition, it is clear that "The inventor also believes that obesity in an obligate carnivore, such as a cat, is caused, at least in part, by a high carbohydrate

intake" and "this consumption of carbohydrates with the concomitant increase in circulating insulin causes the energy of the diet to be stored as fat," of the above A in Publication 1, means the case where weight management is needed in animals.

C As indicated in the above A and B, Publication 1 suggests that the Invention of Publication 1 is directed to use in cats which "are in need of weight management and have a temporary abnormal carbohydrate metabolism," and therefore a person skilled in the art could have easily conceived of such constitution.

#### (4) Effect of the Invention

The effect exerted by the Invention due to the above differences 1-3 is within the scope of the extent to which a person skilled in the art could have easily predicted based on the Invention of Publication 1, and the matters described in Publications 2 and 3, and therefore it is not deemed that the effect is remarkable.

#### (5) Appellant's allegation

A The Appellant alleged in the trial brief that "even if the descriptions of Cited Documents 2 and 3 are combined with the description of Cited Document 1, a person skilled in the art could not have conceived of a food composition comprising the composition of claim 1 of the present application; i.e., "a high fat content of 10 wt% to 60 wt%," "a low carbohydrate content of 12 wt% to 20 wt%," and "non-fermentable fibers in an amount of 8 to 15 wt%," and could not have predicted that pet weight can be effectively reduced using non-fermentable fibers in an amount of 8 to 15 wt%" (see page 5, lines 23-27).

However, for the above reasons mentioned in Items 4(4), 5(1), and 5(2), the Appellant's allegation cannot be accepted.

B In addition, the Appellant alleged in the argument dated December 10, 2014 that "animals to which a food composition according to the invention is provided are cats which are in need of weight management and have a temporary abnormal carbohydrate metabolism," as claimed in claim 1 of this application. As described in paragraph [0020] of the specification, the phrase "temporary abnormal carbohydrate metabolism" as claimed in claim 1 does not refer to condition caused from diseases such as diabetes mellitus, but excludes diabetes described in Cited Document 1. Specifically, although diseases such as diabetes refer to a (not temporary) chronic carbohydrate metabolism; i.e., hyperglycemia, claim 1 excludes companion animals suffering from chronic

carbohydrate metabolism, from subjects to which the food composition according to the invention is administered" (see page 4, lines 3-9).

However, considering that Publication 1 lists obesity as an example of abnormal carbohydrate metabolism diseases (see the above 3(1), A), and describes that "examples of abnormal carbohydrate metabolism diseases are not limited to diabetes or obesity" (see the above 3(1), H), animals to which a diet according to the Invention of Publication 1 is provided are not limited to animals suffering from diabetes, and therefore the Appellant's allegation cannot be accepted.

## 6 Closing

For the above reasons, the invention could have been easily conceived by a person skilled in the art based on Publication Invention 1, the matters described in Publication 2, and the matters described in Publication 3, and therefore is unpatentable under the provisions of Article 29, paragraph 2 of the Patent Law.

Thus, it is not necessary to examine the patentability of the inventions of claims 2-26, and the present application should be rejected.

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

September 21, 2016

Chief administrative judge: AKAGI, Keiji

Administrative judge: TANIGAKI, Keiji

Administrative judge: SUMIDA, Hidehiro