BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 9 May 2007

Case Number: T 1084/03 - 3.3.02

Application Number: 97402327.7

Publication Number: 0835658

IPC: A61K 31/375

Language of the proceedings: EN

Title of invention:
Enhancing and stabilizing agent of the activity of bifidus factor

Applicant:
Meiji Dairies Corporation

Opponent:
-

Headword:
Bifidus factor/MEIJI DAIRIES CORPORATION

Relevant legal provisions:
EPC Art. 111

Keyword:
"Main request - remittal - yes: unexamined subject-matter"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1084/03 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 9 May 2007

Appellant: Meiji Dairies Corporation
2-10, Shin-suna 1-chome
Koto-ku
Tokyo (JP)

Representative: Uchida, Kenji
S.A. Fedit-Loriot et Autres
Conseils en Propriété Industrielle
38, avenue Hoche
FR-75008 Paris (FR)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 14 May 2003 refusing European application No. 97402327.7 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Willems

Summary of Facts and Submissions

I. European patent application No. 97 402 327.7 was refused by a decision of the Examining Division dated 14 May 2003 on the ground that the claimed subject-matter did not fulfil the requirements of Article 84 EPC and of Article 56 EPC.

II. The decision was based on independent claims 1, 8 and 15, which read:

"1. A use of a compound selected from salts of ascorbic acid, esters of ascorbic acid, hyposulfurous acid, salts of hyposulfurous acid, esters of hyposulfurous acid, and acetic anhydride in manufacturing an agent containing Bifidus factor to enhance and stabilize the bifidobacterial growth promoting activity of said Bifidus factor, wherein said Bifidus factor is produced by culturing at least one bacterial species selected from the group consisting of Propionibacteria, Enterococcus, Bacteroidaceae, Enterobacteriaceae, Lactococcus, Pediococcus and Bacilliaceae, and is selected from the group consisting of compounds, crude products comprising compounds, cells, cultures, culture filtrates, culture supernatants, and processed products thereof.

8. A method for enhancing and stabilizing in vitro the bifidobacterial growth promoting activity of Bifidus factor in manufacturing an agent containing said Bifidus factor, which comprises adding to Bifidus factor at least one compound selected from the group consisting of salts of ascorbic acid, esters of ascorbic acid, hyposulfurous acid, salts of

hyposulfurous acid, esters of hyposulfurous acid, and acetic anhydride, wherein said Bifidus factor is produced by culturing at least one bacterial species selected from the group consisting of Propionibacteria, Enterococcus, Bacteroidaceae, Enterobacteriaceae, Lactococcus, Pediococcus and Bacilliaceae, and is selected from the group consisting of compounds, crude products comprising compounds, cells, cultures, culture filtrates, culture supernatants, and processed products thereof."

15. A composition for enhancing and stabilizing the bifidobacterial growth promoting activity of Bifidus factor, which comprises (1) Bifidus factor and (2) at least one compound selected from the group consisting of salts of ascorbic acid, esters of ascorbic acid, hyposulfurous acid, salts of hyposulfurous acid, esters of hyposulfurous acid, and acetic anhydride, wherein said Bifidus factor is produced by culturing at least one bacterial species selected from the group consisting of Propionibacteria, Enterococcus, Bacteroidaceae, Enterobacteriaceae, Lactococcus, Pediococcus and Bacilliaceae, and is selected from the group consisting of compounds, crude products comprising compounds, cells, cultures, culture filtrates, culture supernatants, and processed products thereof.

III. The following documents, cited during the proceedings before the Examining Division and the Board of Appeal, are relevant for the present decision:

(1) DATABASE WPI Section Ch, Week 9644 Derwent Publications Ltd., London, GB; Class B04, AN

96-441521 XP002098263 & RU 2 053 294 C (APPL MICROBIOLOGY RES INST), 27 January 1996

(3) DATABASE WPI Section Ch, Week 9313 Derwent Publications Ltd., London, GB; Class D16, AN 93-103614 XP002098264 & JP 05 041995 A (MEIJI MILK PROD CO LTD), 23 February 1993

IV. The arguments in the decision may be summarised as follows:

The Examining Division considered that claim 1 did not meet the requirements of Article 84 EPC because no therapeutic indication was defined in the claim and because it was not drafted according to the wording suggested in the Guidelines (C IV, 4.2).

It further held that the problem to be solved by the present application was the provision of a composition for promoting the selective growth of bifidobacteria.

In its view, the solution provided by the applicant was to combine: i) Bifidus factor produced by culturing at least one bacterial species selected from the group consisting of Propionibacteria, Enterococcus, Bacteroidaceae, Enterobacteriaceae, Lactococcus, Pediococcus and Bacilliaceae, and selected from the group consisting of compounds, crude products comprising compounds, cells, cultures, culture filtrates, culture supernatants, and processed products thereof; and ii) salts of ascorbic acid, esters of ascorbic acid, hyposulfurous acid, salts of hyposulfurous acid, esters of hyposulfurous acid, and acetic anhydride.

It submitted that document (1) or (3) could be regarded as the closest prior art.

Document (1) disclosed that the use of ascorbic acid when culturing bifidobacteria shortens the growth process 2 to 3- fold, increases the biomass yield, increases the resistance of the cells to drying out and increases the cell viability 3 to 5-fold. The addition of ascorbic acid was thus said to be useful in the preparation of therapeutic bacterial compositions and in veterinary testing.

Document (3) described the use of a culture of a propionic acid or a lactic acid bacterium to promote the growth of Bifidobacteria. Propionibacterium freudenreichii was cultured in TPYG medium; the culture was then filtered and the filtrate added to cultures of different Bifidobacteria in TPYG medium. It was stated that the material used (Propionibacterium freudenreichii culture filtrate) has a very high selectivity and a very high growth promoting activity for Bifidobacteria.

In view of the above, the Examining Division was of the opinion that the man skilled in the art, when faced with the problem of providing compositions according to claim 15, would know from Document (3) that Bifidus factor (F. freudenreichii culture filtrate) was highly selective for Bifidobacteria and had a very high growth-promoting activity. When looking for an agent to enhance or stabilize the growth promoting activity of this Bifidus factor, the man skilled in the art would then turn to document (l), which disclosed that

ascorbic acid promotes the growth of Bifidobacteria, and it would thus conclude that the addition of ascorbic acid would be a suitable solution.

Therefore, the Examining Division concluded that the subject-matter of the request under consideration did not involve an inventive step.

V. The appellant (applicant) lodged an appeal against the said decision.

VI. Oral proceedings before the Board of appeal were held on 9 May 2007.

VII. During the oral proceedings, the Board indicated that the claims submitted by the appellant contained new subject-matter, which was not examined by the Examining Division.

In that respect, the appellant stated that it would be in favour of a remittal of the case to the first instance for a decision on this subject-matter.

VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request, or of auxiliary requests 1 or 6 filed with its letter dated 27 April 2007, or auxiliary requests 2 to 5 corresponding respectively to the main request and auxiliary requests 1 to 3 filed with the grounds of appeal.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

Independent claim 1 of this request reads:

1. A composition comprising:
- a Bifidus factor having a bifidobacterial growth promoting activity, **said Bifidus factor being an a-naphthoquinone-related substance** or a bacterial product obtained by culturing a bacterial species selected from the group consisting of Propionibactenum, Bacteroidaceae, Enterobacteriaceae, Enterococcus, Lactococcus, Pediococcus, and Bacilliaceae; and
- an agent for enhancing and stabilizing the bifidobacterial growth promoting activity of Bifidus factor, which is at least one member selected from the group consisting of ascorbic acid or an ester or salt thereof, hyposulphurous acid or an ester or salt thereof, and acetic anhydride. (Emphasis added).

The Board observes that the claimed subject-matter contains the following two alternatives:

a) A composition comprising an a-naphthoquinone-related substance and ascorbic acid or an ester or salt thereof, hyposulphurous acid or an ester or salt thereof, and acetic anhydride.

b) A composition comprising a bacterial product obtained by culturing a particular bacterial species and ascorbic acid or an ester or salt thereof,

hyposulphurous acid or an ester or salt thereof, and acetic anhydride.

As it is clear from points II and IV above, the subject-matter of alternative a) was not submitted to the Examining Division and no decision was therefore taken concerning this alternative.

3. *Remittal to the first instance*

3.1 Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances, it is well-recognised that any party should, where possible, be given the opportunity to have two readings of the important elements of a case. The essential function of an appeal is to consider whether the decision which has been issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

3.2 The observations and comments made above apply in full to the present case. The Examining Division decided on the subject-matter of alternative b) but could not decide on alternative a) as it was not submitted in the request before it. This issue, however, now forms the basis for the examination of the application and must therefore be considered an essential substantive issue in the present case.

3.3 Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances

of the present case, it is necessary to remit the case to the Examining Division for further prosecution.

4. *Other matters*

As to the decision of the Examining Division the Board is of the opinion that, having regard to the experimental data filed by the appellant with its letter dated 27 April 2007, the combination of documents (1) and (3) does not appear to be relevant for the assessment of the inventive step of alternative b).

In fact, the report shows that the Bifidus factor is rendered thermally more stable by addition of sodium ascorbate independently of the redox potential of the medium.

Since document (1) is totally silent about this, the skilled person would have had no incentive to combine it with document (3), contrary to the conclusions of the Examining Division's decision.

The Board is however of the opinion that the clarity and scope of the term "a bacterial product" used in alternative b) should be considered.

In particular, in the absence of a definition of the product "*per se*" in the claim, the question whether its functional definition provided in the claim, namely a product "having a bifidobacterial growth promoting activity" fulfils all the requirements to satisfy Article 84 EPC should also be considered.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution.

The Registrar The Chairman

A. Townend U. Oswald