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**Datasheet for the decision
of 11 January 2021**

Case Number: T 1866/16 - 3.3.08

Application Number: 08841594.8

Publication Number: 2211879

IPC: C12N1/20, A61K35/74

Language of the proceedings: EN

Title of invention:

PROBIOTIC COMPOSITIONS AND METHODS FOR INDUCING AND SUPPORTING
WEIGHT LOSS

Patent Proprietor:

Moore, Brenda E.

Opponent:

DuPont Nutrition BioSciences ApS

Headword:

Probiotic compositions/MOORE

Relevant legal provisions:

EPC Art. 123(2)
EPC R. 103(1)(a)
RPBA Art. 12(4)
RPBA 2020 Art. 12(2), 25(2)

Keyword:

Main request - admission (no);

Auxiliary request 1 - admission new objection (yes);

Auxiliary request 1 - added subject-matter (yes);

Reimbursement of the appeal fee (no);

Decisions cited:

G 0009/91, G 0010/91

Catchword:



Beschwerdekammern
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Case Number: T 1866/16 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 11 January 2021

Appellant: Moore, Brenda E.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 14 June 2016
revoking European patent No. 2211879 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman B. Stolz
Members: P. Julià
R. Winkelhofer

Summary of Facts and Submissions

- I. European patent no. 2 211 879 is based on European patent application no. 08 841 594.8, published under the PCT as International patent application WO 2009/055362 (hereinafter, "the patent application"). The patent was granted with 16 claims.
- II. An opposition was filed on the grounds set forth in Articles 100(a), (b) and (c) EPC. The opposition division considered the main request to contravene Article 123(3) EPC, auxiliary requests 1 and 2 to contravene Article 123(2) EPC, and auxiliary requests 3 and 4 not to fulfil the requirements of Article 56 EPC.
- III. The patent proprietor (appellant) lodged an appeal and, with the statement setting out the grounds of appeal, filed new evidence, a main request and auxiliary request 1.
- IV. In reply thereto, the opponent (respondent) filed new evidence and requested the board not to admit the main request into the appeal proceedings. The respondent maintained the objections raised in first instance under Articles 123(2), 83, 54 and 56 EPC against the main request, and raised objections under Articles 123(2) and 56 EPC against auxiliary request 1.
- V. Since both parties requested oral proceedings as an auxiliary measure, the board summoned them for 28 January 2021. In a communication pursuant to Article 17 of the Rules of Procedure of the Boards of Appeal (RPBA 2020), the parties were informed of the board's provisional opinion on the issues at stake. The board stated, *inter alia*, that it was minded not to

take into account the main request into the appeal proceedings (Article 12(4) RPBA 2007) and to consider the objection raised under Article 123(2) EPC against auxiliary request 1, and that auxiliary request 1 appeared to contravene Article 123(2) EPC. The board also stated that appellant's request for the reimbursement of the appeal fee was not substantiated and thus, it could not be justified. The board concluded that the appeal was likely to be dismissed.

- VI. No substantive submissions were filed by any of the parties in response to the board's communication. Whilst the respondent announced attendance to the oral proceedings and requested them to be held by video conference, the appellant announced the intention not to attend the oral proceedings and requested a decision on the appeal to be made based on the written submissions on file.
- VII. The board cancelled the oral proceedings and informed the parties that a decision would be handed down in writing.
- VIII. The main request has five claims; claim 1 reads as follows:

"1. Use of a probiotic composition for the manufacture of a medicament for inducing or supporting weight loss in a subject, said probiotic composition comprising an effective amount of a bacteria, wherein the bacteria is lyophilized and the bacteria is selected from the group consisting of *Bacteroides thetaiotaomicron*, *B. fragilis*, *B. vulgatus*, *B. distasonis*, *B. ovatus*, *B. stercoris*, *B. merdae*, *B. uniformis*, *B. eggerithii*, and *B. caccae*, and a pharmaceutically acceptable

carrier for allowing delivery of said bacteria to said subject in use."

Claims 2 to 5 are directed to particular embodiments of claim 1.

IX. Auxiliary request 1 has three claims; claim 1 reads as follows:

"1. Use of a probiotic composition for the manufacture of a medicament for inducing or supporting weight loss in a subject, said probiotic composition consisting of 200mg of lyophilized *B. thetaioaomicron* cells in powdered form, 180mg of Lactose USP, 60mg Corn Starch, 10mg Magnesium Stearate NF in a capsule for allowing delivery of said bacteria to said subject in use."

Claims 2 and 3 are directed to particular embodiments of claim 1.

X. In the statement setting out the grounds of appeal, the appellant stated that the main request filed in appeal was identical to auxiliary request 3 submitted during the opposition proceedings, with the exception that the reference to *B. adolescentis* had been deleted from claim 1. This amendment did not extend beyond the content of the patent application as originally filed since this was always an optional feature in the claims. Auxiliary request 1 in appeal was identical to auxiliary request 4 submitted during the opposition proceedings. The opposition division considered auxiliary requests 3 and 4 to comply with Articles 123(2), 84, 83 and 54 EPC but not to fulfil the requirements of Article 56 EPC. The appellant provided new evidence and, based thereupon, argued that

auxiliary request 4 fulfilled the requirements of Article 56 EPC.

- XI. The respondent argued that the main request included an amendment that dealt with an issue (lack of priority) raised in the Notice of opposition and thus, an issue that had been on file from the beginning of the opposition proceedings. The appellant had had ample time and opportunities to file the main request at earlier stages of the proceedings and thus, the main request could not be admitted into the appeal proceedings.

Auxiliary request 1 was identical to a request filed during the oral proceedings at first instance, and certain issues relating to this request, in particular the basis for this request in the patent application (Article 123(2) EPC), had not been discussed at the oral proceedings. Several features disclosed in Example 1 of the patent application were not present in claim 1 of auxiliary request 1; these features concerned the corn starch used, the components of the mixture with the *B. thaitotaomicron* cells before encapsulation, and the capsule used for allowing delivery of the bacteria cells. Thus, claim 1 of auxiliary request 1 contravened Article 123(2) EPC.

- XII. The appellant (patent proprietor) requests that the decision under appeal be set aside and the patent be maintained on the basis of the main request or, in the alternative, of auxiliary request 1. The appellant requests also the reimbursement of the appeal fee.
- XIII. The respondent (opponent) requests that the appeal be dismissed.

Reasons for the Decision

1. The present decision is based on the same grounds, arguments and evidence on which the board's provisional opinion was based. It was neither questioned by any of the parties, nor did other aspects come up that would require its reconsideration.

Admission of the main request

2. Article 12(2) RPBA 2020 refers to the primary object of an appeal, namely to review the decision under appeal in a judicial manner, and states that a party's case shall be directed, *inter alia*, to the requests on which the decision under appeal was based.

Article 12(4) RPBA 2007 which, according to Article 25(2) RPBA 2020, applies to those appeals for which the statement of grounds of appeal was filed before the date of entry into force of the RPBA 2020 (1 January 2020), such as the present appeal, refers to the power of the Boards of Appeal to hold inadmissible, i.e. not to take into account, *inter alia*, requests filed for the first time with the statement of grounds of appeal which could have been submitted in the proceedings leading to the decision under appeal.

3. In line therewith, the established case law acknowledges that the primary object or function of an appeal is to give a judicial decision upon the correctness of a separate earlier decision taken by an examining or opposition division. Appeal proceedings are not an opportunity to re-run or re-open proceedings before any of these divisions. The purpose of an appeal is not to give the patent proprietor an opportunity to

improve the drafting of the claims or to recast them as they see fit and to have all requests admitted into the proceedings. The admission of new claim requests into the appeal proceedings is thus at the board's discretion (Article 12(4) RPBA 2007; see "Case Law of the Boards of Appeal of the EPO", 9th edition 2019, V.A.1, 1133; V.A.4, 1206; and V.A.4.11.3.d), 1233).

4. The main request is identical to auxiliary request 3 filed at first instance except for the deletion of the bacterium *B. adolescentis* in claim 1. According to the appellant, the deletion of this bacterium results in the main request being entitled to the claimed priority right (26 October 2007, US 982 844). As a consequence thereof, document (2) (WO 2008/076696) is not prior art under Article 54(2) EPC and cannot be used in the assessment of Article 56 EPC (cf. page 34, point 72 of the statement of grounds of appeal; page 4, last paragraph of the decision under appeal).
5. The respondent referred to the proceedings at first instance where the issue of priority rights was raised in the respondent's submissions of 19 February 2016 prior to the oral proceedings before the opposition division, as well as to the opportunity to file new requests given to the appellant by the opposition division at these oral proceedings, which was waived by the appellant. Therefore, according to the respondent, the appellant had ample time to file an appropriate request at first instance and thus, the main request should not be admitted into the proceedings.
6. In the communication pursuant to Article 17 RPBA 2020, the board drew the parties' attention to the following points:

- 6.1 Priority entitlement was discussed in opponent's submissions of 19 February 2016, wherein reference was explicitly made to the problems arising from the bacterium *B. adolescentis* (cf. page 4, fourth paragraph from the bottom). As a result of the alleged non entitlement to priority rights, document (2), published after the claimed priority date, was cited as the closest prior art in the sole "problem and solution approach" put forward by the opponent in these submissions (cf. page 6, point 4 *et seq.*).
- 6.2 According to the Minutes of the oral proceedings held on 25 April 2016 before the opposition division (hereinafter "the Minutes"), entitlement to the claimed priority right was not acknowledged for the bacterium *B. adolescentis* (cf. page 3 of the Minutes, paragraph before the heading "D11 - Admissibility"). In the discussion of inventive step, the opponent identified document D3 (US 2004/0028689) as the closest prior art and argued lack of inventive step on the basis of a combination of documents D3 and D2. The lack of inventive step was acknowledged by the opposition division (cf. page 4 of the Minutes under the heading "AR3 - Article 56 EPC").
- 6.3 On page 5, first line of the Minutes, it is stated that "[t]he PA [patent proprietor] did not wish to file new requests or to make further comments".
7. In its communication pursuant to Article 17 RPBA 2020, the board further informed the parties that, in view of this course of events in the opposition proceedings, the consideration/admission of the main request into the appeal proceedings would, in fact, amount to a continuation or re-opening of the opposition proceedings, giving the appellant yet another

opportunity to improve their position by redrafting the claims in a manner that could, and should, have been done during the proceedings before the first instance. Thus, the admission of the main request into the appeal proceedings was not in line with the primary object or purpose of the appeal proceedings as mentioned above (cf. "Case Law", *supra*, V.4.11.3.d), 1233). Moreover, the board also observed that no reasons had been provided by the appellant to explain why the main request had been filed at this late stage of the proceedings and why it could not have been filed at the proceedings before the opposition division.

8. Thus, in the board's communication, the parties were informed that the board, in the exercise of its discretion, was minded not to take into account the main request in the appeal proceedings.

The board sees no reasons to deviate from its provisional opinion and therefore, the main request cannot be admitted into the appeal proceedings (Article 12(4) RPBA 2007).

Auxiliary request 1

9. Auxiliary request 1 is identical to auxiliary request 4 underlying the decision under appeal and thus, it already forms part of the appeal proceedings.
10. Neither the decision under appeal nor the Minutes of the oral proceedings at first instance mention the raising of any objection under Article 123(2) EPC against this auxiliary request. In the Minutes, it is stated only that this request was filed - together with auxiliary request 3 - after a break and that it did not

fulfil the requirements of Article 56 EPC (cf. page 2, first paragraph; page 4, last paragraph).

Consideration of the objection raised under Article 123(2) EPC

11. The objection raised under this article by the respondent against auxiliary request 1 has not been raised, as such, before the opposition division. Thus, the objection is new and based on new arguments submitted for the first time in appeal proceedings. Thus, it is at the board's discretion to consider or disregard the objection and the new arguments in these proceedings (Article 12(4) RPBA 2007) (cf. "Case Law", *supra*, V.A.4, 1206; and V.A.4.10, 1223).
12. In the communication pursuant to Article 17 RPBA 2020, the board drew the parties' attention to the following points:
 - 12.1 Although auxiliary request 1 was filed (as auxiliary request 4) only at the oral proceedings before the opposition division, it was identical to auxiliary request 2, except for the deletion of claim 2. Auxiliary request 2 was filed before the oral proceedings at first instance and thus, the opponent had time to raise all objections - and put forward arguments to support them - against this auxiliary request, if so wished. Thus, the respondent could, and should, have raised the objection under Article 123(2) EPC in the proceedings before the opposition division, and not at this late stage of the proceedings.
 - 12.2 On the other hand, neither from the decision under appeal nor from the Minutes of the oral proceedings at first instance, was it clear whether the opponent was

given any opportunity to put forward arguments on Article 123(2) EPC as regards the specific subject-matter of auxiliary request 1. A discussion on Article 123(2) EPC was reported in the Minutes only for auxiliary request 1 (cf. page 1 of the Minutes), a general statement was given for auxiliary requests 2 and 3 (cf. page 2, third and sixth paragraphs of the Minutes), but there was nothing at all on auxiliary request 4, upon which the opposition division appeared to have decided, by analogy with auxiliary request 3, only on a lack of inventive step (cf. page 4 of the Minutes).

12.3 In decisions G 9/91 and G 10/91 (OJ EPO 1993, 408 and 420, respectively), the Enlarged Board of Appeal stated that "in case of amendments of the claims ... in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC (e.g. with regard to the provisions of Article 123(2) and (3) EPC)" (cf. G 9/91, *supra*, point 19 of the Reasons) (see also, in this context, "Case Law", *supra*, V.A. 3.4.1, 1196).

13. Thus, in its communication pursuant to Article 17 RPBA 2020, the board informed the parties that, upon consideration of the course of events at first instance, the arguments put forward by the parties and the established case law, the board was minded to consider, in the exercise of its discretion (Article 12(4) RPBA 2007), respondent's objection raised under Article 123(2) EPC against the specific subject-matter of auxiliary request 1.

The board sees no reasons to deviate from its provisional opinion and thus, the objection raised

under Article 123(2) EPC against the specific subject-matter of auxiliary request 1 is admitted into the proceedings (Article 12(4) RPBA 2007).

Article 123(2) EPC

14. It is common ground between the parties that Example 1, paragraphs [0030] and [0031] and Table 1, are the sole parts of the patent application relevant for assessing whether the subject-matter of auxiliary request 1 contravenes Article 123(2) EPC. According to the established case law, a claim comprising a specific feature that is disclosed in an example of the patent application may have a basis in this example only if the skilled person would have readily recognised this specific feature not to be so closely associated with the other features disclosed in that example (cf. "Case Law", *supra*, II.A.1.5.2, 455, and II.E.1.9, 482, in the context of ranges and intermediate generalisations, respectively).

15. In reply to the appeal, the respondent argued that several essential features disclosed in Example 1 of the patent application were not mentioned in claim 1, in particular: i) the Corn Starch used in the composition described in Example 1 was "Food Grade", whilst claim 1 allowed the use of any corn starch; ii) according to paragraph [0030], the *B. thetaiotaomicron* cells were mixed with the other components of the mixture indicated in Table 1 before being encapsulated, a feature which was not included in claim 1; and iii) paragraph [0031] stated that the capsule used for allowing delivery of the bacteria cells was a two-piece gelatin capsule, which was also not mentioned in claim 1.

16. In the communication pursuant to Article 17 RPBA 2020, the board drew the parties' attention to the following points:
- 16.1 As regards feature i), claim 1 referred to "a subject" in general, wherein said subject may be "a human" (claim 3), but also, according to the description of the patent application, "horses, rats, mice, ruminants, primates, monkeys, hamsters, rabbits, cats and various avian and fish species" (cf. page 5, paragraph [0016]). Whilst it was doubtful whether, for all these "subjects", the preparation of a medicament may require the use of "Food Grade" Corn Starch, such a grade was certainly required for "a human" subject. The use of Corn Starch other than "Food Grade" in a medicament intended for delivery and administration to "a human" would neither be appropriate nor in line with the standards for preparing a medical composition for human use. Indeed, this was common general knowledge of a skilled person who, when reading the information provided in Example 1, would certainly understand that "Corn Starch" was an essential element of this mixture but that "Food Grade" was a feature directly linked to, or associated with, the "subject" for whom the medicament was intended to be delivered and/or administered. Thus, the absence of the feature "Food Grade" in claim 1 did not result in the claim contravening Article 123(2) EPC.
- 16.2 As regards feature ii), it was known in the art that the properties of a medical or pharmaceutical composition may directly depend on the particular method, and the specific steps, used in the preparation of said composition. The activity and half-life of the active principle/agent as well as the efficiency of delivery, etc. may depend on, *inter alia*, whether the

components of the composition have been mixed or only added, the conditions under which said mixture or addition has been performed, etc. A skilled person reading Example 1, would have understood the information provided in paragraph [0031], namely the mixing of all four components indicated in Table 1 for 10 min in a suitable mixer, as an essential step or feature of the method of preparation of the probiotic composition and, as such, conferring specific properties to said composition. However, none of this was mentioned in claim 1. Contrary to the probiotic composition disclosed in Example 1, the composition of claim 1 may be obtained by mere addition - not mixing - of the components indicated in the claim. In this sense the subject-matter of claim 1 extended beyond the one originally disclosed in the patent application and thus, claim 1 contravened Article 123(2) EPC. Moreover, the patent application referred only to the species *B. thetaiotaomicron*, not to *B. thetaioamicron*.

- 16.3 As regards feature iii), whilst the use of a capsule, as in Example 1 was explicitly mentioned in claim 1, the claim, contrary to Example 1, did not mention the use of a "two-piece gelatine [sealed] capsule". It was an open question whether this information would be understood by the skilled person as a feature not essential, not closely associated with the other features of the composition disclosed in Example 1, such as was the case for the feature "Food Grade" (*supra*), or else as an essential feature closely linked to all other features, such as was the case for the 10 min mixing of the components (*supra*).

This issue was left open in the board's communication and, in view of the board's considerations in

point 16.2 above, there is no need for the board to take a stand here thereupon.

17. In the board's communication, the parties were, lastly, informed that auxiliary request 1 appeared to contravene Article 123(2) EPC.

The board sees no reasons to deviate from its provisional opinion and thus, auxiliary request 1 contravenes Article 123(2) EPC.

Reimbursement of the appeal fee

18. As the appeal is not allowable, this question does not pose any more (Rule 103(1) (a) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



L. Malécot-Grob

B. Stolz

Decision electronically authenticated