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**Datasheet for the decision
of 30 April 2010**

Case Number: T 1002/09 - 3.3.09

Application Number: 04740928.9

Publication Number: 1643861

IPC: A23L 1/29

Language of the proceedings: EN

Title of invention:

High fibre high calorie liquid or powdered nutritional composition

Applicant:

Nestec S.A.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 53(c), 54(1), 54(4), 56

Relevant legal provisions (EPC 1973):

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Keyword:

"Novelty, Inventive step (yes)"

"First medical use of a new compound in analogy to Art. 54(4)
EPC (yes)"

Decisions cited:

T 0144/83

Catchword:

-



Case Number: T 1002/09 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 30 April 2010

Appellant: Nestec S.A.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office orally announced
30 October 2008 and posted 26 November 2008
refusing European application No. 04740928.9
pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: W. Sieber
Members: W. Ehrenreich
M-B. Tardo-Dino

Summary of Facts and Submissions

- I. European patent application No. 04 740 928.9 entitled "*High fibre high calorie liquid or powdered nutritional composition*" and filed on 12 July 2004 as International application PCT/EP2004/007674 in the name of *Nestec S.A.* was refused by the decision of the examining division announced orally on 30 October 2008 and issued in writing on 26 November 2008.
- II. Basis for the decision were sets of claims according to a main request filed with the letter dated 13 July 2007 and an auxiliary request filed with the letter dated 27 October 2008. Claim 1 of each of the requests read as follows:

Main Request

"1. A liquid nutritional composition comprising a protein source, a source of digestible carbohydrates and a source of dietary fibre, characterised in that it has an energy density of 5.4-7.5 kJ/ml (1.3-1.8 kcal/ml) and dietary fibre in an amount of more than 2.5 g/100ml."

Auxiliary Request

"1. A liquid nutritional composition comprising a protein source, a source of digestible carbohydrates and a source of dietary fibre, characterised in that it has an energy density of 5.4-7.5 kJ/ml (1.3-1.8 kcal/ml) and dietary fibre in an amount of more than 2.5 g/100ml in which the source of fibre comprises 25-35% by weight of soluble non-starch polysaccharides, 37-47% by weight

of insoluble polysaccharides, and 25-35% by weight of oligosaccharides."

Both sets of claims contained inter alia a claim which was directed to the use of a protein source, a source of digestible carbohydrates and a source of dietary fibre in the manufacture of a liquid composition for promoting gut health or comfort in an elderly patient (main request: Claim 12; auxiliary request: Claim 10).

III. The examining division acknowledged novelty of the subject-matter of the claims of both requests. However, in its view, the subject-matter according to both requests did not involve an inventive step over the disclosure in the documents

D4 US-B 6 200 950 and

D5 EP-A 0 756 828

taken either alone or in combination. The examining division essentially argued that no prejudice had to be overcome by providing a nutritional composition with a high dietary fibre content, especially for elderly people, because the provision of such fibres were already part of the teaching in D5 and the benefits of such compositions were not limited to a specific subgroup of individuals.

IV. On 23 January 2009 the applicant (hereinafter: the appellant) lodged an appeal against the decision of the examining division. The Statement of the Grounds of Appeal was submitted on 9 March 2009. Enclosed with the letter setting out the grounds of appeal were a new main request and auxiliary requests 1 and 2, evidence

in support of inventive step (Annex 4, which corresponded to Exhibit A submitted in the examining procedure with the letter dated 29 August 2008) and data sheets inter alia concerning the nutritional compositions "Clinutren 1.5" and "Clinutren 1.5 Fibre" (Annex 5).

With its letter dated 12 April 2010 the appellant filed three further sets of claims as bases for auxiliary requests 3 to 5.

Furthermore, with respect to the issue of inventive step, the appellant inter alia referred to the document

D3 EP-A 0 721 742

which was already cited in the examining procedure.

- V. Oral proceedings before the board were held on 30 April 2010. During the hearing, in which inventive step of the subject-matter of the application was discussed, the appellant withdrew all requests filed in the written procedure and submitted a new set of claims 1 to 9 with amendments in Claims 1, 4 and 6 as basis for a new single (main) request.

Claim 1 of this request read as follows:

"1. A liquid nutritional composition for use in promoting gut health in an elderly patient comprising a protein source, a source of digestible carbohydrates and a source of dietary fibre, characterised in that it has an energy density of 5.4-7.5 KJ/ml (1.3-1.8 kcal/ml) and dietary fibre in an amount of more than 2.5g/100ml."

Claims 4 and 6 were amended in order to bring the claims in conformity with the description.

The appellant argued that the use of the composition "*in promoting gut health in an elderly patient*" related to a medical indication including a therapeutic use which was neither disclosed in either D4 or D5 nor was rendered obvious when considering the disclosure in D3. In particular D3 taught away from using fibre-rich compositions for elderly people. Therefore, the subject-matter of this purpose-limited product claim and the dependent Claims 2 to 9 was inventive over the prior art.

- VI. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request filed during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. Amendments

Claim 1 is based on Claim 1 as filed including amendments derivable from Claim 13 as filed ("*liquid*") and from the passage on page 10, lines 31-32 of the application as filed ("*for use in promoting gut health in an elderly patient*").

Dependent Claims 2-9 are based on Claims 2-9 as filed whereby Claims 4 and 6 have been further amended to

bring them into conformity with the corresponding passages in the description.

Since, furthermore, the claims are clear, the board has no objections under Articles 84 and 123(2) EPC against the amended claims.

3. Novelty

3.1 As in Claim 1 of the main request before the examining division (point II above) the liquid nutritional composition according to Claim 1 is characterised in that it has an energy density of 5.4-7.5 kJ/ml (1.3-1.8 kcal/ml) and dietary fibre in an amount of more than 2.5 g/100ml. The board shares the view of the examining division that such a composition is novel over the prior art cited in the examining procedure in particular with respect to D3 and D5.

3.1.1 D3 discloses a nutritional composition for elderly patients. In one embodiment, the composition comprises a protein source, a carbohydrate and a lipid source wherein the carbohydrate source includes a source of dietary fibre having a soluble fibre to insoluble fibre ratio of about 1:4 to 4:1 (Claim 2). D3 recommends that the level of fibre should be low with levels of between 0.8 and 1.5 g/100 ml (page 3, line 44). A higher fibre content, let alone in combination with the energy density required in Claim 1, is not disclosed in D3.

3.1.2 D5 relates to a nutritional composition, suitable for enteral administration, comprising dietary fibre, characterised in that it contains 5-120 g of fibre per daily dosage of the composition, and the fibre consists

of 15-50 wt.% of soluble non-starch polysaccharides, 15-45 wt.% of insoluble non-starch polysaccharides, and 8-70 wt.% of oligosaccharides and/or resistant starch (Claim 1). D5 discloses that fibre plays an important role not only in the nutrition of healthy people but also of hospital patients or persons with constipation or with diarrhoea (column 1, lines 3 to 21). However, very little guidance is given as to the actual composition of such a nutritional composition. As far as fibre content is concerned, this may vary between 0.5 and 12 g/100 ml with 1 to 2 g/ 100 ml being disclosed in Example 2. The only guidance on energy content suggests a fibre content of 0.5-12 g/100 ml at an energy content of 2 kcal/ml (derived from Claims 7 and 9). The combination of an energy density of 1.3-1.8 kcal/ml with an amount of dietary fibre of more than 2.5 g/100ml is not clearly and unambiguously derivable from this document.

3.1.3 The board therefore notes that novelty of the claimed composition is given irrespective of the technical meaning of the wording "*for use in promoting gut health in an elderly patient*".

3.2 The feature "*for use in promoting gut health in an elderly patient*"

In order to assess whether the feature in Claim 1 "*... for use in promoting gut health in an elderly patient*" has merely a descriptive character or represents a further technical feature with the result that Claim 1 has to be considered as a claim in accordance with a first medical indication in analogy to Article 54(4) EPC, the relevant question to be

answered is whether the intended use represents a treatment by therapy in the sense of Article 53(c) EPC.

Considering that malnutrition is a cause of digestive and gastro-intestinal disorders, associated with gut discomfort and pain (page 1, lines 20-22 of the application as filed), the invention aims at providing a nutritional composition to regulate gut motility and improve digestive tract health. In the board's judgment, alleviation of pain and suffering by promoting gut health in applying measures which regulate gut flora and improve intestinal transit are therefore therapeutic measures (at least in the sense of prophylaxis) for preventing malfunctions or illness of the human body. This view is in line with the definition given for therapy in the case law of the boards of appeal where it is stated that therapy "clearly relates to the treatment of a disease in general or to a curative treatment in the narrow sense as well as the alleviation of the symptoms of pain and suffering" (eg T 144/83, OJ EPO 1986, 301, point 3). As regards the reference "in an elderly patient" this implies a clear limitation of the therapy to this demographic group. It is only plausible that different age groups have different needs concerning the nutrition (eg due to a change in the metabolism with age).

Thus, in analogy to Article 54(4) EPC ("first medical use of a known compound") Claim 1 is directed to a purpose-related product.

4. Inventive Step

In the light of the above, the claimed invention is concerned with a liquid nutritional composition having a specific energy density and dietary fibre concentration for use in promoting gut health in an elderly patient.

4.1 The closest prior art

D5 is representative of the closest prior art, since it is the aim of the teaching of this document to provide a dietary fibre composition which is suitable for maintaining gut function and keeping the gut wall in good condition (column 1, lines 3 to 21). The composition can be provided with a high or low energy density and a high or low fibre content (column 4, lines 8 to 41 and examples 1 and 2). However, the application of the composition of D5 is not limited to a certain age group of individuals.

4.2 The problem to be solved

The objective technical problem can be seen in the provision of a dietary fibre composition which meets the demands of an elderly patient with respect to energy content and digestive tract health.

With the statement of grounds of appeal the appellant has submitted Annex 4 which represents a study investigating the tolerance of high-fibre nutritional supplements for elderly people that are often at risk of malnutrition. In particular the digestibility of the liquid nutritional composition "Clinutren 1.5"

containing no dietary fibers was compared with that of the liquid nutritional composition "Clinutren 1.5 Fibre" which is a composition with a high fibre content in the sense of the invention and contains 2.6 g fibre/100 ml. The study encompassed investigations in stool quality, faecal microbiological analysis, gut comfort and well being (GCWB) (page 2, the paragraph "Subjects and study design"; page 3 paragraphs 1 and 2 and page 4, paragraph 2). It was concluded that "Clinutren 1.5 Fibre" is tolerated as well as the composition "Clinutren 1.5" without dietary fibers.

Therefore the board is satisfied that the above defined objective technical problem is indeed solved.

4.3 Obviousness

The beneficial effect of dietary fibre compositions on gut health was known from D5. However, there is nothing in D5 that would suggest a nutritional composition for an elderly patient having high fibre content in combination with the high energy level required in Claim 1. In fact, the disclosure of D5 relates to "clinical patients or infants" (abstract).

In addition to the lack of relevant disclosure in D5, a person skilled in the art would have been actively taught against the claimed subject-matter.

In this respect, reference is made to D3. This document, which pertains to compositions as nutritional support for elderly people, states at page 3, line 44 that the total fiber contained in such a composition is approximately 8 to 15 g/l, i.e. 0.8 to 1.5 g/100 ml,

which is well below the lower limit of 2.5 g/100 ml for the claimed composition.

Furthermore, the immediately following sentences at page 3, lines 44-50 refer to the risks of a higher fibre content:

"While fiber is necessary for the elderly population since constipation is a chronic problem, the composition contains less total fiber than other products to alleviate problems associated with impaction and the increased water requirements associated with high amounts of fiber. Some older adults may not easily tolerate large amounts of fiber without adaptation. Moreover, high fiber intake may bind calcium, reducing absorption; particularly given the high incidence of atrophic gastritis in the elderly. In a preferred embodiment, the composition includes approximately 10 g/L of total fiber."

Therefore, the skilled person starting from D5 and considering the information given in D3 would expect that fibre-rich dietary compositions encompassed by the teaching of D5 with a fibre content above a limit of 1.5 g/100 ml cannot be applied to elderly people.

Accordingly, the subject-matter of Claim 1, and by the same token, the subject-matter of dependent Claims 2-9, is not obvious from the prior art.

5. In summary, the appellant's main (sole) request is allowable.

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 in order to grant a patent on the basis of Claims 1 to 9 according to the main request filed during the oral proceedings after any consequential amendment of the description.

The Registrar

The Chairman

G. Röhn

W. Sieber