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Datasheet for the decision of 18 September 2024

Case Number: T 2012/22 - 3.3.07

Application Number: 13702584.7

Publication Number: 2802333

IPC: A61K35/74, A61P11/02, A61P11/04

Language of the proceedings: EN

Title of invention:
LACTOBACILLUS RHAMNOSUS AND BIFIDOBACTERIUM ANIMALIS SUBSP. LACTIS FOR USE IN PREVENTION OR TREATMENT OF UPPER RESPIRATORY TRACT INFECTIONS

Patent Proprietor:
Chr. Hansen A/S

Opponent:
International N&H Denmark ApS

Headword:
Respiratory tract infections/HANSEN

Relevant legal provisions:
EPC Art. 54, 56
RPBA 2020 Art. 13(2)

Keyword:

Novelty - novelty of use - second (or further) medical use
Inventive step - obvious alternative
Amendment after notification of Art. 15(1) RPBA communication (no)

Decisions cited:

G 0002/08, T 0943/13

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Case Number: T 2012/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 18 September 2024

Appellant: (Patent Proprietor)	Chr. Hansen A/S Boege Allé 10-12 2970 Hoersholm (DK)
Representative:	Uexküll & Stolberg Partnerschaft von Patent- und Rechtsanwälten mbB Beselerstraße 4 22607 Hamburg (DE)
Respondent: (Opponent)	International N&H Denmark ApS Parallelvej 16 2800 Kongens Lyngby (DK)
Representative:	D Young & Co LLP 3 Noble Street London EC2V 7BQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 June 2022 revoking European patent No. 2802333 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	M. Steendijk
	L. Basterreix

Summary of Facts and Submissions

I. European patent 2 802 333 ("the patent") was granted on the basis of twelve claims.

Claim 1 as granted defined:

"A combination of *Lactobacillus rhamnosus* and *Bifidobacterium animalis* subsp. *lactis* for use in reducing the duration and/or the severity of upper respiratory tract infection (URI) in teenagers and adults having upper respiratory tract infection (URI)."

II. The grant of the patent was opposed on the grounds that its subject-matter lacked novelty and inventive step, that the claimed invention was not sufficiently disclosed and that the patent comprised subject-matter extending beyond the content of the application as filed.

The patent proprietor filed the appeal against the decision of the opposition division to revoke the patent.

The decision was based on the patent as granted (main request) and auxiliary requests 1-7, which had originally been filed as auxiliary requests 7-11 and 13 on 24 March 2022 and as auxiliary request 12 on 19 May 2022.

Claim 1 of auxiliary request 1 defined with respect to claim 1 as granted more specifically that in the combination the *Lactobacillus rhamnosus* is the strain *Lactobacillus rhamnosus* GG ("LGG") and the

Bifidobacterium animalis subsp. *lactis* is the strain *Bifidobacterium animalis* subsp. *lactis* BB-12 ("BB-12").

Claim 1 of auxiliary request 2 defines a composition comprising probiotics consisting of a combination as defined in claim 1 of auxiliary request 1 for the use as defined in claim 1 of the main request.

Claim 1 of auxiliary request 3 additionally defines with respect to claim 1 of auxiliary request 2 the daily amount of the probiotics (between 10^6 and 10^{12} cfu) to be administered.

Claim 1 of auxiliary request 4 defines with respect to claim 1 of auxiliary request 3 that the combination is administered daily.

Claim 1 of auxiliary request 5 defines with respect to claim 1 of auxiliary request 4 that the combination is administered for a period of at least one week.

Claim 1 of auxiliary request 6 defines with respect to claim 1 of auxiliary request 1 that the combination is specifically for use in reducing the severity of URI (deletion of reducing the duration).

Claim 1 of auxiliary request 7 defines with respect to claim 1 of auxiliary request 1 that the combination is for use in teenagers and adults specifically in the age of 13-70.

The opposition division arrived at the following conclusions:

(a) Claim 1 as granted was interpreted as relating to a composition consisting of the defined bacteria. The

skilled person would have understood from the example in the application as filed that a composition comprising only the defined bacteria represented a preferred embodiment. The patent as granted did therefore not comprise subject-matter extending beyond the content of the application as filed.

