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# Datasheet for the decision of 20 September 2018

Case Number: T 0332/17 - 3.3.09

Application Number: 00992099.2

Publication Number: 1251747

A23K1/16, A23K1/18, A23K1/00, IPC:

A61K35/74

Language of the proceedings: ΕN

#### Title of invention:

PET FOOD COMPOSITION FOR TREATING HELICOBACTER SPECIES IN PETS

### Patent Proprietor:

Société des Produits Nestlé S.A.

# Opponent:

The IAMS Company

### Headword:

### Relevant legal provisions:

EPC Art. 84, 56

# Keyword:

Inventive step - main request (no) - auxiliary requests 1 to 4 (no)

Claims - clarity after amendment auxiliary requests 5 to 7 (no) Oral proceedings - non-attendance of party

### Decisions cited:

### Catchword:



# Beschwerdekammern **Boards of Appeal** Chambres de recours

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Case Number: T 0332/17 - 3.3.09

DECISION Technical Board of Appeal 3.3.09 of 20 September 2018

Appellant: The IAMS Company

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Respondent: Société des Produits Nestlé S.A.

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Rupp, Christian Representative:

> Mitscherlich PartmbB Patent- und Rechtsanwälte

Sonnenstraße 33 80331 München (DE)

Decision under appeal: Interlocutory decision of the Opposition

> Division of the European Patent Office posted on 23 November 2016 concerning maintenance of the European Patent No. 1251747 in amended form.

### Composition of the Board:

Chairman W. Sieber F. Rinaldi Members:

E. Kossonakou

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### 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. 1 251 747 as amended meets the requirements of the EPC.
- II. With its notice of opposition, the opponent had requested revocation of the patent based on Article 100(a) (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

The documents submitted during the opposition proceedings included:

D1: M.-H. Coconnier et al., Applied and Environmental Microbiology, 64(11), 1998, 4573-4580

D2: US 5,578,302.

- III. In the appealed decision, the main request was found to be allowable. Claim 1 read as follows:
  - "1. Use of a lactic acid bacteria strain selected from the group consisting of Lactobacillus johnsonii, Lactobacillus reuterii, Lactobacillus paracasei, Lactobacillus animalis, Lactobacillus ruminis, Lactobacillus rhamnosus, Lactobacillus fermentum, Bifidobacterium sp., Bifidobacterium lactis, Bifidobacterium animalis and/or its metabolites or a medium fermented thereby for the preparation of a composition for the prophylaxis or treatment of GHLOs infection in pets."

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The opposition division decided that the subject-matter of the main request complied with the requirements of Article 123(2) EPC, the disclosure of the invention was enabling and the subject-matter claimed involved an inventive step. In particular, the subject-matter of claim 1 was not obvious, in the light of neither the closest prior art, D1, alone nor D1 in combination with the other documents cited, in particular D2. With respect to claim 1, the opponent had not raised novelty objections.

The main request comprised dependent claims 2 to 5 and claims 6 to 12 directed to a specific pet food composition. However, these claims are not relevant for the present decision.

IV. The opponent (in the following: the appellant) appealed against the decision. It disagreed inter alia with the opposition division's conclusion that the subjectmatter of claim 1 involved an inventive step and filed the following documents:

D18: EP 0 862 863 A2

D19: Product information for Bifidobacterium BB12®.

V. By letter dated 28 June 2017, the patent proprietor (in the following: the respondent) requested that the appeal be dismissed (main request) or that the patent be maintained on the basis of any of auxiliary requests 1 to 7 filed with that letter. It further requested that D18 and D19 not be admitted into the proceedings.

The aspects of claim 1 of these requests which are relevant for this decision are the following:

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Claim 1 of auxiliary request 1 corresponds to claim 1 of the main request (see point III.), except that the micro-organisms are restricted to: Lactobacillus johnsonii, Lactobacillus paracasei and Lactobacillus rhamnosus.

## Claim 1 of auxiliary request 2 reads as follows:

"1. Use of a lactic acid bacteria strain selected from the group consisting of Lactobacillus johnsonii, Lactobacillus paracasei, Lactobacillus rhamnosus and/or its metabolites or a medium fermented thereby for the preparation of a composition for the prophylaxis or treatment of GHLOs infection in dogs or cats, wherein the lactic acid bacteria or the equivalent fermentation medium is used in an amount of  $10^9-10^{12}$  cfu/day for dogs and  $10^7-10^{11}$  cfu/day for cats."

Claim 1 of auxiliary requests 3 and 4 have identical wording, and correspond to claim 1 of auxiliary request 2, except that they are restricted to dogs (i.e. references to cats and the amount of lactic acid bacteria to be administered to cats have been deleted).

Claim 1 of auxiliary requests 5, 6 and 7 begin with the statement:

"1. Use of a lactic acid bacteria strain selected from the group consisting of for [sic] the preparation of a composition for the prophylaxis or treatment of [...]."

The reply also included a claim set allegedly identical to the main request which the opposition division had

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found allowable. However, the newly filed main request contained minor differences.

- VI. The parties were summoned to oral proceedings. By letter dated 18 May 2018, the respondent stated that it would not be represented at the oral proceedings. The board issued a communication dated 30 May 2018 setting out its preliminary and non-binding opinion. Inter alia, it drew the respondent's attention to the unclear wording of claim 1 in auxiliary requests 5 to 7.
- VII. By letter dated 7 August 2018, the appellant *inter alia* filed the following document:
  - D20: G. Solano-Aguilar et al., Applied and Environmental Microbiology, 74(20), 2008, 6338-6347.
- VIII. On 20 September 2018, oral proceedings took place in the absence of the duly summoned respondent.
- IX. The respondent requested in writing that the appeal be dismissed (main request) or that the patent be maintained on the basis of one of auxiliary requests 1 to 7 filed by letter dated 28 June 2017. It also requested that documents D18 and D19 not be admitted into the proceedings.
- X. The appellant requested that the decision of the opposition division be set aside and the patent be revoked in its entirety.
- XI. The **respondent's written arguments** which are relevant for the present decision may be summarised as follows:
  - As regards claim 1 of the main request, D1 was the closest prior art. This document (i) was silent on

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pets, (ii) did not disclose the treatment or prevention of infection by gastric Helicobacter-like organisms (GHLOs) in pets, but concerned humans and (iii) did not refer to the lactic acid bacteria specified in claim 1. The technical problem was the provision of a therapy for pets suffering from GHLOs infection. The solution was not derivable from D1 alone or in combination with D2. It was clear from the way that D2 was drafted and from the test model used therein that D2 only aimed at treating humans. Thus, the skilled person would not take into account the teaching of D2.

- As to the inventive step of claim 1 of auxiliary requests 1 to 4, these claims had been delimited to specific lactic acid bacteria strains for which the opposed patent also provided experimental data showing that GHLOs infections in dogs had been successfully treated using them. No such data was provided in D1 or D2.
- Auxiliary requests 5 to 7 were even further restricted.
- XII. The appellant's arguments which are relevant for the present decision may be summarised as follows:
  - As to the alleged inventive step of claim 1 of the main request and auxiliary request 1, D1 already disclosed the treatment of GHLOs in mice which were suitable to be kept as pets. The only distinguishing feature was that claim 1 no longer referred to Lactobacillus acidophilus. The skilled person would turn to D2, which concerned the prophylaxis and treatment of gastritis in humans and animals. D2 taught that infections caused by Helicobacter species other than Helicobacter pylori could be treated with Lactobacillus johnsonii too.

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- As for auxiliary requests 2, 3 and 4, the "leap" from a mouse model to a human patient had already been made in D1. Mice were equally good model organisms for dogs and cats and the skilled person would expect the teaching of D1 to apply to dogs and cats too. At the oral proceedings, the appellant argued that it was obvious to try the treatment suggested in D2, with a reasonable expectation of success, all the more so because the administration of lactic acid bacteria was not considered to involve any risks for pets. In view of the amount of lactic acid bacteria disclosed in D1, the skilled person would be able to adapt the dosage for larger pets such as cats or dogs.
- Claim 1 of auxiliary requests 5 to 7 was unclear.

