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Datasheet for the decision of 10 October 2023

Case Number: T 0298/20 - 3.3.07

Application Number: 14186663.2

Publication Number: 2839836

IPC: A61K35/74

Language of the proceedings: EN

Title of invention:
Probiotics for use in reducing symptoms of respiratory disease

Patent Proprietor:
DuPont Nutrition Biosciences ApS

Opponent:
Chr. Hansen A/S

Headword:
Probiotic combination/DUPONT

Relevant legal provisions:
EPC Art. 76(1), 123(2), 84, 83, 56
RPBA 2020 Art. 12(6)

Keyword:
Main request, auxiliary requests 1 and 2 - sufficiency of disclosure (no)
Auxiliary request 3 - added subject-matter (no) - clarity (yes) - sufficiency of disclosure (yes) - inventive step (yes)

Decisions cited:
G 0003/14, T 0842/14

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0298/20 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 October 2023

Appellant: (Patent Proprietor)	DuPont Nutrition Biosciences ApS Langebrogade 1 1411 Copenhagen K (DK)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Appellant: (Opponent)	Chr. Hansen A/S Boege Alle 10-12 2970 Hoersholm (DK)
Representative:	Uexküll & Stolberg Partnerschaft von Patent- und Rechtsanwälten mbB Beselerstraße 4 22607 Hamburg (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 16 October 2019 concerning maintenance of the European Patent No. 2839836 in amended form**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Molina de Alba
	Y. Podbielski

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's interlocutory decision rejecting the main request (patent as granted) and auxiliary requests 1 and 2 and concluding that European patent No. 2839836 as amended according to auxiliary request 3, and the invention to which it relates, met the requirements of the EPC.

Claim 1 as granted read as follows:

"*1. A culture comprising* L. acidophilus *and* B. lactis *for use in reducing or preventing flu-like symptoms in a child affected by a respiratory tract infection.*"

Claim 1 of auxiliary request 1 differed from claim 1 as granted in that *L. acidophilus* was limited to the strain *L. acidophilus* NCFM.

Claim 1 of auxiliary request 2 differed from claim 1 as granted in that *B. lactis* was limited to the strain *B. lactis* Bi-07.

Claim 1 of auxiliary request 3 differed from claim 1 as granted in that *L. acidophilus* was limited to the strain *L. acidophilus* NCFM and *B. lactis* to the strain *B. lactis* Bi-07.

Each of the main request and auxiliary requests 1 to 3 contained an additional independent claim which was claim 1 reformulated in the Swiss-type format. The reasons provided in this decision for claim 1 apply equally to the independent Swiss-type claim.

II. The documents cited by the parties during the opposition and appeal proceedings included the following:

D4 WO 2007/040445 A1

D5 J. Winter, "The world of probiotics", New Hope Network, 1 September 2007, 1-2

D6 Guidelines for the Evaluation of Probiotics in Food, Joint FAO/WHO Working Group, London, Ontario, Canada, 30 April and 1 May 2002, 1-11

D7 M.E. Sanders, Clinical Infectious Diseases, 46(Suppl 2), 2008, S58-S61

D12 E. Altermann et al., PNAS, 102(11), 2005, 3906-12

D13 Excerpt from Rhodia Annual Report 2002

D14 B. Foligne et al., World J Gastronterol, 13(2), 2007, 236-43

D17 Scientific Opinion on the substantiation of health claims related to non-characterised bacteria and yeasts pursuant to Article 13(1) of Regulation (EC) No 1924/2006, EFSA Journal, 8(2), 2010, 1470

D18 M.J. Kullen et al., Current Pharmaceutical Design, 2005, 11(1), 55-74

D19 Receipt of deposit with the ATCC dated 3 January 2003

III. In the decision under appeal, the opposition division concluded, among other things, that:

- the invention of the main request (patent as granted) was not sufficiently disclosed because D6 and D7 raised serious doubts that the therapeutic effect shown in the application as filed for two

bacterial strains could be generalised to their corresponding bacterial species
- for the same reasons, the subject-matter of auxiliary requests 1 and 2 was not sufficiently disclosed either
- the limitation in the claims of auxiliary request 3 to the combination of strains tested in the application as filed, and the fact that these strains were well known and available to the public, rendered the claimed subject-matter sufficiently disclosed
- auxiliary request 3 did not add subject-matter, the feature "*Lactobacillus acidophilus* NCFM" was clear, and the claimed subject-matter was inventive starting from D2 as the closest prior art.

IV. The patent proprietor and the opponent each filed an appeal against the decision. As both parties are appellants and respondents, they are referred to as the patent proprietor and the opponent.

V. With its statement of grounds of appeal the patent proprietor re-filed the main request and auxiliary requests 1 to 3 on which the decision under appeal was based.

VI. With the statement of grounds of appeal, the opponent filed documents D17 and D18.

VII. The Board scheduled oral proceedings in line with the parties' requests. The Board issued a communication under Article 15(1) RPBA including its preliminary opinion on the case.

VIII. With a letter dated 20 September 2023 the patent proprietor filed document D19 and an additional auxiliary request.

IX. Oral proceedings were held before the Board on 10 October 2023. At the end of the oral proceedings, the Board announced its decision.

X. The patent proprietor's arguments relevant to the present decision can be summarised as follows.

Admittance of documents D17 and D18 and the sufficiency objection based on the patient group in claim 1

D17 and D18 should not be admitted. Their filing was not a reaction to the decision but a new attempt by the opponent to raise objections discussed in the opposition proceedings and rejected by the opposition division. Furthermore, the documents were not relevant. D17 did not allow the conclusion that *L. acidophilus* NCFM was not sufficiently disclosed, and D18 did not demonstrate that *B. lactis* Bi-07 had been used for treating respiratory tract infections in children.

The sufficiency objection based on the patient group of claim 1 was not admissible. It could and should have been raised in the opposition proceedings.

Sufficiency of disclosure (main request)

The clinical study in the application as filed made credible that the combination of bacteria species in claim 1 achieved the desired therapeutic effect. Documents D6 and D7 did not create serious doubts. They only made general statements on the specificity of some bacterial strains for certain therapeutic effects.

These statements did not apply to the species and the therapeutic effect in claim 1. D7 acknowledged that different strains could have the same effect.

Amendments (auxiliary request 3)

The subject-matter of claim 1 was directly and unambiguously disclosed in the application as filed. The application had to be read as a whole. Paragraphs [10] and [11] disclosed the use of *L. acidophilus* and *B. lactis* for reducing or preventing respiratory disease symptoms in children affected by a respiratory tract infection. The symptoms of respiratory disease according to the invention were flu-like symptoms (paragraphs [15], [17] and [43]). The preferred bacterial strains were the ones now in claim 1 (paragraphs [55] and [56]). The therapeutic use of claim 1 was illustrated in the clinical study of the application as filed.

Clarity (auxiliary request 3)

The "*B. lactis* Bi-07" feature was in claim 2 as granted. Therefore, its clarity could not be objected to (G 3/14). With regard to the "*L. acidophilus* NCFM" feature, it was a well-documented and characterised strain. Its identity was clear, as derivable from the patent (paragraph [61]), D12 and D13. The designation *L. acidophilus* NCFM was not internal but external and public. Although this designation was additionally protected by trademark, the patent never referred to *L. acidophilus* NCFM as a trademark. It was common in probiotics to use a designation to identify a strain and then to register it as a trademark. This situation was not comparable with the case dealt with in

T 842/14, in which the trademark protected a secret composition.

Sufficiency of disclosure (auxiliary request 3)

The clinical study in the application as filed was in line with claim 1. The study made credible that the therapeutic effect of claim 1 was obtained without undue burden. As to the availability of the probiotic strains in claim 1, D12, D13 and D14 demonstrated that they were commercially available on the priority date.

