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**D E C I S I O N**  
**of 4 August 2005**

**Case Number:** T 0329/04 - 3.3.4  
**Application Number:** 98939584.3  
**Publication Number:** 1003532  
**IPC:** A61K 35/74, A23C 9/123,  
A23L 1/03  
**Language of the proceedings:** EN

**Title of invention:**

Lactobacilli to increase absorption of minerals by intestinal cells

**Patentee:**

SOCIETE DES PRODUITS NESTLE S.A.

**Opponents:**

01: Biogaia AB  
02: Friesland Brands B.V.

**Headword:**

Absorption of minerals/NESTLE

**Relevant legal provisions:**

EPC Art. 54, 56, 83, 84, 123(2), 111(1)

**Keyword:**

"Main request, first to sixth auxiliary requests - added subject-matter (yes)"  
"Fifth, seventh, ninth auxiliary requests - clarity (no)"  
"Amended eight auxiliary request - added subject-matter (no), novelty (yes), inventive step (no)"  
"Amended tenth auxiliary request - added subject-matter (no), novelty, inventive step (yes)"  
"Remittal to the department of first instance - (yes)"

**Decisions cited:**

T 0176/84, T 0133/87, T 0766/91, T 939/92, T 249/93, T 0464/94

**Catchword:**

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Case Number: T 0329/04 - 3.3.4

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.4**  
**of 4 August 2005**

**Appellant I:** SOCIETE DES PRODUITS NESTLE S.A.  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
18 December 2003 concerning maintenance of  
European patent No. 1003532 in amended form.

**Composition of the Board:**

**Chair:** U. Kinkeldey  
**Members:** M. Wieser  
R. Moufang

## Summary of Facts and Submissions

- I. Appeals were lodged by the Patent Proprietors (Appellants I), by Opponents 01 (Appellants II) and by Opponents 02 (Appellants III) against the decision of the Opposition Division whereby European Patent No. 1 003 532 was maintained in amended form pursuant to Article 102(3) EPC.
- II. The patent had been opposed under Article 100(a) EPC for lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Article 100(b) EPC on the ground of lack of sufficient disclosure (Article 83 EPC).
- III. The Opposition Division had decided that the claims of the main request and of the first and second auxiliary requests before them were not novel over the disclosure in the following documents:
- (2) JP-A-7-53391 (English translation)
- (6) J. Nutr. Sci. Vitaminol., vol. 40, 1994, pages 613 to 616
- However, they decided that claims 1 to 9 of the third auxiliary request met the requirements of the EPC.
- IV. Oral proceedings before the Board of Appeal were held on 4 August 2005.

The Appellants I requested

- that the decision under appeal be set aside and the patent be maintained on the basis of the main request or the first auxiliary request, both filed with letter of 6 June 2005,

- or, in the alternative and as second auxiliary request, that the appeals of Appellants II and III be dismissed,

- or, in the alternative, that the decision under appeal is set aside and the case be remitted to the department of first instance for further prosecution,

- or, in the alternative, that the decision under appeal be set aside and the patent be maintained on the basis of the third, fourth, fifth, sixth or seventh auxiliary requests, all filed with letter of 6 June 2005, or the amended eighth auxiliary request, filed at the oral proceedings, or the ninth auxiliary request, filed with letter of 6 June 2005, or the amended tenth auxiliary request, filed at the oral proceedings.

The Appellants II and III requested that the decision under appeal be set aside and that the patent be revoked.

V. Claim 1 of Appellants' I main request read:

"Use of lactobacilli which are able to arrive alive in the intestine in the preparation of an enteral nutritional composition for facilitating or improving the absorption of minerals by a mammal, wherein the

lactobacilli directly facilitate or improve the absorption of minerals."

The expression "Use of lactobacilli which are able to arrive alive in the intestine...", is also contained in claim 1 of the first auxiliary request, in the set of claims maintained by the Opposition Division (corresponding to the second auxiliary request), and in the fifth and sixth auxiliary requests.

The third and fourth auxiliary request contain the term "... wherein the lactobacilli are able to arrive in the intestine in a living state ...".