The patent as granted sufficiently disclosed the suitability of the exemplified bacterial strains LGG and BB-12 for use in the defined treatment of teenagers and adults. However, as recognized in the patent itself beneficial probiotic effects were known to be strain specific. The patent therefore failed to provide adequate guidance how to identify within the defined species substantially all other strains suitable for the defined use covered by claim 1 as granted.

The patent as granted did therefore not sufficiently disclose the claimed invention.

(b) Auxiliary request 1 complied with Rule 80 and Articles 83, 84 and 123(2) EPC. The claimed subject-matter was also new over the prior art.

Documents D2 and D3 represented the closest prior art describing the utility of the same composition for the treatment of the same medical condition as defined in claim 1 of auxiliary request 1. The claimed subject-matter only differed in the definition of the subjects treated, namely teenagers or adults instead of infants. The problem to be solved was formulated as the provision of another age group for the medical use known from D2/D3. No evidence suggested that a probiotic

composition effective in infants would not be effective in other age groups. Documents D15 and D16 actually suggested that LGG by itself would be beneficial in young teenagers and adults. The subject-matter of auxiliary request 1 did therefore not involve an inventive step.

(c) Auxiliary requests 2-7 did not define any further distinguishing feature with respect to documents D2 and D3 and did therefore not comply with the requirement of inventive step for the same reason as auxiliary request 1.

III. In the statement setting out the grounds of appeal the patent proprietor maintained the main request relating to the patent as granted and auxiliary requests 1-7 on which the decision under appeal was based.

IV. In the reply to the appeal the opponent maintained *inter alia* that the subject-matter of claim 1 as granted was not sufficiently disclosed and lacked novelty in view of documents D1, D7 and D8 and that the subject-matter of the claims as granted as well as the subject-matter of auxiliary requests 1-7 lacked an inventive step in view of document D13 as closest prior art.

V. In its communication pursuant Article 15(1) RPBA the Board indicated *inter alia* its preliminary assessment that

- the patent does not sufficiently disclose the subject-matter of claim 1 as granted
- that the subject-matter of claim 1 as granted lacks novelty in view of documents D1, D7 and D8

- the subject-matter of auxiliary requests 1-7 lacks an inventive step in view of document D13 as starting point in the prior art taking also account of the enhanced mucosal adherence of the combination of LGG and BB-12 described in documents D2 and D6.

VI. In the letter of 16 August 2024 the patent proprietor argued that the enhanced mucosal adherence of the combination of LLG and BB-12 mentioned in documents D2 and D6 would hinder the adherence of pathogenic bacteria in the intestinal mucus system, but was not of relevance for the reduction of duration or severity of URI.

VII. In its letter of 6 September 2024 the opponent objected that the patent proprietor's argument regarding the relevance of the enhanced mucosal adherence reported in document D2 represented a new late-filed argument, which should not be admitted under Article 13(2) RPBA and which anyway incorrectly represented the teaching of document D2.

VIII. Oral proceedings were held on 18 September 2024.

IX. The arguments of the patent proprietor relevant to the present decision are summarized as follows:

(a) Claim 1 as granted defined the combination of two types of bacteria for a specific therapeutic use. In accordance with the considerations in T 943/13 this definition required a causal relationship between the combination and the therapeutic use. In line with the example described in the patent, which is silent on the use of any further types of bacteria, this definition did not encompass the use

of compositions comprising probiotics other than the two species specifically identified in claim 1.

Documents D1, D7 and D8 described compositions comprising a mixture of three or more different probiotic species, in part further combined with prebiotic agents, for the treatment of partly unspecified respiratory pathologies in an unspecified patient grouping. These documents did thereby not disclose the causal relationship between the combination of the two specific types of bacteria and the utility in treatment of the specific medical condition in the specific patient group as defined in claim 1 as granted.

(b) Claim 1 of auxiliary request 1 defined the utility of the combination of the specific strains LGG and BB-12 for reducing the duration and severity of URI in teenagers and adults. The patent confirmed with the results of a prospective, randomized, double-blind, placebo-controlled trial the efficacy of the defined combination for the defined purpose in a population of college students. In accordance with the established case law the primary consideration in the selection of the closest prior art should be the purpose or effect of the claimed invention. On this basis the closest prior art was represented by document D1 and not document D13, which was primarily concerned with the production of infant formula.

Document D13 described a preparation comprising a prebiotic mixture together with probiotics to be selected from a long list of probiotic species and strains for treatment of a variety of conditions, including infections of the gastrointestinal tract,

an immune condition and infections of the upper respiratory tract. The differences of the subject-matter of claim 1 with respect to the teaching of document D13 concerned the selection of the strain BB-12 and its further combination with the strain LGG, the selection of the conditions to be treated and the selection of the patient group.

Document D13 only demonstrated in its examples the use of an infant formula in a mice-model for testing gastrointestinal infections and provided thereby no suggestion towards any causal relationship between the combination of BB-12 with LGG and the effective treatment of URI in teenagers and adults. The utility of the combination as defined in claim 1 of auxiliary request 1 would not be obvious taking account of the information concerning the utility of the defined combination in the treatment of infants as described in documents D2 and D3 in view of the differences in the immune system of such infants as compared to the immune systems of teenagers or adults. These differences were for instance explained in the review article of document D27 and referred to in document document D2 itself.

The enhanced mucosal adherence of the combination of LGG and BB-12 mentioned in document D2 by reference to document D6 would hinder the adherence of pathogenic bacteria in the intestinal mucus system, but was not relevant in the reduction or severity of URI. It was further questionable whether the results in document D6 actually demonstrated any enhanced mucosal adherence.

The opponent's consideration that the efficacy of probiotics is strain specific, endorsed by the Board in its preliminary opinion that the patent was not sufficiently disclosed, further supported the conclusion that the subject matter of auxiliary request 1 was not obvious in view of the prior art.

(c) Auxiliary request 2 explicitly defined that the use concerned a composition comprising the combination of LGG and BB-12 as the only probiotics. The prior art did not suggest any causal relationship between the specific combination of only these two probiotics and the effective treatment of URI in the defined patient group. Document D2 was concerned with a very specific group of infants and provided no further suggestion towards effective treatment of URI in teenagers and adults.

The subject-matter as defined in the claims of auxiliary requests 3-6 additionally differed from the prior art by the defined effective daily amounts of the probiotics to be administered, the actual daily administration, the actual daily administration for at least one week and the specification of the use for reducing the severity of URI. The prior art provided no suggestion for the efficacy of the defined amounts and the defined dosage regimen in the treatment of URI, in particular the defined reduction of its severity, in the patient group as identified in the relevant claims.

The definition of the teenagers and adults of the age of 13-70 in claim 1 of auxiliary request 7 resolved any objection that the findings in the

patent might not be generalized to the age group including the elderly.

X. The arguments of the opponent relevant to the present decision are summarized as follows:

(a) Claim 1 as granted was in view of the open terminology used in this claim not restricted to the combination of the two defined types of bacteria as the only active probiotic agents for the defined therapeutic application. The example described in the patent did not give rise to a more restrictive interpretation of the claim.

Documents D1, D7 and D8 already described compositions including the two types of bacteria as defined in claim 1 as granted together with a third type of bacteria for use in the treatment of URI infections in adult patients. Claim 1 as granted therefore lacked novelty in view of documents D1, D7 and D8.

(b) Auxiliary requests 1-7 should not have been admitted, because these requests were not convergent and because it was not evident how these requests could overcome a ground of opposition.

(c) Document D13 described the utility of probiotics in the treatment of URI and specifically indicated that this utility was not limited to the treatment of infants, but also included treatment of adults. The document disclosed *Lactobacillus rhamnosus* ATCC 53103, which corresponded to LGG, and BB-12 amongst preferred strains of probiotics. There was no requirement for document D13 to provide itself specific experimental data concerning the treatment

of URI in adults in support of this disclosure. The prior art, including document D9 already provided such support.

The subject-matter of claim 1 of auxiliary request 1 differed from the teaching of document D13 in the combination of two selected strains. No evidence demonstrated any particular unexpected effect resulting from the combination of the strains as defined in claim 1 of auxiliary request 1. The objective technical problem therefore concerned the provision of an alternative probiotic composition for the treatment of URI.

The combination of the selected strains as defined in claim 1 of auxiliary request 1 was obvious to the skilled person in view of the utility of the individual strains as described in document document D13 itself, especially in view of the considerations to combine these strains as presented in documents D2 and D6. The patent proprietor's argument that the enhanced mucosal adherence of the combination of strains was only of concern in relation to gastrointestinal infections and not URI should not be admitted and anyway incorrectly represented the teaching of document D2.

(d) The objection of lack of inventive step against claim 1 of auxiliary request 1 equally applied to the subject-matter of auxiliary request 2 in view of the utility of the individual strains indicated in document D13 and the combination of the selected strains described in document D2.

The definition of the effective daily amount of the probiotics to be administered, the actual daily administration and the daily administration for at least one week in auxiliary requests 3-5 did not contribute to an inventive step, because these features reflected routine measures of implementation taking account of the known use of probiotics in the treatment of URI as described in documents D1, D2, D7 and D9. The limitation to the use for reducing the severity of URI and the definition of the patients in the age of 13-70, did not represent any additional distinguishing feature and could therefore also not contribute to an inventive step.

XI. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or alternatively on the basis of one of auxiliary requests 1-7 as filed with the statement of grounds of appeal.

XII. The respondent-opponent requested that the patent be revoked in its entirety. The opponent further requested that auxiliary requests 1-7 and the new arguments submitted by the appellant in its letter dated 16 August 2024 with regard to Article 56 EPC not be admitted.

Reasons for the Decision

1. Lack of novelty, main request

1.1 Interpretation of claim 1 as granted

Claim 1 as granted defines the combination of two specified types of bacterial agents, *Lactobacillus rhamnosus* and *Bifidobacterium animalis* subsp. *lactis*, for a specified therapeutic use in the format of Article 54(5) EPC, namely the use in reducing the duration and/or the severity of upper respiratory tract infection (URI) in teenagers and adults having upper respiratory tract infection (URI).

In line with the considerations in G 2/08 (see reasons 5.10.9) the novelty and non-obviousness of such subject-matter may be derived from the purpose that the claimed combination is related to. It is therefore the purpose based on the causal relationship between the combination and the achieved effect, namely the utility of the combination of the two types of bacterial species as active principle in the defined therapy, that constitutes a functional feature of the claim (compare T 943/13, reasons 4.1.5).

This feature regarding the utility of the combination of the two types of bacterial agents as active principle in the defined therapy does, however, not require that the two types of bacterial agents are the only active agents used for the defined therapy. In case the combination of the two defined bacterial species is formulated in a composition for the defined therapeutic use together with a further active agent, for instance an additional type of bacterial agent, the

two defined bacterial species are still used in the resulting composition as active agents for the defined therapeutic purpose.

The patent presents under the heading "EXAMPLES" (see paragraph [0056] onwards) a report of a clinical trial involving the use of a combination of two specific strains of the bacterial agents as defined in claim 1 without mention of any other active agent. The Board does not recognize that the report of this trial involving the combination of two specific bacterial strains as an example does in anyway represents a ground for a more restrictive interpretation of claim 1 as granted requiring that the defined two types of bacterial agents are the only active agents used in the defined therapy.

1.2 Lack of novelty in view of Documents D1, D7 and D8

Document D1 describes a composition specifically including a probiotic combination of strains of *Lactobacillus rhamnosus* and *Bifidobacterium animalis* subsp. *lactis* together with *Lactobacillus plantarum* (see D1, claim 5 and page 15) which was used in the treatment of URI in subjects with an average age around 35 and which resulted in a significant decrease of the duration of the condition (see D1, page 19, lines 12-15 and page 21, lines 4-11).

Document D7 describes a composition in the form of a functional food specifically including a probiotic combination of *Lactobacillus casei* subsp. *rhamnosus* and *Bifidobacterium lactis* together with *Lactobacillus plantarum* and further including a prebiotic which was used to reduce the duration of URI in a group of

subjects with an average age of around 35 years (see D7, abstract and page 212).

Document D8 describes a composition specifically including a probiotic combination of strains of *Lactobacillus rhamnosus* and *Bifidobacterium lactis* together with *Lactobacillus plantarum* further including lacto ferrin and a prebiotic which was used to reduce the occurrence, duration and severity of URI in subjects with an average age of around 39 years (see D8, abstract, page S226, left column under "Synbiotic Preparations" and page S227, left column under "Results").

The Board therefore considers that documents D1, D7 and D8 specifically describe the utility of a combination of *Lactobacillus rhamnosus* and *Bifidobacterium animalis* subsp. *lactis* for the reduction of the duration or severity of URI in same type of subjects as defined in claim 1 as granted.

1.3 The patent proprietor did not dispute that the compositions used in documents D1, D7 and D8 include the two types of bacterial agents as defined in claim 1 as granted. The patent proprietor maintained, however, that documents D1, D7 and D8 did not anticipate the subject-matter of claim 1 as granted, because the compositions described in documents D1, D7 and D8 comprised beyond the two bacterial species defined in claim 1 as granted additional active agents. According to the proprietor documents D1, D7 and D8 thereby failed to disclose the causal relationship between the combination of the two specific types of bacteria and their utility in the specific treatment as defined in claim 1 as granted.

The Board does not consider these arguments convincing. Documents D1, D7 and D8 instruct the skilled person to include *Lactobacillus rhamnosus* and *Bifidobacterium animalis* subsp. *lactis* as probiotic agents in compositions intended for the same therapeutic use as defined in claim 1 as granted. Documents D1, D7 and D8 thereby specifically disclose these probiotic agents as active agents in the composition for the defined purpose. Following the interpretation of granted claim 1 as explained in section 1.1 above documents D1, D7 and D8 therefore already disclosed the combination of these two types of bacteria for the specific therapeutic use as defined in claim 1 as granted.

1.4 Accordingly, the Board concludes that the subject-matter of claim 1 of the patent as granted lacks novelty in view of documents D1, D7 and D8.

2. Admittance auxiliary requests 1-7

The decision under appeal was based on auxiliary requests 1-7. The statement of grounds of appeal (see pages 36-43) specifically addressed the relevance of auxiliary requests 1-7. These requests are therefore considered as part of the appeal proceedings (Article 12(1) RPBA).

3. Lack of inventive step, auxiliary request 1

3.1 Starting point in the prior art

Document D13 describes a preparation comprising a probiotic bacterial strain as active component (see D13, claim 1) for use in the prevention or treatment of infections of the upper respiratory tract (see D13, claim 18). Document D13 specifically addresses the

duration and severity of infections (see D13, page 14, line 15). Document D13 presents a list of preferred probiotic bacterial strains including *Lactobacillus rhamnosus* ATCC 53103 and *Bifidobacterium animalis* subsp. *lactis* BB-12 (see D13, page 11, lines 18-19 and 22-23). Document D13 furthermore teaches that the consumption of the preparation is not restricted to infants and children and that the preparation may also be beneficial to the adult population especially the elderly (see D13, page 11, line 35; page 13, lines 29-34; page 14, lines 7-12).

Although document D13 does not present any example specifically dedicated to the treatment of URI in adults, this teaching in document D13 does not lack credibility taking account of the reference in document D13 itself to a report suggesting that some probiotic strains may be effective in the prevention and treatment of URI (page 2, lines 16-18) and the indication in document D9 that an orally administered fermented milk product containing probiotics, including Lactobacillus GG (ATCC 53103), reduced potentially pathogenic bacteria in the upper respiratory tract in an adult population (see D9, abstract and page 518, left column, under "Subject eligibility).

In view of the explicit indication in document D13 that the consumption of described preparation is not limited to infants and children and that the preparation may also be beneficial to adults, in particularly the elderly, the Board considers that the teaching in document D13 includes the same purpose as addressed in claim 1 of auxiliary request 1.

Document D13 therefore represents a suitable starting point in the prior art.

3.2 Objective technical problem

The difference between the subject-matter of claim 1 of auxiliary request 1 and the teaching of document D13 concerns the selection and combination of the strains *Lactobacillus rhamnosus* ATCC 53103 and *Bifidobacterium animalis* subsp. *lactis* BB-12 ("BB-12").

In this context the Board observes that according to the patent (see paragraph [0054]) the strain *Lactobacillus rhamnosus* GG ("LGG") corresponds to the strain ATCC 53103.

The patent describes under the heading "EXAMPLES" (see from paragraph [0056] onwards) a prospective, randomized, double-blind, placebo-controlled trial. The patent presents results of this trial indicating the efficacy of the defined combination in reducing duration and severity of URI in a population of college students.

The patent does thereby not demonstrate any advantage or other particular effect of the use of the defined combination of the two selected bacterial strains with respect to the use of an individual strain as described in document D13. Accordingly, the Board considers that the objective technical problem starting from document D13 concerns the provision of an alternative treatment of the defined condition in the defined group of patients.

3.3 Assessment of the solution

3.3.1 Document D13 itself specifically discloses a list of four particularly preferred strains of the

Lactobacillus species, including the strain LGG, and a list of two particularly preferred strains of the *Bifidobacterium* species, including BB-12 (see page 11, lines 15-25). Faced with the problem of providing an alternative treatment the skilled person would as a matter of obviousness select probiotics from the strains listed in document D13 as particularly preferred. Moreover, from the utility of these individual strains indicated in document D13 the skilled person would derive a reasonable expectation of the same utility of a combination of these strains.

The skilled person would furthermore find in document D2 and the reference therein to document D6 confirmation that the strains LGG and BB-12 may indeed be safely combined to achieve probiotic effects and that *in vitro* experiments indicate increased mucosal adherence of BB-12 from its combination with LGG (see D2, page 1723, left column; see D6, page 12 right column, last paragraph).

3.3.2 The patent proprietor maintained that in view of the strain specific effects of probiotics, which formed the basis for the Board's preliminary opinion regarding the opponent's objection that the patent did not sufficiently disclose the claimed invention, the subject matter of auxiliary request 1 was not obvious in view of the prior art.

The Board's preliminary opinion regarding the opponent's objection of lack of sufficient disclosure concerned the subject matter of claim 1 as granted and not the subject-matter of claim 1 of auxiliary request 1. Moreover, the reasons for the Board's finding of lack of inventive step of the subject-matter of claim 1 of auxiliary request 1 set out in section 3.3.1 above

rely on the teaching of document D13, which describes the specific strains of the combination defined in claim 1 of auxiliary request 1 as particularly preferred examples of a probiotic bacterial strain in a composition indicated for the same purpose as defined in claim 1 of auxiliary request 1.

The patent proprietor's argument relying on the strain specific effects of probiotics is therefore not considered convincing.

3.3.3 The patent proprietor further argued that the skilled person would in the context of treatment of teenagers and adults not consider the teaching of document D2 relating to the treatment of specific infants in view of the differences in the immune system of such infants as compared to the immune systems of teenagers or adults.

Document D2 indeed concerns a study of the effect of specific probiotics for reducing the risk of infections in infants requiring formula before the age of 2 months (see D2, abstract) and explicitly indicates in this context that it is crucial that children are subjected to intervention in early infancy, because the maturing immune system may be more amenable to probiotic modification (see D2, page 1725, left column). Moreover, the review in document D27 indicates that the skilled person is familiar with the development of the human immune system as a continuous process during childhood.

The Board observes, however, that the reasons for the Board's finding of lack of inventive step of the subject-matter of claim 1 of auxiliary request 1 set out in section 3.3.1 above rely in the first place on

the teaching of document D13. This document indicates the specific individual strains of the combination defined in claim 1 of auxiliary request 1 to be useful in a preparation for the treatment of URI and teaches that such a preparation is not only beneficial to infants and children, but also to adults, especially the elderly. Whilst the study in document D2 concerns a study of a combination of probiotics in a specific group of infants, document D2 also explains the choice of the specific combination of LGG and BB-12 on the basis of the documented safety properties of these strains and the long history of their safe use in infant studies and in food products as well as the increased *in vitro* adherence of BB-12 by LGG reported in document D6 (see D2, page 1723, left column). This teaching in document D2 does not specifically concern the treatment of infants and confirms the skilled person's motivation to combine the strains LGG and BB-12 indicated in document D13 to be useful for treatment of URI in adults.

The patent proprietor's argument that the skilled person would in the context of treatment of teenagers and adults not consider the teaching in document D2 is therefore also not considered convincing.

3.3.4 In the letter of 16 August 2024 the patent proprietor argued that the enhanced mucosal adherence resulting from the combination of LLG and BB-12 mentioned in documents D2 and D6 would hinder the adherence of pathogenic bacteria in the intestinal mucus system, but was not of relevance in the reduction of duration or severity of URI.

This argument represents in the Board's view an admissible development of the patent proprietor's prior

argument that the skilled person would in the context of treatment of teenagers and adults not consider the teaching of document D2. The Board concurs with the appellant that any hindrance to the adherence of pathogenic bacteria in the intestinal mucus system resulting from the combination of LLG and BB-12 would not directly affect the reduction of duration or severity of URI. However, as explained in sections 3.3.1 and 3.3.3 above the skilled person would consider the teaching in documents D2 and D6 relevant in the context of treatment of teenagers and adults, because these documents confirm the safety of the defined combination of the probiotic strains LGG and BB-12 and even indicate the increased adherence of BB-12 to intestinal mucosa when administered with LGG.

The patent proprietor's argument that enhanced mucosal adherence from the combination of LLG and BB-12 mentioned in documents D2 and D6 is not relevant to reduction of duration or severity of URI is therefore also not considered convincing.

3.3.5 The patent proprietor's further objection that the results reported in document D6, in particular in Figure 2, would anyway not allow for the conclusion of an increase in adhesion of BB-12 from its combination with LGG is not considered justified.

This increased adhesion is indicated by the results reported in Figure 1 of document D6, which relate to adhesion following the simultaneous incubation with BB-12 and LGG. The results in Figure 2 of document D6 relate to adhesion of BB-12 after pre-incubation with LGG and do therefore not contradict the conclusion in document D6.

3.3.6 Accordingly, the Board concludes that the subject-matter of claim 1 of auxiliary request 1 does not involve an inventive step.

4. Lack of inventive step, auxiliary requests 2-7

4.1 Auxiliary request 2

4.1.1 The formulation of claim 1 of auxiliary request 2, which defines a composition comprising probiotics consisting of a combination as defined in claim 1 of auxiliary request 1, excludes the presence of any additional probiotic agent beyond the combination of the two defined strains in the composition for the defined use.

As explained in section 3.1 above, document D13 already indicates the utility of a composition comprising a probiotic bacterial strain for the defined use and disclosed the individual probiotic strains of the defined combination as particularly preferred strains. In comparison to claim 1 of auxiliary request 1 the definition of subject-matter in claim 1 of auxiliary request 2 does not result in any additional distinguishing feature with respect to the teaching of document D13. Accordingly, the Board considers that the reasons for the finding of the lack of inventive step of the subject-matter of claim 1 of auxiliary request 1 as set out in section 3 above also apply with respect to the subject-matter of auxiliary request 2.

4.1.2 The patent proprietor argued that the subject-matter of claim 1 of auxiliary request 2 involves an inventive step, because the causal link between the combination of the two defined probiotic strains as the only

probiotics and the defined therapeutic use would not be obvious from document D13.

This argument is not convincing. Document D13 already discloses a probiotic bacterial strain as an active component in a composition indicated for the same use as defined in claim 1 of auxiliary request 1 and specifically describes the individual strains of the defined combination as particularly preferred examples of such a probiotic strain. Document D13 thereby clearly indicates the individual strains of the defined combination as active components for the defined therapeutic use, which provides the skilled person with the reasonable expectation that the defined combination retains the activity of the individual components.

4.2 Auxiliary requests 3-7

The additional definition of the effective daily amount of 10^6 and 10^{12} cfu of the probiotics to be administered, the actual daily administration and the actual daily administration for at least one week in the claims of auxiliary requests 3-5 do not contribute to an inventive step. As solution to the problem of providing for alternative treatment of URI in teenagers and adults starting from document D13 the skilled person would consider these features obvious measures of practical implementation taking account of similar doses and dosage regimen involving conventional treatment of adults with probiotics as described in documents D1 (see page 15, "Composition A", and page 19), document D7 (see pages 209 and 211) and document D9 (see page 518).

The limitation to the use for reducing the severity of URI and the definition of the patients in the age of

13-70 as defined in the claims of auxiliary requests 6-7 do not represent any additional distinguishing feature with respect to the teaching of document D13 and do therefore also not contribute to an inventive step of the defined subject-matter.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Vottner A. Usuelli

Decision electronically authenticated