Inventive step (auxiliary request 3)

Starting from D2, the subject-matter of claim 1 differed in the combination of bacterial strains administered to children, i.e. *L. acidophilus NCFM* plus *B. lactis* Bi-07 instead of *L. rhamnosus GG or L. delbrueckii bulgaricus* plus *B. lactis* Bb-12.

In view of the technical effect shown by the clinical study in the patent, the objective technical problem was the provision of a probiotic composition for reducing or preventing flu-like symptoms in a child affected by a respiratory tract infection.

The cited prior art did not suggest that the combination of bacterial strains in claim 1 could solve the problem. This was even more true considering that the main request had been held insufficiently disclosed because the benefits of probiotics on health were strain specific.

XI. The opponent's arguments relevant to the present decision can be summarised as follows.

Admittance of documents D17 and D18 and the sufficiency objection based on the patient group in claim 1

D17 should be admitted as a reaction to the decision under appeal which, in spite of the cited prior art, concluded that the identity of *L. acidophilus* NCFM was clear and sufficiently disclosed. D17 demonstrated that the decision was flawed on these points.

D18 was also filed in response to the decision, which concluded that the cited prior art did not sufficiently show that the micro-organisms in claim 1 had been used for treating respiratory infections in children. D18 demonstrated that this was indeed the case.

The sufficiency objection based on the patient group of claim 1 had been raised in the notice of opposition and was maintained throughout the opposition proceedings.

Sufficiency of disclosure (main request)

D6 and D7 created serious doubts that the bacterial species in claim 1 could achieve the desired therapeutic effect. They taught that the therapeutic effect of probiotics was strain specific. The patent proprietor had not demonstrated that the bacterial species of claim 1 were an exception to this rule.

Amendments (auxiliary request 3)

Claim 1 of auxiliary request 3 added subject-matter because the application as filed did not disclose the

reduction or prevention of flu-like symptoms in children affected by a respiratory tract infection. Paragraphs [10], [11], [15] and [17] and the clinical study (paragraph [69]) of the application as filed did not refer to children affected but at risk of being affected by a respiratory tract infection. There was no link between the flu-like symptoms disclosed in paragraph [43] and the administration of probiotics to children affected by a respiratory tract infection, either. For the same reasons, the insertion of the expression "affected by" in the description added subject-matter.

In addition, the application as filed did not disclose the combination of the two bacterial strains in claim 1.

Clarity (auxiliary request 3)

The designations *L. acidophilus* NCFM and *B. lactis* Bi-07 were internal and therefore unclear. Furthermore, they were also trademarks, and their composition could change over time. In line with the principles stated in decision T 842/14, the identity of the strains in claim 1 was not clear.

Sufficiency of disclosure (auxiliary request 3)

The application as filed did not make credible that the claimed therapeutic effect could be achieved. The clinical study in the application as filed had not been carried out on patients according to claim 1, i.e. children affected by a respiratory tract infection. In addition, the strains of claim 1 were not available to the public on the filing date.

Inventive step (auxiliary request 3)

Starting from D2 as the closest prior art, the subject-matter of claim 1 differed in the probiotic combination administered to children. There was no evidence that this difference produced any technical effect.

Therefore, the objective technical problem was the provision of an alternative composition comprising probiotic bacteria for reducing or preventing symptoms of respiratory tract infection in children.

The solution proposed in claim 1 was obvious because most probiotic strains were known to improve human health. This was also the case for *L. acidophilus NCFM* and *B. lactis* Bi-07 (D12 and D13). Therefore, the skilled person had good reasons to use the strains of claim 1 with the expectation that they would solve the problem posed.

XII. The parties' final requests were as follows.

- The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or, as an auxiliary measure, that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 3 filed with the statement of grounds of appeal.

  In addition, the patent proprietor requested that documents D17 and D18 as well as the opponent's sufficiency objection relating to the patient group in claim 1 not be admitted into the appeal proceedings.

