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**Datasheet for the decision  
of 26 July 2021**

**Case Number:** T 3013/18 - 3.3.01

**Application Number:** 10747838.0

**Publication Number:** 2429557

**IPC:** A61K35/76, A61P37/04,  
A61K35/74, A61P29/00,  
A23K10/18, A23L33/135

**Language of the proceedings:** EN

**Title of invention:**

INFANT FEEDING FORMULAS COMPRISING PROBIOTIC MICRO-ORGANISMS

**Patent Proprietor:**

Société des Produits Nestlé S.A.

**Opponents:**

Valio Ltd  
N.V. Nutricia

**Headword:**

Infant formulas with probiotic micro-organisms / NESTLÉ

**Relevant legal provisions:**

EPC Art. 100(b), 54, 56  
EPC R. 99(2)  
RPBA Art. 12(2), 12(4)  
RPBA 2020 Art. 13(2)

**Keyword:**

Ground for opposition under Article 100(b) EPC - substantiated in the statement of the grounds of appeal (yes)

Late-filed documents - submitted with the statement of the grounds of appeal - admitted (yes)

Main request, auxiliary requests 1 and 2 - sufficiency of disclosure (no)

Auxiliary request 2a - late-filed - admitted (yes)

Auxiliary request 2a - sufficiency of disclosure (yes)

Auxiliary request 2a - novelty (yes)

Auxiliary request 2a - inventive step (yes)

**Decisions cited:**

G 0001/03, T 2061/19



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 3013/18 - 3.3.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.01**  
**of 26 July 2021**

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**Respondent:**  
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**Decision under appeal:**

**Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
25 October 2018 concerning maintenance of the  
European Patent No. 2429557 in amended form**

**Composition of the Board:**

**Chairman**           A. Lindner  
**Members:**         S. Albrecht  
                      L. Bühler

## Summary of Facts and Submissions

- I. European patent No. 2 429 557 ("the patent") is based on European patent application No. 10747838.0 ("patent application"). The patent was granted on the basis of a set of 12 claims.
- II. Opposition proceedings were based on the grounds for opposition under Article 100(a) EPC for lack of novelty and lack of inventive step, and under Article 100(b) EPC.
- III. The documents filed during the opposition and appeal proceedings include the following:
- D1: WO 2004/069156 A2
  - D3: US 2008/0206212 A1
  - D4: US 2008/0206213 A1
  - D5: US 4,980,182
  - D18: US 7,410,653 B1
  - D26: M. Kechagia et al., *ISRN Nutrition* 5, 2013, 1-7
  - D30: The patent proprietor's response to the USPTO action dated 2 October 2015 including exhibit A (Senok A. C. et al., *Clin Microbial Infect* 2005; 11:958-966) and exhibit B (Sanders M. E., "Probiotics: strains matter", 1 June 2007, 8 pages)
  - D31: Declaration of Annick Mercenier regarding US Patent Application No. 13/319,627, signed 8 April 2016
  - D32: Council Directive 92/46/EEC, 39 pages
- IV. The opposition division decided that the patent as amended in the version of auxiliary request 1 and the invention to which it related met the requirements of the EPC. In respect of this request, the opposition division concluded, *inter alia*, the following.

(a) The claimed invention was sufficiently disclosed.

(b) Claim 1 was novel over document D18.

(c) Claim 1 involved an inventive step over documents D3 and D4 as the closest prior art.

- V. Both opponents lodged an appeal against the opposition division's decision.
- VI. In a letter dated 27 February 2019, opponent 2 withdrew its appeal and became party as of right under Article 107, second sentence, EPC.
- VII. In its statement setting out the grounds of appeal, opponent 1 ("appellant") requested that the decision under appeal be set aside and that the patent be revoked in its entirety.
- VIII. In its reply to the statement of grounds of appeal, the patent proprietor ("respondent") requested as its main request that the appeal be dismissed and that the patent be maintained on the basis of a set of claims filed with that reply, this set being identical to the one upheld by the opposition division.

As an auxiliary measure, the respondent requested that the patent be maintained as amended on the basis of one of the sets of claims of auxiliary requests 1 to 9 filed together with its reply to the statement of grounds of appeal.

The respondent further requested that documents D30 to D32 not be admitted into the appeal proceedings.

Independent claims 1 and 6 of the main request read as follows:

"1. Infant feeding formula to be administered to infant as only nutrition source or as only complementary nutrition source in addition to breastfeeding that provides complete nutrition to the infant and comprises non-replicating probiotic micro-organisms, wherein the non-replicating probiotic micro-organisms were rendered non-replicating by a heat-treatment which is a high temperature treatment at 120-140°C for 5-15 seconds, wherein the infant feeding formula is provided as a dried composition to be reconstituted with water prior to use."

"6. Infant feeding formula in accordance with claim 1 for use in the prevention or treatment of inflammatory disorders."

The set of claims of auxiliary request 1 differs from that of the main request in that the following passage was added at the end of claim 1:

", and wherein the IL-12p40/IL-10 ratio is lower for the non-replicating probiotic micro-organisms than for their live counterparts."

Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the following passage was added at the end of claim 1:

"and wherein the probiotic micro-organisms are selected from the group consisting of *Bifidobacterium longum* NCC 3001, *Bifidobacterium longum* NCC 2705, *Bifidobacterium breve* NCC 2950, *Bifidobacterium lactis* NCC 2818, *Lactobacillus paracasei* NCC 2461,

*Lactobacillus rhamnosus* NCC 4007, *Streptococcus thermophilus* NCC 2019, *Streptococcus thermophilus* NCC 2059, *Lactobacillus casei* NCC 4006, *Lactobacillus acidophilus* NCC 3009, *Lactobacillus casei* ACA-DC 6002 (NCC 1825), *Escherichia coli* Nissle, *Lactobacillus bulgaricus* NCC 15, *Lactococcus lactis* NCC 2287, or combinations thereof."

IX. The parties were summoned to oral proceedings at the premises of the boards, initially scheduled to take place on 24 September 2020 but subsequently rescheduled for 25 September 2020.

X. In a communication pursuant to Article 15(1) RPBA 2020 issued on 9 July 2020 ("communication"), the board drew the parties' attention to the points to be discussed during the oral proceedings.

XI. By letter dated 23 July 2020, the respondent filed four sets of claims entitled auxiliary requests 2a, 4a, 7a and 9a.

The claims of auxiliary request 2a are identical to the claims of auxiliary request 2 with the exception that *Streptococcus thermophilus* NCC 2019 and *Streptococcus thermophilus* NCC 2059 have been deleted from the list of probiotic micro-organisms recited in claim 1.

XII. By letter dated 31 July 2020, the respondent withdrew auxiliary requests 5 to 9, 7a and 9a.

XIII. By letter dated 11 August 2020, the appellant submitted further arguments in reply to the board's communication and the respondent's letter of 23 July 2020. In addition, the appellant requested that the oral



proceedings be either postponed or conducted by videoconference.

- XIV. By letter dated 1 September 2020, the party as of right informed the board that it would not be attending the oral proceedings and withdrew its request for postponement of the oral proceedings.
- XV. Likewise, by letter dated 3 September 2020, the appellant informed the board that it would not be attending the oral proceedings.
- XVI. In a letter dated 24 September 2020, the respondent informed the board that it would not be able to attend the oral proceedings at the premises of the boards because of the COVID-19 pandemic.
- XVII. In a communication dated 25 September 2020, the registry of the board informed the parties that the oral proceedings scheduled for 25 September 2020 could not take place and had been rescheduled to 26 July 2021.
- XVIII. Consequently, the board changed the format of the oral proceedings to a videoconference in accordance with the respondent's request submitted in its fax dated 21 July 2021.
- XIX. Oral proceedings took place on 26 July 2021 in the presence of the respondent only.
- XX. At the end of the oral proceedings, the chairman announced the board's decision.

XXI. The appellant's written submissions, in so far as they are relevant to the present decision, may be summarised as follows.

*Admittance of documents D30 and D31 into the appeal proceedings*

These documents should not be rejected as late-filed. Documents D30 and D31 could not have been presented earlier because they turned out to be *prima facie* relevant for the sufficiency of disclosure of the claimed invention as a result of the respondent's submissions at the oral proceedings before the opposition division.

*Admittance of auxiliary request 2a*

This request should not be admitted into the proceedings. The experimental data of Figure 4B of the patent had already been objected to in the grounds of appeal. Therefore, the respondent could and should have filed auxiliary request 2a in response to this objection at the latest with its reply to the statement of grounds of appeal.

*Sufficiency of disclosure of claim 6 of each of the main request and auxiliary requests 1, 2 and 2a*

First, the patent did not contain a single example or other information on how to produce an infant feeding formula as claimed. In the examples of the patent, solely probiotic micro-organisms as such had been tested, and the reported results had not been obtained with different quantities of non-replicating probiotic micro-organisms. Therefore, it was not clear which quantities were needed to obtain the desired effects.

Second, the claimed anti-inflammatory effects could not be achieved across the scope of claim 6, as evidenced by the experimental data in example 1 of the patent itself.

*Novelty of auxiliary request 2a*

The subject-matter of claim 1 of the main request lacked novelty over example 2 of document D18.

*Inventive step of auxiliary request 2a*

Document D3 or D4 could be considered the closest prior art. The subject-matter of claim 1 differed from example 1 of these documents on account of the heating conditions applied to the probiotic micro-organisms. The alleged anti-inflammatory effects resulting from this difference were not plausible across the scope of claim 1 since only some of the probiotic micro-organisms tested in example 1 of the patent exhibited the anti-inflammatory effects postulated by the respondent. Furthermore, these effects were the same as those obtained after heat-treatment of the probiotic micro-organisms at 74°C and 90°C for 15 seconds, as evidenced by the results presented in Figures 2 and 5 of the patent. The claimed heat-treatment was thus merely an arbitrary selection rendered obvious by the closest prior art either alone or in combination with document D18, D5 or D32.

XXII. The respondent's written and oral submissions, in so far as they are relevant to the present decision, may be summarised as follows.

*Admittance of the appellant's ground for opposition pursuant to Article 100(b) EPC*

The appellant's objection of lack of sufficiency of disclosure presented in the statement of grounds of appeal consisted exclusively of three types of argument, namely:

- (a) arguments that were literally identical to those presented in the appellant's letter of 17 July 2018 filed before the opposition division
- (b) arguments directed to the claimed feature "provided as a dried composition to be reconstituted with water prior to use"
- (c) arguments presented for the first time in the statement of grounds of appeal

The first two types of argument lacked substantiation contrary to the requirements of Rule 99(2) EPC and Article 12(2) RPBA 2007. The third type of argument should be disregarded under Article 12(4), first half-sentence, RPBA 2007.

As a consequence, the appellant's ground for opposition under Article 100(b) EPC should not be considered to be included in the legal framework of the appeal.

*Admittance of documents D30 and D31 into the appeal proceedings*

The appellant could and should have filed these documents D30 and D31 during the opposition proceedings. These documents had been publicly available before the expiry of the opposition period.

Furthermore, they did not appear to add anything to the teaching of document D26.

*Admittance of auxiliary request 2a*

This request had been filed promptly after the board's communication, in which the board had, among other things, expressed doubts concerning the anti-inflammatory effects of the two *Streptococcus thermophilus* strains NCC 2059 and NCC 2019 reported in Figure 4B of the patent. Since these effects had not been seriously questioned prior to the board's communication, the admittance of auxiliary request 2a at this stage of the proceedings was fully justified. Furthermore, the claims of this request differed from those of auxiliary request 2 merely in that the two allegedly problematic *Streptococcus thermophilus* strains had been deleted from the list of probiotic micro-organisms in claim 1. This amendment was easy to understand and complied with the requirements of Articles 123(2), 123(3) and 84 EPC. It addressed the board's doubts head-on and did not create a fresh case.

*Sufficiency of disclosure of claim 6 of each of the main request and auxiliary requests 1, 2 and 2a*

Preparing dried infant feeding formulas formed part of the skilled person's common general knowledge. The other objections put forward by the appellant in respect of the claimed infant feeding formulas were mere speculations which, for want of any corroborating evidence, could not create serious doubts.

With respect to the medical uses recited in claim 6 of both the main request and auxiliary request 2, the results depicted in Figure 4B of the patent in respect

of the two *Streptococcus thermophilus* strains NCC 2059 and NCC 2019 heat-treated at 120°C for 15 seconds did not raise serious doubts as to the suitability of the claimed infant feeding formulas for preventing or treating anti-inflammatory disorders over the whole scope claimed. Furthermore, even if infant feeding formulas comprising these two specific *Streptococcus thermophilus* strains were to be considered non-working embodiments of the claimed invention, they represented at most two single, isolated failures in view of the large number of heat-treated probiotic micro-organisms that had been successfully tested in the patent. No lack of sufficiency arose as a result of these two formulas because the patent explained in detail the relevant criteria for finding appropriate alternatives.

The scope of claim 6 of both auxiliary requests 1 and 2a did not include the two *Streptococcus thermophilus* strains heat-treated at 120°C for 15 seconds. Accordingly, the appellant's objections did not apply anymore.

#### *Novelty of auxiliary request 2a*

Example 2 of D18 concerned a liquid, ready-to-use infant formula - not a dried infant formula as claimed. This was evident from the heading of that example and the teaching in column 4, lines 52 to 57.

#### *Inventive step of auxiliary request 2a*

Starting from document D3 or D4 as the closest prior art, the objective technical problem to be solved by the claimed invention was providing an alternative infant formula comprising non-replicating probiotic

micro-organisms having an increased anti-inflammatory effect as compared with their live, replicating counterparts. In view of the experimental results reported in the patent it was credible that this problem had been solved across substantially the entire scope of claim 1. The solution proposed by the patent was not rendered obvious by the closest prior art either alone or in combination with document D18, D5 or D32. The heating conditions recited in claim 1 did not amount to an arbitrary choice but instead represented a purposive selection, as evidenced by document D1. None of the prior-art documents relied on by the appellant taught that probiotic micro-organisms heated in accordance with claim 1 exhibited anti-inflammatory effects. An inventive step was thus to be acknowledged.

XXIII. The parties' final requests, in so far as they are relevant to the present decision, were as follows.

The appellant requested in writing that the decision under appeal be set aside and that the patent be revoked in its entirety. The appellant further requested that auxiliary requests 2a and 4a not be admitted into the appeal proceedings.

The respondent requested that the appeal be dismissed and the patent be maintained on the basis of a set of claims filed as the main request with its reply to the statement setting out the grounds of appeal, this claim set being identical to that of auxiliary request 1 considered in the opposition division's decision.

As an auxiliary measure, the respondent requested that the patent be maintained as amended on the basis of one of the sets of claims of auxiliary requests 1, 2, 2a,

3, 4 and 4a, the sets of claims of auxiliary requests 1, 2, 3 and 4 having been filed together with the reply to the statement setting out the grounds of appeal, and the sets of claims of auxiliary requests 2a and 4a having been filed by letter dated 23 July 2020. The respondent further requested that documents D30 to D32 not be admitted into the proceedings and that the ground of lack of sufficiency of disclosure (Article 100(b) EPC) not be considered (Rule 99(2) EPC and Article 12(4) RPBA 2007).

### **Reasons for the Decision**

1. Admissibility of the appeal

The appeal is admissible. This was not contested by the respondent.

2. Admittance of the ground of lack of sufficiency of disclosure (Article 100(b) EPC) into the appeal proceedings

2.1 The respondent requested that this ground not be considered within the legal framework of the appeal, arguing *inter alia* that the appellant had merely repeated the arguments already presented before the opposition division in the statement of grounds of appeal without explaining why the opposition division's positive finding on sufficiency of disclosure in the impugned decision was incorrect (see point XXII. above). In support of its objection, the respondent relied on case law of the boards of appeal stipulating the requirements for sufficient substantiation of a ground of appeal, citing in particular decision T 2061/19.



- 2.2 Under this case law, a reference to earlier submissions in opposition proceedings and/or the verbatim repetition of arguments presented in those earlier submissions was not, by itself, sufficient to render a submission in the statement of grounds of appeal admissible. Submissions in the statement of grounds of appeal had to be such as to enable the board and any other party to understand immediately why the decision was alleged to be incorrect, without first having to make investigations on their own (see the Case Law of the Boards of Appeal, 9th edition, 2019, V.A.2.6.3 and V.A.2.6.4 and the case law cited in those chapters).
- 2.3 In the case in hand, there is no doubt that the appellant's submissions presented in the statement of grounds of appeal in support of the alleged insufficient disclosure of the claimed invention include arguments that are indeed very similar, if not identical, to those presented in the appellant's letter of 17 July 2018 ("arguments of 17 July 2018").
- 2.4 The arguments of 17 July 2018 set out in detail why, contrary to the opposition division's view expressed in point 21 of its communication annexed to the summons to attend oral proceedings, the anti-inflammatory activity demonstrated for some probiotic strains in example 1 of the patent was not achievable across the entire scope of probiotic micro-organisms claimed.
- 2.5 Subsequently, oral proceedings were held at which the opposition division concluded, *inter alia*, that the then pending main request and first auxiliary request (i.e. the current main request) met the requirements of sufficiency of disclosure. Detailed reasons were given in points 18 and 22 of the impugned decision, which were essentially the same as those already indicated as

the provisional opinion in point 21 of the opposition division's communication annexed to the summons to attend oral proceedings.

- 2.6 In light of these particular circumstances, repeating the arguments of 17 July 2018 in the statement of grounds of appeal can be seen as a reasonable reaction to the impugned decision, enabling the board to understand immediately why the impugned decision is alleged to be incorrect in this respect.
- 2.7 For these reasons, the board is satisfied that the ground for opposition under Article 100(b) EPC is sufficiently substantiated in the statement of grounds of appeal. This ground thus forms part of the legal framework of the appeal.
3. Admittance of documents D30 and D31 into the appeal proceedings (Article 12(4) RPBA 2007)
  - 3.1 The appellant filed these documents with its statement of grounds of appeal to further support its objection of lack of sufficiency of disclosure against claim 6 of auxiliary request 2a.
  - 3.2 In its communication (see points 1.4.1 and 1.4.2), the board expressed the preliminary view that the appellant could and should have filed documents D30 and D31 with its reply to the opposition division's communication annexed to the summons to oral proceedings. The board remarked in particular that the opposition division had already expressed a positive preliminary opinion on sufficiency of disclosure in respect of a claim which was broader in scope than claim 6 of auxiliary request 2a.

- 3.3 In reply to the board's communication, the appellant merely contended that documents D30 and D31 had been filed in reaction to the respondent's submissions at the oral proceedings before the opposition division (see letter of 11 August 2020, point 1). It did not, however, provide any explanation as to which new issues had been raised during the oral proceedings which could justify filing documents D30 and D31 with the statement of grounds of appeal.
- 3.4 Given these circumstances, the board did not see any reason to change its preliminary opinion and decided to hold documents D30 and D31 inadmissible under Article 12(4), first half-sentence, RPBA 2007.
4. Admittance of document D32 into the appeal proceedings
  - 4.1 Document D32, filed by the appellant with its statement of grounds of appeal, reflects common general knowledge.
  - 4.2 The board decided to admit this document into the proceedings (Article 12(4), second half-sentence, RPBA 2007). In view of the outcome of the appeal proceedings, detailed reasoning on the admission of this document is not necessary.
5. Absence of the appellant and the party as of right from the oral proceedings
  - 5.1 The appellant and the party as of right had been duly summoned but chose not to attend the oral proceedings.
  - 5.2 In accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, the board decided to continue the proceedings in the absence of the appellant and the

party as of right and to treat them as relying on their written case.

- 5.3 By absenting themselves from the oral proceedings the appellant and the party as of right gave up the opportunity to make any further submissions on the relevant issues of the case. Hence, the board was in a position to announce a decision at the conclusion of the oral proceedings, as provided for in Article 15(6) RPBA 2020.

*Main request*

6. The subject-matter of claim 6
- 6.1 Claim 6 is a purpose-restricted product claim drawn up in accordance with Article 54(5) EPC. It is directed to an infant feeding formula in accordance with claim 1 for use in preventing or treating inflammatory disorders.
- 6.2 This infant feeding formula recited in claim 1 is a dried composition comprising non-replicating probiotic micro-organisms, these being
- "rendered non-replicating by a heat-treatment which is a high temperature treatment at about 120-140°C for 5-15 seconds".*
- 6.3 This latter feature is a "product-by-process" feature and is to be construed as relating to the technical properties imparted on the product by the process by which it is defined as being obtainable.
- 6.4 Applied to the case in hand, this means that the term "non-replicating probiotic micro-organisms" in claim 1

encompasses any population of probiotic micro-organisms endowed with technical properties given to it by the heat-treatment defined in claim 1. These properties include the non-replicating character of the claimed probiotic micro-organisms.

6.5 Summarising the above, claim 6 pertains to:

- (a) an infant feeding formula as defined in claim 1, comprising non-replicating probiotic micro-organisms exhibiting technical properties imparted on them by a heat-treatment in accordance with claim 1
- (b) for use in preventing or treating inflammatory disorders

7. Article 100(b) EPC - sufficiency of disclosure

7.1 As set out in respondent's letter dated 23 July 2020 (see point 1, third paragraph), attaining the claimed therapeutic effects, i.e. the prevention or treatment of inflammatory disorders, is a technical feature of claim 6. As a consequence, in order to meet the requirement of sufficiency of disclosure, the therapeutic efficacy of the claimed infant feeding formula must be credible across the scope claimed.

7.2 On the other hand, for an objection of insufficient disclosure to succeed, there have to be serious doubts, substantiated by verifiable facts, that the invention is disclosed sufficiently clear and complete for it to be carried out by a person skilled in the art.

7.3 In the case in hand, a first point of dispute was whether the experimental results reported in Figure 4B

of the patent gave evidence for the existence of non-working embodiments of the invention defined in claim 6.

- 7.4 In the board's judgement, this is indeed the case, for the reasons set out below.
- 7.4.1 Figure 4B forms part of the disclosure of example 1 of the patent, in which an *in-vitro* PBMC assay was used to determine the anti- or pro-inflammatory profile of probiotic micro-organisms ("probiotics") heat-treated for 15 seconds at 120°C and 140°C, respectively, as well as of their live counterparts. 42 probiotics were tested in total, covering 14 different bacterial strains.
- 7.4.2 The experimental results of this assay are reported in Figures 1A to 4B of the patent, which show the effects of the tested probiotics on the secretion of the cytokines IL-10, IL-12p40, TNF- $\alpha$  and IFN- $\gamma$  from human peripheral blood mononuclear cells. In addition, these figures display the calculated IL-12p40/IL-10 ratio ("Ratio IL-12/IL-10") of each tested probiotic population as a predictive value of an *in-vivo* anti-inflammatory effect (see paragraph [0063] of the patent).
- 7.4.3 Specifically, Figure 4B of the patent reports on the aforementioned secretory effects and ratios in respect of the probiotic strains *Streptococcus thermophilus* NCC 2059 and *Streptococcus thermophilus* NCC 2019.

*Experimental results relating to Streptococcus thermophilus NCC 2059*

7.4.4 The first row of Figure 4B unequivocally shows that, compared with its live counterpart, *Streptococcus thermophilus* NCC 2059 heat-treated at 120°C for 15 seconds exhibits:

(a) a similar level of TNF- $\alpha$  and slightly increased levels of IL-12p40 and IFN- $\gamma$  (i.e. pro-inflammatory cytokines)

(b) a slightly reduced level of IL-10 (i.e. an anti-inflammatory cytokine)

(c) and, as a result, an increased Ratio IL-12/IL-10

7.4.5 In light of these results, doubts arise as to whether an infant feeding formula as defined in claim 6 comprising *Streptococcus thermophilus* NCC 2059 heat-treated at 120°C for 15 seconds ("NCC 2059 heat-treated at 120°C for 15 seconds") displays anti-inflammatory activity. These doubts are further reinforced by the fact that, with the exception of *Streptococcus thermophilus* NCC 2019, all of the other tested probiotics give rise to a significantly reduced Ratio IL-12/IL-10 compared with their live counterparts after heat-treatment at 120°C for 15 seconds (see Figures 1A to 4A).

7.4.6 In the oral proceedings, the respondent admitted that the experimental results relating to NCC 2059 heat-treated at 120°C for 15 seconds could cast doubt on the therapeutic efficacy of this particular strain. These doubts could not, however, be deemed serious because, for want of any indication in the patent of

whether the live NCC 2059 strain had *in-vivo* anti-inflammatory properties or not, it could not be concluded from the data in Figure 4B of the patent that NCC 2059 heat-treated at 120°C for 15 seconds and its live counterpart lacked anti-inflammatory activity.

- 7.4.7 As a matter of fact, the slightly higher Ratio IL-12/IL-10 reported for NCC 2059 heat-treated at 120°C for 15 seconds could also mean that this strain exhibited a lower but still acceptable anti-inflammatory activity compared with its live counterpart. Support for this interpretation was provided by the general teaching of document D3, according to which live and heat-killed micro-organisms including *Streptococcus thermophilus* (see page 5, right-hand column, lines 2 and 8) were expected to have anti-inflammatory properties.
- 7.4.8 Likewise, document D1 mentioned *Streptococcus thermophilus* in paragraph [0042] and demonstrated in example 1 that a mixture of different viable probiotics including *Streptococcus thermophilus* (see paragraph [00184]) attenuated the severity of DSS-induced colitis in mice (see page 51, Table 1). These facts demonstrated that live *Streptococcus thermophilus* was expected to have at least some anti-inflammatory activity.
- 7.4.9 The board does not concur with the respondent. It is common ground that health benefits for the host immune system delivered by live probiotics are generally considered to be strain-specific (see paragraph [0057] of the patent). Thus, to serve as an indication for the alleged anti-inflammatory activity of the live NCC 2059 strain, the disclosures of documents D1 and D3 relied on by the respondent would need to mention the specific



*Streptococcus thermophilus* strain "NCC 2059". But they do not.

- 7.4.10 It follows that the experimental data disclosed in Figure 4B in respect of NCC 2059 heat-treated at 120°C for 15 seconds cast serious doubt on the suitability of an infant feeding formula in accordance with claim 6 comprising this probiotic strain for the claimed therapeutic application.

*Experimental results relating to Streptococcus thermophilus NCC 2019*

- 7.4.11 Figure 4B (see second row, third graph) discloses Ratios IL-12/IL-10 of *Streptococcus thermophilus* NCC 2019 heat-treated at 120°C for 15 seconds ("NCC 2019 heat-treated at 120°C for 15 seconds") and its live counterpart of approximately 24 and 30, respectively. Since the latter indisputably does not have any anti-inflammatory activity (see paragraph [0068] of the patent), the board has doubts as to whether a heat-treatment at 120°C for 15 seconds, leading to a reduction of the Ratio IL-12/IL-10 from about 30 to about 24 (i.e. a reduction of about 20%), is sufficient to give *Streptococcus thermophilus* NCC 2019 anti-inflammatory properties.

- 7.4.12 The board further notes that, with the exception of *Streptococcus thermophilus* NCC 2059 discussed above, all of the other probiotic strains tested in example 1 exhibit a significantly more reduced Ratio IL-12/IL-10 after heat-treatment at 120°C for 15 seconds, compared with their respective live counterparts, than NCC 2019 heat-treated at 120°C for 15 seconds (see Figures 1 to 3 of the patent).

- 7.4.13 In view of the above, the board considers that the experimental data disclosed in Figure 4B in respect of NCC 2019 heat-treated at 120°C for 15 seconds cast serious doubt on the suitability of an infant feeding formula in accordance with claim 6 comprising this probiotic strain for the claimed therapeutic application.
- 7.4.14 To support its case, the respondent essentially relied on the same arguments as those presented in respect of NCC 2059 heat-treated at 120°C for 15 seconds.
- 7.4.15 The board notes, however, that neither document D1 nor document D3 mentions the specific *Streptococcus thermophilus* strain "NCC 2019". Hence, for the same reasons as set forth in point 7.4.9 above, the respondent's arguments are not found convincing.
- 7.4.16 As a consequence, the board concludes that both NCC 2059 heat-treated at 120°C for 15 seconds and NCC 2019 heat-treated at 120°C for 15 seconds constitute non-working embodiments of the invention defined in claim 6.
- 7.5 In a second line of reasoning, the respondent argued that even if the two tested *Streptococcus thermophilus* strains heat-treated at 120°C for 15 seconds were held to be non-working embodiments, this would still not justify a finding of lack of sufficiency of disclosure of the claimed invention. First of all, the group of non-replicating probiotics in accordance with claim 6 was not as significant as it would appear. As evidenced by document D26 (see page 2, Table 1), there was only a limited number of live micro-organisms to choose from as starting materials for the heating processes specified in claim 1. Furthermore, these processes

covered a rather narrow range of heating temperatures and heating times. At the same time, the patent contained numerous examples demonstrating that a heat-treatment in accordance with claim 1 generated or enhanced anti-inflammatory properties of a wide range of probiotics varying at genus, species and strain levels. Against this background, the two tested *Streptococcus thermophilus* strains heat-treated at 120°C for 15 seconds represented, if anything, single failures. Including these two strains in claim 6 was of no harm because - following the principles laid down in decision G 1/03, reasons 2.5.2 - the patent disclosed a large number of conceivable alternative probiotics and contained sufficient information on the relevant criteria for finding appropriate alternatives. In fact, Figure 4B of the patent itself taught the person skilled in the art that all that was required was to increase the heating temperature from 120°C to 140°C to obtain a significantly reduced Ratio IL-12/IL-10.

7.6 The board does not agree.

7.6.1 As indicated in point 6.5 above, claim 6 pertains to an infant feeding formula as defined in claim 1, comprising non-replicating probiotics exhibiting technical properties imparted on them by a heat-treatment in accordance with claim 1. These properties can vary significantly depending on the chosen heating conditions. For instance, as discussed at the oral proceedings and evidenced by Figure 4B of the patent, heating the *Streptococcus thermophilus* strains NCC 2059 and NCC 2019 at 140°C for 15 seconds instead of at 120°C for 15 seconds significantly increases the secretion of the anti-inflammatory cytokine IL-10 and significantly reduces the secretion

of the pro-inflammatory cytokines IL-12p40, TNF- $\alpha$  and IFN- $\gamma$ .

7.6.2 Thus, contrary to the respondent's position, claim 6 covers a large variety of non-replicating probiotics, this variety resulting not only from the very probiotic selected as the starting material, but also from the specific heating conditions applied to it (i.e a temperature range of 120-140°C and a heating time of 5-15 seconds). These conditions determine the properties of the probiotic product resulting from the heating process, including its cytokine profile.

7.6.3 In view of the foregoing, the two tested *Streptococcus thermophilus* strains NCC 2059 and NCC 2019 heat-treated at 120°C for 15 seconds cannot be considered isolated failures. Instead, on the basis of the experimental data in Figure 4B of the patent, the board has serious doubts as to the suitability of any *Streptococcus thermophilus* strain heat-treated at 120°C for 15 seconds for the claimed therapeutic application, i.e. in respect of a whole class of non-replicating micro-organisms. Accordingly, the principles set out in G 1/03 (see point 7.5 above) do not apply to the case in hand and the respondent's arguments based on them cannot help its case.

7.7 In view of the above considerations, the board finds that the subject-matter of claim 6 of the main request is not sufficiently disclosed over the whole scope of the claim.

*Overall conclusion on the main request*

8. The board concludes that the appellant's objection of insufficiency of disclosure under Article 100(b) EPC

prejudices the maintenance of the patent as amended according to the main request.

*Auxiliary requests 1 and 2*

9. Claim 6 of auxiliary request 1 differs from claim 6 of the main request in that the non-replicating probiotics contained in the infant feeding formula are further defined as follows:

*"and wherein the IL-12p40/IL-10 ratio is lower for the non-replicating probiotic micro-organisms than for their live counterparts."*

10. As explained in point 7.4.11 above, the *Streptococcus thermophilus* strain NCC 2019 heat-treated at 120°C for 15 seconds exhibits this reduced IL-12p40/IL-10 ratio compared with its live counterpart.
11. It follows that auxiliary request 1 must fail for lack of sufficient disclosure under Article 100(b) EPC for the same reasons as set out for claim 6 of the main request.
12. The same conclusions apply in respect of auxiliary request 2 since claim 6 of this request still encompasses infant feeding formulas comprising the probiotics *Streptococcus thermophilus* NCC 2019 and NCC 2059, rendered non-replicating by a heat-treatment at 120°C for 15 seconds (see point VIII. above).

*Auxiliary request 2a*

13. Admittance of this request into the appeal proceedings
- 13.1 The respondent filed auxiliary request 2a by letter dated 23 July 2020, i.e. after notification of the summons to oral proceedings.
- 13.2 Auxiliary request 2a differs from auxiliary request 2 in that the two *Streptococcus thermophilus* strains NCC 2059 and NCC 2019 have been deleted from the list of non-replicating probiotic micro-organisms in claim 1.
- 13.3 Article 13(2) RPBA 2020 stipulates that "[a]ny amendment to a party's appeal case made after the expiry of a period specified by the Board in a communication under Rule 100, paragraph 2, EPC or, where such a communication is not issued, after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned."
- 13.4 In the board's judgement, the filing of auxiliary request 2a by letter dated 23 July 2020 does not constitute an amendment to the respondent's case within the meaning of Article 13(2) RPBA 2020. The reasons are as follows.
  - 13.4.1 The only amendment made to claim 1 of auxiliary request 2a is the deletion of two alternatives (see point 13.2 above). This kind of amendment is only minor, it does not introduce any new subject-matter or raise new objections requiring further consideration and can therefore not be considered as an amendment to the respondent's case.

13.4.2 Furthermore, the board cannot see that any disadvantage would be caused to the appellant by the late filing of auxiliary request 2a, if it was admitted into the proceedings. As explained in point 13.4.1 above, the claims of auxiliary request 2a merely recite subject-matter already embraced by the claims of auxiliary request 2. The latter has been filed in due time by the respondent in reply to the statement of the grounds of appeal and its admittance has not been objected to by the appellant.

13.5 As a consequence of these findings, the board decided to admit auxiliary request 2a into the appeal proceedings.

14. Article 100(b) EPC - sufficiency of disclosure

*Sufficiency of disclosure in respect of the medical use recited in claim 6*

14.1 As set out in point 7.4.5 above, Figures 1A, 1B, 2, 3A, 3B and 4A of the patent demonstrate that the probiotics listed in claim 1 of auxiliary request 2a give rise to a significantly reduced Ratio IL-12/IL-10 compared with their live counterparts after heat-treatment at 120°C for 15 seconds. Similar low Ratios IL-12/IL-10 are observed after heat-treatment of these strains at 140°C for 15 seconds.

14.2 In view of these low ratios, the board is satisfied that the claimed anti-inflammatory effects can be achieved across the scope of claim 6.

14.3 The appellant's observation that, compared with their live counterparts, several of the probiotic strains

tested in example 1 of the patent do not maintain or induce additional production of IL-10 when treated at 120°C or 140°C for 15 seconds does not alter this finding. As explained in point 7.4.2 above, the decisive parameter for predicting whether a tested probiotic strain will exhibit anti-inflammatory activity *in vivo* is the Ratio IL-12/IL-10 calculated for this strain. The appellant did not submit any arguments or facts to invalidate this finding. Accordingly, contrary to the appellant's allegation, the board does not find the data presented in Figures 1A, 1B, 2, 3A, 3B and 4A of the patent to be ambiguous. As a consequence, the appellant's argument that beneficial effects observed for one particular strain cannot be assumed to be provided by another strain must fail.

14.4 In a further line of reasoning, the appellant contended that the examples of the patent did not provide any guidance on the quantities of non-replicating probiotics needed to obtain the desired effects, nor did they show any technical effects of infant feeding formulas in general.

14.5 These arguments are not found convincing either. As acknowledged by the appellant itself, claim 5 of auxiliary request 2a discloses specified quantities of non-replicating probiotics. These quantities are the same as those mentioned in claim 6 as granted. The appellant has not provided any facts or evidence that said quantities are unsuitable for the claimed therapeutic application or that adding the micro-organisms tested in example 1 to an infant feeding formula according to claim 1 of auxiliary request 2a would result in a loss of the technical effects demonstrated in example 1. Consequently, the



appellant's arguments amount to no more than unsubstantiated allegations, which cannot lead to a finding of insufficiency of disclosure.

*Sufficiency of disclosure in respect of the infant feeding formula recited in claims 1 and 6*

14.6 In point 22 of its decision, the opposition division provided detailed reasoning why, in its view, a person skilled in the art would be able to produce the claimed dried infant feeding formulas on the basis of the information provided in the patent application and common general knowledge.

14.7 In its statement of grounds of appeal, the appellant contested the opposition division's finding, alleging that the patent did not contain any guidance on how to produce the claimed compositions.

14.8 However, the appellant has not submitted any evidence or facts in support of its contention. Consequently, the board sees no reason to deviate from the opposition division's finding.

*Overall conclusion on sufficiency of disclosure of auxiliary request 2a*

14.9 It follows that the appellant's objection of insufficiency of disclosure under Article 100(b) EPC does not prejudice maintenance of the patent as amended according to the set of claims of auxiliary request 2a.

*Novelty*

15. In the decision under appeal (see point 23), the opposition division concluded, *inter alia*, that the

subject-matter of claim 1 of auxiliary request 1 considered in the impugned decision was novel over document D18. In the opposition division's view, it was not directly and unambiguously derivable from this document that the liquid composition in example 2 would undergo a dehydration step after heat-treatment at 140°C for 6-7 seconds.

16. In its statement of grounds of appeal, the appellant, referring to the disclosure of dehydrated milk foods in column 3, lines 6 to 17 of document D18, disagreed with the opposition division's finding and contended that the dehydration of the composition in example 2 was disclosed in this document "*considering the shortness and conciseness of the description in D18*".
17. The board does not agree. Example 2 of D18 (see heading) describes the manufacture of a ready-to-use, UHT-sterilised and aseptically packaged, diabetic, *Bifidobacterium breve*-containing milk preparation for unweaned babies with immunostimulant activity. As correctly noted by the respondent (see point 5.1 of its reply to the statement of grounds of appeal), this manufacture involves producing a liquid mixture which is then subjected to a UHT treatment at 140°C for 6-7 seconds before being aseptically packaged. This example does not explicitly mention a dehydration step. Nor is this step implicit from the disclosure of example 2 since, as observed by the appellant itself, D18 (see column 1, lines 5 to 8) not only pertains to immunostimulant milk products in powdered form, but also discloses such products in liquid form.
18. It follows that the appellant's objection of lack of novelty does not prejudice the maintenance of the

patent based on the set of claims of auxiliary request 2a.

*Inventive step - claim 1*

19. The closest prior art
  - 19.1 The board, in agreement with the opposition division and both parties, considers documents D3 and D4 to represent suitable starting points ("D3/D4") for the assessment of inventive step, in particular example 1 of these documents.
  - 19.2 In this example, infant rats fed with rat milk substitute and supplemented with *Lactobacillus rhamnosus* GG, inactivated via lethal heat-treatment, exhibited markedly reduced LPS-induced inflammation. This heat-treatment is not further specified.
  - 19.3 Hence, claim 1 differs from D3/D4 *inter alia* in that it requires the probiotics to have been rendered non-replicating by a heat-treatment at 120-140°C for 5-15 seconds.
20. Objective technical problem and solution
  - 20.1 In order to formulate the objective technical problem effectively solved by the claimed subject-matter, the technical effects associated with the distinguishing feature need to be identified.
  - 20.2 For the reasons set out in points 14.1 and 14.2 above, the board is satisfied that the claimed probiotics bring about anti-inflammatory effects. The board does not accept the appellant's argument that the anti-inflammatory effects relied on by the respondent

were not plausible across the scope of claim 1, for the reasons indicated in point 14.3 above.

20.3 However, as already outlined in point 4.2.7 of the board's communication, the experimental data described in example 1 of documents D3/D4 are not comparable with those reported in Figures 1 to 4A of the patent. Hence, no conclusions can be drawn from these data as to whether the infant feeding formula of claim 1 exerts the same anti-inflammatory activity as the infant feeding formula disclosed in example 1 of documents D3/D4, or higher or lower anti-inflammatory activity.

20.4 As a consequence, the objective technical problem is to be formulated as providing a further infant feeding formula exhibiting anti-inflammatory properties.

20.5 The proposed solution to this problem is an infant feeding formula according to claim 1, comprising one or more of the specified probiotics, the latter having been rendered non-replicating by a heat-treatment at 120-140°C for 5-15 seconds.

21. Obviousness

21.1 Documents D3/D4 (see paragraphs [0029] and [0019], respectively) generally relate to methods for reducing or preventing systemic inflammation in formula-fed infants, comprising the administration of inactivated probiotics. Details on this inactivation are provided in paragraph [0071] of D3 and paragraph [0052] of D4, in which the following is stated:

*"Inactivation may occur through any method currently known in the art or yet to be developed. The inactivation may be accomplished, for example, via heat*

*treatment, lyophilization, ultraviolet light, gamma radiation, pressure, chemical disruption, or mechanical disruption. For example, the probiotic may be inactivated with heat treatment via storage between 80°C. and 100°C. for 10 minutes."*

- 21.2 No other examples of heat-treatment are reported in D3/D4. Heating temperatures and heating times falling within the ranges specified in claim 1 are, however, known from the prior art (see example 2 of D18).
- 21.3 Accordingly, the question arises whether, in light of the teachings of documents D3/D4, selecting probiotics that have been rendered non-replicating by a heat-treatment at 120-140°C for 5-15 seconds is an arbitrary choice devoid of inventive merit, as contended by the appellant.
- 21.4 In the board's judgement, doing so is not an arbitrary choice.
- 21.4.1 At the time documents D3/D4 were filed, it was known from document D1 (see paragraph [00184], Table 1) that the anti-inflammatory properties of viable probiotics would be lost if heat-treated at 100°C for 30 minutes. In contrast, probiotics heat-treated at 63°C for 30 minutes, at 70°C for 5 minutes or at 80°C for 10 minutes would retain some anti-inflammatory effect (see Table 8 of D1). These findings undoubtedly show that the selected heating conditions have a decisive impact on whether the heat-treated probiotics retain their anti-inflammatory properties.
- 21.4.2 The board acknowledges the appellant's observation in this context that *Lactobacillus rhamnosus* NCC 4007 exhibits similar anti-inflammatory profiles after

heat-treatment for 15 seconds at 74°C, 90°C, 120°C and 140°C (compare Figures 2 and 5 of the patent). However, this fact does not alter the board's considerations on the obviousness of the claimed invention. As correctly noted by the respondent, Figure 5 of the patent does not represent prior art and therefore cannot be taken into account when assessing the obviousness of the claimed solution.

21.4.3 In view of the foregoing, the board is satisfied that the invention defined in claim 1 is not an arbitrary choice but rather a purposive selection.

21.4.4 This selection is not rendered obvious by documents D3/D4 alone or by documents D3/D4 taken in combination with document D5, D18 or D32.

*Documents D3/D4*

21.4.5 As explained in points 21.1 and 21.2 above, documents D3/D4 do not disclose the heating temperatures and heating times falling within the ranges specified in claim 1. Therefore, documents D3/D4 taken alone would not have led the skilled person to the claimed subject-matter.

*Documents D5, D32 and D18*

21.4.6 Document D5 (see column 2, lines 60 to 63) discloses heat-treatment of beverages containing milk protein at 135-150°C for 2-30 seconds. Likewise, document D32 states in Annex C, chapter I, section 4(b) that UHT milk must have been obtained by subjecting the raw milk to a continuous flow of heat, entailing the application of a high temperature for a short time (no less than 135°C for no less than a second). Neither of these two

documents teaches or suggests that the heat-treatments they disclose provide non-replicating probiotics with anti-inflammatory properties.

21.4.7 Document D18 reports on the heat-treatment of a *Bifidobacterium breve*-containing milk preparation for unweaned babies at 140°C for 6-7 seconds (see point 17. above). However, as correctly noted by the opposition division (see point 24(iii) in conjunction with point 24(i) of the impugned decision), document D18 does not link the heat-treatment of the milk preparation in example 2 to any anti-inflammatory activity.

21.4.8 It follows that none of documents D5, D32 and D18 would have prompted the skilled person to select infant feeding formulas comprising the probiotics recited in claim 1 to solve the objective technical problem posed.

21.5 Hence, the subject-matter of claim 1 and, by the same token, of independent claim 6 and dependent claims 2 to 5, 7 and 8 involves an inventive step within the meaning of Article 56 EPC.

*Overall conclusion on inventive step of auxiliary request 2a*

22. The board concludes that the appellant's objection of lack of inventive step under Article 56 EPC does not prejudice maintenance of the patent as amended on the basis of the set of claims of auxiliary request 2a.

*Overall conclusion*

23. The board finds that none of the grounds for opposition invoked by the appellant prejudice maintenance of the patent as amended on the basis of the set of claims of auxiliary request 2a. Accordingly, there is no need for

the board to consider the respondent's auxiliary requests 3, 4 and 4a.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted thereto:

claims 1 to 8 of auxiliary request 2a filed by letter dated 23 July 2020

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated