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**Datasheet for the decision
of 18 January 2007**

Case Number: T 0515/06 - 3.3.04

Application Number: 03765107.2

Publication Number: 1531841

IPC: A61K 35/74

Language of the proceedings: EN

Title of invention:

Probiotics for gut neuromuscular functions

Applicant:

NESTEC S.A.

Headword:

Probiotics/NESTEC

Relevant legal provisions:

EPC Art. 54, 123(2), 111(1)

Keyword:

"Added subject-matter - (no)"
"Novelty over document (1) - (yes)"
"Remittal - (yes)"

Decisions cited:

G 0005/83, T 1020/03

Catchword:

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Case Number: T 0515/06 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 18 January 2007

Appellant: NESTEC S.A.
(Applicant) Avenue Nestlé 55
CH-1800 Vevey (CH)

Representative: Dixon, Sarah
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 17 November 2005
refusing European application No. 03765107.2
pursuant to Article 97(1) EPC.

Composition of the Board:

Chair: U. Kinkeldey
Members: M. Wieser
G. Weiss

Summary of Facts and Submissions

I. The appeal was lodged by the Applicant (Appellant) against the decision of the Examining Division to refuse under Article 97(1) EPC the patent application EP 03 765 107.2 (published as WO 2004/009103), having the title: "Probiotics for gut neuromuscular functions".

II. The Examining Division decided that claims 1 to 4 of the sole request before them did not meet the requirements of the EPC as the subject-matter of the claims was not novel (Article 54 EPC) in the light of the disclosure in the following document:

(1) WO-01/52 667

III. Claim 1 before the Examining Division read:

"The use of a probiotic *Lactobacillus paracasei* in the manufacture of a nutritional composition or a medicament to prevent or treat gut neuromuscular abnormalities."

Claims 2 to 4 referred to preferred embodiments of the use according to claim 1.

IV. The Board expressed its preliminary opinion in a communication dated 9 June 2006.

Oral proceedings were held on 18 January 2007.

V. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 6 filed at the oral proceedings (main

request), or on the basis of one of the auxiliary requests filed with letter received on 24 July 2006.

VI. Claims 1 to 4 of the main request read as follows:

"1. The use of a probiotic *Lactobacillus paracasei* in the manufacture of a therapeutic nutritional composition or a medicament to prevent or reduce abnormal or disturbed gut muscle contractions, contractility or motility after infection and the pain or discomfort related symptoms linked to such abnormalities.

2. The use of a probiotic *Lactobacillus paracasei* in the manufacture of a therapeutic nutritional composition or a medicament to treat irritable bowel syndrome.

3. The use of a probiotic *Lactobacillus paracasei* in the manufacture of a therapeutic nutritional composition or a medicament to prevent or treat abnormal or disturbed gut muscle contractions, contractility or motility associated with extensive exercise and athletics.

4. The use of a probiotic *Lactobacillus paracasei* in the manufacture of a therapeutic nutritional composition or a medicament to prevent or treat infant colic."

Dependent claims 5 and 6 referred to preferred embodiments of the use according to claims 1 to 4.

VII. The submissions made by the Appellant as far as relevant for the present decision may be summarised as follows:

Claims 1 to 6 of the main request were based on the application as originally filed. Although the term "therapeutic nutritional composition" was not explicitly disclosed, it was inherent in the disclosure of the application as filed that any nutritional composition which fell within the scope of the claims was therapeutic in nature.

Document (1) was solely concerned with prevention and treatment of a bacterial infection per se. The effect of the treatment was the prophylaxis or reduction of the infection by the bactericidal activity of certain probiotics. This is different from the prevention or treatment of post infective abnormalities, which appeared after the cause of infection (in document (1) gastric Helicobacter like organisms) was removed. As the therapeutic applications referred to in claims 1 to 4 were such post infective abnormalities the subject-matter of the claims was novel over document (1).

Reasons for the decision

Amendments - Article 123(2) EPC

1. Claim 1 is based on page 3, lines 6 to 13, page 5, lines 32 to 34 and page 12, lines 27 to 28 of the application as originally filed, published as WO 2004/009103.

The application as filed refers to the manufacture of a "nutritional composition" and does not explicitly mention the term "therapeutic nutritional composition" as used in the claims. However, as it is evident from the description as a whole that *Lactobacillus paracasei*, which is the active ingredient of the manufactured composition, has a therapeutic effect (see for instance page 2, line 34 to page 3, line 22), this therapeutic activity is an inherent feature of a nutritional composition containing it.

2. In addition to the passages indicated for claim 1 above, claim 2 is based on page 20, lines 18 to 27, and claims 3 and 4 on page 6, lines 4 to 7 of the published WO-document.

Claims 5 and 6 are based on original claims 10 and 11.

3. Accordingly, the Board decides that claims 1 to 6 of Appellant's main request meet the requirements of Article 123(2) EPC.

Novelty - Article 54 EPC

4. Claims 1 to 4 refer to the use of a probiotic *Lactobacillus paracasei* in the manufacture of a therapeutic nutritional composition or a medicament, for specific therapeutic applications.

The Enlarged Board of Appeal in decision G 5/83 (OJ EPO 1985, 64) decided that the novelty of such claims derived from their sole new feature, that is the new pharmaceutical use of a known substance and considered that it was legitimate to allow claims of this kind

directed to a specified new and inventive therapeutic application, even where the process of manufacture as such did not differ from known processes using the same active ingredients (points (11) to (19) of the reasons).

Thus, the Enlarged Board considered for the special case where the intended purpose of the preparation of the composition was for this composition then to be used for the treatment of the human or animal body by surgery or therapy or in diagnostic methods, that then Article 54(5) EPC allowed the preparation of the composition to be treated as notionally novel, even if the medicament resulting from the preparation was not in any way different from a known medicament (cf decision G 5/83, supra, point (20) and decision T 1020/03 of 29 October 2004, to be published in the OJ EPO).

The therapeutic application according to claim 1 is the prevention and reduction of abnormal or disturbed gut muscle contractions, contractility or motility after infection and the pain or discomfort related symptoms linked to such abnormalities.

5. Document (1) discloses the use of lactic bacteria, for instance *Lactobacillus paracasei*, in the manufacture of a composition for the treatment of disorders related to GHLOs (gastric *Helicobacter* like organisms) infection in pets (see claims 1,3,4).

The therapeutic effect results from a strong anti-*Helicobacter* bactericidal activity of the used lactic bacteria. Example 2 of document (1) shows that dogs

having a gastric GHLOs infection when fed with a composition containing a selected strain of lactic bacteria showed a significant decrease of GHLO's load and activity, identified as decrease in the urease activity of GHLOs (see page 19). The fermented supernatants of specific lactic bacteria totally inhibited the urease activity of various Helicobacter strains (example 3, page 21). Example 5 describes that dogs having had a gastric infection with GHLO's which were treated with different antibiotics stayed GHLO negative when fed with a composition comprising strains of lactic bacteria as claimed, while others fed with dog food available on the market became GHLO positive again (pages 22 to 23).

Thus, document (1) describes the use of *Lactobacillus paracasei* to prevent or treat an infection, namely the colonization and propagation of pathologic bacteria (GHLO's) in a host.

6. Contrary to this, the therapeutic application of *Lactobacillus paracasei* according to claim 1 lies in the prevention or reduction of phenomena taking place after the infection. It is not based on the bactericidal effect of the probiotic disclosed in document (1) but on a prophylactic and therapeutic effect directed towards symptoms which are results of an infection and which can appear when the actual cause of the infection, here pathologic bacteria, is no longer present in the host organism.

Therefore, the therapeutic application of compositions comprising *Lactobacillus paracasei* according to claim 1 is not disclosed in document (1).

7. Treatment of IBS (irritable bowel syndrome; claim 2), prevention or treatment of abnormal or disturbed gut muscle contractions, contractility or motility associated with extensive exercise and athletics (claim 3) and prevention or treatment of infant colic (claim 4) are therapeutic applications not mentioned in document (1).

The subject-matter of claims 1 to 4, and of claims 5 and 6 dependent thereon is novel over the disclosure in document (1) (Article 54 EPC).

Remittal - Article 111(1) EPC

8. In the appealed decision the Examining Division has given reasons only with regard to the issue of novelty of the claimed subject-matter in the light of the disclosure in document (1).

Neither the requirements of Article 54 EPC in the light of all other prior art documents on file, nor the other substantive requirements for granting of a European patent, like inventive step (Article 56 EPC) or sufficiency of disclosure (Article 83 EPC) have been dealt with in said decision.

The Board considers it justified and appropriate to have these issues examined by two instances and, at its discretion under Article 111(1) EPC, remits the case to the Examining Division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of claims 1 to 6 of the main request filed at the oral proceedings.

Registrar:

Chair:

P. Cremona

U. Kinkeldey