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**Datasheet for the decision  
of 17 June 2019**

**Case Number:** T 1190/14 - 3.3.04

**Application Number:** 04812935.7

**Publication Number:** 1694273

**IPC:** A61K38/43, A61K38/46,  
A61K45/06, A61K35/74, A61P1/00

**Language of the proceedings:** EN

**Title of invention:**

Methods for the Dietary Management of Irritable Bowel Syndrome  
and Carbohydrate Malabsorption

**Applicant:**

Ganeden Biotech, Inc.

**Headword:**

Management of IBS/GANEDEN

**Relevant legal provisions:**

EPC Art. 54, 56, 83, 84, 123(2)

**Keyword:**

Main Request - allowable (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

Case Number: T 1190/14 - 3.3.04

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.04**  
**of 17 June 2019**

**Appellant:** Ganeden Biotech, Inc.  
(Applicant) 5800 Landerbrook Drive, Suite 300  
Mayfield Heights, OH 44124 (US)

**Representative:** Ladendorf, Oliver  
Kraus & Weisert  
Patentanwälte PartGmbB  
Thomas-Wimmer-Ring 15  
80539 München (DE)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 2 January 2014  
refusing European patent application No.  
04812935.7 pursuant to Article 97(2) EPC**

**Composition of the Board:**

**Chairwoman** G. Alt  
**Members:** A. Chakravarty  
M. Blasi

## Summary of Facts and Submissions

- I. An appeal was filed by the applicant (appellant) against the decision of the examining division to refuse European application No. 04 812 935.7, entitled "*Methods for the Dietary Management of Irritable Bowel Syndrome and Carbohydrate Malabsorption*".
- II. The examining division considered claims of a main and two auxiliary claim requests and held that the subject-matter of claims 1 and 2 of all requests lacked an inventive step.
- III. The appellant submitted claim sets of a main and five auxiliary requests together with the statement of grounds of appeal. The claims of the main request corresponded to those of the main request filed before the examining division on 21 October 2013. The auxiliary requests were filed for the first time in the appeal proceedings. The appellant also submitted document D14 (see section IV., below) with the statement of grounds of appeal.
- IV. The following documents are referred to in this decision:

D4: Ara K. et al., "*Effect of spore-bearing lactic acid-forming bacteria (Bacillus coagulans SANK 70258) administration on the intestinal environment, defecation frequency, fecal characteristics and dermal characteristics in humans and rats*", *Microbial Ecology in Health and Disease*, 2002, 14(1), 4 - 13.

D5: WO 00/07606

D12: Drossman D. et al., "*Irritable Bowel Syndrome: A Technical Review for Practice Guideline Development*", *Gastroenterology*, vol. 112(1), June 1997, pages 2120-2137.

D14: Dolin B.J., "*Effects of a proprietary Bacillus coagulans preparation on symptoms of diarrhea-predominant irritable bowel syndrome*", *Methods Find. Exp. Clin. Pharmacol.*, vol. 31(10), 2009, pages 655-659.

- V. The board issued a communication informing the appellant of its preliminary appreciation of some of the relevant issues concerning the appeal.
- VI. The appellant replied to this communication and filed claim sets of a new main request and of five new auxiliary requests, replacing all the previous claim requests.
- VII. The board subsequently issued a further communication dealing with issues resulting from the filing of the new claim requests. In particular, the appellant was requested to inform the board about how the biological material referred to in the present claims met the requirements of Article 83 EPC 1973 in combination with Rule 28 EPC 1973 and Rule 13bis.3 PCT (in the version of 1 July 1998).
- VIII. Oral proceedings before the board were held on 30 October 2018. During these proceedings, the appellant withdrew all pending claim requests and replaced them with a claim sets of a new main request and an auxiliary request 1.

- IX. At the oral proceedings, the appellant also filed, *inter alia*, deposit receipts for *Bacillus coagulans* GBI-30 (ATCC designation number PTA-6086) and print-outs from the ATCC website concerning the availability of *Bacillus coagulans* Hammer strain accession No. ATCC 31284.
- X. At the end of the oral proceedings, the Chair stated that the board was of the opinion that the claims of the auxiliary request 1 and the invention claimed therein fulfilled the requirements of the EPC. The Chair also announced that the proceedings would be continued in writing. The appellant was given the opportunity to submit evidence concerning the strains GBI-20 and GBI-40 within two months of notification of the minutes of the oral proceedings and to indicate, within the same time limit, whether the appeal case could be decided in written proceedings.
- XI. With a letter dated 19 December 2018, the appellant responded to the minutes of the oral proceedings. In this letter it was requested that the appeal case be decided in writing. The previous main request was withdrawn and the previous auxiliary request 1 was designated as the main and sole claim request.
- XII. Claims 1 and 2 of the main request read:
- "1. Use of *Bacillus coagulans* Hammer spores in the manufacture of a medicament for reducing symptoms of irritable bowel syndrome (IBS) in a patient suffering from irritable bowel syndrome, wherein said *Bacillus coagulans* is selected from the group consisting of *Bacillus coagulans* Hammer strain accession No. ATCC 31284, and GBI-30 strain (ATCC designation number PTA-6086).

2. A composition comprising *Bacillus coagulans* Hammer spores for use in reducing symptoms of irritable bowel syndrome in a patient suffering from irritable bowel syndrome, wherein said *Bacillus coagulans* is selected from the group consisting of *Bacillus coagulans* Hammer strain accession No. ATCC 31284, and GBI-30 strain (ATCC designation number PTA-6086)".

The request also includes dependent claims 2 to 8.

XIII. The appellant's arguments relevant to the decision can be summarised as follows:

*Main request - all claims*

*Inventive step - Article 56 EPC 1973*

The skilled person, starting from the treatments for irritable bowel syndrome (IBS) discussed in document D12, would not have turned to document D5 because it related to the use of *Bacillus coagulans* for increasing the solubility of nutritional materials, preferably essential vitamins and minerals (see document D5, page 1, lines 5 to 8), but not to the treatment of IBS. Moreover, even if the skilled person had considered document D5, they would not have arrived at the claimed invention because document D5 disclosed several *Bacillus* species, but did not provide any incentive for the skilled person to select *Bacillus coagulans* Hammer strain for use in treating symptoms of IBS (see page 4, paragraphs 3 to 6).

The examining division had formulated the problem to be solved as the provision of an alternative composition for use in the reduction of a symptom of IBS in a patient suffering from IBS. However, there were further

advantageous technical effects associated with the use of *Bacillus coagulans* Hammer strain for reducing symptoms of IBS in a patient suffering from IBS, such as the ability to grow in the acidic pH conditions of the stomach environment and the basic environment of the intestines, as well as enhanced germination and survival in the presence of bile acids (see page 8, lines 4 to 8 of the application). *Bacillus coagulans* Hammer ameliorated the symptoms associated with IBS and also improved the conditions within the gut by removing an underlying cause of IBS (see document D14, page 655, right-hand column). Therefore, *Bacillus coagulans* Hammer not only relieved the symptoms of IBS but also treated the underlying condition.

*Disclosure of the invention - Article 83 EPC 1973*

Examples 3 to 5 of the application confirmed the beneficial effects of *Bacillus coagulans* Hammer strain deposited under ATCC accession no. 31284.

Post-published document D14 confirmed the beneficial effects of *Bacillus coagulans* Hammer strain GBI-30, deposited under ATCC designation number PTA-6086 (referred to as "GBI-30, 6086" in document D14), for the symptoms of diarrhea-predominant IBS (IBS-D). As set out in the "Results" section spanning pages 656 to 657, the analysis showed that the average number of bowel movements per day was significantly reduced in the IBS-D patient group taking "GBI-30, 6086" compared to the placebo group. The analysis also showed that "GBI-30, 6086" was well tolerated. Although the study of the patient self-assessment measures did not show significant differences between the placebo and active treatment groups, this was due to the large baseline variance which likely skewed the analysis.



In addition, the article referred to a randomised, double-blind, placebo controlled clinical trial which evaluated the effects of GBI-30, 6086 on abdominal pain and bloating in patients with IBS-D (see page 658, left-hand column, 4th paragraph). The results obtained from the trial displayed statistically significant changes in abdominal pain and bloating scores from baseline for patients treated with "GBI-30, 6086" when compared after 7 weeks ( $p < 0.01$ ). In patients receiving the placebo, changes in abdominal pain scores did achieve statistical significance on weeks 6 and 8 ( $p < 0.05$ ). However, this was likely due to the high placebo effect reported among IBS patient populations.

In summary, the article confirmed that treatment with *Bacillus coagulans* "GBI-30, 6086" had the ability to reduce the number of daily bowel movements in patients with IBS-D and alleviate abdominal pain and bloating. It was well tolerated and a safe and effective therapy for treating symptoms of IBS.

It was noted that *Bacillus coagulans* "GBI-30, 6086", referred to in document D14, was derived from *Bacillus coagulans* Hammer strain deposited under accession number ATCC 31284, see page 2, lines 11 to 15 of the application.

## Reasons for the Decision

1. The European patent application in suit was filed as an international application under the PCT in 2004 and pending at the time of the entry into force of the revised version of the EPC on 13 December 2007. Therefore, pursuant to Article 7(1) and (2) of the Revision Act, the applicability of the revised provisions of the EPC is governed by the transitional provisions as set out in the Decision of the Administrative Council of 28 June 2001 (Special edition No. 1, OJ EPO 2007, 197). It is indicated by using the established citation practice what version of a provision applies.
2. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.

### *Main request - Claims 1 and 2*

3. The claims are for the second medical use of the spores of two particular *Bacillus coagulans* Hammer strains for reducing symptoms of irritable bowel syndrome (IBS) in a patient suffering from IBS. Claim 1 is in the "Swiss-type" format which is still allowable in the circumstances of the present case (cf. decision of the Enlarged Board of Appeal, G 2/08, OJ EPO 2010, 456, point 7 of the reasons), while claim 2 is in the format of a purpose-limited product claim pursuant to Article 54(5) EPC.

*Inventive step - Article 56 EPC 1973*

*Closest prior art*

4. Inventive step was the only issue dealt with in the decision under appeal. The examining division considered that the disclosure in document D12 of the treatment (reduction) of (the symptoms) of IBS with, *inter alia*, antispasmodics, 5-HT antagonists and/or loperamide represented the closest prior art for the assessment of inventive step for the claimed invention.
5. Since both the claimed invention and document D12 aim at ameliorating the symptoms of IBS, the board accepts that this document can represent the closest prior art for the assessment of inventive step for the claimed invention.

*The objective technical problem*

6. The subject-matter of claims 1 and 2 differs from the disclosure in document D12 in that it employs a different agent (two particular *Bacillus coagulans* Hammer strain spores, the strains being deposited under ATCC No. 31284 and ATCC designation number PTA-6086) instead of antispasmodics, 5-HT antagonists and/or loperamide to achieve the aim of ameliorating the symptoms of IBS.
7. In view of the above difference and the technical effect thereof, the board considers that the technical problem to be solved by the subject-matter of claim 1 may be formulated as the provision of an alternative treatment for IBS.

*Obviousness*

8. The board can find no suggestion in any of the cited prior art documents that would have lead the skilled person to employ the two particular *Bacillus coagulans* Hammer strain spores as a solution to the above problem. In particular, the board considered whether document D4 contained such a suggestion, since it stems from a field related to that of the invention, i.e. *Bacillus coagulans* and its use in the intestinal environment (see abstract). However, document D4 is concerned with a different strain of *Bacillus coagulans* (SANK 70258) More importantly, document D4 contains no disclosure suggesting that the use of strains belonging to the *Bacillus coagulans* Hammer strain sub-species, and certainly no disclosure that the use of Hammer strains ATCC 31284 or PTA-6086, could be useful in treating symptoms (i.e. at least two symptoms) of IBS. Instead, document D4 relates to an investigation on the effect of the SANK 70258 strain on the intestinal flora and the decomposition products in the intestine, as well as on various dermal characteristics in healthy humans and rats (see abstract).
9. The examining division considered that the skilled person would have turned to the disclosure in document D5 and here would have found a disclosure of the use of *Bacillus coagulans* to "*control constipation and diarrhea in humans and animals*" (see decision under appeal, paragraph 40).
10. The board however is not persuaded that the skilled person, starting from the disclosure of the above mentioned closest prior art document D12, would have turned to document D5 at all because, as argued by the appellant, the document primarily concerns the use of

*Bacillus coagulans* for increasing the solubility of nutritional materials such as essential vitamins and minerals (see document D5, page 1, lines 5 to 8) but not to the treatment of IBS or its symptoms.

11. Although there is indeed a passage on page 12, lines 15 and 16 of document D5 that reads "*[i]n particular, Bacillus coagulans strains have been used as general nutritional materials and agents to control constipation and diarrhoea in humans and animals*" and which might be considered to represent other knowledge in the state of the art, this passage is not accompanied by any literature reference and is not confirmed in any of the other cited documents. Thus, at best, the skilled person would have seen the passage as referring to the knowledge disclosed in document D4, dealt with above, and would thus have not taken any conclusions from that passage going beyond those taken in the light of document D4.
12. The board therefore concludes that the skilled person, starting from the disclosure of the closest prior art document D12 and seeking a solution to the objective technical problem formulated above in point 7., would not have found any disclosure in the cited state of the art that would have suggested the claimed invention. The subject-matter of claims 1 and 2 therefore meets the requirements of Article 56 EPC 1973. This reasoning applies equally to the subject-matter of dependent claims 3 to 8.
13. The appellant's appeal is therefore allowable.
14. In line with the appellant's requests, the board decided, pursuant to Article 111(1) EPC 1973, to

examine the remaining criteria for patentability, thereby exercising the power of the examining division.

*Novelty - Article 54(1), (2) EPC 1973*

15. There is nothing in the proceedings before the examining division to suggest that there were any reservations about the novelty of the claimed subject-matter. The board has no objections of its own. The claimed subject-matter is novel and thus fulfils the requirements of Article 54(1) and (2) EPC 1973.

*Disclosure of the invention - Article 83 EPC 1973*

16. Pursuant to Article 83 EPC 1973 the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
17. In the case of present claims 1 and 2, the *Bacillus coagulans* Hammer spores referred to in the claims have been deposited with the American Type Culture Collection (ATCC, Manassas, VA) under accession no. 31284 and ATCC designation number PTA-6086. Since the invention relies on the properties of these particular strains, the requirements of Article 83 EPC 1973 are met if the biological material is available to the public, or if Rule 28(1) EPC 1973 on the deposit of biological material is complied with.
18. In relation to *Bacillus coagulans* Hammer spores deposited with the ATCC under accession no. 31284, evidence provided by the appellant demonstrates the commercial availability of this strain from the ATCC (see annex 2 to minutes of oral proceedings before the board). The board is therefore satisfied that it is

available to the public. In the case of *Bacillus coagulans* Hammer spores deposited with the ATCC under accession no. PTA-6086, the requirements of Rule 28(1) EPC 1973 are fulfilled. The relevant deposit receipt (see annexe 1 to minutes of oral proceedings before the board) establishes that the deposit of *Bacillus coagulans* GBI-30 (ATCC designation number PTA-6086) with the ATCC took place before the filing date of the application in suit and indicates the appellant as the depositor.

19. A second aspect of assessing the compliance of the claimed subject-matter with Article 83 EPC 1973 relates to the therapeutic use. It is established case law that where a therapeutic application is claimed, either in the Swiss-type form or in the form of a purpose-limited product claim pursuant to Article 54(4) and (5) EPC, attaining the claimed therapeutic effect is a functional technical feature of the claim. As a consequence, the application has to disclose the suitability of the product to be manufactured for the claimed therapeutic application unless this was already known to the skilled person at the priority date (see also Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, II.C.6.2).
  
20. Since the appellant's submissions on inventive step rely on the above mentioned suitability not being known in the art, the board must be satisfied that this is disclosed in the application. Example 3 of the application provides evidence of the suitability of a composition comprising *Bacillus coagulans* Hammer strain having the ATCC deposit number 31284 for the alleviation of the symptoms of diarrhoea, constipation and bloating (see page 25, lines 32 and 33).

21. Furthermore, Example 4 provides evidence of the effects of a composition comprising the same strain of bacteria in alleviating various symptoms of IBS.
22. In the board's view, the evidence disclosed in the application for *Bacillus coagulans* Hammer strain having the ATCC deposit number 31284 supports the suitability for the claimed use of the *Bacillus coagulans* Hammer strain having the ATCC designation number PTA-6086 (GBI-30; see application, page 2, lines 14 and 15) because the latter strain is, as disclosed in the application on page 2, lines 11 to 15, derived from the former.
23. Thus, the board concludes that claims 1 and 2 meet the requirements of Article 83 EPC 1973. This reasoning extends to the subject-matter of the dependent claims 3 to 8.

*Amendments - Article 123(2) EPC*

24. Pursuant to Article 123(2) EPC the European patent application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.
25. As far as strain ATCC 31284 is concerned, the basis for the subject-matter of claims 1 and 3 can be found in claims 1 to 3 of the application as filed. The basis for the subject-matter of claims 3 to 7 is to be found in claims 17, 4, 5 to 7, 6 and 24 to 29 as filed, respectively. As far as strain GBI-30 with the ATCC designation number PTA-6086 is concerned (claims 1 to 8), a basis can be found on page 12, line 14 and page 12, paragraph 1 of the description as filed in



combination with the aforementioned claims as filed and pages 2 to 8 of the description as filed.

26. Thus, the claims of the main request and their subject-matter meet the requirements of the EPC.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division with the order to grant a patent with claims 1 to 8 of the main request filed with the letter dated 19 December 2018, and a description to be adapted thereto.

The Registrar:

The Chair:



S. Lichtenvort

G. Alt

Decision electronically authenticated