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Case Number: T 2259/10 - 3.3.01

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Language of the proceedings: EN

Title of invention:
COMPOSITIONS AND METHODS FOR ENHANCING THE ANTIOXIDANT STATUS OF ANIMALS

Applicant:
Hill's Pet Nutrition, Inc.

Headword:
Antioxidant diet for dogs/HILL'S PET NUTRITION

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(1)

Keyword:
Inventive step (no): obvious combination of prior art teaching

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Case Number: T 2259/10 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 13 February 2015

Appellant: (Applicant)	Hill's Pet Nutrition, Inc. 400 Southwest 8th Street Topeka, KS 66603 (US)
Representative:	Daniels, Jeffrey Nicholas Page White & Farrer Bedford House John Street London WC1N 2BF (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 26 May 2010 refusing European patent application No. 07754933.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	L. Seymour
	L. Bühler

Summary of Facts and Submissions

I. The present appeal lies from the decision of the examining division refusing the European patent application No. 07 754 933.5, published as WO 2007/114945.

II. The following documents, cited during the examination and appeal proceedings, are referred to below:

(2) GB-A-2 367 489

(3) WO 2005/006878

(7) Hand et al. (Ed.), Small Animal Clinical Nutrition, 4th Edition, 2000, pages 1052 and 1053

III. The decision under appeal was based on a main request filed during oral proceedings before the examining division, and auxiliary requests 1 to 3 filed with letter of 16 February 2010.

With respect to the auxiliary requests, the subject-matter of the respective claims 1 was found to lack an inventive step starting from document (2) as closest prior art. The problem to be solved was defined as lying in the provision of an alternative composition for enhancing oxidative status and for decreasing oxidative stress. The proposed solution of including methionine in the compositions was considered to be obvious in the light of document (3). The claimed ranges for the amounts of ingredients represented an arbitrary selection over the prior art, since the data in the application in suit did not convincingly demonstrate that these were associated with an unexpected effect.

IV. With the statement of grounds of appeal of 5 October 2010, the appellant (applicant) refiled the auxiliary requests 1 to 3 considered in the decision under appeal (cf. point III), as main request, and auxiliary requests 1 and 2, respectively.

Claim 1 of the main request reads as follows:

"1. A composition suitable for administration to a canine, which composition comprises from about 0.9 to about 1.5% methionine, from about 1200 to about 1400 ppm taurine, from about 120 to about 450 ppm vitamin C, and from about 700 to about 2000 IU/kg vitamin E, all on a dry matter basis."

Claim 1 of auxiliary request 2, which was subsequently renumbered as auxiliary request 1 (see point V below), differs from that of the main request in that the upper limit for the concentration of methionine is reduced from 1.5% to 1.1%.

V. Oral proceedings were held before the board on 13 February 2015.

At the beginning of oral proceedings, the appellant withdrew its previous auxiliary request 1 and renumbered its auxiliary request 2 accordingly (see above point IV).

In addition the appellant submitted document (7), and filed a new auxiliary request 2 with a claim 1 differing from that of the main request in the replacement of the feature "suitable for administration to a canine" with "for use in canine therapy".

VI. The appellant's arguments, insofar as they are relevant to the present decision, may be summarised as follows:

In its submissions on inventive step of the subject-matter of claim 1 of the main request, the appellant started from document (2) as closest prior art. This document disclosed antioxidant compositions for use in cats and dogs, comprising combinations of taurine, vitamin C and vitamin E. The amounts of these components were largely expressed in terms of amounts per 400 kcal of diet. However, it was known from the handbook excerpt submitted as document (7) that the standard energy density for dog foods was 3.5 kcal metabolisable energy per gram of dry matter. Based on this conversion factor, it could be derived that, in the two examples according to document (2) that related to dogs, namely, Examples 2 and 3, the amounts of taurine were higher, and of vitamin E lower than specified in claim 1; vitamin C levels were within the claimed range in the former, and too high in the latter.

