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Datasheet for the decision of 4 February 2021

Case Number: T 0816/16 - 3.3.01

Application Number: 10171504.3

Publication Number: 2289505

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A61K31/715, A23L1/30, A61P1/14

Language of the proceedings: EN

Title of invention:

Nutritional composition and food supplement containing such a nutritional composition.

Patent Proprietor:

Alpiflor S.R.L.

Opponent:

Société des Produits Nestlé S.A.

Headword:

Nutritional composition/ALPIFLOR

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - main request (no)
Inventive step - auxiliary request 13 (no)



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 0816/16 - 3.3.01

DECISION
of Technical Board of Appeal 3.3.01
of 4 February 2021

Appellant: Société des Produits Nestlé S.A.

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on 25 February 2016 concerning maintenance of the European Patent No. 2289505 in amended form

Composition of the Board:

M. Blasi

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Summary of Facts and Submissions

I. European patent No. 2289505 is based on European patent application No. 10171504.3.

It was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and an inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

II. In the opposition proceedings, the patent proprietor requested the rejection of the opposition and submitted auxiliary requests 1 to 17, all filed on 26 October 2015. During the oral proceedings, the proprietor withdrew its main request (patent as granted) and replaced it with the then auxiliary request 1 (main request filed during oral proceedings on 26 November 2015).

Claim 1 of the main request reads:

- "1. A nutritional composition comprising any non-zero amount of:
- at least one probiotic, and
- at least one prebiotic,

furthermore comprising any non-zero amount of butyric acid or of a salt thereof

characterised in that said at least one probiotic, said at least one prebiotic and the butyric acid or said salt thereof are present in the following amounts

- from 0.5×10^9 to 2.5×10^9 CFU of probiotic;
- from 50 to 150 mg of prebiotic;

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- from 150 to 350 mg of butyric acid or of said salt thereof."

Claim 1 of auxiliary request 13 reads:

- "1. A food supplement of the pill or tablet type, comprising a core composed of a composition comprising any non-zero amount of:
- at least one probiotic,
- at least one prebiotic, and
- any non-zero amount of butyric acid or of a salt thereof

said at least one probiotic, said at least one prebiotic and the butyric acid or said salt thereof being present in the following amounts

- from 0.5×10^9 to 2.5×10^9 CFU of probiotic;
- from 50 to 150 mg of prebiotic;
- from 150 to 350 mg of butyric acid or of said salt thereof

furthermore comprising one or more gastro-resistant coatings around said core, the compounds used to make said one or more gastro-resistant coatings being selected such that they only dissolve in the presence of a pH greater than 6.5, characterised in that it furthermore comprises at least one stabilising additive which permits controlled dissolution of said food supplement and controlled release of said nutritional composition."

The opposition division found that the main request, filed during oral proceedings on 26 November 2015, fulfilled the requirements of Rule 80 and Articles 123(2) and (3), 83, 84, 54 and 56 EPC.

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III. The opponent filed an appeal against the decision of the opposition division.

Together with the reply to the statement setting out the grounds of appeal, the patent proprietor (respondent) re-submitted auxiliary requests 2 to 17.

- IV. The board issued a communication pursuant to Article 15(1) RPBA, identifying crucial issues in the discussion of inventive step.
- V. The following documents, cited during the opposition and appeal proceedings, are referred to below:
 - (6) EP904784 A1
 - (7) Losada et al., Nutr. Res., 2002, 22, 71-84
 - (8) Scarpellini et al., Dig. Liver Dis. Suppl. 1 (translation), 2007, 19-22
 - (10) Chourasia et al., J. Pharm. Pharmaceut. Sci, 2003, 6(1), 33-66
 - (28) Bundle of documents relating to FeedColon, submitted 24 February 2020, 25 pages in total
 - (29) "Protocollo studio FeedColon", submitted
 24 February 2020, 24 pages
 - (30) D.R. Strobel et al., "FLAVOR OF MILK A Review of Literature", Waschington, D.C. 1953, Library College of Agriculture University of Wisconsin, pages i to iii and 56 to 62

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(31) DE10244359

- VI. Oral proceedings before the board took place on 4 February 2021.
- VII. The arguments of the appellant (opponent), insofar as they are relevant for the present decision, may be summarised as follows.

Admission of documents (28), (29), (30) and (31)

Documents (28), (29), (30) and (31) were late filed and not prima facie relevant. Document (28) had no publication date. Furthermore, its data were flawed and should not be taken into account due to the lack of data in the patent in suit. Document (29) was irrelevant as it did not relate to a comparison with the closest prior art. Document (30) could not provide any information for nutritional compositions since it dealt merely with butyric acid in milk. Document (31) related to animal feeds and thus also had no relevance for a nutritional composition. Consequently, these documents should not be admitted into the proceedings.

Inventive step

Document (7) could be considered as the closest prior art. It discussed the benefits of combining probiotics with prebiotics and related to the same intestinal conditions as the patent in suit. The difference between the subject-matter of claim 1 of the main request and document (7) was the addition of butyric acid or its salt. The data of the patent in suit showed no technical effect for this difference. Document (28) could not show any such effect either. It was deficient

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in not providing information on the amounts of prebiotics and probiotics of the Symbiotix capsules. Furthermore, it was not known whether these capsules were gastro-resistant. Document (28) did not contain any data for the administration of butyric acid alone.

The technical problem was thus the provision of an alternative nutritional composition for treating intestinal disorders.

Alternatively, the technical problem could also be seen as the provision of a mere alternative nutritional composition since claim 1 of the main request did not necessarily provide a therapeutically effective amount of its ingredients.

The solution would have been obvious. Document (8), which was in the same technical field, taught the addition of butyric acid. The amounts of the ingredients were arbitrary in the absence of any indication as to the type of product. Furthermore, document (6) suggested the use of amounts that were within the claimed ranges. The known unpleasant smell and taste of butyric acid would not have deterred the skilled person from its use in the medical context. The coating suggested in document (8) would mask the smell and taste to a great degree.

The additional technical features of claim 1 of auxiliary 13 could not lead to an inventive step. These features would have been obvious to the skilled person when providing a medicament for delivering actives to the intestine, especially the colon. This was reflected in the mention of enteric-coated tablets of butyric acid in document (8). The skilled person would have got further instruction on galenic forms for the colon from

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document (10), which summarised the common general knowledge pertaining to protective coatings, certain stabilising additives and pH requirements.

VIII. The arguments of the respondent, insofar as they are relevant for the present decision, may be summarised as follows.

Admission of documents (28), (29), (30) and (31)

The filing of document (28) had to be seen as the mere provision of documents that had been filed during the examination proceedings, referred to in the decision under appeal and discussed in the grounds of appeal.

Document (29) was filed to show the context of the invention. Document (30) confirmed the common general knowledge on butyric acid. Document (31) had been cited several times by both parties and should therefore be admitted into the proceedings.

Inventive step

Other documents on file were closer to the subjectmatter of claim 1 of the main request than document (7)
and therefore represented the closest prior art.
However, the following arguments were relevant in view
of document (7). While document (7) disclosed the
positive effects of probiotics, prebiotics and a
combination of them on the gastro-intestinal tract, it
could not have lead the skilled person towards the
synergistic effect achieved by the addition of butyric
acid or a salt thereof. The subject-matter of claim 1
of the main request differed from the disclosure of
document (7) in the exact amounts of ingredients and in
the addition of butyric acid or a salt thereof. It
could be seen from document (28) that the addition of

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butyric acid led to a synergistic effect. The technical problem was thus the provision of an improved nutritional composition for providing benefits to the intestine. None of the documents on file would have led the skilled person to add butyric acid. On the one hand, document (7) mentioned that butyric acid was obtained by metabolising prebiotics and was thus present in the intestine. On the other hand, the skilled person would have been aware from document (31) that the administration of free butyric acid had no beneficial effect. Furthermore, there were several issues with butyric acid. Apart from its bad smell and taste, it had to be administered in a galenic form that involved a complex manufacturing process. In addition, the skilled person would not have considered document (8) since it provided merely a hypothesis, by using the term "may", and gave no evidence on any effect of butyric acid on its own. In addition, document (7), and also document (6), suggested alternative solutions for improving benefits to the intestine. One such solution was the careful selection of the probiotic strains.

The subject-matter of claim 1 of auxiliary request 13 was even farther removed from the teaching of document (7). Claim 1 of auxiliary request 13 was directed to a food supplement having gastro-resistant coatings and a means leading to controlled dissolution and release. It thus provided for the release of the right concentration of the actives in the right parts of the human body. Such a delivery was due to the totality of the technical features of claim 1 of auxiliary request 13. The combination of these features would not have been obvious to the skilled person. Furthermore, as document (7) showed that its combination of probiotics and prebiotics was inherently

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gastro resistant, the skilled person would not have come to a solution that would have appeared to have more drawbacks than advantages.

- IX. The parties' final requests were as follows.
 - The appellant requested that the decision under appeal be set aside and the patent be revoked.
 - The respondent requested that the appeal be dismissed and the patent be maintained in the form of the main request. Alternatively, it was requested that the patent be maintained on the basis of auxiliary request 13, filed together with the reply to the statement of grounds of appeal.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Admission of documents
- 2.1 Documents (28) and (31)

Document (28) is a bundle of brochures and data relating to FEEDColon. The brochures and data making up document (28) were first filed in examination proceedings, have been referred to in the decision under appeal and have been discussed by the appellant in its statement setting out the grounds of appeal. Document (28) had been submitted in response to the board's communication pursuant to Article 15(1) RPBA pointing to the fact that these brochures and data had not been formally submitted during the opposition proceedings nor at the appeal stage. Therefore, the

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filing of document (28) must be seen as the mere provision of the documentary evidence for facts that already formed part of the opposition and appeal proceedings. It added no further complexity to the case.

Consequently, the board decided to admit document (28) into the appeal proceedings in accordance with Article 13(2) RPBA 2007, applicable pursuant to Article 25(3) RPBA 2020.

Document (31) had been submitted together with the reply to the statement setting out the grounds of appeal. Its filing represents a reaction to arguments brought forward in the grounds of appeal. The fact that it relates to animal feeds does not automatically make it irrelevant in the context of nutritional compositions. Consequently, document (31) was admitted into the proceedings in accordance with Article 12(4) RPBA 2007, applicable pursuant to Article 25(2) RPBA 2020.

2.2 Documents (29) and (30)

Document (29) had been filed only after summons to oral proceedings had been issued by the board. It relates to experimental data unrelated to the subject-matter under consideration, i.e. data concerning a comparison of FEEDColon and an active called mesalazine. It was thus not prima facie relevant and could not serve to overcome any issues related to the claimed subject-matter. Consequently, the board decided no to admit it into the proceedings in accordance with Article 13(2) RPBA 2007.

Document (30) had been filed by the respondent in reply

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to the appellant's challenging of the common general knowledge and added no further complexity to the proceedings. The board therefore admitted document (30) into the proceedings under Article 13(2) RPBA 2007.

- 3. Inventive step main request
- 3.1 The patent in suit relates to a nutritional composition or a food supplement containing this composition capable of providing benefits to the intestine and aid for alleviating intestinal disorders (paragraphs [0001] and [0002]). The patent in suit is based on the finding that the addition of butyric acid, or a salt thereof, increases the beneficial action of probiotics, reduces the growth of pathogenic bacteria and has positive effects for the intestinal mucosa. The nutritional composition comprising probiotics, prebiotics and butyric acid, or a salt thereof, thus effectively contributes to the treatment of intestinal disorders (paragraphs [0026] to [0031]).

When the nutritional composition is in the form of a food supplement, it may be coated to pass intact through the gastric tract and allow for release in the intestine. Addition of stabilising additives which delay the dissolution of the food supplement and extend the release of the nutritional composition ensure the release of the actives along the whole length of the colon (paragraphs [0044] and [0050]).

3.2 Document (7) deals with the influence of fructooligosaccharides, which are prebiotics, and lactobacilli, which are probiotics, on intestinal health, especially of the colon (title). A synergistic and symbiotic effect between prebiotics and probiotics is considered to be of considerable importance for

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intestinal health (page 72, second paragraph). Several abnormal conditions are identified in which probiotics, especially Lactobacillus sporogenes, are beneficial (Table 3). Prebiotics promote the number of probiotic bacteria, bifidobacteria and lactobacilli being mentioned, by providing short-chain fatty acids and lactic acid as a result of their fermentation. This leads to a drop in the pH of the large intestine, thus promoting the development of the bifidogenic flora and limiting at the same time the development of bacteria considered to be pathogens (page 80, paragraph 5 and last paragraph). Prebiotics, especially in the form of FOS (fructooligosaccharides) have a high bifidogenic capacity and constitute an important source of butyric acid, which is an essential nutrient of the colonocyte (page 83, paragraph 3). Finally, document (7) states that symbiotics, i.e. the association of probiotics and prebiotics, are a promising and safe tool against different intestinal and metabolic disorders (page 83, last paragraph).

Thus, document (7) teaches to use a combination of probiotics and prebiotics in the treatment of intestinal disorders. It represents an appropriate starting point for the assessment of inventive step.

3.3 The difference between the subject-matter of claim 1 of the main request and the disclosure of document (7) lies in the presence of butyric acid or a salt thereof and the definition of the amounts of probiotic and prebiotic.

The respondent has argued that a synergistic effect was linked to the addition of butyric acid or a salt thereof and has referred to document (28).

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However, the data presented in document (28) are not suitable for establishing a synergistic effect. Document (28) relates to the product FEEDColon and contains comparative data between FEEDColon and Symbiotix/Mix Symbiotics. On page 2, the principal ingredients and excipients of the FEEDColon tablets having "programmed release" are disclosed. The core of the tablets contains bifidobacterium lactis and bifidobacterium bifidus as probiotics, FOS as a prebiotic, and butyric acid in granulated form with a gastro-resistant coating. Furthermore, PVP and HPMC are present in the core. The core is coated with a modified starch and shellac for protection against gastric juices and bile acids. However, such detailed information on ingredients and excipients is not available for Symbiotix. On page 9, it is stated that Symbiotix capsules contain bifidobacterium bifidus, bifidobacterium lactis, FOS and a "Hard gelatine cap". No information on the presence or absence of a release control or protective coating is given. But most importantly, no information on the amounts of probiotics and prebiotics is provided.

According to established case law, comparative tests must establish that the effect is attributable to the feature distinguishing the invention. Thus, comparative tests must disclose enough information to determine that the effect is due to the distinguishing feature and not due to a further difference between the two, or more compositions, tested (see also Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, I.D.10.9).

In the present case, even when disregarding the issue of controlled release or protection against gastric fluids, it is not possible to determine whether any

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difference in effects is due to the presence of butyric acid or a salt thereof or to variations in the amounts of probiotics and/or prebiotics. Consequently, the data presented in document (28) are not suitable for establishing that the triple combination of probiotic, prebiotic and butyric acid (or a salt thereof) has any surprising effect over the prior art in the form of the combination of probiotic and prebiotic disclosed in document (7). Therefore, a synergistic effect cannot be acknowledged. No further surprising effect has been invoked.

3.4 The technical problem is thus the provision of an alternative nutritional composition providing benefits to the intestine.

In view of the conclusion reached by the board, it was not necessary to assess whether these benefits arise over the whole scope of the claim.

3.5 The board considers that it would have been obvious to the person skilled in the art to add further ingredients known to bring benefits to the intestine when providing an alternative nutritional composition.

Further beneficial ingredients are disclosed in document (8), which relates to the beneficial effects of a combination of inulin (a prebiotic) and the short-chain fatty acid (SCFA), butyric acid (page 21, point 3.3). The butyric acid is formulated in a form adapted to ensure that it reaches the colon (page 21, right-hand column, paragraph 5).

The further addition of components well known for their activity in the technical field concerned is considered an arbitrary choice among components which the skilled

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person would have had at their disposal. Such an addition, or combination of actives, does not involve an inventive step. The skilled person would thus have added the active ingredients suggested by document (8) in the context of providing benefits to the intestine. The fact that document (8) does not provide data for each of its active ingredients separately does not change this finding. Document (8) is very clear in its teaching. It reports that the "results obtained using a new formulation of butyric acid demonstrate that oral administration of SCFAs can significantly reduce symptoms and induce normalisation of status in IBS-PD [diarrhoea-predominant irritable bowel syndrome] patients" (page 22, last paragraph). The fact that this paragraph also mentions that "[c]learly, confirmation is needed by randomised, double-blind, placebocontrolled trials" merely reflects the fact that such trials are required by the authorities before a new medicament can be approved.

The optimisation of concentrations of such components is a matter of routine. In the present case, concentrations are disclosed in documents (8) and (6), which would have been considered by the skilled person when carrying out routine tests. Document (8) teaches to administer 1 g/day of sodium butyrate (abstract) to be given in unit doses of 250 mg (page 20, right-hand column, paragraph 3). Document (6) suggests the amount of 10⁷ to 10¹³ cells of probiotics per day in 1 to 10 doses per day (paragraph 0023]) and 1 to 100 g prebiotic per 10¹⁰ microorganisms present in the composition (paragraph [0040]). In the absence of a surprising technical effect, the optimisation of concentrations of ingredients is considered to be within the normal routine tasks that would have been

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carried out by the skilled person.

- 3.6 Thus, the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.
- 3.7 Further arguments
- 3.7.1 The respondent has stressed that other documents, especially documents mentioning all three mandatory ingredients, are closer to the claimed subject-matter than document (7).

In the board's opinion, the question of whether a particular disclosure is closer or further removed in relation to the subject-matter claimed is irrelevant. Starting the assessment of inventive step from the "closest prior art" serves the purpose of avoiding the need to consider a multitude of potential starting points as it can be assumed that wherever a particular claimed subject-matter involves an inventive step having regard to this "closest prior art", it will all the more involve an inventive step when the assessment is based on a disclosure which is not the "closest" prior art. Under Article 56 EPC, a claimed invention can only be considered as involving an inventive step if it is not obvious to the skilled person having regard to the state of the art, i.e. any prior art disclosure subject to Article 56, second sentence, EPC. The board considers that in view of the outcome of the assessment of inventive step, it is irrelevant that other documents might potentially be closer.

3.7.2 The respondent has argued that document (28) contains comparative tests carried out according to standards accepted in the field.

The board does not doubt the relevance of the data of document (28) in a clinical setting. However, the requirements for comparative tests, especially when synergy is to be established, are not fulfilled by document (28) for the reasons given under point 3.3.

3.7.3 The respondent pointed to the fact that document (7) already mentioned that butyric acid was generated in situ when prebiotics were administered. Therefore, the skilled person would not have considered adding butyric acid in free form. In addition, the skilled person would have had reservations due to the known bad smell of butyric acid and the fact that document (31) threw doubts on the effectiveness of its addition.

The board cannot accept these arguments. Firstly, the addition of any ingredient known to be beneficial in a certain setting would have been considered by the skilled person when trying to provide an alternative composition. Furthermore, document (8) taught to add not just butyric acid but a combination of a prebiotic and butyric acid. The skilled person would consequently have added butyric acid in addition to or in combination with a prebiotic irrespective of the fact that the metabolisation of the prebiotic would generate butyric acid in situ. Secondly, a bad smell or a bad taste is not a primary concern of the skilled person when aiming at providing a medicament. Finally, it is acknowledged that document (31), in the discussion of the background art, mentions that the direct addition of butyric acid or butyrate does not have a prebiotic or immune stimulatory activity (paragraph [0006]). However, document (8) teaches to administer the butyric acid (in the form of sodium butyrate) as an entericcoated tablet, discussing its potential metabolism

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before reaching the colon in the case of oral administration of unprotected butyric acid (page 21, right-hand column, paragraph 5) and thus explaining one potential reason for the failure reported in document (31). It goes without saying that the skilled person would have administered the butyric acid in the galenic form taught by document (8).

3.7.4 In addition, the respondent has argued that the skilled person would have had other options when trying to provide nutritional compositions. For example, the skilled person, following the suggestions in documents (7) and (6), could have optimised the probiotic strains. As this option would have allowed for a considerably easier manufacturing process, the skilled person would not have considered the more tedious addition of butyric acid.

The board cannot accept this argument. The skilled person, when aiming at providing an alternative composition, could have considered several solutions. Just because further solutions exist does not render a certain solution, in the present case the addition of butyric acid, less obvious or, in other words, inventive. Furthermore, the provision of an enteric coating is routine when providing a medicament to act in the intestine (on top of it being suggested in document (8)) and devoid of any technical difficulty.

4. Inventive step - auxiliary request 13

Auxiliary request 13 has been admitted into the proceedings. It is, however, not allowable for the following reasons.

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4.1 Claim 1 of auxiliary request 13 differs from claim 1 of the main request in that the ingredients of the nutritional composition are incorporated into a food supplement in the form of a pill or tablet comprising certain excipients/galenic elements.

In particular, claim 1 of auxiliary request 13 defines:

- the form of a pill or tablet
- a gastro-resistant coating around a core comprising the active ingredients, the coating dissolving at a pH $_{
 m qreater}$ than 6.5
- the presence of at least one stabilising additive permitting controlled dissolution of the pill or tablet and the controlled release of this nutritional composition
- 4.2 Starting from document (7), it would have been clear to the skilled person that the medicament was intended to act in the intestine, in particular in the colon. This can already be seen from the abstract of document (7), referring to the "colonic metabolism" and to "the colonocyte". The same can be inferred from two further passages cited by the parties. On page 80, last paragraph, a drop in the pH of the large intestine due to the short-chain fatty acids resulting from the metabolism of the FOS by fermentative bacteria and the benefits resulting from this drop for the bifidogenic flora are discussed. The penultimate paragraph on page 83 mentions that FOS are an important source of butyric acid, which is an essential nutrient of the colonocyte. It is thus clear from the overall disclosure of document (7) that the probiotics and prebiotics act in the colon.
- 4.3 In addition to the difference between the subjectmatter of claim 1 of the main request and the

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disclosure of document (7), the presence of butyric acid or its salts, and the definition of the amounts of probiotic and prebiotic, the subject-matter of claim 1 of auxiliary request 13 further differs from the disclosure of document (7) by requiring specific galenic forms (pills or tablets) and galenic features of these forms due to the presence of certain excipients (certain gastro-resistant coating(s) surrounding a core and the presence of stabilising additives permitting controlled dissolution and release).

No surprising effect has been shown to be linked to these further differences.

- 4.4 The technical problem is thus the same as for claim 1 of the main request, i.e. the provision of an alternative nutritional composition providing benefits to the intestine (see point 3.4 above).
- 4.5 As already found for claim 1 of the main request, the person skilled in the art would have added butyric acid or a salt thereof in the form suggested by document (8), i.e. in form of a tablet having a coating that allows the delivery of butyric acid or its salt to the colon. Grouping all active ingredients in the core of this tablet would have been obvious. The skilled person would have been aware, e.g. from document (10) (page 41, left-hand column, paragraph 2), that delivery to the colon requires a coating withstanding pH values lower than 6 to 7 (the pH of the lower intestine). The addition of further additives that, in addition to the effects achieved by the gastro-resistant coating taught by document (8), control dissolution or release would have been well known to the skilled person and would have been employed when carrying out routine tests when

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optimising the delivery of the active ingredients (see document (10), page 52, section headed "Timed release systems").

4.6 The respondent has argued that claim 1 of auxiliary request 13 defined the combination of a great number of technical features. Such a combination would not have been obvious to the person skilled in the art.

However, in the present case the combination of all features, with the exception of an additional stabilising additive, was already suggested by the combination of documents (7) and (8). In the absence of any data showing that the addition of a stabilising additive leads to any combinative effect beyond the known effect of the stabilising additive, the addition of the stabilising additive has to be assessed on its own. As it has not been shown to be linked to any effect, the addition of such components has to be regarded as arbitrary.

- 4.7 Consequently, the use of known galenic forms and the excipients known to lead to these forms would have been obvious to the skilled person aiming at providing a product that released its active agents in a certain part of the human body.
- 4.8 The subject-matter of claim 1 of auxiliary request 13 does not involve an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

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

The Registrar:

The Chairwoman:



M. Schalow

T. Sommerfeld

Decision electronically authenticated