- The opponent requested that the decision under appeal be set aside and that the patent be revoked.

  It also requested that document D19 not be admitted into the appeal proceedings.

Reasons for the Decision

1. Admittance of D17 (Article 12(6) RPBA)

D17 was filed by the opponent with its statement of grounds of appeal, allegedly in response to the decision. D17 is a scientific opinion from the European Food Safety Authority, published in 2010, which deals with health claims related to non-characterised bacteria and yeasts. The filing of D17 was intended to call into question that the strain *B. lactis* Bi-07 was sufficiently characterised on the filing date.

It was apparent from the patent as granted (paragraphs [0052] and [0061], the clinical study and claim 2) that *B. lactis* Bi-07 belonged to the core of the invention. *B. lactis* Bi-07 was also in claim 1 of auxiliary requests 2 and 3 filed on 7 November 2018 and auxiliary requests 2 and 3 filed on 4 July 2019. The question of the sufficient characterisation of *B. lactis* Bi-07 was raised by the opponent in its letters of 4 July 2019 (point 3.1) and 4 September 2019 (page 1), and it was ultimately dealt with in point 18 of the decision under appeal.

Therefore, the Board cannot agree with the opponent that the filing of D17 was a response to the decision.

Rather, it was a further attempt to raise an objection that had failed in the opposition proceedings. As D17 could and should have been filed in the opposition proceedings, it was not admitted under Article 12(6) RPBA.

As a consequence D19, filed by the patent proprietor as a direct response to D17, was not admitted either.

2. Admittance of D18 (Article 12(6) RPBA)

D18 was also filed by the opponent with its statement of grounds of appeal, allegedly in response to the decision. In the decision, the opposition division had concluded that priority was validly claimed for auxiliary request 3. This had the consequence that documents D4, D5 and D14 did not belong to the prior art under Article 54(2) EPC. D18 was intended to fill the probatory gap left by the exclusion of D4, D5 and D14, on which the opponent had relied as combination documents for its inventive-step objections.

Knowing that the D4, D5 and D14 had been published between the priority and the filing date, the opponent could not ignore that its inventive-step objections would be moot if the priority date was held valid. The opponent could and should have filed combination documents published before the priority date, e.g. D18, in case the priority date was found to be valid. The filing of D18 in the appeal proceedings, rather than a reaction to the decision, was a new attempt for an objection that had failed in the opposition proceedings. Therefore, D18 was not admitted under Article 12(6) RPBA.

3. Admittance of the sufficiency objection based on the patient group (Article 12(2) RPBA)

In its reply to the patent proprietor's statement of grounds of appeal (point 2.2), the opponent argued that the patient group in claim 1 was not the patient group tested in the clinical study of the application as filed. Claim 1 was directed to children affected by a respiratory tract infection, while the clinical study was on children that had not been diagnosed as affected by a respiratory tract infection. Therefore, there was no evidence on file demonstrating that the combination of strains in claim 1 could reduce or prevent flu-like symptoms in children affected by a respiratory tract infection.

The patent proprietor requested that this sufficiency objection not be admitted because it had first been raised in the appeal proceedings. However, it appears from the decision under appeal (page 6, point 16.3) that this aspect of sufficiency had indeed been raised in the opposition proceedings against the main request. As the objection had been presented in accordance with Article 12(2) RPBA, it was part of the file and the patent proprietor's request to exclude it was rejected.

4. Main request - sufficiency of disclosure (Article 100(b) EPC)

4.1 Claim 1 as granted is directed to the use of a combination of two bacterial species, *L. acidophilus* and *B. lactis*, for reducing or preventing flu-like symptoms in a child affected by a respiratory tract infection. The patent proprietor relied on the clinical study in the application as filed to demonstrate that the combination of bacterial species in claim 1

achieved the claimed therapeutic effect. The study was based on the administration of a combination of strains belonging to those species, namely *L. acidophilus* NCFM and *B. lactis* Bi-07.

According to the opponent, there were serious doubts that the bacterial species in claim 1 could achieve the claimed therapeutic effect. One reason for this was that, according to D6 and D7, the effect of probiotics on health was strain specific. Therefore, if an effect was shown for the strains *L. acidophilus* NCFM and *B. lactis* Bi-07, the effect could not be extrapolated to their respective species *L. acidophilus* and *B. lactis*.

4.2 The Board agrees with the opponent.

D6 (points 1 and 3) is a draft of the guidelines proposed by a group of experts consulted by the FAO and the WHO for evaluating the use of therapeutic probiotics in food. In the first paragraph of point 3.1, D6 underlines the importance of identifying probiotic strains because, according to the available evidence, the effect of probiotics on health is strain specific. This is not critical in the exceptional cases in which there is scientific substantiation that health benefits are not strain specific, for instance, the use of *S. themophilus* and *L. delbrueckii ssp. bulgaricus* for enhancing lactose digestion in lactose intolerant individuals.

D7 (page S60, paragraph bridging the columns) confirms the teaching of D6. It states that clinical results from one study are applicable only to the strains evaluated in that study. For claiming a physiologic benefit, the genus, species and strain for which the

effect was observed should be specified. D7 acknowledges that in certain cases further research could reveal that an effect is not strain- but species- or genus-specific.

It follows from D6 and D7 that on the filing date it was generally accepted that the health benefit provided by a probiotic was strain specific. Only in exceptional cases had it been observed that the effect of a strain was common to the whole species. There is no experimental evidence on file that the health benefits obtained by the administration of *L. acidophilus* NCFM and *B. lactis* Bi-07 can also be obtained with other strains of the species *L. acidophilus and B. lactis*.

4.3 The patent proprietor's argument that D6 and D7 only make general statements and that they are not applicable to the case at hand is not convincing. D6 and D7 establish what the skilled person considered as a rule for the therapeutic effect of probiotics on the filing date. Although D6 and D7 contemplate the possibility that there may be exceptions to the rule, they also establish that exceptions need to be supported by scientific evidence. In the case at hand, such evidence is missing.

4.4 Therefore, the Board has serious doubts that, on the filing date, the skilled person could carry out the invention of claim 1 without undue burden. As a consequence, the ground for opposition of Article 100(b) EPC precludes the maintenance of the patent as granted.

5. *Auxiliary requests 1 and 2 - sufficiency of disclosure (Article 83 EPC)*

Claim 1 of auxiliary request 1 differs from claim 1 as granted in that the species *L. acidophilus* has been limited to the strain *L. acidophilus* NCFM. Similarly, claim 1 of auxiliary 2 differs from claim 1 as granted in that *B. lactis* has been limited to the strain *B. lactis* Bi-07.

In the written proceedings, the patent proprietor did not provide arguments specifically on auxiliary requests 1 and 2. It relied on the arguments put forward for the main request (patent proprietor's statement of grounds of appeal, page 8, point 2).

The Board indicated in its communication in preparation for the oral proceedings that it agreed with the decision under appeal that if the subject-matter of the main request was not sufficiently disclosed, that of auxiliary requests 1 and 2 would not be sufficiently disclosed either. At the oral proceedings before the Board, the patent proprietor did not wish to comment on this point.

Although one of the species in claim 1 of each of auxiliary requests 1 and 2 has been restricted to a strain, the other species remains in the claim - auxiliary request 1 refers to *B. lactis* and auxiliary request 2 to *L. acidophilus*. As explained for the main request, the therapeutic effect recited in claim 1 is considered to be strain specific. Therefore, for the reasons explained for the main request, the subject-matter of auxiliary requests 1 and 2 does not meet the

requirements of sufficiency of disclosure, contrary to Article 83 EPC.

6. *Auxiliary request 3 - interpretation of claim 1*

6.1 Claim 1 of auxiliary request 3 is directed to the use of a combination of the strains *L. acidophilus* NCFM and *B. lactis Bi-07* for reducing or preventing flu-like symptoms in a child affected by a respiratory tract infection.

The opponent's case on added subject-matter, sufficiency of disclosure and inventive step was partially based on the understanding that the expression in claim 1 "affected by" implied that children treated according to the claim were necessarily infected with a respiratory tract pathogen from the outset of the treatment.

6.2 The Board construes claim 1 more broadly. Although the claim refers to a child affected by a respiratory tract infection, the Board does not read in its wording a limitation as to when the combination of bacterial strains must be administered. In the Board's view, claim 1 also covers the situation in which the strains are administered before infection and, if a respiratory tract infection then occurs, the flu-like symptoms suffered by the child are prevented or reduced.

This interpretation is technically sensible and consistent with the fact that claim 1 includes the prevention of flu-like symptoms. As the usual way of detecting whether a child is affected by a respiratory tract infection is the occurrence of flu-like symptoms, it appears reasonable to assume that the prevention of flu-like symptoms according to claim 1 is carried out

by administering the bacterial strains prior to infection.

7. *Auxiliary request 3 - amendments (Articles 76(1) and 123(2) EPC)*

7.1 The patent in suit stems from a divisional of European patent application 07838266.0. It was common ground between the parties that both applications had essentially the same description and that the added-matter arguments based on one were applicable to the other. Therefore, in the following assessment of added subject-matter, the Board only refers to the application as filed (Article 123(2) EPC), but the same reasoning applies to the earlier application as filed (Article 76(1) EPC).

7.2 Considering the interpretation of claim 1 in point 6.2 above, the Board agrees with the patent proprietor that the application as filed, read as a whole, directly and unambiguously discloses the subject-matter of claim 1.

In paragraph [10], second sentence, the application as filed discloses the use of the combination of *L. acidophilus* with *B. lactis* for reducing or preventing the symptoms of a respiratory disease in a child. The symptoms first appear when the child is affected by the respiratory disease, as confirmed in the last part of paragraph [10]. The latter states that the combination of *L. acidophilus* with *B. lactis* is suitable for preventing symptoms of respiratory disease in children upon subsequent exposure to an organism capable of producing a respiratory disease. Paragraph [11] also refers to the prevention and reduction of the symptoms of respiratory disease.

With regard to the "flu-like symptoms" feature in claim 1, it is clear from paragraphs [15], [17] and [43] and from the clinical study in the application as filed that the symptoms of respiratory disease within the meaning of the invention, i.e. those referred to in paragraphs [10] and [11], are flu-like symptoms. Paragraph [15] states that during the development of the invention, it was found that the combination of *L. acidophilus* with *B. lactis* prevented and reduced flu-like symptoms. Paragraph [17] states that the consumption of probiotics according to the invention was assessed for reducing flu-like symptoms of illness. The symptoms encompassed by the term "flu-like symptoms" were specified in paragraph [43]. Lastly, in the clinical study, the bacterial strains of claim 1 were administered to children during the months in which respiratory tract infections are more prevalent, and the occurrence of eight flu-like symptoms was assessed (see e.g. paragraphs [83], [96] and [101]).

As to the combination of the probiotic strains in claim 1, paragraphs [55] and [56] teach that the preferred strains of the species combined in paragraph [10] are *L. acidophilus NCFM* and *B. lactis* Bi-07. These were also the strains administered to the children in the clinical study of the application as filed (paragraph [94], Table 2).

7.3 Consequently, the application as filed and the earlier application as filed disclose the use of a combination of *L. acidophilus NCFM* and *B. lactis* Bi-07 for reducing or preventing flu-like symptoms in a child affected by a respiratory tract infection. Therefore, auxiliary request 3 meets the requirements of Articles 123(2) and 76(1) EPC.

8. *Auxiliary request 3 - clarity (Article 84 EPC)*

8.1 According to the opponent, the identity of the strains in claim 1 *L. acidophilus* NCFM and *B. lactis* Bi-07 was unclear. The patent proprietor correctly noted that *B. lactis* Bi-07 was in claim 2 as granted. Therefore, in accordance with decision G 3/14, its clarity cannot be objected to in opposition or subsequent appeal proceedings.

8.2 With regard to the feature "*L. acidophilus* NCFM" the opponent argued that it was unclear because it was both an internal designation and a trademark.

8.2.1 D12 states (abstract and page 3906, right-hand column, lines 5 and 6) that *L. acidophilus* NCFM has been commercially available since the early seventies and that it has been widely investigated for its physiological, biochemical, genetic and fermentative properties. D12 discloses the complete genome sequence of *L. acidophilus* NCFM. In addition, D13 (last page, right-hand column, second paragraph) states that *L. acidophilus* NCFM is a unique strain commercialised by Rhodia. Therefore, the Board agrees with the patent proprietor that *L. acidophilus* NCFM is not an internal designation and that its identity is well known and clear.

8.2.2 Citing T 842/14, the opponent also argued that because *L. acidophilus* NCFM was a trademark, its identity could changed over time and therefore was unclear. The Board disagrees for the following reasons.

It was undisputed that *L. acidophilus* NCFM is a trademark. Nevertheless, *L. acidophilus* NCFM is firstly

a well-known, clearly identified strain. The patent never refers to it as a trademark. The fact that the designation *L. acidophilus* NCFM is additionally protected by trademark does not create doubts as to the identity of the designated and protected strain.

The rationale of T 842/14 is not applicable. T 842/14 (Reasons 28) dealt with anti-foam reagents of secret composition designated by trademarks. The competent board held in T 842/14 that there could be no certainty that the composition of the anti-foam reagents had not changed over the lifetime of the patent because the composition had been kept secret. The case at hand entails a bacterial strain which, contrary to the chemical composition in T 842/14, is a single-component biological entity that has been extensively used in research and the identity of which is public and generally known. The Board has no doubts that the identity of *L. acidophilus* NCFM is clear and has not changed over time.

8.3 Therefore, claim 1 complies with Article 84 EPC.

9. Auxiliary request 3 - sufficiency of disclosure (Article 83 EPC)

9.1 According to the opponent, the subject-matter of claim 1 was not sufficiently disclosed for two reasons.

(i) The clinical study in the application as filed did not make credible that the therapeutic effect of claim 1 could be achieved without undue burden because the study had not been carried out on children affected by a respiratory tract infection

(ii) The probiotic strains in claim 1 were not available to the public on the filing date.

9.2 In the Board's view, neither of these objections create serious doubts that the skilled person could carry out the invention without undue burden.

9.2.1 With regard to objection (i), the clinical study in the application as filed (paragraphs [69] to [73]) was carried out on a population of children of three to five years of age attending a daycare centre five days per week during the months in which respiratory tract infections are more prevalent. The children took a placebo or a probiotic supplement containing either *L. acidophilus* NCFM or a combination of *L. acidophilus* NCFM with *B. lactis* Bi-07, twice daily. The frequency of illness and the occurrence of flu-like symptoms were observed. The results of the study were presented in Tables 2 and 3 and summarised in paragraph [101]. They showed that the children who took the supplement with bacterial strains experienced respiratory tract infections less frequently and that their flu-like symptoms lasted less time than in the children of the placebo group. Furthermore, the effect in the group of children receiving the two strains was superior to that in the group receiving only *L. acidophilus* NCFM.

The Board set out in point 6.2 above that claim 1 does not require that the bacterial strains be administered once the respiratory tract infection has occurred. The strains can be administered before infection to prevent or reduce the flu-like symptoms associated with a subsequent respiratory tract infection. Therefore, the clinical study in the application as filed reflects the subject-matter of claim 1 and makes credible that the

claimed effect can be achieved. The opponent has not raised serious doubts in that respect.

9.2.2 With regard to objection (ii), the opponent is wrong that the two strains of claim 1 were not available to the public on the filing date. The commercial availability of *L. acidophilus* NCFM is proven by D12 and D13, as discussed in point 8.2 above. In addition, D14 demonstrates that *L. acidophilus* NCFM and *B. lactis* Bi-07 were commercial strains on the priority date of the patent. D14 (abstract) discloses a pre-clinical study on lactic acid bacteria. Table 1 of D14 discloses a list of the bacterial strains tested and their origins. It specifies that *L. acidophilus* NCFM and *B. lactis* Bi-07 were commercial strains. Although D14 was published in the priority period of the patent, it was received by the editor before the priority date, namely on 9 September 2006. Consequently, the strains in claim 1 were commercially available before the priority date.

9.3 It follows that auxiliary request 3 meets the requirements of Article 83 EPC.

10. Auxiliary request 3 - inventive step

10.1 The parties agreed that D2 was the closest prior art. D2 (abstract) discloses the combination of a *Bifidobacteria* strain with an adherence-promoting probiotic for preventing or treating respiratory infections and acute otitis media in infants. According to paragraphs [00022] and [00023] of D2, the preferred *Bifidobacteria* strain is *B. lactis* Bb-12 and the preferred adherence-promoting probiotic is a member of the *Lactobacillus* species such as *L. rhamnosus GG*,

L. delbrueckii ssp. *bulgaricus* or a combination of these.

10.2 The parties also agreed that the subject-matter of claim 1 differed from D2 at least in the combination of bacterial strains that were administered to children. In claim 1, it was a combination of *L. acidophilus NCFM* and *B. lactis* Bi-07, while in D2 it was a combination of *L. rhamnosus GG or L. delbrueckii bulgaricus* and *B. lactis* Bb-12.

As set out in point 9.2.1 above, the results of the clinical study in the patent (see Tables 2 and 3 and paragraph [0097]) demonstrate that the administration of the bacterial strains in claim 1 prevents or reduces flu-like symptoms in children affected by respiratory tract infections. Therefore, the objective technical problems is, as proposed by the patent proprietor, the provision of a probiotic composition for reducing or preventing flu-like symptoms in a child affected by a respiratory tract infection.

10.3 The solution proposed in claim 1, i.e. the combination of *L. acidophilus NCFM* and *B. lactis* Bi-07, was not obvious to the skilled person. None of the cited prior-art documents suggests that *L. acidophilus NCFM* and *B. lactis* Bi-07 could reduce or prevent flu-like symptoms in children affected by a respiratory tract infection.

In the written appeal proceedings, the opponent relied on D4, D5 and D14 as documents to be combined with D2. However, D4, D5 and D14 do not belong to the prior art under Article 54(2) EPC. They were published after the priority date of the patent (2 October 2006) and the opponent did not challenge the opposition division's

decision that priority was validly claimed for auxiliary request 3 (decision under appeal, points 19.5 and 19.6). Therefore, at the oral proceedings before the Board, the opponent did not rely on D4, D5 and D14. Its position was instead that probiotics were known to promote human health and, therefore, the skilled person would expect known probiotic strains such as *L. acidophilus* NCFM and *B. lactis* Bi-07 to solve the problem posed.

As concluded for sufficiency of disclosure of the main request (point 5.2 above), on the priority date, it was generally accepted by the scientific community that the beneficial effects of probiotics on human health were strain dependent. The fact that *L. acidophilus* NCFM and *B. lactis* Bi-07 were known probiotics did not provide the skilled person with a reasonable expectation that they would have an effect on the flu-like symptoms of children affected by respiratory tract infections. Neither of the two strains had been disclosed to have such an effect.

10.4 Therefore, the subject-matter of auxiliary request 3 involves an inventive step, and the request meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

D. Hampe A. Usuelli

Decision electronically authenticated