Starting from document (2), the appellant defined the problem to be solved as providing an improved composition for lowering DNA damage in dogs. The data in Example 1 of the application in suit rendered it plausible that this problem had been solved by the compositions claimed. Here, Foods A to D had been fed to four groups of dogs, of which only Food A fell within the scope of claim 1, and Food D most closely reflected the teaching of document (2). Table 3 demonstrated that cells from dogs fed Food A had the least damaged DNA, as indicated by the lowest tail length measured in the comet assay.

This effect could not have been predicted from the cited prior art.

Thus, document (2) itself did not suggest the use of methionine, or disclose the required amounts of taurine, vitamin C and vitamin E in combination. Moreover, the focus of document (2) was on immunological status and vaccine response. There was no teaching that decreased DNA damage was a technical effect obtainable from the disclosed antioxidant supplemented diets.

Document (3) related to the same technical area, namely, the use of diet compositions for decreasing oxidative stress in companion animals by increasing blood antioxidant levels, and listed decreased DNA damage amongst the potential effects resulting. However, the teaching with respect to suitable sulfur-containing amino acids was very broad, and methionine only appeared in a long list of options. Moreover, document (3) made a clear distinction between the dietary requirements of cats and dogs, in keeping with the common general knowledge of the skilled person, and taught that lower levels of the sulfur-containing amino acids were to be used in dogs. Therefore, even were the skilled person to select methionine, the maximum amount thereof suggested for use in dogs was 0.6 % by weight, as, for example, set out in paragraphs [0008] and [0015], and in claim 19. The amounts taught in paragraphs [0021] and [0023] were not specifically concerned with dogs. It was therefore to be concluded that document (3) taught away from the claimed invention.

Furthermore, there was also no suggestion in document (3) that methionine should be combined with further antioxidants such as those disclosed in document (2). Accordingly, whilst the skilled person could have considered a combination of all four of the components of the present claims, there was no reason why he would have done so, and certainly not in the amounts claimed. The skilled person would understand that biological systems were particularly complex and unpredictable. For example, methionine had multiple uses in the metabolic pathway. Based on an activity thereof in isolation, the skilled would not know whether it would have the same effect when administered in combination with other ingredients, nor could predictions be made as to how much of any individual component would be absorbed into the blood stream. There was no teaching in the prior art that the compositions claimed would provide the correct balance to enhance the antioxidant status of canines. Therefore, even if the problem to be solved were to be seen as lying in the provision of alternative compositions, as argued by the examining division, the subject-matter claimed would not follow logically and plainly from the prior art.

With respect to claim 1 of auxiliary request 1, the appellant submitted that the same considerations applied as for claim 1 of the main request. The subject-matter of claim 1 of auxiliary request 2 had been formulated as a medical use claim limited to canine therapy. Therefore, it was all the more evident that the skilled person, faced with the problem posed, would not have employed the high levels of methionine disclosed in relation to cats in document (3).

VII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis

of the main request filed on 5 October 2010, or, alternatively, on the basis of the first auxiliary request filed as second auxiliary request on 5 October 2010, or, alternatively, on the basis of the second auxiliary request filed during the oral proceedings of 13 February 2015.

VIII. At the end of the oral proceedings, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Admission of document (7) and auxiliary request 2*

Document (7) and auxiliary request 2 were submitted during oral proceedings before the board. The former merely demonstrates the general knowledge of the skilled person in the field of pet nutrition, and the latter contains straightforward amendments intended to reinforce the validity of arguments previously presented. The board therefore decided to admit these submissions into the proceedings, in accordance with Article 13(1) RPBA.

3. *Main request, inventive step (Articles 52(1), 56 EPC)*

3.1 Claim 1 of the main request is directed to compositions, suitable for administration to a canine, comprising methionine, taurine, vitamin C and vitamin E in specified amounts. The compositions may be food compositions (claim 12). They are useful in enhancing antioxidant status and thus lowering oxidative stress,

which may cause cell damage, contributing to ageing and developing chronic disease; they can also lower damage to DNA (cf. application in suit, paragraph [0010]).

3.2 The board considers, in agreement with the appellant and the examining division, that document (2) represents the closest state of the art.

Document (2) is concerned with providing means for reducing oxidative stress in the domestic cat and dog, in particular in order to enhance vaccine efficiency and strengthen the immune response (page 2, lines 1 to 4; page 3, lines 11 to 13). In addition, foodstuffs are provided, which deliver a concentration of ingredients sufficient to increase the antioxidant status of the animal, and can be used to treat disorders with a component of oxidative stress, such as ageing and cancer (page 12, lines 12 to 14; page 13, line 22 to page 14, line 8; claims 7 and 13 to 17).

One of the means disclosed involves supplementation with vitamin E in an amount sufficient to increase plasma levels (page 2, line 6 to page 6, line 15; claims 1 and 8). Preferred concentrations of vitamin E in the diet of dogs is "from 30IU/400kcal, ... up to about from 100IU/400kcal or above", whereby "400kcal" refers to the total metabolisable energy intake (page 6, lines 4 to 6, 13 to 15).

Additional supplementation with vitamin C is also described (page 6, line 17 to page 7, line 30; claims 2 and 9). Preferred levels of vitamin C for dogs are "from 12 to 50 mg/400kcal" (page 7, lines 14 to 19, 28 to 30).

The passage on page 8, line 1 to page 9, line 8 relates to taurine supplementation, in addition to, or instead of vitamin C (see also claims 3 and 10). It is explained therein that taurine is is an essential nutrient for the cat which, unlike the dog, is unable to synthesise taurine from precursor amino acids (page 8, lines 6 to 8). For a product which is not subjected to a high temperature method, preferred levels of taurine are "from about 80mg/400kcal, more preferably from about 100, increasing even more preferably from 120, 150, 180, 200 ... 400 and above"; higher concentrations are disclosed for high-temperature processing (page 8, line 25 to page 9, line 2).

Combinations comprising all three components are disclosed on page 11 (see also claims 4 and 11), and exemplified for use in dogs in Examples 2 and 3. In particular, the combination disclosed on page 11, lines 11 to 20, and in Example 2, comprise the following concentrations per 400 kcal of dry product (note: for alpha-tocopherol, 1 IU = 1 mg; cf. page 2, lines 25 to 26):

Taurine	200 mg
Vitamin C (ascorbate)	20 mg
Vitamin E (alpha-tocopherol)	50 IU (mg)

Applying the standard energy density for dog foods of 3.5 kcal metabolisable energy per gram of dry matter, as disclosed in document (7), the appellant calculated this to correspond to the following concentrations expressed in the units employed in the application in suit (cf. above point VI):

Taurine	1750 ppm
Vitamin C (ascorbate)	175 ppm
Vitamin E (alpha-tocopherol)	437.5 IU/kg

The board agrees with the appellant that this conversion fairly reflects the manner in which the skilled person would assess the teaching of document (2). Accordingly, the ranges as set out above can be calculated to correspond to the following ranges in the units of the application in suit:

Taurine: from about 700 ppm, more preferably from about 875, increasing even more preferably from 1050, 1312.5, 1575, 1750 ... 3500 and above;

Vitamin C: from 105 to 437.5 ppm;

Vitamin E: from 262.5 IU/kg, ... up to about from 875 IU/kg or above.

3.3 The appellant defined the problem to be solved, in the light of document (2), as lying in the provision of an improved composition for lowering DNA damage in dogs.

As support that this problem had been solved, the appellant relied on the results presented in Table 3 of Example 1 in the application in suit. According to this example, four groups of geriatric beagle dogs were fed one of dry foods A, B, C, or D, as set out in Table 1. The ability of cells drawn from these dogs to withstand oxidative stress was then measured, for inherent damage, and in samples challenged with hydrogen

peroxide. The appellant argued that the results obtained, as shown in Table 3, demonstrated that dogs that had been fed a food falling within the scope of present claim 1, namely, Food A, had the least damaged DNA, and that this rendered it plausible that the problem had been solved.

However, according to the consistent case law of the boards of appeal, if comparative tests are chosen to demonstrate an inventive step with an improved effect, the comparison with the closest state of the art must be such that the effect is convincingly shown to have its origin in the distinguishing feature of the invention.

In the present case, the appellant identified the distinguishing features of the claimed subject-matter over the closest composition disclosed in Example 2 of document (2) as lying in the inclusion of methionine at specific concentrations, and in the lower concentration of taurine and higher concentration of vitamin E. However, as can be seen from the following excerpt from Table 1 (page 16 of application), the foods listed each contain very different amounts of all the relevant components, and none of the combinations of Food A with comparative Foods B, C, or D can be said to fairly reflect said differences:

Food Ingredients (DMB)	Food A	Food B	Food C	Food D
...				
Taurine (ppm)	1400	1090	<100	1600
Methionine (%)	1.00	0.49	0.51	0.66
Vitamin E (IU/kg)	1492	594	894	421
Vitamin C (ppm)	127	288	86	21

For example, Food A contains more rather less taurine than Foods B and C. Similarly, none of the foods display comparable levels of vitamin C; in particular, in Food D, the amount of vitamin C is much lower than in Food A. Moreover, it is noted that the levels of vitamin E in Food A has been chosen at the upper end of the claimed range, rather than at the lower end, where the claimed compositions would most closely resemble those exemplified in the closest prior art.

In view of these deficiencies, it cannot be concluded that any differences in the results reported in Table 3 have their origin in the distinguishing features of the invention. Consequently, the comparative data relied on by the appellant is not considered to be pertinent and must be disregarded in the assessment of inventive step.

3.4 The problem to be solved must therefore be reformulated in a less ambitious manner, as lying in the provision of alternative compositions suitable for enhancing oxidative status, decreasing oxidative stress and treating corresponding disorders in canines.

3.5 The solution proposed in claim 1 relates to compositions characterised in the combination of specific ranges of concentrations for taurine, vitamin C and vitamin E, and in the inclusion of methionine at specific concentrations.

Having regard to the experimental results reported in Example 1 of the patent in suit for Food A, the board is satisfied that the problem has been solved.

3.6 It remains to be investigated whether the proposed solution would have been obvious to the skilled person in the light of the prior art.

3.6.1 As becomes evident from the analysis under point 3.2 above, document (2) specifically discloses compositions comprising taurine, vitamin C and vitamin E, designed for the same purpose as the patent in suit. In addition, the ranges of concentrations generally suggested therein overlap in large areas with those recited in present claim 1, and the skilled person would therefore clearly contemplate working within the ranges claimed for these constituents.

Starting from the compositions specifically and generally disclosed in document (2), the skilled person would also have been aware of further documents in the same technical field of antioxidant diets for companion animals, such as document (3). This document discloses food compositions comprising a sulfur-containing antioxidant, and in particular a sulfur-containing amino acid, for use in dogs or cats, as a means of increasing the levels of antioxidants, and preventing the development of disease states related to oxidative stress (see e.g. paragraphs [0003] to [0005], [0016] and [0018]). The list of suitable sulfur-containing amino acids includes methionine and taurine (see e.g. paragraph [0013]). Consequently, it would have been obvious for the skilled person to have considered supplementing the antioxidant cocktails taught in document (2) with a further sulfur-containing amino acid as taught in document (3), such as methionine, as a solution to the problem defined above in point 3.4.

Concerning the amounts of methionine envisaged, it is disclosed in paragraph [0023] of document (3) that

methionine can be present at a concentration of at least about 0.15 wt%, and "up to about 1.5% or greater". Therefore, the concentrations claimed for methionine fall within the general ranges suggested in document (3).

Consequently, the skilled person would not require inventive skill in order to arrive at the subject-matter claimed.

3.6.2 The appellant's further arguments in favour of inventive step do not hold for the following reasons:

As set out above in point 3.2, the teaching of document (2) is not limited to the influence of antioxidant diets on immunological status and vaccine response, but also more generally relates to the use thereof in improving the antioxidant status of companion animals, including dogs. Moreover, the fact that document (2) does not disclose the effect of decreasing DNA damage is not considered to be relevant, since this was already known in the prior art to be linked to an increase in antioxidant levels (cf. e.g. document (3), paragraph [0009]).

Regarding the teaching of document (3), it is evident that methionine is a preferred representative of the disclosed class of sulfur-containing amino acids (see e.g. paragraphs [0016] and [0023]), and would certainly be considered as a suitable candidate for incorporation into the compositions according to document (2). Moreover, it cannot be accepted that abstract concerns regarding the complexity of metabolic systems, or possible effects of pharmacokinetics or interactions between constituents, would detract the skilled person

from the clear combined teaching of documents (2) and (3), as set out above in point 3.6.1.

Finally, concerning the disclosure of document (3) in relation to the concentrations of methionine, the appellant argued, with reference to paragraphs [0008] and [0015], and claim 19, that a maximum of 0.6 wt% was taught for use in dogs. However, in the cited paragraphs, the range of 0.3 to 0.6 wt% is merely exemplified or indicated as being acceptable for use in dogs. Similarly, claim 19, which discloses the same range, is a dependent claim. Therefore, although it can be accepted that said range is preferred for use in dogs, it does not follow that document (3) teaches away from using higher concentrations. Indeed, paragraph [0021] specifically discloses that "levels of methionine ... may be added to the feed up to the toxic levels". In the same paragraph it is stated that "methionine levels in cat foods are not allowed to exceed 1.5 wt% by the American Association of Feed Controllers" (abbreviated as AAFCO); however, no maximum level is given for dog foods. It cannot therefore be concluded that the higher ranges generally suggested in paragraph [0023] of document (3), of "up to about 1.5% or greater", would be toxic or unsuitable for use in dogs. This finding is corroborated by document (7): Tables J-4 and J-5 list the AAFCO minimum nutrient allowances for methionine-cystine in dog foods; in Table J-6, relating to maximum nutrient allowances, no values are given for methionine. Consequently, it is maintained that the skilled person would contemplate including higher levels of methionine, within the claimed range, as a solution to the problem posed.

3.7 In view of the above analysis, it is concluded that the subject-matter of claim 1 represents an obvious solution to the problem posed and does not involve an inventive step. Consequently, the appellant's main request is rejected for lack of inventive step.

4. *Auxiliary request 1, inventive step (Articles 52(1), 56 EPC)*

Claim 1 of this request differs from that of the main request in a narrower range for the concentration of methionine (cf. above point IV). The appellant did not submit any additional arguments in favour of inventive step, and the board also does not consider that this amendment alters the reasoning and conclusions set out above in point 3.

Hence, auxiliary request 1 is rejected for lack of inventive step.

5. *Auxiliary request 2, inventive step (Articles 52(1), 56 EPC)*

Claim 1 of this request is drafted as a purpose-limited product claim within the meaning of Article 54(5) EPC, whereby the composition is specified to be "for use in canine therapy" (cf. above point V).

The appellant reiterated its argument, as put forward for the main request, to the effect that document (3) only disclosed the higher levels of methionine as claimed in relation to cats but not dogs. However, the board notes that the general disclosure of paragraph [0023] of document (3) is not limited to any particular animal, and, as explained above in the last paragraph of point 3.6.2, it cannot be accepted that

document (3) teaches away from using such higher concentrations in the treatment of dogs. The assessment presented under point 3 above therefore applies to this request *mutatis mutandis*.

Hence, auxiliary request 2 is also rejected for lack of inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated