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Datasheet for the decision of 10 July 2018

Case Number: T 2251/14 - 3.3.09

Application Number: 06846849.5

Publication Number: 1978821

IPC: A23K1/16, A23L1/29, A23L1/30, A23L1/302, A23L1/308

Language of the proceedings: EN

Title of invention:
METHOD FOR MODIFYING GUT FLORA IN ANIMALS

Patent Proprietor:
Hill's Pet Nutrition, Inc.

Opponent:
THE IAMS COMPANY

Headword:

Relevant legal provisions:
EPC Art. 54(5), 56, 100(b), 100(c), 114(2)
RPBA Art. 12(4)

Keyword:

Added subject-matter - no
Admittance of late-filed document - no
Sufficiency of disclosure - yes
Novelty - yes
Inventive step - yes

Decisions cited:

G 0005/83, G 0010/91, T 0254/93, T 0241/95, T 0836/01, T 0609/02, T 0466/05, T 0406/06, T 1549/07, T 0923/09, T 1685/10, T 0734/12

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 2251/14 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 10 July 2018

Appellant: (Opponent)	THE IAMS COMPANY 7250 Poe Avenue Dayton, Ohio 45414 (US)
Representative:	Schiweck, Weinzierl & Koch Patentanwälte Partnerschaft mbB Ganghoferstraße 68B 80339 München (DE)
Respondent: (Patent Proprietor)	Hill's Pet Nutrition, Inc. 400 Southwest 8th Avenue Topeka, KS 66603 (US)
Representative:	Daniels, Jeffrey Nicholas 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 30 September 2014 concerning maintenance of European patent No. 1978821 in amended form**

Composition of the Board:

Chairman	W. Sieber
Members:	N. Perakis
	O. Loïzou

Summary of Facts and Submissions

I. The present appeal lies from the interlocutory decision of the opposition division according to which European patent No. 1 978 821 as amended meets the requirements of the EPC.

II. In its notice of opposition the opponent had requested that the patent be revoked in its entirety on the basis of Article 100(a) (lack of novelty and lack of inventive step) and Article 100(b) EPC.

The documents cited in opposition included:

D2: WO 2005/032545 A1;

D3: Yukihiko Hara, "Green Tea: Health Benefits and Applications", Marcel Dekker Inc., 2001, 16 pages;

D5: WO 00/44375 A1;

D6: EP 0 965 344 A1, and

D11: A. Propst *et al.*,"Die Wirkung apathogener Clostridien auf bösartige Tumoren", *Zeitschrift für Krebsforschung*, 1966, vol. 68, p. 337 (filed after the time limit set in Article 99(1) EPC).

III. The opposition division held that claims 1 to 10 filed as main request during the oral proceedings on 8 July 2014 met the requirements of the EPC.

Claims 1-4 and 10 of this request read as follows:

"1. One or more antioxidants for use in enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of an animal having or at risk for inflammatory bowel disease (IBD)."

"2. The one or more antioxidants of Claim 1 wherein the enhancement comprises an increase in level of beneficial bacteria and a decrease in level of deleterious bacteria."

"3. The one or more antioxidants of Claim 1 or Claim 2 wherein the beneficial bacteria comprise one or more of Lactobacillus spp. and Bifidobacterium spp and/or the deleterious bacteria comprise one or more of Clostridium spp., Desulfovibrio spp., Helicobacter spp. and pathogenic forms of Escherichia coli."

"4. The one or more antioxidants of any preceding claim wherein the enhancement is associated with reduction of inflammation, and wherein preferably the reduction of inflammation is evidenced by a decrease in a pro-inflammatory biomarker and/or increase in an anti-inflammatory biomarker in a biofluid or tissue of the animal."

"10. Use of at least one antioxidant in preparation of a composition for enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of an animal having or at risk for IBD."

It might be worth mentioning at this juncture that apart from the synonymous wordings "one or more antioxidants" in claim 1 and "at least one antioxidant" in claim 10, both independent claims relate to the same second medical use: claim 1 formulated in accordance

with Article 54(5) EPC, claim 10 using the Swiss-type formulation.

IV. Notice of appeal was filed by the opponent (in the following: the appellant), which requested that the opposition division's interlocutory decision be set aside and that the patent be revoked in its entirety. With the statement setting out its grounds of appeal it re-submitted D11, which had not been admitted into the proceedings by the opposition division.

V. By letter of 19 June 2015 the patent proprietor (in the following: the respondent) filed observations on the appeal, including three auxiliary requests, and requested that the appeal be dismissed or that the patent be maintained in amended form in accordance with any one of auxiliary requests 1 to 3. It also requested that D11 not be admitted into the proceedings.

VI. By letter of 5 April 2018 the appellant further requested that auxiliary request 2 not be admitted into the proceedings.

VII. On 9 May 2018 the board issued a communication in preparation for the oral proceedings, expressing its preliminary non-binding opinion on the outstanding issues.

VIII. Oral proceedings were held before the board on 10 July 2018 as scheduled. During the oral proceedings the appellant withdrew its previous request that auxiliary request 2 not be admitted into the proceedings.

IX. The relevant arguments put forward by the appellant in its written submissions and during the oral proceedings may be summarised as follows:

- The subject-matter of dependent claims 3, 4 and 6 to 9 extended beyond the content of the application as filed. In particular, the subject-matter of claims 3 and 4 when depending on claim 1 was not disclosed in the application as filed.

- The patent in suit did not sufficiently disclose the following aspects of the claimed invention:
  - the technical effect of "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of an animal" over the entire scope of the claim;
  - how to classify "beneficial and deleterious bacteria";
  - how to determine "the balance of beneficial and deleterious bacteria"
  - the animal having or at risk for IBD;
  - the kind of antioxidants to be used;
  - the absence of evidence of a causal link between IBD and the enhancement of the balance of beneficial and deleterious bacteria;
  - the skilled person did not know whether he was operating within or outside the scope of the claim.

- The subject-matter of independent claims 1 and 10 of the main request lacked novelty in view of D2-D8, in particular D2, D5 and D6, which disclosed antioxidants used in the treatment of IBD. The technical effect of "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of animals having or at risk

for inflammatory bowel disease (IBD)" could not be considered a further therapeutic application, since it was merely the discovery of an underlying mechanism of the treatment of IBD.

- The subject-matter of independent claims 1 and 10 of the main request did not involve an inventive step in view of the obvious combination of D2, considered as the closest prior art, with D3. If at all, the subject-matter of these claims differed from D2 in terms of the technical effect of "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of animals having or at risk for inflammatory bowel disease (IBD)". However, the patent in suit did not contain any evidence showing any causal link between the enhancement of the balance of bacteria and IBD, with the consequence that the technical problem consisted in finding an additional property of the known antioxidant(s) used in the treatment of IBD. The solution to this problem was obvious in view of D3, which disclosed antioxidants having as an additional property the enhancement of the balance of beneficial/deleterious bacteria in the gastrointestinal tract of an animal.

X. The relevant arguments put forward by the respondent in its written submissions and during the oral proceedings may be summarised as follows:

- The subject-matter of claims 3, 4 and 6 to 9 did not extend beyond the content of the application as field. The subject-matter of claim 3 derived from the combination of claims 3 and 4 as filed with the disclosure of paragraphs [0019] to [0021] of the application as filed. The subject-matter of claim 4

derived from the combination of claim 5 as filed with the disclosure of paragraph [0036] of the application as filed.

- The skilled person, on the basis of the patent in suit and his common general knowledge, was able to carry out the claimed invention without undue burden. The experimental part of the patent made it plausible that the technical effect of "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of animals having or at risk for inflammatory bowel disease (IBD)" was obtained across the scope of the claimed invention and that this effect had an influence on IBD (the causal link referred to by the appellant). More importantly, the appellant had not submitted any evidence to prove the contrary. With regard to the objection to the scope of the claim and as to whether the skilled person could tell if he was working within or outside this scope, this issue concerned clarity, which was not a ground for opposition.

- The subject-matter of independent claims 1 and 10 was novel in particular over D2, D5 and D6 on the basis of the new technical effect of "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of animals having or at risk for inflammatory bowel disease (IBD)", which identified a new clinical situation (an indirect therapeutic effect versus the direct therapeutic effect of the prior art) and thus defined a new further medical indication.

- The subject-matter of independent claims 1 and 10 was inventive over the prior art. D2 could

reasonably be considered to represent the closest prior art. The new technical effect of enhancing the balance of beneficial/deleterious bacteria was the differentiating feature which identified a new clinical situation. The patent in suit provided the required evidence which made a causal link between the new technical effect and IBD plausible. Thus the technical problem consisted in the provision of a further treatment for IBD patients. The solution proposed by the claimed subject-matter was not obvious without the benefit of hindsight. Contrary to the appellant's assertions, the skilled person would not have consulted D3, since it did not relate to IBD and did not contain any hint towards its combination with D2.

XI. The appellant (opponent) requested that the decision under appeal be set aside and that European patent No. 1 978 821 be revoked in its entirety.

XII. The respondent (patent proprietor) requested that the appeal be dismissed, or alternatively that the patent be maintained in amended form on the basis of the set of claims of one of auxiliary requests 1 to 3 as filed by letter of 19 June 2015.

Reasons for the Decision

1. **Added subject-matter** - Article 100(c) EPC

1.1 The main request

The amendments made to the claims as granted so as to arrive at the main request consist only of the deletion of claims 11 to 15. Claims 1 to 10 of the main request

are the same as claims 1 to 10 of the patent as granted.

1.2 During the oral proceedings before the opposition division the appellant argued for the first time that the subject-matter of dependent claims 3 and 4 extended beyond the content of the application as filed (minutes, point 5; decision, point 2.2). As these objections concerned granted claims, their legal basis was Article 100(c) EPC (and not Article 123(2) EPC as held by the opposition division).

This fresh ground for opposition had implicitly been admitted into the opposition proceedings, since the opposition division had dealt with the objections in its decision (points 2.1 to 2.4).

1.3 In the appeal proceedings the appellant reiterated that the subject-matter of dependent claims 3 and 4 extended beyond the content of the application as filed. Additionally, it raised a similar objection against the subject-matter of dependent claims 6 to 9.

1.4 As set out above, the ground for opposition under Article 100(c) had been implicitly admitted into the proceedings by the opposition division and is thus not a fresh ground for opposition introduced into the appeal within the meaning of G 10/91 as argued by the respondent. Thus the respondent's approval for considering this ground for opposition in appeal is not required (e.g. T 1549/07, Reasons 2.2 and 2.3).

1.5 However, with respect to the objections raised against the subject-matter of dependent claims 6 to 9, which had not been raised before the opposition division, the board had noted in its preliminary opinion that these

objections appeared not to be admissible under Article 12(4) RPBA. No further explanation or justification for the late filing of these objections was provided by the appellant, and therefore the board saw no reason to deviate from its preliminary opinion and not admit them into the proceedings (Article 12(4) RPBA).

1.6 As regards the subject-matter of dependent claims 3 and 4, the board considers that it does not extend beyond the content of the application as filed:

1.6.1 **Claim 3** (see point III above) lists specific beneficial and deleterious bacteria and is dependent on claim 1 or claim 2.

When depending on claim 2, the specific beneficial and deleterious bacteria are presented in relation to the specific way of enhancing the balance of beneficial and deleterious bacteria of claim 2. This subject-matter is disclosed in the combination of claims 3 (beneficial bacteria) and 4 (deleterious bacteria) as filed. Both claims 3 and 4 as filed refer to claim 2 as filed, which is identical to claim 2 as granted.

When depending on claim 1, i.e. without specifying how the enhancement of the balance of beneficial and deleterious bacteria is obtained, its subject-matter directly and unambiguously derives from the combination of claim 1 as filed with general statements from the description as filed. Reference is made to paragraph [0022]:

""Enhancing" or "enhancement" of the balance herein means shifting the balance in favor of beneficial bacteria, and thus can involve an increase in

*beneficial **and/or** a decrease in deleterious bacteria"* [highlighting added by the board],

which in view of the terms "and/or" concerns all alternatives of enhancing the balance of beneficial and deleterious bacteria;

to page 4, lines 3-9:

"... for the purpose of the present invention certain types or species of bacteria can be considered beneficial and others deleterious. Examples of beneficial members of the gut flora include bifidobacteria (species of the genus Bifidobacterium) and lactic acid bacteria, more particularly species of the genus Lactobacillus. Deleterious bacteria include pathogenic bacteria. Examples of deleterious members of the gut flora include Clostridium spp., Desulfovibrio spp. (including without limitation D. desulfuricans, D. intestinalis and D. vulgaris), Helicobacter spp. (incuding without limitation H. bizzozeronii , H. felis, H. heilmannii, H. pylori and H. salomonis) and pathogenic forms of Escherichia coli",

which discloses the types or species of the beneficial and deleterious bacteria involved;

and to page 4, lines 11-15:

"An increase in the **population of deleterious bacteria** and/or a decrease in the **population of beneficial bacteria** can be associated with a decline in gastrointestinal health. Conversely, an increase in the **population of beneficial bacteria** and/or a decrease in **the population of deleterious bacteria** can be

associated with an improvement in gastrointestinal health ..." [highlighting added by the board],

which discloses that the balance of beneficial and deleterious bacteria concerns one or more bacteria of each category.

Thus, the subject-matter of claim 3 of the main request when depending on claim 1 is directly and unambiguously disclosed in the application as filed.

1.6.2 **Claim 4** is dependent on any preceding claim. When depending on claim 1, it corresponds to claims 5 and 6 as filed. When depending on claims 2 and 3, its subject-matter directly and unambiguously derives from the application as filed (page 8, lines 5-6 and 8-11), which discloses in general terms that the enhancement of gut flora balance is associated with the reduction of inflammation and that the reduction of inflammation is evidenced by a decrease in a pro-inflammatory biomarker and/or an increase in an anti-inflammatory biomarker in a bio-fluid or tissue of the animal. This disclosure obviously concerns any type of balance, including that of claim 2, and any type of bacteria, including those of claim 3.

It is thus concluded that the subject-matter of claim 4 of the main request when depending on claims 2 and 3 is directly and unambiguously disclosed in the application as filed.

2. Admittance of D11

The opposition division did not admit the late-filed document D11 into the proceedings because it was irrelevant to inflammatory bowel disease (IBD).

The appellant simply re-submitted this document with the statement setting out its grounds of appeal, but did not provide any reasons as to why the opposition division had incorrectly exercised its discretionary power under Article 114(2) EPC. Thus the board saw no reason to reverse the opposition division's decision, and did not admit this document into the appeal proceedings (Article 12(4) RPBA).

3. **Sufficiency of disclosure** - Article 100(b) EPC

3.1 According to the appellant the invention as defined in claims 1 and 10 of the main request was insufficiently disclosed for various reasons:

(a) the effect of "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of an animal" was not plausibly obtained over the entire scope of claim 1;

(b) the patent did not disclose how to actually classify "beneficial and deleterious bacteria";

(c) it was not disclosed how the balance of beneficial and deleterious bacteria might be determined;

(d) the patent did not properly define "an animal having or at risk for inflammatory bowel disease (IBD)";

(e) the patent did not disclose what kind of antioxidants was to be used;

(f) there was no evidence of a causal link between IBD and enhancement of the balance/imbalance of

beneficial and deleterious bacteria in the gastrointestinal tract of an animal having or at risk for IBD;

(g) the skilled person did not know whether he was operating within or outside the scope of the claims.

3.2 With regard to (a), the technical evidence in the patent in suit, in particular example 2, shows that the claimed effect was indeed obtained, admittedly for a specific mixture of antioxidants (tocopherol, vitamin C and β-carotene), four species of bacteria (Clostridia, E.coli, lactic acid bacteria, bifidobacteria) and one type of animal (cats). However, in the absence of any evidence to the contrary, it appears to be plausible that the invention as claimed would work with other antioxidants, other populations of beneficial/ deleterious bacteria and other animals.

The appellant asserted that the examples of the patent themselves provided evidence for serious doubts that the invention was not sufficiently disclosed.

The board cannot accept the appellant's argument. Example 1 (table 2) shows that cats diagnosed with IBD after having been fed with a pet food enriched with antioxidants attained after two weeks a level of the antioxidant biomarker GSH which was the same as the level measured in healthy cats used as a control. Thus example 1 confirms that the curing/treating of IBD has been achieved. Furthermore, example 2 (table 4, "test" food) shows that the administration of an antioxidant-enriched food to animals with IBD enhances the balance of beneficial and deleterious bacteria in the gut flora.

In view of the technical evidence of the patent in suit, and in the absence of any evidence to the contrary, it appears to be plausible that the antioxidants fed to animals shift the balance of beneficial/deleterious bacteria in their gastrointestinal tract and that by doing so they have an impact on the treatment of IBD.

3.3 With regard to (b), the patent in suit in paragraph [0019] lists examples of beneficial and deleterious bacteria. Certainly this list is not exhaustive. However, the skilled person would know as part of his common general knowledge which bacteria of the gastrointestinal tract are beneficial and which are deleterious. Thus this argument of the appellant must also fail.

3.4 With regard to aspect (c), the patent in suit discloses in paragraph [0022] methods for determining the balance of beneficial and deleterious bacteria:

"Bacterial populations in the gut flora can be estimated by any procedure known in the art. For example, stool samples can be cultured using traditional plating methodologies, or illustratively by the fluorescence in situ hydridization (FISH) technique".

Thus, the board cannot identify any insufficiency in this context.

3.5 With regard to (d), the patent in suit provides clear definitions of what is meant by animals having IBD or animals at risk for IBD. Thus, paragraph [0023] states:

"An animal having IBD is an animal in which any one of a spectrum of inflammatory, gastrointestinal diseases and disorders recognized as a form of IBD has been, professionally diagnosed or an animal exhibiting symptoms consistent with such diagnosis. Such diseases and disorders include without limitation irritable bowel syndrome (IBS), ulcerative colitis and Crohn's disease. An animal having chronic IBD but in remission at the time of application of the method is considered herein to be an animal "having IBD". An animal at risk for IBD is an animal not having a history of IBD or exhibiting IBD symptoms but having one or more risk factors indicating a susceptibility to development of IBD. Such risk factors can include genetic factors (e.g., a family history of IBD) and physiological factors (e.g., elevated levels of one or more pro-inflammatory biomarkers and/or depressed levels of one or more anti-inflammatory biomarkers)".

In view of the above, the target animal population consists of animals in a pathological status or animals susceptible to fall into a pathological status but not healthy animals. Thus this argument of the appellant must also fail.

The appellant objected that paragraph [0023] indicated that IBS was a form of IBD, whilst the skilled person would consider that IBS was a distinct medical condition from IBD. The board agrees with the respondent that the reference to IBD in claim 1 would be interpreted by the skilled person as encompassing IBD (including ulcerative colitis and Crohn's disease) and IBS in the light of the definition provided in paragraph [0023]. However, it appears that this issue relates to the clarity of the claims rather than to sufficiency of disclosure.

3.6 With regard to aspect (e), the patent in suit in paragraphs [0026] lists a number of possible antioxidants. Paragraph [0027] further mentions that in some embodiments the composition to be administered comprises one or more of vitamin E, vitamin C and a carotenoid. The board fails to see why this information is not enough to select suitable antioxidants.

3.7 With regard to aspect (f), the patent in suit provides a causal link between the technical effect of enhancing the balance of beneficial and deleterious bacteria and the disease IBD. Paragraph [0036] states:

"In some embodiments of the invention, the enhancement of gut flora balance attributable to practice of the method is associated with reduction of inflammation, more particularly reduction of gastrointestinal inflammation, such as inflammation of the colonic mucosa".

Furthermore, the experimental part of the patent in suit shows that antioxidant-enriched foods enhance the balance of beneficial and deleterious bacteria in cats' gut flora (example 2, table 4) and reduce IBD inflammation (example 1, tables 2 and 3). On the basis of these examples and in the absence of any counter-evidence filed by the appellant, it is plausible to conclude that the antioxidants enhance the balance of beneficial and deleterious bacteria and that by doing so they reduce IBD inflammation.

Thus, the patent in suit plausibly demonstrates that the technical effect directly and unambiguously reflects a therapeutic application (T 609/02, Reasons

9; T 923/09, Reasons 3 to 7; T 1685/10, Reasons 3; T 734/12, Reasons 18).

3.8 Lastly, with regard to aspect (g), the case law of the boards of appeal of the EPO finds that addressing the question as to the scope of protection conferred by the claims is an issue of clarity rather than of sufficiency of disclosure. With regard to sufficiency of disclosure the relevant question is whether the patent in suit provides sufficient information to enable the skilled person, when taking into account common general knowledge, to reproduce the invention without undue burden (T 466/05, Reasons 4.5 to 4.7). Furthermore, the appellant has not shown that this uncertainty leads to insufficient disclosure. Thus this argument too must fail.

3.9 In view of the foregoing, the board concludes that the patent in suit discloses the invention underlying the claims of the main request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

4. Novelty

4.1 The appellant acknowledged that independent claims 1 and 10 of the main request were directed to a second/ further medical application for known antioxidants. However, it contended that the feature "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract" was merely the observation of an effect when using a known compound (an antioxidant) for treating IBD, which was a known application for such compounds. Therefore the subject-matter of claims 1 and 10 lacked novelty in view of D2-D8. During

the oral proceedings, the appellant relied only on D2, D5 and D6.

4.1.1 D2 discloses the administration of a therapeutic dosage of a gamma-homologue of vitamin E, which is well known to be an antioxidant, to a patient having IBD (claim 1). It also discloses that the antioxidant reduces the expression of endothelial cell adhesion molecules in the vasculature of the bowel wall (claim 1, page 3, lines 9-11; figure 1).

4.1.2 D5 discloses dog or cat foodstuff comprising vitamin E, vitamin C or a combination thereof for use in the prevention or treatment of any disorder which has a stress component (claims 14, 26). Furthermore, it provides a list of possible disorders including IBD (claims 15 and 27). However, the reference to the treatment of IBD appears rather speculative and is not supported by any data providing evidence that the compositions do in fact treat IBD. Furthermore, D5 is entirely concerned with oxidative stress, the antioxidant status of the animal and the avoidance of oxidative damage (page 1, lines 3-21, and page 2, lines 24-30).

4.1.3 D6 discloses a preventive and curative agent for IBD having as an active ingredient thereof a specific chromanol glucoside (claims 1-3). It states that this agent possesses "a tine anti-oxidising action" such as to bring effective repression and control of a free radical reaction possibly occurring on the intestinal mucous membrane at the site of an IBD (paragraph [0008]). Paragraph [0011] further discloses that the chromanol glucoside represses development of cell adhesion molecules.

4.2 As shown above D2, D5 and D6 disclose the use of at least one known antioxidant for the treatment of IBD. It was undisputed that they do not disclose the specific technical effect of "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of an animal having or at risk for inflammatory bowel disease (IBD)". The same applies to the other documents cited by the appellant in the written procedure as being novelty-destroying for the claimed subject-matter.

Thus, the decisive question in the present case is whether the new technical effect of "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of an animal having or at risk for inflammatory bowel disease (IBD)" defines **a new second/further medical use** in accordance with Article 54(5) EPC and G 5/83, respectively.

4.3 The relevant decision in this context is T 836/01 (Reasons 8), where it is held that a new technical effect alone is not sufficient to establish novelty for a second/further medical use of a known substance. Such a claim can only be considered novel if the new technical effect leads to a truly new industrial/ commercial application arising from e.g. the opening of a new field of application, the healing of a different pathology/clinical situation or the creation of a distinct group or sub-group of subjects, or if the new use has to involve new physical means/measures for its practice. The same approach was taken in T 406/06 (Reasons 12.3).

4.4 Turning to the present case and applying the principles developed in T 836/01 and T 406/06, the conclusion cannot be that the technical effect cited in claims 1

and 10 is merely the observation of an effect occurring when using a known compound (an antioxidant) for treating IBD or a mere explanation of how an antioxidant treats IBD.

4.4.1 As pointed out by the respondent, D2 discloses a **direct** therapeutic effect of the antioxidants as to the reduction of the expression of endothelial cell adhesion molecules in the vasculature of the bowel wall. This is in contrast to the therapeutic effect relied upon in claims 1 and 10, namely the **indirect** influence of antioxidants on the bowel wall via the enhancement of the balance of beneficial/deleterious bacteria.

4.4.2 D5 discloses the effect of reducing oxidative stress in companion animals by controlling free radical production (again a **direct** therapeutic effect), which is different from the **indirect** therapeutic effect recited in claims 1 and 10 of the main request.

4.4.3 Similar considerations apply to the therapeutic effects referred to in D6, namely the repression and control of a free radical reaction possibly occurring on the intestinal mucous membrane at the site of an IBD and the suppressed development of cell adhesion molecules.

4.4.4 In summary, the claimed new technical (therapeutic) effect identifies **a new clinical situation**, namely one where it is possible to target the gastrointestinal flora of an animal having or at risk for IBD. On the basis of this new clinical situation the technical (therapeutic) effect referred to in claims 1 and 10 defines a further medical application which is different from that of D2, D5 and D6 (or of any other

document cited by the appellant in the written procedure).

4.5 The appellant has referred to T 254/93 and T 241/95.

In T 254/93 the board decided that the prevention of corticosteroid-induced skin atrophy by a retinoid, although based on a pharmaceutical effect which was not known to be due to the retinoid, could not confer novelty, since the skilled person was already aware of the occurrence of the desired effect (prevention of corticosteroid-induced skin atrophy) when applying the known process. It merely provided the explanation of the phenomenon underlying the treatment with a preparation described in the prior art (Reasons 4.4 to 4.9).

In T 241/95 the board decided that the selective occupation of the 5-HT_{IC} receptor by (R)-fluoxetine, although indisputably being a pharmacological effect, could not in itself be considered a therapeutic application, since it still needed to find a practical application in the form of a defined, real treatment of a pathological condition in order to make a technical contribution to the art (Reasons 3.1.2).

These decisions do not support the appellant's case. In fact, the conclusion reached by the board in the present case is in conformity with these decisions, since the new technical (therapeutic) effect, unlike the situations in the two decisions, identifies a new clinical situation and thus makes a technical contribution to the art.

4.6 In view of the above, the board acknowledges the novelty of the subject-matter of claims 1 and 10 of the

main request vis-a-vis D2, D5 and D6 (and the other documents cited by the appellant in the written procedure).

5. Inventive step

5.1 Closest prior art

D2, which discloses compositions comprising antioxidants for treating inflammatory bowel disease, is considered by the parties to represent the closest prior art. The board has no reason to disagree.

As already set out, the subject-matter of independent claims 1 and 10 differs from the disclosure of D2 as regards the new technical effect/feature of "enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of an animal having or at risk for inflammatory bowel disease (IBD)".

5.2 Technical problem

5.2.1 The technical problem underlying the invention of independent claims 1 and 10 in the light of D2 is the provision of a further therapeutic application for the treatment of an animal having or at risk for IBD.

The board does not agree with the appellant's definition of the problem, namely the finding of an additional property of an antioxidant for the treatment of IBD, because it contains part of the solution, namely the use of antioxidants. Furthermore, this problem does not take into account the whole issue with regard to the new clinical situation.

5.2.2 Contrary to the appellant's assertions, the experimental part of the patent makes it plausible that the set technical problem has indeed been solved by using one or more antioxidants (claim 1) or at least one antioxidant (claim 10) in enhancing the balance of beneficial and deleterious bacteria in the gastrointestinal tract of such patients (see points 3.2 and 3.8 above).

5.3 Obviousness

The skilled person starting from D2 and aiming at a further therapeutic application for the treatment of an animal having or at risk for IBD would not find any motivation in the prior art to use for such an animal one or more antioxidants in enhancing the balance of beneficial and deleterious bacteria in its gastrointestinal tract.

D2 itself provides no hint or suggestion in that direction. On the contrary, as pointed out previously, it discloses that the antioxidant reduces the expression of endothelial cell adhesion molecules.

As regards D3, referred to by the appellant, this document discloses that the administration of tea polyphenols (green tea catechins and black tea polyphenols, both being antioxidants) to humans alters the balance of bacteria in the gut (I. Introduction; page 7, lines 20-24). D3 neither discloses nor suggests that the human has or is at risk for IBD as required by claims 1 and 10. On the contrary, it discloses that "none of the subjects had conditions related to the gastrointestinal tracts or endocrine organs" (page 7, lines 4-6) and teaches away from use of the tea

polyphenols in the diet of animals having or at risk for IBD.

Thus, it appears that the combination of D2 with D3 is based on hindsight with the knowledge of the invention in mind.

5.4 In view of the above, the subject-matter of independent claims 1 and 10 of the main request involves an inventive step.

6. Dependent claims 2-9

The above considerations apply *a fortiori* to dependent claims 2-9 of the main request, which directly or indirectly relate to claim 1 and correspond to specific embodiments of it. Thus they are patentable too.

7. Adapted description

The description of the patent in suit was adapted during the oral proceedings held before the opposition division on 8 July 2014. The appellant raised no objections.

8. As the main request is patentable, assessment of the patentability of the auxiliary requests is redundant.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated