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**Datasheet for the decision
of 13 March 2018**

Case Number: T 1244/15 - 3.3.01

Application Number: 05763869.4

Publication Number: 1768681

IPC: A61K35/74

Language of the proceedings: EN

Title of invention:

METHOD FOR PREVENTING OR TREATING RESPIRATORY INFECTIONS AND
ACUTE OTITIS MEDIA IN INFANTS

Applicant:

MJN U.S. Holdings LLC

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - (no)



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Case Number: T 1244/15 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 13 March 2018

Appellant:
(Applicant)

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 26 January 2015
refusing European patent application No.
05763869.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman L. Bühler
Members: R. Hauss
G. Seufert

Summary of Facts and Submissions

- I. The decision under appeal is the decision of the examining division, announced on 20 November 2014 and posted on 26 January 2015, refusing European patent application No. 05 763 869.4.
- II. The documents cited in the course of the examination and appeal proceedings included the following:
- D1: BMJ 2001; 322:1327, pages 1-5 (2 June 2001)
- D5: Journal of Pediatric Gastroenterology and Nutrition 38(3), 288-292 (March 2004)
- D6: Clinical and Diagnostic Laboratory Immunology, 8(2), 293-296 (2001)
- D7: British Journal of Nutrition 101, 1722-1726 (2009)
- D8: BMJ 2001; 322:1318-9 (2 June 2001)
- III. The decision under appeal is based on a main request and auxiliary request 1, both filed during oral proceedings on 20 November 2014.
- Claim 1 of the main request reads as follows:
- "1. *Bifidobacterium lactis* Bb-12 and *Lactobacillus rhamnosus* GG for use in preventing or treating respiratory infections or acute otitis media in an infant, by administering to the infant between about 10^5 and 10^{11} cfu/day each of *Bifidobacterium lactis* Bb-12 and *Lactobacillus rhamnosus* GG, wherein the ratio of *Bifidobacterium lactis* Bb-12 and *Lactobacillus rhamnosus* GG is between about 10:1 and 1:10 and wherein the *Bifidobacterium lactis* Bb-12 and *Lactobacillus rhamnosus* GG are incorporated into an infant formula and consumed by the infant until the infant is one year of age."
- The remaining claims of the main request are dependent on claim 1.

Claim 1 of auxiliary request 1 differs from claim 1 of the main request solely in the definition of the purpose of the treatment, as follows (difference underlined):

"1. *Bifidobacterium lactis* Bb-12 and *Lactobacillus rhamnosus* GG for use in preventing or treating acute otitis media in an infant up to one year of age, (...)"

IV. In the decision under appeal, the examining division found that the subject-matter of each request did not involve an inventive step within the meaning of Article 56 EPC.

Document D1, which was regarded as the closest prior art, taught that the consumption of probiotic milk containing *Lactobacillus rhamnosus* GG, at a daily dosage of 1 to 2×10^8 cfu, reduced the occurrence and severity of respiratory infections and acute otitis media among children aged from one to six years of age.

The age group of the patients targeted by claim 1 of the main request overlapped with the age group of document D1, since the term "infant" was defined in the application (paragraph [0034]) as a human less than about two years old. The claimed subject-matter differed from the disclosure of document D1 in that *Bifidobacterium lactis* Bb-12 was added to *Lactobacillus rhamnosus* GG and was consumed by the infant until the infant was one year of age. In the absence of comparative data in relation to D1, the technical problem to be solved was the provision of an alternative medicament for treating and preventing respiratory infections in children. The solution to that problem was the combination of the two bacteria strains as defined in claim 1. Without evidence of a specific technical effect, an inventive step could not

be acknowledged on the basis of the addition of another probiotic bacteria strain to a formulation as described in document D1. Moreover, it had not been shown that the combination of *Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* Bb-12 achieved a benefit over the entire scope claimed (namely, the treatment of respiratory infections and acute otitis media in infants up to two years of age).

The objective technical problem in relation to auxiliary request 1 was the provision of an alternative medicament for treating and preventing acute otitis media in infants up to one year of age. In the absence of experimental data showing that in respect of otitis media in an infant up to one year of age, a significant benefit was obtained over the entire scope claimed, it could not be acknowledged that the subject-matter of claim 1 of auxiliary request 1 involved an inventive step.

- V. The applicant (appellant) lodged an appeal against that decision. With the statement setting out the grounds of appeal dated 28 May 2015, the appellant filed a main request and five auxiliary requests.

The **main request** is identical to the main request examined in the decision under appeal (for the wording of claim 1 see point III above).

Claim 1 of **auxiliary request 1** differs from claim 1 of the main request solely in the insertion of the words "up to one year of age" after the passage "for use in preventing or treating respiratory infections or acute otitis media in an infant".

Auxiliary request 2 is identical to former auxiliary request 1 examined in the decision under appeal (for the wording of claim 1 see point III above).

Claim 1 of **auxiliary request 3** differs from claim 1 of the main request in the definition of the purpose of the treatment, as follows (difference underlined):

"1. *Bifidobacterium lactis* Bb-12 and *Lactobacillus rhamnosus* GG for use in preventing or treating respiratory infections in an infant up to one year of age, (...)"

Claim 1 of **auxiliary request 4** corresponds to claim 1 of auxiliary request 1, except that it replaces "one year of age" with "7 months of age"; thus the prevention or treatment is "in an infant up to 7 months of age", and the probiotic is to be consumed by the infant "until the infant is 7 months of age".

Claim 1 of **auxiliary request 5** corresponds to claim 1 of auxiliary request 1 except that it defines the purpose of the treatment as follows (differences underlined):

"for use in preventing or treating recurrent respiratory infections or recurrent acute otitis media in an infant up to one year of age".

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request or, alternatively, of one of auxiliary requests 1 to 5, all filed with the statement setting out the grounds of appeal dated 28 May 2015.

VII. The appellant's arguments may be summarised as follows:

The experimental data provided in the application and in document D7 rendered it credible that the combined administration of *Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* Bb-12 as envisaged in claim 1

of the main request achieved a reduction in the overall and/or recurrent incidence of respiratory infections and acute otitis media in infants up to one year of age.

That effect was not achieved with the treatment of document D1, as the data presented in D1 had been obtained with subjects in a different age group and did not show an effect of *Lactobacillus rhamnosus* GG on the incidence of respiratory infections and acute otitis media, but only a reduction in the severity of disease (mainly apparent from a reduction in infections with complications and a reduction in absence from day care).

Furthermore, the prior art did not mention any effect of *Bifidobacterium lactis* Bb-12 on respiratory infections or acute otitis media. Document D6 mentioned the combination of *Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* Bb-12 only for its usefulness in improving diarrhoeal infections. On the basis of document D1, alone or in combination with document D6, a person skilled in the art would not have combined *Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* Bb-12 in an infant formula for such treatment in the expectation of obtaining the benefit of a reduction in the incidence of those disorders.

Moreover, even if the technical problem was defined as the provision of an alternative medicament, as in the decision under appeal, it would not have been obvious for the person skilled in the art to combine *Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* Bb-12 for the treatment of respiratory infections and/or acute otitis media, since the prior art did not disclose or suggest the use of *Bifidobacterium lactis* Bb-12 for such treatment.

In view of these considerations, the claims according to the main request involved an inventive step.

Essentially the same arguments in favour of inventive step applied with regard to the claims of each of the auxiliary requests.

- VIII. In a communication issued in preparation for oral proceedings and advising the appellant of its preliminary opinion, the board gave a negative opinion on inventive step. In that context, the board mentioned *inter alia* that the data reported in the application and in document D7 were based on the administration of a higher daily dosage of *Lactobacillus rhamnosus* GG than the data reported in document D1, and that no particular technical effect had been shown to be associated with the additional administration of *Bifidobacterium lactis* Bb-12.
- IX. By letter of 9 March 2018 the appellant advised the board that it would not be represented at the oral proceedings scheduled for 13 March 2018 and requested that the proceedings be cancelled and that a decision be issued based on the written submissions and requests on file, dated 28 May 2015. The appellant did not provide any further arguments in reply to the board's communication.
- X. Oral proceedings were held on 13 March 2018 in the absence of the appellant, in accordance with Article 15(3) RPBA and Rule 115(2) EPC.

Reasons for the Decision

1. Main request - inventive step

Content of the application and claimed subject-matter

1.1 The present application acknowledges that respiratory infections and otitis media are known to be common in infants and seeks to provide options for the prevention or treatment of those conditions, in particular with a view to reducing the need to use antibiotics (see the description, paragraphs [0002], [0003], [0009], [0013], [0026]).

1.2 The main request relates to a combination of the probiotic bacteria strains *Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* Bb-12 for use in preventing or treating respiratory infections or acute otitis media in infants. For administration, the bacteria are to be incorporated into an infant formula which is to be consumed by the infant until the infant is one year of age.

Starting point in the prior art

1.3 Document D1, used throughout the opposition and appeal proceedings as the starting point for the assessment of inventive step, teaches that daily administration of about 1 to 2 x 10⁸ cfu of *Lactobacillus rhamnosus* GG to children aged from one to six years may reduce the incidence and in particular the severity of respiratory infections and the incidence of complications including otitis media (see D1: abstract; page 4: column 1, paragraph 3; page 4: table 3 and Discussion). The study described in D1 was conducted over a period of seven months.

Technical problem and solution

1.4 The subject-matter of claim 1 of the main request differs from the disclosure of document D1 in the requirement for the additional administration of *Bifidobacterium lactis* Bb-12 and in the age of the subjects to be treated (namely, up to one year). Claim 1 also requires the probiotic bacteria to be incorporated into an infant formula to be consumed by the patient, whereas according to the study design disclosed in document D1, the probiotic bacteria were administered in milk.

In support of inventive step, the appellant argued that the treatment as defined in claim 1 of the main request provided improved medical benefits which could not have been derived from the teaching of document D1, since D1 did not relate to patients in the same age group and merely taught a reduction in the severity of infection, and that the activity of *Bifidobacterium lactis* Bb-12 in the treatment and prevention of respiratory infections and otitis media was surprising in view of the prior art. The appellant did not rely on any technical effect in connection with the use of infant formula as a carrier for the probiotic bacteria.

1.4.1 Age group

Claim 1 specifies that the probiotic formula is to be consumed by infants up to one year of age. As a result, the probiotic medicament is made available to patients belonging to a different age group than the patients tested according to document D1.

1.4.2 Additional administration of *Bifidobacterium lactis* Bb-12

The present application contains experimental data on the incidence of respiratory infections and otitis media, obtained from a study conducted with infants up to one year of age (see pages 15 ff and figures). Document D7 (published after the filing date of the application) relates to the same study and resulting data.

These data are not, however, the result of a comparison between the combined administration of the two bacteria strains and of *Lactobacillus rhamnosus* GG alone; rather, the combination of the two bacteria strains is compared to a placebo.

As a consequence, the data provided in the application and in document D7 cannot establish that the administration of *Bifidobacterium lactis* Bb-12 provides any benefit in the prevention or treatment of acute respiratory infections or acute otitis media, since it cannot be ruled out that any effect observed may be due to the administration of *Lactobacillus rhamnosus* GG alone.

The appellant argued that document D1 merely suggested that the administration of *Lactobacillus rhamnosus* GG might reduce the severity of disease, whereas the combined administration of *Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* Bb-12 according to claim 1 achieved a reduction in the incidence of respiratory infections and acute otitis media; therefore, the addition of the *Bifidobacterium* provided an improvement.

The board considers, however, that it is not possible to infer from a comparison of the disclosure of D1 with

the information provided in the application and in D7 that the reduction in the incidence of disease which was purportedly observed must be due to the additional administration of *Bifidobacterium lactis* Bb-12.

Comparing the study design disclosed in the application and in D7 with that of D1, it appears that different carriers were used to administer the bacteria, namely infant formula "Enfamil®" or milk, and different dosages of *Lactobacillus* were administered, namely 1-2 x 10⁸ cfu/day according to D1, but a higher dosage of 1 x 10¹⁰ cfu/day according to the present application (see paragraph [0065]) and D7 (see page 1723, column 1, paragraph 2). In view of these differences, the appellant conceded that the experimental data shown in the present application do not provide a comparison of the claimed subject-matter with the subject-matter of document D1 (see the appellant's statement of grounds, page 4, lines 15 ff). Indeed, it cannot be ruled out that in particular the dosage of *Lactobacillus*, and possibly also the composition of the carrier, would affect the outcome. The board further observes that document D1 also refers in several passages to reduced incidence of disease (see D1: abstract/conclusions; table 3: line 5; last page: box). Reduced incidence (i.e. prevention) and reduced severity would, moreover, appear to relate to different degrees of the same effect (which would presumably vary according to dosage), rather than to fundamentally different effects.

For these reasons, the board concludes that the addition of *Bifidobacterium lactis* Bb-12 has not been shown by the appellant to be associated with any particular technical effect beyond the provision of a further probiotic including *Lactobacillus rhamnosus* GG.

- 1.5 Taking into account the considerations in section 1.4, the technical problem to be solved may thus be defined as the provision of a further probiotic including *Lactobacillus rhamnosus* GG for treating or preventing respiratory infections or otitis media in a further patient group.
- 1.6 The experimental data shown in the present application (see pages 15 ff and figures), and to a certain extent the results known from document D1 (obtained with a lower daily dosage of *Lactobacillus*, albeit with older infants), render it credible that the administration of probiotic bacteria as defined in claim 1 of the main request may solve that technical problem by contributing to the prevention or treatment of respiratory infections or otitis media in infants up to one year of age.

Obviousness of the solution

- 1.7 As acknowledged in the present application, respiratory infections and otitis media have been known also to be extremely common in infants younger than one year of age (see paragraphs [0002] and [0003] of the description). Starting from the teaching of document D1 and based on the common general knowledge that there is a need for treatment options for younger infants, the person skilled in the art would therefore consider conducting further studies on younger children involving the administration of *Lactobacillus rhamnosus* GG. This is furthermore explicitly suggested in document D8 (see page 1319, right-hand column, lines 8 to 14) when commenting on the data shown in D1. Such studies would routinely also involve dosage optimisation.

- 1.8 In view of the results reported in document D1, and considering that a higher dosage of *Lactobacillus* was administered in the study reported in the present application, any benefit observed according to that study in the treatment and prevention of respiratory infections and otitis media in infants up to one year cannot be regarded as surprising.
- 1.9 As explained above in point 1.4.2, the data presented in the application and in document D7 do not provide proof of any technical effect potentially associated with the addition of the *Bifidobacterium* strain.
- 1.10 *Bifidobacterium lactis* Bb-12 was known from the prior art as a probiotic bacterium (and thus with potential benefits with regard to immune reaction and protection against diarrhoea) which was safe for very young infants including those younger than one year of age and which could be administered without difficulty together with *Lactobacillus rhamnosus* GG, both showing good adherence to intestinal mucus (see document D5: abstract, and document D6: abstract and discussion).
- 1.11 The board is not aware of any specific reason which might have discouraged the person skilled in the art, when seeking to solve the above-mentioned technical problem, from studying the administration of *Lactobacillus rhamnosus* GG in younger infants as well, or from combining the *Lactobacillus* with *Bifidobacterium lactis* Bb-12, which was known to be safe and could be expected to provide potential advantages in its function as a further probiotic bacterium.
- 1.12 For these reasons, the board arrives at the conclusion that the subject-matter of claim 1 of the main request

does not involve an inventive step within the meaning of Article 56 EPC.

2. Auxiliary requests 1 to 3 - inventive step
 - 2.1 Claim 1 in each of auxiliary requests 1 to 3 differs from claim 1 of the main request in the addition of the words "up to one year of age".
 - 2.2 Claim 1 of auxiliary request 2 additionally restricts the envisaged use of the probiotic medicament to the prevention or treatment of acute otitis media, while claim 1 of auxiliary request 3 restricts the use to the prevention or treatment of respiratory infections.
 - 2.3 The appellant argued, with regard to claim 1 of the main request, that the person skilled in the art would infer from the requirement for the probiotic formula to be consumed by the infant until it was one year of age that the envisaged treatment concerned an infant up to one year of age, without the explicit additional statement "for use (...) in an infant up to one year of age". In any case, the appellant did not base its arguments with regard to inventive step on the hypothetical possibility (covered by claim 1 of the main request) that ingestion of the probiotic up to the age of one year might prevent infection in older infants. Thus the amendment introduced into claim 1 of auxiliary request 1 does not change the reasoning concerning inventive step presented in section 1 above.
 - 2.4 The further amendments in claims 1 of auxiliary requests 2 and 3 do not create additional features distinguishing the claimed subject-matter from the disclosure of document D1, and thus do not affect any part of the reasoning presented in section 1 above.

2.5 As a consequence, the subject-matter of claim 1 of each of auxiliary requests 1, 2 and 3 does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as given for the subject-matter of claim 1 of the main request.

3. Auxiliary request 4 - inventive step

3.1 Claim 1 of auxiliary request 4 specifies that the prevention or treatment of respiratory infections or acute otitis media concerns an infant up to seven months of age and that the probiotic formula is to be consumed by an infant until the infant is seven months of age.

3.2 The arguments presented in section 1 above in the context of the main request equally apply to the subject-matter of claim 1 of auxiliary request 4, i.e. to the scope which relates to infants up to 7 months of age instead of up to 12 months of age.

3.3 Hence, the subject-matter of claim 1 of auxiliary request 4 does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as the subject-matter of claim 1 of the main request.

4. Auxiliary request 5 - inventive step

4.1 Claim 1 of auxiliary request 5 corresponds to claim 1 of auxiliary request 1 but additionally specifies that the treatment or prevention concerns recurrent respiratory infections or recurrent acute otitis media.

4.2 As already explained (see point 2.3 above), the amendment "up to one year of age" does not change anything in the board's assessment of inventive step.

- 4.3 With respect to the amendment concerning "recurrent" infections, the appellant argued that it could not have been derived from the prior art that the incidence of recurrent respiratory infections and acute otitis media could be reduced.
- 4.4 The scope of claim 1 of auxiliary request 5 is not restricted to achieving a reduction in the incidence of recurrent infections, but also concerns the treatment of recurrent infections. As conceded by the appellant, document D1 teaches at least that the severity of respiratory infections and the incidence of complications may be reduced by ingestion of *Lactobacillus rhamnosus* GG. It would therefore not be surprising to the person skilled in the art that a treatment effect can also be obtained in the case of recurrent infections.
- 4.5 In view of these considerations in conjunction with the reasoning presented in section 1 above with regard to claim 1 of the main request, the board concludes that the subject-matter of auxiliary request 5 does not involve an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

L. Bühler

Decision electronically authenticated