The term "..., wherein the lactobacilli directly facilitate or improve the absorption of said minerals" is contained in claim 1 of the fifth, seventh and ninth auxiliary requests.

VI. Claim 1 of the amended eighth auxiliary request, filed at oral proceedings, read as follows:

"Use of probiotic lactobacilli in the preparation of an enteral nutritional composition for the treatment or prophylaxis of mineral deficiencies."

Claim 1 of the amended tenth auxiliary request, filed at oral proceedings, read as follows:

"Use of probiotic lactobacilli in the preparation of an enteral nutritional composition for the treatment or prophylaxis of deficiencies in calcium, magnesium and/or zinc."

VII. Besides the documents mentioned in section (III) above the present decision refers to the following documents:

(9) US-A-5 531 988

(12) Appl. Environ. Microbiol., vol. 59, 1993,  
pages 4121 to 4128

(22) Microbial Ecology in Health and Disease, vol. 8,  
1995, pages 41 to 50

(27) Report of the 46<sup>th</sup> ECVAM workshop, 2001,  
pages 649 to 668

(28) Int. J. Food Microbiology, vol. 41, 1998,  
pages 45 to 51

(29) US-A-4 591 503

VIII. The submissions made by Appellants I as far as they are relevant to the present decision may be summarised as follows:

Document (29), which had been filed late and was not prima facie relevant, had to be disregarded. The expression "lactobacilli which are able to arrive alive in the intestine" had a basis in the application as filed and did not contravene the requirements of Article 123(2) EPC. The term "directly", as used in claim 1 of the main request expressed that it was the Lactobacillus as such, and not a fermentation product produced ex vivo, which was responsible for the technical effect obtained. Thus, the term was clear and did not violate Article 84 EPC.

All requests following the second auxiliary request should be remitted to the department of first instance, as they referred to subject-matter not yet having been subject to a substantive discussion before the Opposition Division. The amended eighth and tenth auxiliary requests, filed at the oral proceedings, should be allowed into the procedure as they contained only minor amendments when compared with requests that have been filed two months before the oral proceedings, the time limit set by the Board.

The subject-matter of claim 1 of the eighth auxiliary request was novel over the disclosure in documents (2) and (6), which did not disclose that the used Lactobacilli were probiotic, and over the disclosure in document (22) which referred to safety and tolerance of Lactobacilli in healthy humans and did not disclose a composition for facilitating and improving the absorption of minerals. For the question of inventive step, a skilled person would not have considered this technically unrelated document at all.

Claim 1 of the tenth auxiliary request was restricted to calcium, magnesium and/or zinc deficiencies. As documents (2) and (6) related to iron absorption only, and document (22) did not disclose any data referring to improved absorption of calcium, magnesium and/or zinc, the subject-matter of the claim was novel and inventive.

The arguments presented by Appellants II and III with regard to lack of sufficient disclosure (Article 83 EPC) of the amended tenth auxiliary request were partly



new, complex and unexpected. As they moreover had not been examined by the department of first instance the case should be remitted for further prosecution.

IX. The submissions made by Appellants II and III as far as they are relevant to the present decision may be summarised as follows:

Document (29), being highly relevant, had been introduced by Appellants II in their grounds for appeal on 27 April 2004. A copy of the document, which was easily retrievable by all parties for instance via internet, was filed shortly before oral proceedings. Therefore, the document should be allowed into the procedure. Claim 1 of the main request had no basis in the application as filed (Article 123(2) EPC). Moreover the claim lacked clarity and contravened the requirements of Article 84 EPC.

Remittal of all requests following the second auxiliary request to the department of first instance would unduly delay the procedure and was not regarded to be necessary. The amended eighth and tenth auxiliary request were filed late and should be disregarded.

Claim 1 of the eighth auxiliary request was not novel over documents (2) and (6), which both disclosed compositions containing *Lactobacillus acidophilus*, used to improve iron absorption in rats and human patients. The disclosure in documents (9) and (12) made clear that all strains belonging to the species *Lactobacillus acidophilus* were probiotic.

The skilled person looking for an alternative to the composition disclosed in document (2) would have come across document (22), which disclosed that probiotic Lactobacilli improved the intestinal absorption of at least iron. The claim therefore lacked inventive step (Article 56 EPC).

Document (29) was considered to represent the closest state of the art for the assessment of inventive step of claim 1 of the tenth auxiliary request. A skilled reader learning from this document that Lactobacilli improve calcium, magnesium and/or zinc absorption in human patients, would have thought of using probiotic bacteria and thus would have arrived at the claimed subject-matter in an obvious way.

The patent did not disclose the invention according to the tenth auxiliary request in a manner sufficiently clear and complete for it to be carried out by person skilled in the art (Article 83 EPC). The patent relied on an in vitro system using a cell line which was not suitable to predict mineral absorption in vivo in the human intestine. Only a small number of the probiotic Lactobacilli tested was shown to improve calcium absorption in this in vitro system. Document (22) showed that a probiotic Lactobacillus reuteri had no influence on calcium absorption, thus it disclosed a non-working embodiment falling within the scope of claim 1.

No objection was raised against Appellants' I request to remit the case to the department of first instance for further prosecution on the basis of the amended tenth auxiliary request.

## Reasons for the Decision

### *Admissibility of document (29)*

1. The document has been mentioned by Appellants II in their grounds for appeal submitted on 27 April 2004. A short resume of its content has been given on page 5 of this letter. A copy of document (29) was submitted by Appellants II on 26 July 2005 only, nine days before the oral proceedings.

The document, a US patent, consisting of 25 lines of description, three examples and eight claims, relates to compositions for improved absorption of various cations comprising yeast or lactobacillus.

The Board considers the disclosure of document (29) to be relevant for the present case. The document is very short, its teaching does not require extensive study and its disclosure is easy to understand. It has been introduced and shortly discussed by Appellants II more than one year before the oral proceedings. Under these circumstances the Board finds it appropriate to admit the document into the procedure.

### *Main request*

### *Amendments - Article 123(2) EPC*

2. Claim 1 refers to the "[U]se of lactobacilli which are able to arrive alive in the intestine ...". This formulation is not contained in the claims as granted.

Appellants I pointed to page 2, lines 18 to 20 and to page 5, lines 12 to 15, of the application as filed, which they considered to be a basis for this amendment.

The Opposition Division when deciding that the amendment did not violate the requirements of Article 123(2) EPC, additionally referred to page 4, lines 11 to 12 and page 3, lines 6 to 8 of the application as filed.

3. None of these passages contains an explicit disclosure of the amendment introduced into claim 1.

Page 2, lines 18 to 20 states that it has surprisingly been found that lactobacilli **in an in vitro model** are able to directly facilitate or improve the absorption of minerals. As this in vitro model does not allow to draw any conclusion if and to which extent the lactobacilli survive a transport through the stomach, this cannot form a basis for the amendment in question.

On page 3, lines 6 to 8 it is said that the ingestion of lactobacilli increases the bioavailability of minerals by making them more available to the intestinal cells. This is not a disclosure referring to the state in which the lactobacilli arrive in the intestine.

According to page 4, lines 11 to 12 the nutritional compositions of the patent in suit preferably comprise a sufficient quantity of live lactobacilli. Again, this is not a statement disclosing that the lactobacilli arrive in the intestine alive.

Finally, on page 5, lines 12 to 15 it is stated that microencapsulation has been found to increase the survival of lactobacilli and therefore the number of live lactobacilli which arrive in the intestine. The Board does neither agree that this statement teaches that even without encapsulation a significant number of lactobacilli arrives in the intestine alive, nor that it is a basis for the amendment introduced into claim 1.

4. On page 3, line 27 the application as filed reads as follows: "Probiotic lactobacilli are of particular interest."

Appellants I, on page 12 of their letter, dated 6 June 2005 argue, that "[a] prominent representative of such kind of bacteria - that survive the deleterious transit through the gut - are probiotics, that exhibit a resistance to low pH in the stomach, resistance to bile acids and also resistance to a sudden change of the pH to a basic one (in the intestine)."

5. The application as originally filed neither explicitly nor implicitly discloses the "use of lactobacilli which are able to arrive alive in the intestine" according to claim 1. A basis can be found for probiotics only, which are "a prominent representative" of such bacteria.

Thus, the term introduced into claim 1 represents the generalization of an explicitly disclosed example.

According to the case law of the Boards of appeal such generalisation contravenes the requirements of Article

123(2) EPC (cf Case Law of the Boards of Appeal of the European Patent Office, 4th Ed. 2001; page 199, English version).

*Clarity - Article 84 EPC*

6. Claim 1 requires that "... the lactobacilli directly facilitate or improve the absorption of minerals". This formulation is not contained in the claims as granted. The patent does not contain an explicit explanation what the word "**directly**" stands for.

The Appellants I argued that according to the patent in suit the lactobacilli per se are responsible for the obtained effect, namely the improvement of mineral absorption. They referred to page 3, line 8 of the patent pointing to the importance of the lactobacilli being able to adhere to the intestinal cells. Contrary to this, compositions disclosed in documents (2) and (6) consisted of products fermented by lactobacilli. These compositions contained acids produced ex vivo by the fermentative activity of the lactobacilli, which acids were responsible for the improved mineral absorption in the patients.

7. The Board is not convinced by this line of argumentation.

Firstly, the patent states on page 5, lines 50 to 51, that the capacity of the bacteria to adhere to the intestinal cells did not correlate directly with their capacity to increase the absorption of calcium by these cells.

Secondly, on page 2, lines 39 to 41, of the patent it is said that the improved mineral absorption is thought to be linked to induction of acidification of the microenvironment around the intestinal cells and the bacteria in contact with these cells. In the light of this disclosure, the same chemical substances, namely acids, either produced by lactobacilli ex vivo by fermentation according to the state of the art, or produced in vivo in the intestine by lactobacilli, are considered to be responsible for improved mineral absorption by intestinal cells.

Accordingly the meaning of the word "directly", which Appellants I have introduced into claim 1 in order to differentiate the claimed subject-matter from the disclosure in the prior art, is not clear.

8. For the reasons elaborated in points (2) to (7) above, claim 1 of the main request violates the requirements of Articles 123(2) and 84 EPC.

*First and second auxiliary requests*

9. The term "[u]se of lactobacilli which are able to arrive alive in the intestine...", which has been decided to violate Article 123(2) EPC, is contained in claim 1 of the first auxiliary request and of the set of claims as maintained by the Opposition Division, which therefore also do not meet the requirements of the EPC.

*Remittal of other requests - Article 111(1) EPC*

10. Remittal to the department of first instance is at the discretion of the Board (cf decision T 249/93 of 27 May 1998).

Appellants I based their request on the sole argument that the subject-matter of their remaining eight requests had not yet been subject to a substantive discussion before the Opposition Division.

It has been acknowledged in the jurisprudence of the Boards of Appeal that there is no absolute right of a party to have every aspect of a case examined in two instances (T 133/87 of 23 June 1988, point (2) of the reasons).

11. In the present case, considering the structure and content of Appellants' I remaining requests when compared to the requests examined by the Opposition Division, the Board comes to the conclusion that it is procedurally adequate for itself to examine the claims of these requests with regard to the formal requirements (Articles 123(2) and (3) and Article 84 EPC) and with regard to novelty (Article 54 EPC) and inventive step (Article 56 EPC).

*Third to seventh and ninth auxiliary requests*

12. Claim 1 of the third and fourth auxiliary requests contain the phrase "... wherein the lactobacilli are able to arrive in the intestine in a living state ...".



Although this term is not identical to the one contained in claim 1 of the main request, the Board's findings, as elaborated in points (2) to (5) above, also apply to these requests, which therefore do not meet the requirements of Article 123(2) EPC.

13. Claim 1 of the fifth and sixth auxiliary requests violates Article 123(2) EPC (cf points (2) to (5) above).
14. Claim 1 of the fifth, seventh and ninth auxiliary requests is not clear within the meaning of Article 84 EPC (cf points (6) to (7) above).
15. Thus, the third to seventh and ninth auxiliary requests do not meet the requirements of the EPC.

*Admissibility of the amended eighth and tenth auxiliary requests*

16. Appellants II and III objected to the admissibility of these two requests filed at the oral proceedings.

The claims of the requests differ from the eighth and tenth auxiliary request, filed by Appellants I two months before the oral proceedings, only in so far as in both requests claim 1 has been deleted and claim 9 has become the new claim 1, and in addition an obvious error in the tenth auxiliary request has been corrected. The term "in calcium, magnesium and zinc" has been replaced by "in calcium, magnesium and/or zinc" as contained in claim 5 as originally filed and in claim 5 as granted.

17. The deletion of independent claim 1 and its replacement by independent claim 9, which was originally present in the request, is not an amendment putting Appellants II and III in a different, unexpected situation. The deletion does not effect that other pieces of evidence or different arguments become relevant which were not of importance before the deletion.

The amendment results in a restriction of the scope of the claims. Therefore, the Board, by exercising its discretion, allows the amended eighth and amended tenth auxiliary requests into the procedure.

*Amended eighth auxiliary request*

*Amendments - Articles 123(2) and (3) EPC*

*Clarity - Article 84 EPC*

18. Claim 1 is based on claim 9 and page 3, line 27 of the application as originally filed. Claims 2 to 8 correspond to original claims 2 to 8.

Claims 2 to 9 as originally filed are identical to claims 2 to 9 as granted.

The claims meet the requirements of Articles 84, 123(2) and 123(3) EPC.

*Novelty - Article 54 EPC*

19. Document (2) discloses a compound for the treatment of iron-deficiency anaemia containing milk fermented by *Lactobacillus acidophilus* and ferrous ions (page 2, summary of the invention). The document does not

disclose that the used strain, *L. acidophilus* SBT2062, is probiotic.

20. In document (6), from the same authors as document (2), the iron bioavailability in rats is tested. The test animals were fed with a ferrous sulphate-supplemented diet. One group additionally received skim milk fermented by *L. acidophilus*. The used strain, *L. acidophilus* SBT2062, is not designated as being probiotic. The results obtained show that skim milk fermented by *L. acidophilus* SBT2062 is effective for increasing iron bioavailability in rats.

21. Appellants II and III argue that it is known in the art that all strains belonging to the species *L. acidophilus* are probiotic. They refer in this respect to the following documents:

Document (9) discloses that beneficial human intestinal organisms are organisms, such as bacteria, that inhabit the human intestine and exert a beneficial effect on the gastrointestinal health of an individual. *L. acidophilus* is mentioned as being especially preferred (column 5, lines 19 to 29).

Document (12) contains a definition of the term "probiotics", as being live microorganisms which when administered to humans or animals, as dried cells or fermented products, affect beneficially the host by improving the properties of the endogenous microflora (page 4124, right column, first sentence). On page 4121, left column, lines 1 to 18, it is said that lactobacilli and bifidobacteria are two species of the human normal microflora, which are sometimes claimed to

exert probiotic effects in humans. One of the desirable properties of these species is their adhesion to the mucosal surfaces which is an important prerequisite for bacterial maintenance in the intestinal tract. It is mentioned that two selected strains of *L. acidophilus* exhibit adhesive properties but that not all strains possess this ability.

22. Appellants I strongly contest that all strains belonging to the species *L. acidophilus* are probiotics. According to them probiotic activity of a bacteria has to be tested and determined for each single strain and cannot be automatically attributed to each strain of a species.

23. The Board agrees with the definition of the term "probiotics" as given in document (12), which is not in dispute between the parties. This definition, which teaches that these microorganisms in order to exert their beneficial effect in the intestine must be present in a living state, is in line with Appellants' I statement, that probiotics are prominent representatives of bacteria that survive the deleterious transit through the gut (see point (4) above).

The Opposition Division in point (7) of their decision under appeal, when dealing with the question of novelty of claim 1 of the main request before them, decided that, since *L. acidophilus* strains which are able to arrive alive in the intestine are known from the prior art, the strain SBT2062 used in documents (2) and (6) **may** also have this ability.

24. In the Board's view it is not justifiable to decide whether a document is prejudicial to novelty on the **basis of probability**. In order to decide that the subject-matter of a claim lacks novelty, the department concerned, having taken all facts and arguments put forward during the proceedings into consideration, has to be **sure** that the decision is justified (cf decision T 464/94 of 21 May 1997; point (16) of the reasons).

In the present case, although there is some probability that *L. acidophilus* SBT2062 might be probiotic, there is no convincing evidence on file that would allow arriving at this conclusion with certainty.

25. Accordingly, in the light of the relevant case law of the Boards of Appeal, documents (2) and (6) do not anticipate the subject-matter of claims 1 to 8.
26. Document (22) refers to safety and tolerance of *Lactobacillus reuteri* in healthy adult male subjects. The document, on page 41, left column, defines the term "probiotic" almost identically as document (12), (see point (21) above) and describes the potential of probiotics to treat and/or prevent various gastrointestinal infections (page 42, left column, first full paragraph). A microorganism of particular interest is *L. reuteri*. Experiments are carried out with strain MM53 (ATCC SD2112), which is found to be able to survive the passage through the stomach and maintain viability through the gastrointestinal tract (page 48, right column, lines 31 to 35).

Gelatine capsules filled with either lyophilised *L. reuteri* or with nonfat dairy milk powder,

maltodextrin and sucrose (placebo) were administered to two groups of fifteen subjects each. The test persons underwent various physical examinations. Blood samples were drawn by venipuncture on day 0, 7, 14, 21 and 28 and serum samples were analysed for a large number of parameters, among them calcium and iron (page 43).

By using analysis of covariance, a significantly higher difference between the baseline value for iron (before treatment) and on day 28 after treatment is shown to exist for the group treated with *L. reuteri* when compared with the placebo group (page 44, right column, lines 13 to 20). No such effect is shown for calcium.

27. Appellants I argue that the lactobacillus strain used in document (22) is not probiotic as it has to be encapsulated before administration to arrive in the intestine alive.

According to page 42, right column, first full paragraph, lyophilised *L. reuteri* MM53 is weighed into gelatine capsules before administration. This is not considered to be a microencapsulation to increase the survival of lactobacilli during their transport through the stomach. For this purpose the bacteria would have to be incorporated into a material such as described on page 3, lines 55 to 57 of the patent in suit. As gelatine is not acid resistant it is unable to protect the bacteria and so to increase their survival on their transport through the stomach. As convincingly explained by Appellants II, the use of gelatine capsules in the experimental design of document (22) serves the only purpose to create preparations containing the active agent and others containing

placebo, which cannot be distinguished by the test persons.

28. Claim 1 refers to the use of probiotic lactobacilli for the preparation of a composition for the treatment or prophylaxis of mineral deficiencies.

This use is not disclosed in document (22), which investigates safety and tolerance of a potentially beneficial probiotic strain of *L. reuteri* in healthy subjects. Although it is found that ingestion of this strain results in an improved iron absorption by the test persons, it is not disclosed or even suggested to use the strain for this purpose.

Document (22) does not anticipate the subject-matter of claims 1 to 8.

29. Accordingly, claims 1 to 8 are novel and meet the requirements of Article 54 EPC.

*Inventive step - Article 56 EPC*

30. In accordance with the problem and solution approach, the Boards of Appeal have developed in their case law certain criteria for identifying the closest prior art which provides the best starting point for assessing inventive step. It has been repeatedly pointed out that this should be prior art relating to subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications (cf Case Law of

the Boards of Appeal of the European Patent Office, 4<sup>th</sup> Edition 2001, chapter I.D.3).

31. The invention according to claim 1 aims at the objective to provide a composition for the treatment or prophylaxis of mineral deficiencies.

This objective is met by the use of probiotic lactobacilli in the preparation of such composition.

32. The Board, in agreement with the opinion expressed by all parties, considers document (2), providing a compound for the treatment of iron-deficiency anaemia, as closest state of the art. The compound contains milk fermented by a strain of *L. acidophilus*, which is not characterised as being probiotic.

The problem underlying the present invention in the light of the disclosure in this state of the art is seen in the provision of an alternative compound or composition.

33. Document (22), investigating safety and tolerance of a probiotic strain of *L. reuteri* in healthy humans, reports of improved iron absorption by the test persons.

The question to be answered by the Board is whether a skilled person trying to solve the problem underlying the patent in suit would have considered the teaching in document (22). Appellants I argue that this document, relating to tests performed on healthy individuals, is not concerned with the provision of a medicament for treating or preventing mineral deficiencies. As it belongs to a technically non-



related field a skilled reader would not have considered combining its teaching with the disclosure in document (2).

34. The skilled person in the here relevant technical field is considered to be an expert in the field of medical nutrition research having a sound knowledge of microbiology. As such he/she is not only concerned with the development of new medicaments for people suffering from a disease or deficiency but also with the provision of nutritional compositions having a beneficial effect on healthy individuals.

When examining for inventive step, a skilled person would, as well as considering the state of the art in the specific technical field of the patent, look for suggestions in neighbouring fields or a broader general technical field if the same or similar problems arose, and if he could be expected to be aware of such general fields (cf decision T 176/84, OJ EPO 1986, 50; point (5.3.1) of the reasons).

35. Therefore, the Board is convinced that a skilled person trying to solve the problem underlying the patent in suit, would have considered the teaching in document (22). Thus, when looking for an alternative for the composition disclosed in document (2) and knowing that probiotic lactobacilli improve the absorption of iron in humans (document (22), page 44), he/she would have replaced the bacteria used in document (2) by the probiotic strain of *L. reuteri* disclosed in document (22) and would have arrived at the claimed subject-matter in an obvious way.

36. In consequence, claim 1 of the amended eighth auxiliary request does not involve an inventive step and violates the requirements of Article 56 EPC.

*Amended tenth auxiliary request*

*Amendments - Articles 123(2) and (3) EPC*

*Clarity - Article 84 EPC*

37. Claim 1 is based on claims 9 and 5, wherein the reference to iron has been deleted, and on page 3, line 27 of the application as originally filed. Claims 2 to 7 correspond to original claims 2 to 4 and 6 to 8.

Claims 2 to 9 as originally filed are identical to claims 2 to 9 as granted.

The claims meet the requirements of Articles 84, 123(2) and 123(3) EPC.

*Novelty - Article 54 EPC*

38. The decision taken with regard to novelty of the subject-matter of the amended eighth auxiliary request (see points (19) to (29) above) applies in the same way to claims 1 to 7 of the amended tenth auxiliary request.

Thus, the claims meet the requirements of Article 54 EPC.

*Inventive step - Article 56 EPC*

39. The invention according to claim 1 aims at the objective to provide a composition for the treatment or

prophylaxis of deficiencies in calcium, magnesium and/or zinc.

This objective is met by the use of probiotic lactobacilli in the preparation of such composition.

40. The closest state of the art is represented by document (29), disclosing a method and a combination for improving the absorption of metallic cations in a mammal, including calcium, magnesium and zinc. For this purpose organic and/or inorganic salts are admixed with a pharmaceutically acceptable microorganism (column 1, lines 1 to 10, and claim 1). The preferred microorganism, used in all examples of document (29), is yeast. However, it is mentioned in column 1, lines 35 to 37 and in claim 1 that other microorganisms such as lactobacillus can be used.
41. The problem underlying the present invention in the light of the disclosure in the closest state of the art is seen in the provision of an alternative compound or composition.
42. The only prior art document on file that deals with the role of probiotic lactobacilli in the absorption of minerals by humans is document (22), (see point (26) above). The document teaches that the administration of a probiotic strain of *L. reuteri* has no influence on calcium absorption by healthy human subjects (page 44, right column, lines 20 to 21 and table 1 on page 45, lines 1 and 2).
43. Appellants II and III argued that a skilled person, based on his/her common general knowledge would have

thought of using probiotic lactobacilli in the composition of document (29). As these bacteria were normal inhabitants of the gastrointestinal tract of healthy humans, it was logic to use them for the claimed purpose.

They did not rely on a piece of prior art to substantiate this argument.

44. Appellants I argued that a skilled person when reading document (29), which relates to yeast mainly and mentions lactobacilli only in passing without referring to probiotic lactobacilli, did not get any suggestion that would have prompted him/her to change its teaching and to arrive at the claimed subject-matter in an obvious way. It was denied that such suggestion can be derived from the common general knowledge.
  
45. The question of inventive step can only be considered on the basis of the relevant state of the art, see Article 56 EPC. However, Article 54(2) EPC does not limit the state of the art to written disclosure in specific documents; rather it defines it as including all other ways ("in any other way") by which technical subject-matter can be made available to the public. Therefore, the absence of a reference to a particular document does not mean that there is no state of the art, as this could reside solely in the relevant common general knowledge, which, again, may or may not be in writing, i.e. in textbooks or the like, or be simply a part of the unwritten "mental furniture" of the notional "person skilled in the art". However in the case of any dispute as to the extent of the relevant common general knowledge this, like any other fact

under contention, has to be proved, e.g. by documentary or oral evidence (cf decisions T 939/92, OJ EPO 1996, 309, point (2.3) and T 766/91 of 29 September 1993, point (8.2) of the reasons).

46. In the present case the extent of the common general knowledge is disputed between the parties.

The Board takes the view that a skilled person faced with the underlying problem, namely to provide an alternative to the composition disclosed in document (29), could have taken a multitude of different approaches to arrive at a solution.

As Appellants II and III did not provide documentary or other evidence to substantiate their argument, their objection must fail.

Claims 1 to 7 involve an inventive step and meet the requirements of Article 56 EPC.

*Sufficiency of disclosure - Article 83 EPC*

47. In their letter, dated 16 November 2004, Appellants III argued that the in vitro model disclosed in the patent in suit, based on the use of the Caco-2 cell line, was not predictive for the in vivo situation. They referred in this respect to post-published documents (27) and (28), which disclosed several shortcomings of the used cells and both concluded that the Caco-2 cell line should not be used as an indicator for the in vivo situation (document (27), page 660, right column, first full paragraph; document (28), page 50, left column, 2<sup>nd</sup> full paragraph). Accordingly, the patent did not

provide any support for the statement that the in vitro results are indicative for the in vivo situation, which was the subject of the claims.

48. At the oral proceedings Appellants II and III furthermore argued that the patent, relying on an unsuitable in vitro model, failed to prove that all bacteria falling under the definition "probiotic lactobacilli" are able to improve absorption of calcium. The results obtained with nine tested strains shown in figures 2 and 3 prove that many thereof are unable to raise calcium absorption above the control level (100%).

Finally, Appellants II and III argued that document (22) disclosed that the administration of a probiotic strain of *L. reuteri* had no influence on calcium absorption in humans. Thus, the document disclosed a non-working embodiment falling within the scope of claim 1 of the amended tenth auxiliary request.

49. Appellants I submitted that these arguments, which had been made at a very late stage of the procedure, had not been discussed before the Opposition Division. They were not in a position to address these complex and unexpected arguments which partly were made for the first time at the oral proceedings before the Board. They requested therefore to remit the case to the department of first instance for further prosecution, according to Article 111(1) EPC.

Appellants II and III did not object to this request.

50. The Board considers the arguments put forward by Appellants II and III with regard to an alleged lack of sufficiency of disclosure under Article 83 EPC (points (47) and (48) above), which partly were made for the first time at the oral proceedings before the Board, to be significant for the claims of the request in question.

The Board, exercising its discretion under Article 111(1) EPC, remits the case to the department of first instance for further prosecution.

## **Order**

### **For these reasons it is decided:**

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution on the basis of the amended tenth auxiliary request filed during oral proceedings.

Registrar:

Chair:

P. Cremona

U. Kinkeldey