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Datasheet for the decision of 22 March 2022

Case Number: T 0848/18 - 3.3.01

Application Number: 13160279.9

Publication Number: 2612562

IPC: A61K35/745, A61P37/04, A23L33/135

Language of the proceedings: EN

Title of invention:
Probiotics for use in expecting female mammals for enhancing the immunity of their offsprings

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
Chr. Hansen A/S

Headword:
Probiotics for enhancing immunity of offspring/SOCIETE DES PRODUITS NESTLE

Relevant legal provisions:
EPC Art. 100(c), 100(a), 54(2), 56

Keyword:
Grounds for opposition - subject-matter extends beyond content of earlier application (no) - added subject-matter (no) - lack of patentability (yes)
Novelty - (yes)
Inventive step - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0848/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 22 March 2022

Appellant: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
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 18 January 2018 concerning maintenance of the European Patent No. 2612562 in amended form**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	L. Bühler

Summary of Facts and Submissions

I. European patent 2612562 is based on application 13160279.9, which was filed as a divisional application of the earlier European patent application 09724569.0, filed as an international application and published as WO 2009/118243. The patent is entitled "Probiotics for use in expecting female mammals for enhancing the immunity of their offsprings" and was granted with 14 claims.

II. Opposition was filed against the granted patent, the opponent requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

III. By an interlocutory decision announced at oral proceedings on 23 November 2017, the opposition division decided that the patent could be maintained in amended form on the basis of the claims of the second auxiliary request filed on 22 September 2017 (Articles 101(3)(a) and 106(2) EPC).

The opposition division considered that the claim set according to the main request (claims as granted) did not comply with Article 54 EPC, and that the claim set according to the first auxiliary request contravened Articles 123(2) EPC and 84 EPC.

IV. The patent proprietor and the opponent both lodged an appeal against that decision.

With the statement of its grounds of appeal, the appellant-patent proprietor requested that the patent be maintained as granted (main request) or alternatively according to the first auxiliary request of 22 September 2017.

With the statement of its grounds of appeal, the appellant-opponent requested that the decision be set aside and the patent revoked in its entirety.

V. With a letter of reply to the opponent's grounds of appeal, the patent proprietor submitted auxiliary requests 1 to 15, which were identical to the requests that had been filed with a letter dated 22 September 2017.

The **main request** consists of the claims as granted. Claim 1 reads as follows:

"1. The use of probiotics in the manufacturing of a composition for oral administration to expecting female mammals for boosting the immunity of their offsprings after birth, characterized in that said probiotics are *Bifidobacterium lactis* CNCM I-3446."

Claim 1 of **auxiliary request 1** differs from claim 1 of the main request as shown:

"1. The use of probiotics in the manufacturing of a composition for oral administration to expecting female mammals for boosting the immunity of their offsprings after birth, characterized in that said probiotics are *Bifidobacterium lactis* CNCM I-3446, wherein the composition is not administered directly to the offsprings to boost immunity."

Auxiliary request 2 is the set of claims that were considered allowable by the opposition division. Claim 1 differs from claim 1 of the main request as shown:

"1. The use of probiotics in the manufacturing of a composition for oral administration to expecting female mammals for boosting the immunity of their offsprings after birth, characterized in that said probiotics are *Bifidobacterium lactis* CNCM I-3446, wherein the composition is used to promote a specific immune response to infectious antigens of said offsprings."

Claim 1 of the further auxiliary requests differs from claim 1 of the main request in that the following features have been added:

Auxiliary request 3: "... wherein the immunity boost comprises an increase in the ability of the offsprings to respond to an antigenic exposure, wherein said response to the antigenic exposure comprises an elevation of the specific antibodies to said antigens."

Auxiliary request 4: "... wherein the immunity boost comprises an increase in the ability of the offsprings to respond to an antigenic exposure, wherein said antigenic exposure comprises the exposure to viruses, infective bacteria or infective parasites, wherein said response to the antigenic exposure comprises an elevation of the specific antibodies to said antigens."

Auxiliary requests 5, 6 and 7 all comprise the amendment of auxiliary request 1 in combination with the amendments of auxiliary requests 2, 3 and 4, respectively.

Auxiliary request 8: "... wherein the administration includes all or part of the lactation period."

Auxiliary requests 9, 10, 11 and 12 all comprise the amendment of auxiliary request 8 in combination with the amendments of auxiliary requests 1, 2, 3 and 4, respectively.

Auxiliary requests 13, 14 and 15 all comprise the amendments of auxiliary requests 1 and 8 in combination with the amendments of auxiliary requests 2, 3 and 4, respectively.

VI. With a letter dated 22 February 2022, the appellant-opponent submitted new documents D14 to D17 and requested that auxiliary requests 2 (sic) to 15 not be admitted.

VII. Oral proceedings before the board took place on 22 March 2022 by videoconference. At the end of the oral proceedings, the chairman announced the board's decision.

VIII. The documents cited during the proceedings before the opposition division and the board include the following:

D1 Bliss RM, Agricultural Research Nov.-Dec. 2006, p.8
D2 Bliss RM, International Pest Control 2007, p.86
D9 Rautava S et al., J. Allergy Clin. Immunol. 2002, 109, p.119-121
D10 Kalliomäki M et al., Lancet 2003, 361, p.1869-71

IX. The submissions of the appellant-patent proprietor, in so far as they are relevant to the present decision, may be summarised as follows.

Main request: Article 100(c) EPC

Claim 1 was based on claims 1, 5 and 6 of the parent application, together with the disclosure on page 8, lines 5 to 7. No selections were made from multiple lists; rather, the probiotic was selected from among a list of two in claim 6 and corresponded to the probiotic used in Example 2 of the application. As to oral administration, this was disclosed on page 8 as the most preferred form of administration; the other methods of administration listed therein were in fact examples of oral administration.

Main request: Article 100(a) EPC

The claim required that the effect of boosting immunity be linked to the administration of the probiotic to the pregnant mothers. This link, however, was not disclosed in D1 or D2, which in fact taught away from such a link in the left column when disclosing the effect on the offspring's colon. The further effect referred to in the right column did not even include administration to the mothers at all. Paragraph [0043] of the patent, which also contemplated administration to the offspring, did not detract from the fact that the effect of boosting immunity was a result of the administration to the mother. Moreover, D1 looked only at biomarkers, and it was not clear which ones were analysed and whether they indeed reflected immunity boosting. The statement in the right column that the best results were obtained when administration was to the mother and the piglet did not imply that there was

an effect when administering only to the mother. Hence D1 or D2 did not anticipate the claimed subject-matter.

As to inventive step, starting from D1 the skilled person would not reasonably expect that administration to the mother alone would have the desired effect, in particular in view of the last sentence in the left column, which led to the consideration that administration to the piglets was required. No other document suggested that administration of the probiotic solely to the mother would have an effect on the offspring's immune system. While D1 disclosed treatment of the mothers alone as one of the study arms, it did not present any results that could justify a reasonable expectation of success. In fact, it would actually be counter-intuitive that the claimed effect could be achieved by administration only to the mothers.

Auxiliary request 2: Article 56 EPC

The claim required the promotion of a specific immune response, i.e. the boosting of the immunity required the effect on the specific immune response. There was nothing in D1 in this respect, while the patent demonstrated the effect in Example 2, paragraph [0066]. D1 related only to innate immune response. D1's study in worms was not in the context of administration to the mothers; moreover, it was not necessarily related to antigen-specific immunity, since innate immune response could still be responsible for the effect shown, being the first immune defence line. The claimed subject-matter thus represented a new clinical situation with advantages in the context of vaccination. This was not an inherent disclosure of D1 because, even if the effect was already there, it had not been made available. On the basis of D1, the

skilled person would not consider using the claimed probiotic for the purpose of the claim, namely for achieving long-term immunity, which was a benefit over what was disclosed in D1. Even the study mentioned in the right column would not have led to the expectation that the specific immune response had been boosted.

Auxiliary requests 3 to 15: Article 56 EPC

The wording of claim 1 of auxiliary request 3 related very closely to Example 2. It related to a well-defined boosting of immunity, implying an elevation of specific antibodies, which was of high relevance for vaccination. The limitation corresponded to a new commercial use, as the generation of specific antibodies was a new teaching that would motivate mothers to administer Bb12. This could be relevant e.g. in developing countries, where greater exposure to infections was expected to occur. The therapeutic effect was a long-term effect, as shown in Figure 4 of the patent. Auxiliary request 4, on the other hand, was specifically directed to pathogens, so there was a further incentive for administration.

As to auxiliary request 8, Example 2, paragraph [0066], taught that Bb12 was administered during the first two weeks of lactation. This additional mode of administration was nowhere in D1, so there would be no motivation based on D1 to add it. The problem to be solved was an alternative mode of administration to the mother of the offspring, and the solution was not obvious from D1 alone or in combination with the remaining prior art.

X. The submissions of the appellant-opponent, in so far as they are relevant to the present decision, may be summarised as follows.

Main request: Article 100(c) EPC

Claim 1 of the parent application differed from claim 1 as granted in that neither the probiotic nor the form of administration was specified. To arrive at the claimed subject-matter, the skilled person would have to select the specific probiotic from a laundry list of possible probiotics disclosed on page 6, line 26 to page 7, line 19 and combine it with a further selection from among the possible methods of administration listed on page 7, line 36 to page 8, first paragraph. Even if claim 6 of the parent application was taken as the basis for the probiotic, a selection still had to be made. Example 2 used a specific form of oral administration, namely by applying the composition to the drinking water, so it could not provide a basis for oral administration in general.

Main request: Article 100(a) EPC

Claim 1 had to be interpreted as also encompassing treatment of the offspring, in accordance with paragraph [0043] of the patent. Document D1 (and D2) was directed to exactly the same teaching as the patent, as was already apparent from the title. The term "boosting" only meant improvement and did not imply any particular therapeutic effect. The mode of administration in D1 was clearly oral administration, namely as part of the fed composition, which was one of the forms envisaged in the patent. Biomarkers were measured, which was the same as in the patent (paragraph [0047]), antibodies being simply biomarkers.

The sentence in the right column made clear that there also had to be an effect when only the mothers were treated. The same animals were treated with the same composition by the same mode of administration, and the same effect was obtained. No new clinical situation was identified.

If the technical effect recited in the claim could be considered a distinguishing feature, then the technical problem was to provide an alternative medical use in that a boosting of the immune response was also achieved by treating expecting mothers alone. The solution was the link between the effect and the treatment and would be obvious from D1 alone. D1 also disclosed the treatment of mothers alone as one study arm, so all that would be required would be to test this group. There was no teaching away in D1 because the last sentence of the left column did not exclude that effects were also present when only mothers were treated. On the contrary, the sentence at the top of the right column implied that there was an effect in the other treated groups as well and therefore provided a reasonable expectation of success.

Auxiliary request 2: Article 56 EPC

The further feature in the claim did not change anything because it was inherent to the disclosure of D1 and in fact only specified the function of the immune system, which was to fight infectious antigens. In any case, the existence of this particular effect was further supported by the separate study of D1, showing the effect on worm infection, which was also encompassed in the scope of claim 1, as was apparent from claims 11 and 12, which further defined the infectious agents as also including parasites such as

worms. The technical problem would be to find an alternative medical use, and said alternative in fact corresponded to the majority of uses that were related to boosting immunity. The solution was obvious from D1 alone. The claim merely specified an effect that was achieved by the prior-art treatment. No new patient group was identified. In fact, since it was only a prophylactic treatment, it was not known whether the offspring would suffer from infection or not.

Auxiliary requests 3 to 15: Article 56 EPC

The same problem-solution approach still applied for auxiliary request 3. The teaching of D1 was to administer Bb12 to all mothers, and paragraph [0047] of the patent taught that the type of immune response depended on the antigenic exposure. A better explanation for what was known from the prior art could not contribute to novelty, let alone to an inventive step. The same applied to auxiliary requests 4 and 5.

As for auxiliary request 8, the problem was to provide an alternative mode of administration to the offspring, but the solution was still obvious. If the effect was achieved by administering to the mother, then further administration after birth added nothing, and there would have been no reason not to do so, since it was safe. D9 (title) and D10 (page 1869, second paragraph) both disclosed administration to offspring by lactation.

XI. The appellant-patent proprietor requests that the decision of the opposition division be set aside and the patent be maintained as granted (main request) or, alternatively, on the basis of the claims according to auxiliary request 1. Further alternatively, it requests

that the opponent's appeal be dismissed (auxiliary request 2) or that the patent be maintained on the basis of one of the sets of claims according to auxiliary requests 3 to 15, all auxiliary requests having been filed with the letter of reply to the opponent's grounds of appeal. The appellant-patent proprietor moreover requests that documents D14 to D17 and the opponent's arguments based thereon not be admitted.

The appellant-opponent requests that the decision of the opposition division be set aside and the patent be revoked in its entirety. It moreover requests that auxiliary requests 3 to 15 not be admitted.

Reasons for the Decision

1. The appeals are admissible.

2. Admission of auxiliary requests 3 to 15 and documents D14 to D17

2.1 Auxiliary requests 3 to 15 were filed with the letter of reply to the opponent's grounds of appeal, and the appellant-opponent objected to their admission. According to Article 12(4) RPBA 2007, which applies to the present case, the board has the discretionary power to exclude these requests from the appeal proceedings. Documents D14 to D17 were filed by the appellant-opponent by letter dated 22 February 2022, i.e. after summons to the oral proceedings had been issued. Their admission is thus governed by Article 13(2) RPBA.

2.2 Admission of auxiliary requests 3 to 15 and of documents D14 to D17 was discussed at the oral proceedings. The board decided not to exclude auxiliary requests 3 to 15 from the appeal proceedings and not to admit documents D14 to D17 into the proceedings. However, in view of the outcome of the present decision, the board sees no need to substantiate this part of the decision.

Main request

3. Article 100(c) EPC

3.1 In the appealed decision, the opposition division considered that the claim set according to the main request (claims as granted) complied with Articles 76(1) and 123(2) EPC. On appeal, the appellant-opponent maintained the objections under these provisions.

3.2 The board notes that the granted claims are identical to the claims of the application as filed. Hence all claims of the main request comply with Article 123(2) EPC.

3.3 As to Article 76(1) EPC, claim 1 is based on claims 1 and 6, page 8, first paragraph, and Example 2 of the parent application. It differs from claim 6 of the parent application in that one of the alternatives for the Bifidobacterium lactis species has been selected and in that the feature "for oral administration" has been added. The first difference consists merely in the selection of one from among two alternatives, and the selected probiotic is in fact the one used in the examples (Example 2). The second difference consists in the insertion of a feature that is disclosed on page 8, first paragraph, as being the most preferred mode of

administration and that is also the mode of administration used in the examples.

3.4 Accordingly, the board considers that claim 1 of the main request also complies with Article 76(1) EPC.

4. Article 100(a) EPC: novelty over D1 and D2

4.1 In the appealed decision, the opposition division came to the conclusion that the subject-matter of claims 1, 2 and 5 is anticipated by the disclosure of documents D1 and D2. The appellant-opponent maintained its novelty objections on appeal. Since the disclosures of D1 and D2 are identical in substance, in the following reference will be made only to D1.

4.2 Claim 1 is a second medical use claim wherein the therapeutic composition is the probiotic Bifidobacterium lactis CNCM I-3446 (also known as Bb12) and the medical indication is boosting the immunity of the mammal offspring upon administration of the composition to the expecting female mammal. The board agrees with the appellant-opponent that the claim does not exclude that the offspring may also be administered the probiotic. However, the claim requires that the therapeutic effect be linked to the administration to the expecting female mammal. Accordingly, a prior-art disclosure can be novelty-destroying for this subject-matter only if it establishes the link between the administration of the probiotic to the expecting mother and the attained therapeutic effect, namely the boosting of the immunity of the offspring.

4.3 Document D1, entitled "Boosting immunity using beneficial bacteria", discloses a study in which the effect of the probiotic strain Bifidobacterium lactis

(Bb12) on maturation and stimulation of the immune system of piglets was tested. In the four experimental groups tested, either the pregnant sows or the litter or both or none were fed with Bb12, and 46 biomarkers were analysed to document the activity of immunity- and nutrition-related genes; gene expression in treated and non-treated pigs was compared. As to the results, D1 states that "[t]he probiotic was found to induce innate immune activity in the colon, where it was most concentrated" (left column, last paragraph) and that "[t]he animals that were both treated through their mother and treated themselves had the best immune response" (right column, first paragraph).

4.4 The board considers that these statements of D1, which are the only statements concerning the results of the study, do not allow a link to be established between the administration of the probiotic to the expecting mother and the therapeutic effect of boosting of the immunity of the offspring. As argued by the appellant-patent proprietor, the statement in the left column of D1 appears to relate to the experimental groups in which the probiotic was administered to the piglets, meaning either the group where both the expecting mothers and then the piglets were treated, or the group where only the piglets were treated. It therefore does not, by itself, allow the conclusion that the therapeutic effect is linked already to the administration to the expecting mothers. Similarly, the second statement clearly refers to the group in which both the expecting mothers and the piglets were treated. While it indicates that the best results were obtained in this group, it does not allow a conclusion to be made as to what the results in the other two treated groups were (mothers alone or piglets alone).

4.5 The board thus comes to the conclusion that D1 does not directly and unambiguously disclose the subject-matter of claim 1 of the main request. The same applies to D2.

4.6 Hence, claim 1 of the main request is novel over D1 and D2 (Article 54(2) EPC).

5. Article 100(a) EPC: inventive step

5.1 Document D1 is the closest prior art, and the difference is that it does not disclose that the technical effect of boosting immunity in the offspring is obtainable by administering the probiotic to the expecting mother. The technical problem can be formulated as the provision of an alternative therapy for boosting the immunity of the offspring. The solution is the subject-matter as claimed and it solves the technical problem.

5.2 The board, however, considers that the skilled person would arrive at the claimed solution in an obvious way. Treatment of expecting mothers alone was already disclosed in D1, and there would be no reason for the skilled person to doubt that such treatment would have a positive effect on the offspring's immune system. The statement in the right column of D1 allows the conclusion that an effect was also present in at least one of the other treated groups. The skilled person would thus just have to repeat the experiment of D1 for treatment of expecting mothers alone and would have a reasonable expectation that the desired effect would be obtained. Claim 1 of the main request thus lacks an inventive step in view of document D1 alone.

5.3 The appellant-patent proprietor essentially argued that there was no suggestion in any of the prior-art

documents that administration of the probiotic solely to the mother would have an effect on the offspring's immune system, and that D1 in fact even taught away, since the statement in the left column implied that administration to the piglets was required. The board disagrees that D1 teaches away from the claimed subject-matter. As noted above, it indeed appears that the statement in the left column refers to the groups where piglets were treated. However, this statement only indicates what was observed in said piglets but does not in any way imply that administration to the expecting mothers would not have the desired effect. Moreover, the skilled person would not read this statement in isolation but would also consider the statement in the right column and the whole teaching of D1, which is directed to achieving a boosting of the offspring's immunity. The very design of D1's study implies that D1's researchers expected an effect to be present when administering the probiotic to the pregnant mother. The fact that D1 does not present the results for each treated group would not reduce this expectation, in particular in view of the overall teaching of D1 on the administration of probiotics.

5.4 The board thus considers that the main request does not comply with Article 56 EPC. Accordingly, Article 100(a) EPC prejudices the maintenance of the patent as granted.

6. Auxiliary request 1 - Article 56 EPC

6.1 In this request, claim 1 has been amended by the insertion of the feature "wherein the composition is not administered directly to the offsprings to boost immunity".

6.2 The board's conclusions regarding the lack of inventive step of the main request were based on a claim interpretation that requires the effect to be linked to the administration of the probiotic to the expecting mothers alone. Hence the board considers that the insertion of this feature into claim 1 does not change the conclusions on inventive step.

6.3 Claim 1 of auxiliary request 1 is thus also considered not to comply with Article 56 EPC.

7. Auxiliary request 2 - Article 56 EPC

7.1 Claim 1 of auxiliary request 2 further defines the therapeutic application as being "for boosting the immunity (...) wherein the composition is used to promote a specific immune response to infectious antigens of said offsprings". The board considers that the therapeutic application is in fact to promote a specific immune response to infectious antigens of the offspring, whereby the promotion of the specific immune response is one of the two aspects or embodiments falling within the definition of "boosting immunity" according to the patent (paragraph [0045], see also below).

7.2 In agreement with the conclusions of the opposition division, the board considers that the feature "wherein the composition is used to promote a specific immune response to infectious antigens of said offsprings" is not disclosed in D1. In the context of the study that includes administration to the expecting mothers, D1 only refers to "boosting immunity" generally (title) and to induction of innate immune activity in the colon (last statement in the left column), and does not refer to induction of antigen-specific immunity. D1 then

refers to a "separate study" (right column, second paragraph) where Bb12 was administered to pigs, a worm-induced infection was subsequently induced, and the pigs' response to the infection assessed; preliminary results are said to "show a better response to the worm infection because of improved nutrient absorption in the piglets that were fed the probiotic bacteria". This separate study, however, is not in the context of administration to the expecting mothers. Hence the board considers that the effect on the specific immune response to antigens in the claim is a specific embodiment, which further distinguishes the claimed subject-matter from the disclosure of document D1.

7.3 The technical problem can be formulated as the provision of a specific medical use within the general medical use of boosting immunity in the offspring.

7.4 It is common general knowledge that the main role of the immune system is to protect from infection. It is also known, and acknowledged in the patent (e.g paragraph [0045]), that this is achieved by a first line of defence, which consists of the innate immune response, followed by a second, more specific line of defence, which is antigen-specific and involves the production of antigen-specific antibodies.

7.5 While the specific medical use now claimed is novel, it is based on a technical effect which, as argued by the appellant-opponent, was inevitably already present in the prior art, since the same composition was administered to the same group of patients for the same general purpose, namely boosting of the immunity of the offspring. As such, an inventive step could be acknowledged only if the specific medical use indeed led to a new clinical situation.

7.6 The board considers this not to be the case. Being a prophylactic treatment that is not directed to a particular group of individuals but rather to offspring in general, no new group of patients can be identified for which the treatment would be particularly suitable. Moreover, no new mechanism is described that could be advantageously exploited. In this context, the arguments of the appellant-patent proprietor that there was a new clinical situation with advantages in the context of vaccination are not convincing because, again, the prophylactic treatment is independent of the vaccination that may or may not be administered later on. In essence, based on D1, the skilled person would already consider the administration of probiotic to the expecting mothers in order to boost the immunity of the offspring and would thereby expect that this would have a positive impact on the response to infection and to vaccination.

7.7 The board thus comes to the conclusion that claim 1 of auxiliary request 2 does not comply with Article 56 EPC.

8. Auxiliary requests 3 to 7 - Article 56 EPC

8.1 The same conclusions apply to auxiliary requests 3 and 4, which only further define antigen-specific immunity, and to auxiliary requests 5 to 7, which combine the amendment of auxiliary request 1 with those of auxiliary requests 2 to 4, respectively.

8.2 Hence, claim 1 of auxiliary requests 3 to 7 does not comply with Article 56 EPC either.

9. Auxiliary requests 8 to 15 - Article 56 EPC

9.1 The same conclusions also apply to auxiliary requests 8 to 15, which further specify that the administration to the mothers is continued throughout lactation. Administration of probiotics to the mothers during lactation with the purpose of having an effect on the offspring's immune system was known from the prior art (D9, D10), even if in a different context, namely for the prevention of atopic disease. Hence, the skilled person would know from the prior art that probiotics administered to the lactating mother are capable of exerting an effect on the immune system of the breastfed offspring. On the other hand, the skilled person knew from D1 that the best therapeutic effect in terms of immune boosting of the offspring was achieved when both the expecting mother and the offspring were given the probiotic, i.e. when administration of the probiotic was continued after birth (D1, first sentence of the right column). Accordingly, the skilled person would have reasons to expect that further administration during lactation would have a positive effect and would have no reasons not to try such a further mode of administration. Therefore these claims also fail to comply with Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated