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Datasheet for the decision of 23 May 2017

Case Number: T 1139/13 - 3.3.09

Application Number: 04756796.1

Publication Number: 1641352

IPC: A23K1/18, A23K1/16

Language of the proceedings: EN

Title of invention:
COMPOSITIONS FOR IMPROVED OXIDATIVE STATUS IN CATS

Patent Proprietor:
Hill's Pet Nutrition, Inc.

Opponent:
THE IAMS COMPANY

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
Novelty attack - not admitted
Swiss type claim - interpretation of amounts
Inventive step

Decisions cited:
T 0485/99, T 1020/03

Catchword:

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Case Number: T 1139/13 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 23 May 2017

Appellant: (Opponent)	THE IAMS COMPANY 8060 South Mason-Montgomery Road Mason, OH 45040 (US)
Representative:	Schiweck, Weinzierl & Koch Patentanwälte Partnerschaft mbB Landsberger Straße 98 80339 München (DE)
Respondent: (Patent Proprietor)	Hill's Pet Nutrition, Inc. 400 Southwest 8th Avenue Topeka, KS 66603 (US)
Representative:	Jenkins, Peter David Page White & Farrer Bedford House John Street London WC1N 2BF (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 12 April 2013 concerning maintenance of the European Patent No. 1641352 in amended form.**

Composition of the Board:

Chairman	W. Sieber
Members:	M. O. Müller
	F. Blumer

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent against the interlocutory decision of the opposition division that European patent No. 1 641 352 as amended met the requirements of the EPC.

II. With the notice of opposition the opponent had requested revocation of the patent in its entirety on the grounds under Article 100(a) EPC (lack of novelty and lack of inventive step).

The documents cited during the opposition proceedings included:

D4: K. C. Hayes, Nutrition Research Reviews, volume 1, 1988, pages 99 to 113;

D5: D.L. Zoran, JAVMA, volume 221, No. 11, 2002, pages 1559 to 1567; and

D6: M.J. Fettmann et al., AJVR, volume 60, No. 3, 1999, pages 328 to 333.

III. The opposition division's decision was based on the main request filed during the oral proceedings, claim 1 of which read as follows:

"1. Use of a food composition comprising a sulfur-containing antioxidant which is a mixture of cysteine and methionine in a total amount of from 1.0 wt% to 2.2 wt%, wherein the methionine is at a concentration of from 0.8 wt.% to 1.5 wt.% in the manufacture of a companion-animal diet composition for increasing blood antioxidant levels in a feline."

IV. In its decision, the opposition division admitted late-filed documents D4 to D6 into the proceedings. It considered the claims of the main request to meet the requirements of Articles 84, 123(2) and 123(3) and Rule 80 EPC. It lastly held that the main request was novel and inventive in view of the closest prior art D4 and D6, taking common general knowledge D5 into account.

V. This decision was appealed by the opponent (hereinafter "appellant"). In the statement setting out the grounds of appeal the appellant raised objections under Articles 123(2) and (3) and 56 EPC against the claims held allowable by the opposition division. The statement included copies of decisions T 2017/07 and T 1312/08 and

D7: Publication of American Feed Control Officials Incorporated, 1994, pages 116 to 119.

VI. In its response, the proprietor (hereinafter "respondent") requested that the appeal be dismissed (main request) and filed first to ninth auxiliary requests and

H1: Statement of Mr Jewell signed on 25 October 2013.

VII. With letter dated 28 June 2016, the respondent filed first to sixth auxiliary requests replacing the previously-filed auxiliary requests.

VIII. With its communication dated 10 January 2017, the board issued its preliminary opinion.

IX. With its letter dated 23 March 2017, the appellant raised for the first time novelty objections based on D7 and the following documents cited during the examination proceedings:

D2E: GB 1497211 A;

D4E: WO 03037103 A1;

D6E: ZA 9605149 A;

D8E: GB 2315674 A; and

D9E: DE 20104950 U.

X. On 23 May 2017, oral proceedings were held before the board. At the very outset of the oral proceedings, the appellant withdrew its novelty objections raised on the basis of D2E, D4E, D6E, D8E and D9E but maintained the novelty objection based on D7. It furthermore raised a new novelty objection based on D4. The respondent requested that these two novelty attacks not be admitted into the proceedings. After the board had announced its conclusion that the main request (i.e. the claims found allowable by the opposition division) did not meet the requirements of Article 123(2) EPC, the respondent submitted a new main request and new first and fourth to sixth auxiliary requests.

XI. The only independent claim of the new main request reads as follows:

"1. Use of a food composition comprising a sulfur-containing antioxidant which is a mixture of cysteine and methionine in a total amount of from 1.0 wt% to 2.2 wt%, wherein the methionine is at a concentration

of from 0.8 wt.% to 1.5 wt.% and the cysteine is in an amount of from 0.2 wt% to 0.7 wt% in the manufacture of a companion-animal diet composition for increasing blood antioxidant levels in a feline."

XII. So far as relevant to the present decision, the appellant's arguments can be summarised as follows:

The subject-matter of claim 1 lacked inventive step over D6 as the closest prior art. The composition defined in claim 1 differed in terms of the methionine concentration from the composition denoted "nominal" in this document. The objective technical problem to be solved in view of this composition of D6 was the provision of a further composition for increasing blood antioxidant levels. The claimed solution was obvious, since (i) D6 taught to increase the methionine concentration above 0.45 wt%, (ii) cysteine and methionine were interconverted into each other so that the skilled person would know that instead of increasing the concentration of cysteine, he could also increase that of methionine and (iii) one would stay below 1.5 wt%, as higher amounts were toxic. The subject-matter of claim 1 was also obvious in view of D6 in combination with D4, which taught the skilled person to use methionine at a concentration of 1 wt%.

The subject-matter of claim 1 lacked inventive step also starting from D4 as the closest prior art. The difference between the subject-matter of this claim and the diet containing *inter alia* 1 wt% methionine and 36 wt% casein as disclosed in D4 was the exact amount of cysteine. The objective technical problem was again the provision of a further composition for increasing blood antioxidant levels. The skilled person not knowing how much cysteine to add would look at D6 and,

in view of the nominal composition disclosed therein, use 0.59 wt% cysteine, which was within the claimed range.

Lastly, inventive step had to be denied over D4 and D6 also on the ground that the diet to be administered to the feline according to claim 1 was not formulated as a proper second-medical-use claim, so the methionine and cysteine concentrations did not restrict the diet composition. Thus, these concentrations could not contribute to inventive step.

XIII. So far as relevant to the present decision, the respondent's arguments can be summarised as follows:

The subject-matter of claim 1 was inventive in view of D6 as the closest prior art. The composition defined in claim 1 differed from the composition denoted "nominal" in this document in terms of the methionine concentration only. The objective technical problem to be solved in view of D6 was to further increase blood antioxidant levels in a feline. D6 did not teach to increase the methionine concentration to achieve this goal but actually taught the skilled person to increase the cysteine concentration to a level above the upper limit of the range defined in claim 1. Contrary to the appellant's argument, D6 did not teach any interconversion of methionine into cysteine and even if it did, the skilled person, in view of the metabolic pathways depicted in figure 1 of D4 and D5, would still not increase the methionine instead of the cysteine concentration. D4 did not contain any motivation to use methionine and cysteine concentrations as claimed either. In fact it taught away from the methionine concentration as claimed and rather suggested using high cysteine concentrations.

Contrary to the appellant's argument, D4 could not be considered to represent the closest prior art, since it did not address the problem of reducing oxidative stress. However, even if D4 had been regarded as the closest prior art, the skilled person would not have used the composition containing 1 wt% methionine therein disclosed, since this was reported in D4 to have only a minimal effect. Lastly, since D4 taught the skilled person to use high cysteine concentrations, the skilled person would not necessarily have arrived at a concentration as claimed. The same applied when additionally taking D6 into consideration; this document taught the skilled person to use cysteine concentrations above the upper limit of claim 1.

It was not true that claim 1 was not restricted as regards the methionine and cysteine concentrations of the diet composition. The skilled reader would recognise that claim 1 was drafted in the Swiss-type format and it was generally accepted that the active ingredient cited in such a claim, in the present case the food composition including its methionine and cysteine concentrations, was still present in the medicament, in the present case the diet composition.

XIV. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the patent be maintained on the basis of the new main request filed during the oral proceedings before the board on 23 May 2017.

Reasons for the Decision

New main request

1. Amendments - Articles 123(2) and (3) and 84 EPC

The appellant did not raise any objections under Articles 123(2) and (3) and 84 EPC and the board is satisfied that the requirements of these articles are met.

2. Novelty

2.1 The appellant objected to novelty on the basis of D4 and D7 only at an extremely late stage of the proceedings. The respondent requested that these novelty attacks not be admitted into the proceedings.

2.2 The novelty attack based on D7 was filed with letter dated 23 March 2017, i.e. after the board's communication and less than two months before the oral proceedings. The novelty attack based on D4 was not filed until the oral proceedings only.

The board notes that no novelty attacks were made in the statement of grounds of appeal. Holding such attacks back until after the board's communication and even the oral proceedings amounts almost to an abuse of procedure. It would therefore not have been equitable to consider these attacks at this late stage. The board therefore decided not to admit them into the proceedings (Article 13(1) RPBA).

3. Inventive step

3.1 Interpretation of claim 1

3.1.1 Claim 1 is directed to the use of a food composition comprising a sulfur-containing antioxidant which is a mixture of cysteine and methionine in a total amount of from 1.0 wt% to 2.2 wt%, wherein the methionine is at a concentration of from 0.8 wt% to 1.5 wt% and the cysteine is in an amount of from 0.2 wt% to 0.7 wt%, in the manufacture of a companion-animal diet composition for increasing blood antioxidant levels in a feline.

For the sake of brevity, the concentrations of methionine, cysteine and their mixture will be referred to below also as "methionine/cysteine concentrations" and the companion-animal diet composition will be referred to as "the diet".

3.1.2 The food composition cited in claim 1 is limited as regards the methionine/cysteine concentrations. It was a matter of dispute between the parties whether this limitation also applied to the diet to be administered to a feline for increasing its blood antioxidant levels.

3.1.3 Claim 1 is drafted in the Swiss-type claim format, i.e. use of an active ingredient for the manufacture of a medicament for a therapeutic treatment. The food composition of claim 1 with the specific methionine/cysteine concentrations corresponds to the active ingredient, the diet represents the medicament and the increase in the blood antioxidant level in a feline corresponds to a therapeutic treatment.

The appellant argued that claim 1 was not a Swiss-type claim, since it did not use the term "medicament". The board does not agree. The Swiss-type claim format does not require the use of the term "medicament"; equivalent expressions such as "diet" can be used instead (T 485/99, point VI in conjunction with points 3.1 and 3.2). Therefore, the fact that claim 1 makes reference to a diet does not disqualify it from being in the Swiss-type claim format.

The appellant furthermore argued that claim 1 was not a medical-use claim since an increase in blood antioxidant level was not a true therapeutic effect.

The board does not agree with this argument either. If claim 1 had been directed to a method of using a diet to increase blood antioxidant levels in a feline, its subject-matter would have been excluded from patentability under Article 53(c) EPC, since it covers therapeutic treatments, such as improvements in conditions like diabetes as well as cardiovascular and gastrointestinal diseases, as mentioned in paragraph [0010] of the patent. As set out in T 1020/03 (OJ EPO 2007, 204, point 36), if in such a situation the claim is re-drafted in the Swiss-type format, it is to be considered a medical-use claim ("medical indication" in point 36 of T 1020/03). As explained by the board in point 36 of T 1020/03, this follows the logic that

> "... there is a seamless fit, either a method of using a composition is not a treatment by therapy and therefore falls outside the provision of Article 52(4) EPC [Article 53(c) EPC 2000] first sentence, and so is patentable subject to compliance with the other provisions of the EPC, or

> else a method is a treatment by therapy and therefore inside the provision of Article 52(4) EPC [Article 53(c) EPC 2000] first sentence, and so not itself patentable, but use of a composition for making a medicament for use in such treatment by therapy is patentable for unspecified therapy as a first medical indication or for a specified therapy as a further medical indication, again subject to compliance with the other provisions of the EPC, in particular novelty and inventive step" (insertion in square brackets made by the present board).

But even if claim 1 were not a true medical-use claim, the skilled reader would still recognise that the format of claim 1 is that of a Swiss-type claim.

The skilled reader would be aware that the active ingredient in such a claim must be present in the medicament so that it can achieve the desired therapeutic effect. For instance, the only technically sensible reading of a claim directed to the use of aspirin to manufacture a medicament to treat pain is that the active ingredient aspirin must be present in the medicament to deliver the desired therapeutic effect. In the same way, the skilled reader looking at claim 1 of the new main request would assume that the active ingredient, i.e. the food composition with the specific methionine/cysteine concentrations, must still be present in the diet so that when it is fed to a feline it increases its blood antioxidant levels.

Therefore, the board follows the respondent's interpretation of claim 1 that the methionine/cysteine concentrations cited for the food composition are also the concentrations present in the diet to be administered to the feline.

3.1.4 The appellant argued that claim 1 merely defined the methionine/cysteine concentrations in the starting material (food composition) but not in the end product (diet) obtained therefrom. According to the appellant, the diet was thus not limited at all as regards its methionine/cysteine concentrations. This would however deprive claim 1 of any technical sense, since it is the diet that is administered to the feline and hence the methionine/cysteine concentrations in the diet are what matter. This is also supported by the patent (paragraph [0011]), according to which certain concentrations of the sulphur-containing amino acids cysteine and/or methionine must be present in the diet to increase blood antioxidant levels:

> "The present invention uses compositions for increasing blood antioxidant levels in a feline companion animal. The use can involve the manufacture of a diet comprising at least one sulfur-containing antioxidant selected from cysteine and/or methionine and, in particular, a sulfur-containing amino acid at a concentration effective in increasing blood antioxidant levels in the companion animal as indicated above."

3.1.5 The board's conclusion thus remains valid that the diet in claim 1 is restricted as regards its methionine/cysteine concentrations. These concentrations will therefore be taken into account when discussing inventive step below.

3.2 Inventive step in view of D6

3.2.1 The patent aims at reducing oxidative stress by increasing blood antioxidant levels (paragraph [0007]).

3.2.2 D6 aims at ameliorating the effects of oxidative damage in cats ("Clinical Relevance" on page 328) and at deactivating oxidative toxicants (first sentence of the last paragraph in the right-hand column of page 328 and first full paragraph in the left-hand column on page 329). D6 thus addresses the same problem as the opposed patent. Consequently, in line with the arguments of both parties, D6 can be considered to represent the closest prior art.

Table 3 on page 330 of D6 describes a study on feeding cats to prevent antioxidant damage. In this study, the cats were fed three diets in which the dietary cysteine content was varied from "nominal" (0.59 wt%) to "moderate" (1.19 wt%) and "high" (1.54 wt%) while the methionine concentration was kept roughly constant (0.63 wt%, 0.62 wt% and 0.64 wt%).

As agreed by both parties, the composition that comes closest to the subject-matter of claim 1 is the nominal composition. In this composition, the concentration of cysteine is 0.59 wt%, that of methionine is 0.63 wt% and the total amount of cysteine and methionine is 1.22 wt%. Hence, the concentrations of cysteine and of the cysteine and methionine mixture are within the claimed ranges. The composition differs from the food composition and diet defined in claim 1 in terms of the methionine concentration (0.63 wt%), which is below the lower limit required by this claim (0.8 wt%).

3.2.3 There is no evidence on file that by increasing the methionine concentration from 0.63 wt% to 0.8 wt% or higher, the blood antioxidant level is further increased. The board therefore concurs with the appellant that the objective technical problem to be

solved in view of D6 is to provide a further composition for increasing blood antioxidant levels.

3.2.4 It needs to be examined whether the solution as proposed in claim 1 is obvious.

According to the appellant, the claimed solution was obvious in view of D6 itself.

The appellant argued that page 328, right-hand column, lines 10 to 24 of D6 taught the skilled person to use methionine concentrations above 0.39 to 0.45 wt%, so values within the claimed range, i.e. of 0.8 wt% or higher, were obvious.

The board does not agree. It is true that this passage discloses methionine concentrations of 0.39 to 0.45 wt% and that it suggests even higher methionine concentrations. However, these higher concentrations are taught for phospholipid synthesis to facilitate lipid transport associated with the consumption of a high-fat diet or in view of higher hepatic transaminase activities. This is not related to achieving higher blood antioxidant levels. The skilled person trying to find a further composition for increasing blood antioxidant levels would thus not have been motivated by this passage of D6 to increase the methionine concentration to a value above 0.45 wt%. If anything, he would have been discouraged by this document from using such a methionine concentration, since this concentration is already referred to in D6 as a high concentration (page 328, right-hand column, line 10) and since D6 warns of methionine toxicosis (page 331, right-hand column, lines 11 to 13).

What D6 actually teaches the skilled person to do in order to increase blood antioxidant levels is to increase the concentration of cysteine in the diet. More specifically, D6 starts from the hypothesis that increased dietary cysteine content would increase cysteine absorption, promote the synthesis of the antioxidant glutathione and diminish baseline levels of oxidative damage in circulating erythrocytes (page 329, left-hand column, lines 9 to 12). Accordingly, in the three compositions "nominal", "moderate" and "high" applied in the experiments of D6, it was the cysteine concentration that was varied. It was found that with "moderate" and "high" cysteine concentrations, namely 1.19 wt% and 1.54 wt%, the blood glutathione (GSH) concentration was significantly increased (first and second full paragraphs in the left-hand column of page 331). The skilled person confronted with the objective technical problem would thus not increase the concentration of methionine but that of cysteine, namely to a value of 1.19 wt% or higher. The resulting composition would not be according to claim 1, but the concentration of methionine would be below, and that of cysteine above, the corresponding ranges defined in claim 1.

The appellant also argued that cysteine and methionine were interconverted into each other, so the skilled person would know that instead of increasing the concentration of cysteine he could increase that of methionine. By doing so, he would arrive at the subject-matter of claim 1. However, such interconversion as allegedly taught by D6 is not as simple as presented by the appellant. In fact, D6 (page 331, right-hand column, first sentence of last paragraph in conjunction with page 328, right-hand column, lines 6 to 8) teaches that cysteine cannot be

converted to methionine in humans and that metabolic conversion of cysteine and methionine is no greater in cats than in other species. Furthermore, looking at figure 1 of each of D4 and D5, it appears that an interconversion, if present at all in cats, is such that methionine is a precursor of cysteine which in turn is a precursor of the antioxidants taurine (figure 1 of D4) and glutathione (figure 1 of D5). Thus, taking this interconversion into account, the skilled person would be motivated to increase the concentration of cysteine rather than that of methionine to obtain the desired antioxidants.

Lastly, the appellant argued that, as acknowledged by the patent (page 4, line 4), it was common general knowledge that methionine levels exceeding 1.5 wt% were toxic. However, the board fails to see how this would motivate the skilled person to increase the methionine concentration disclosed in D6.

In addition to attacking inventive step on the basis of D6 alone, the appellant also used D6 in combination with D4. The appellant referred in particular to the first full paragraph of page 105 of D4, according to which a diet containing *inter alia* 1 wt% methionine and 36 wt% casein had minimal effect on plasma taurine status. Since the effect was not zero but minimal, the appellant concluded that the skilled person would have been motivated to use methionine in an amount of 1 wt%, which was within the claimed range.

The board does not agree. In fact the appellant turns the teaching of D4 upside down. Instead of motivating the skilled person to use methionine in an amount of 1 wt%, the minimal effect referred to in the cited passage of D4 actually discourages the skilled person

from using this methionine concentration. Furthermore, in the text preceding this passage, D4 teaches the skilled person that the bottleneck for the synthesis of the antioxidant taurine is cysteine availability. In the same way as discussed above for D6, the skilled person would therefore use high cysteine rather than high methionine concentrations and would thus not necessarily arrive at the subject-matter of claim 1.

3.2.5 The subject-matter of claim 1 is therefore inventive in view of D6, taken alone or in combination with D4.

3.3 Inventive step in view of D4

In a second attack, the appellant started from D4 as the closest prior art. It referred again to the diet disclosed in the first full paragraph of page 105 of D4 containing 1 wt% methionine and 36 wt% casein. The appellant argued that the difference between this diet and the subject-matter of claim 1 was the exact amount of cysteine. The objective technical problem was again to provide a further composition for increasing blood antioxidant levels. The skilled person not knowing how much cysteine to add would look at D6 and, in view of the nominal composition disclosed therein, use 0.59 wt% cysteine, which was within the claimed range.

However, D4 does not mention the objective aimed at in the opposed patent, i.e. that of reducing oxidative stress by increasing blood antioxidant levels. Therefore, D4 is less close to the claimed invention than D6. It is thus D6 rather than D4 that constitutes the closest prior art. Furthermore, as already set out above, D4 discourages the skilled person from using a diet with 1 wt% methionine, since this has only a minimal effect. So, even if the skilled person started

from D4 as the closest prior art, he would not use the diet with this methionine concentration. And even if he had used this diet, he would not have arrived at a cysteine concentration as defined in claim 1. More specifically, D4 nowhere teaches a diet containing a combination of methionine and cysteine in the claimed amounts. Furthermore, when looking at D6 as the secondary document, the skilled person would have been taught to use concentrations of cysteine of at least 1.19 wt% in order to increase antioxidant levels (see point 3.2.4 above). Therefore, the skilled person would arrive at a cysteine concentration above the upper limit of claim 1. Consequently, the subject-matter of claim 1 is also inventive in view of D4 alone or in combination with D6.

3.4 During the written proceedings, the appellant had relied on D7 with regard to inventive step of the previous main request. It had requested that this attack be admitted into the proceedings. However, during the oral proceedings, D7 was no longer relied on for inventive step. Therefore, the board did not need to decide on the appellant's request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of claims 1 to 4, filed as new main request during the oral proceedings before the board on 23 May 2017, and after any necessary consequential adaptation of the description.

The Registrar: The Chairman:

I. Aperribay W. Sieber

Decision electronically authenticated