### Reasons for the Decision

- 1. Respondent's request for dismissal of the appeal
- 1.1 By letter dated 28 June 2017, the respondent stated as its highest-ranking request that the board "dismiss the appeal and [...] maintain the patent in suit on basis of the Main Request (MR, claims as maintained after opposition proceedings)". Annexed to this letter was a main request, the claims of which were allegedly identical to the claims which the opposition division had held allowable. However, the newly filed main request contained some minor (editorial) changes. Since, however, the respondent's overriding request was that the appeal be dismissed, the board continued on the basis of the main request which the opposition division had held allowable.

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- 1.2 The board notes that, apart from the minor (editorial) changes, the wording of claim 1 of these two versions of the main request is identical.
- 2. Main request inventive step of claim 1
- 2.1 The opposed patent relates to the prophylaxis or treatment of disorders related to infection by gastric <code>Helicobacter-like</code> organisms (GHLOs) in pets using specific strains of lactic acid bacteria (paragraph [0001]). The contamination of cats' and dogs' stomachs by <code>Helicobacter</code> species is considered to be an important risk factor leading to the development of gastritis (paragraph [0005]).
- 2.2 The parties agreed that D1 is the closest prior art for assessing whether the subject-matter of claim 1 involves an inventive step, and the board has no reason to differ. D1 relates to a study on the activity of the human Lactobacillus acidophilus strain LB, which secretes antibacterial substances against Helicobacter pylori in vitro and in vivo (abstract). One of the results presented in D1 is that the spent culture supernatant of the strain LB protects mice against Helicobacter felis infection (page 4573, right column, first full paragraph, last five lines). Helicobacter felis is a member of the Helicobacter species which the opposed patent defines as GHLOs (paragraphs [0003] and [0015]). The in vivo experiments in D1 were carried out with BALB/c mice infected with Helicobacter felis (page 4574, left column, last two lines).

### 2.3 Distinguishing features

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- 2.3.1 The parties agreed that D1 does not mention the specific micro-organisms required by claim 1.
- 2.3.2 The respondent considered that D1 did not relate to pets. In its view, the BALB/c mice did not qualify as pets, since they were albino, immunodeficient inbred strains, prone to cancer development and showing high levels of anxiety. Moreover, the mice had been intentionally infected with Helicobacter felis. Thus, D1 did not relate to the treatment or prevention of GHLOs in pets. The appellant contested the respondent's view, and argued extensively that the BALB/c mice qualified as pets.
- 2.3.3 It could be accepted in the respondent's favour that D1 does not disclose the treatment or prevention of GHLOs in pets (instead, D1 concerns humans and investigations were carried out with a mouse model), and this provides a further distinguishing feature over D1.
- 2.4 The objective technical problem
- 2.4.1 The board agrees with the respondent that the technical problem starting from D1 is the provision of a therapy for pets suffering from GHLOs infection. In view of the experimental evidence provided in the patent (e.g. examples 2 and 3), this technical problem can be considered to be solved.

In the statement setting out the grounds of appeal, the appellant argued that the technical problem of providing micro-organisms for the treatment of GHLOs was not credibly solved over the entire scope of the claims. However, this argument was not further pursued at the oral proceedings.

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2.4.2 Thus, the technical problem proposed by the respondent is considered to be the objective technical problem.

#### 2.5 Obviousness

- The opposition division acknowledged in the appealed 2.5.1 decision (Reasons for the decision, point 7.3.1) that the (intentional) oral infection of BALB/c mice with Helicobacter felis was an established animal model for studying the infection of human patients with Helicobacter pylori. The parties agreed (statement of grounds of appeal, page 6; respondent's letter dated 28 June 2017, page 9). In the same context, the opposition division also acknowledged that "mice in general are considered to be pets in the traditional sense". However, the opposition division then continued by reasoning that "the skilled person would not have expected that scientific findings obtained with artificially infected laboratory mice could (let alone would) automatically be applicable to naturally infected pets" (emphasis in the original).
- 2.5.2 The board does not agree. The authors of D1 have set up their experiments with the expectation that what is tested on the mouse model infected with Helicobacter felis will be effective in humans (unintentionally) infected with Helicobacter pylori. In other words, the authors of D1 were prepared to "make the leap" from mice to humans, while at the same time expecting results obtained with Helicobacter felis to be applicable to infections with Helicobacter pylori. The board is convinced that the least the skilled person would derive from the teaching of D1 is that the results obtained on an intentionally infected BALB/c laboratory mouse would equally apply to a pet mouse naturally infected with the same micro-organism. In

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this context, the board agrees with the appellant's argument that "all disease models, regardless of whether they are for human or other animals [...] are intended to apply on naturally occurring diseases" (statement of grounds of appeal, page 6). Thus, even accepting that D1 does not disclose the treatment or prevention of GHLOs in pets, it is a straightforward and obvious measure for the skilled person to treat pet mice naturally infected with GHLOs with the strain described in D1. The board cannot recognise any inventive contribution in this aspect.

- 2.5.3 Whether the skilled person would turn to D2 was a further contentious issue. D2 discloses that strains of lactic acid bacteria, such as strains of Lactobacillus acidophilus, "are capable of displacing pathogenic bacteria, such as Helicobacter (H.) pylori for example, from the intestinal cells to which they adhere" (column 1, lines 49 to 52). The strains are "intended for administration to human beings or animals for therapeutic or prophylactic treatment of the stomach and particularly for the treatment of gastritis or ulcers of the stomach or the pylorum" (column 1, lines 58 to 62). The strain discussed in D2 is Lactobacillus johnsonii CNCM I-1225, which belongs to a subgroup of Lactobacillus acidophilus (column 2, lines 3 to 14).
- 2.5.4 The respondent considered that, starting from D1, the skilled person would not turn to D2 because it envisaged treatment of infections with Helicobacter pylori. Although D2 referred to animals, it described experimental data obtained from specific human cells only, and no animal other than humans was exemplified.

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- 2.5.5 The board does not agree. D2 concerns the use of lactic acid bacteria strains "for displacing pathogenic bacteria such as Helicobacter pylori for example" (column 1, lines 51 to 52; emphasis added by the board). Thus, the teaching of D2 is not limited to Helicobacter pylori. On the contrary, it concerns pathogenic bacteria which are involved in the development of gastritis (column 1, line 61) or adhere to intestinal and gastric cells (column 1, lines 51 to 52, and column 2, lines 35 to 40). Moreover, in D2 the strain is "intended for administration to human beings or animals" (column 1, line 59; emphasis added by the board). This statement refers to two distinguished target groups: humans and animals. Thus, the respondent's argument that D2 relates only to humans is not convincing in view of the explicit disclosure of D2. Having regard to these aspects, it is evident that D2 describes the administration of Lactobacillus johnsonii to animals in need of a treatment against pathogenic bacteria of the type of Helicobacter pylori. The skilled person would understand that not only the explicitly mentioned Helicobacter pylori but also other bacteria from the GHLOs group are encompassed by the treatment of D2.
- Therefore, the skilled person who starts from D1 and who is faced with the task of solving the objective technical problem would find the solution in D2, which teaches administering the strain Lactobacillus johnsonii to animals in need of a treatment against GHLOs infection. In doing so, the skilled person would arrive at the subject-matter of claim 1. It follows from this that the subject-matter of claim 1 of the main request does not involve an inventive step (Article 56 EPC).

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### 3. Auxiliary request 1

The subject-matter of claim 1 of auxiliary request 1 differs from the subject-matter of claim 1 of the main request only in that the list of lactic acid bacteria strains has been restricted. However, claim 1 of auxiliary request 1 still includes the *Lactobacillus johnsonii* suggested in D2. Therefore, for the same reasons as for the main request, this request cannot be allowed for lack of inventive step (Article 56 EPC).

- 4. Auxiliary requests 2, 3 and 4
- 4.1 The subject-matter of claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the pets are restricted to cats or dogs and in that the dosage of lactic acid bacteria (or equivalent fermentation medium) is of  $10^9-10^{12}$  cfu/day for dogs and  $10^7-10^{11}$  cfu/day for cats.
- 4.2 Thus, a first aspect to consider is whether, in view of what has been decided with respect to the subjectmatter of claim 1 of the main request, it was obvious to select cats and dogs as the pets to be treated. The appellant argued that, in D1, the "leap" from the mouse model to the human patient had already been made. In view of this, the skilled person would expect the teaching of D1 to be applicable to animals such as dogs and cats. The board finds this argument convincing and is not aware of any valid reason, in the specific circumstances of the disclosure of D1, against this approach. Furthermore, the board considers that it was obvious to use Lactobacillus johnsonii, which D2 describes for use in animals, for treating GHLOs in

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cats and dogs. In this context, the appellant's argument that no risks are involved in using cultures of D2 on dogs and cats because lactic acid bacteria are regularly used in pet nutrition, for instance as probiotic micro-organisms, is valid. Thus, it was obvious to try the teaching of D2, with a reasonable expectation of success, on cats and dogs.

- The respondent argued that the opposed patent provided clear experimental data demonstrating that GHLOs infection in pets may be treated, and it insisted that, in example 2, dogs had been successfully treated. As explained above, in the light of the teaching of D1 in combination with D2, the board considers it obvious, with a reasonable expectation of success, to use Lactobacillus johnsonii for treating GHLOs infection in animals such as cats and dogs. The fact that, in the opposed patent, experimental confirmation is presented for subject-matter which in view of the prior art, D1 and D2, is obvious does not alter the board's assessment that the subject-matter of claim 1 does not involve an inventive step.
- 4.4 Finally, with regard to the amounts of lactic acid bacteria used, the board is not aware of any argument that these amounts are purposive or provide any particular effect. On the contrary, the board considers that the skilled person would arrive at the claimed dosage of lactic acid bacteria by routine experimentation. In this context, the board agrees with the appellant that D1 suggested administering to mice an amount of lactic acid bacteria corresponding to 5 x 108 cfu/day (page 4574, left column, lines 2 and 3, and right column, lines 8 to 10). Starting from these amounts, adjusting the dosage for the

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requirements of larger pets, such as dogs, would be a routine measure for the skilled person.

- 4.5 It follows from this that the subject-matter of claim 1 of auxiliary request 2 does not involve an inventive step under Article 56 EPC.
- A.6 The subject-matter of claim 1 of auxiliary requests 3 and 4 is identical. It differs from the subject-matter of claim 1 of auxiliary request 2 in that the alternative relating to cats and the corresponding amount of lactic acid bacteria have been deleted. However, in view of the fact that the subject-matter of claim 1 of auxiliary request 2 does not involve an inventive step, neither for cats nor for dogs, these two requests do not involve an inventive step either (Article 56 EPC).

### 5. Auxiliary requests 5, 6 and 7

In its communication, the board raised the issue that claim 1 of auxiliary requests 5 to 7 contained unclear wording ("Use of a lactic acid bacteria strain selected from the group consisting of for the preparation of a composition [...]"). The respondent did not amend these requests. The board considers it inappropriate to continue examination on the basis of these defective sets of claims, in particular in view of the fact that the respondent has been made aware of these deficiencies. Thus, auxiliary requests 5 to 7 are not allowable either (Article 84 EPC).

6. Admission of documents D18 and D19

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It is evident from what is stated above that D18 and D19 played no role in arriving at the present decision. Consequently, the board did not decide on the admission of these two documents.

### Order

### For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The patent is revoked.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated