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D E C I S I O N
of 1 March 2001

Case Number: T 0845/97 - 3.3.2

Application Number: 91810813.5

Publication Number: 0483070

IPC: A23L 1/308

Language of the proceedings: EN

Title of invention:
Nutritionally complete feeding composition containing hydrolysed soluble fiber

Patentee:
Novartis Nutrition AG

Opponent:
Fresenius AG

Headword:
Feeding composition/NOVARTIS

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty - yes - generic term does not destroy novelty of a specific type of food"
"Inventive step: no - obvious combination"

Decisions cited:
-

Catchword:
-

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Case Number: T 0845/97 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 1 March 2001

Appellant: (Opponent)
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Representative:
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 6 June 1997 concerning maintenance of European patent No. 0 483 070 in amended form.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: J. Riolo
S. U. Hoffmann

Summary of Facts and Submissions

I. European Patent No. 0 483 070 based on application No. 91 810 813.5 was granted on the basis of 11 claims.

Independent claims 1 and 11 as granted read as follows:

"1. A feeding composition which is nutritionally complete comprising hydrolysed soluble fiber which are able to undergo fermentation in the colon to produce short fatty acids in an amount such that the daily dosage of the feeding composition provides from 10 to 60 grams of hydrolysed soluble fiber per day.

11. The use of a hydrolysed soluble fiber which is able to undergo fermentation in the colon to produce short fatty acids for the manufacture of a nutritionally complete feeding composition for preventing bacterial sepsis or gut atrophy or for treating or preventing diarrhea in the human body."

II. Notice of opposition was filed against the granted patent by the appellant (opponent).

The patent was opposed under Article 100(b) EPC for insufficiency of disclosure and under Article 100(a) EPC for lack of novelty and lack of inventive step and because the patent claimed a method of treatment.

The following documents were inter alia cited during the proceedings:

(3) Partial English translation of JP-A-63/269993

(4) Partial English translation of JP-A-64/20063

(5) Journal of parenteral and enteral nutrition, **14**, March/April 1990, pages 204 to 209

(7) Journal of parenteral and enteral nutrition, 1988, pages 104S to 106S

(11) Scand. J. Plast. Reconstr. Surg. **13**, 1979, pages 193 and 194

(20) British medical journal, 1978, pages 1392 to 1394

III. The interlocutory decision of the Opposition Division established that the patent could be maintained in an amended form on the basis of the text as submitted during the oral proceedings with the set of 10 claims filed on 8 June 1996.

Amended independent claim 1 corresponds to claim 1 as granted with the addition of the word "tube" before "feeding composition". claims 2 to 10 correspond to claims 2 to 11 as granted with the deletion of claim 9 and the renumbering of claims 10 and 11 as claims 9 and 10 respectively.

The Opposition Division was of the opinion that the appellant's objections under Article 83 EPC were in fact directed to lack of clarity and not to the insufficiency of disclosure as it was not argued that the specification did not contain sufficient information, with the result that the skilled person could not carry out the invention.

As to novelty over documents (3) and (4), it concluded that these documents did not anticipate the subject-matter of claim 1 of the contested patent because they

did not disclose nutritionally **complete** food.

Starting from document (5) as closest state of the art, the Opposition Division maintained that it was not obvious to replace the non-hydrolysed soluble fibers in the tube feeding compositions of document (5) with the hydrolysed soluble fibers described in the food compositions of document (4) because the skilled person would not expect the hydrolysed fibers to retain the same pharmacological effects as the non-hydrolysed fibers.

IV. The appellant lodged an appeal against the said decision.

V. Oral proceedings were held before the Board on 1 March 2001.

VI. The submissions of the appellant, in the written procedure and oral proceedings, can be summarised as follows:

It maintained its objection under Article 83 EPC with respect to the feature of claim 1 of the patent in suit relating to the amount of hydrolysed soluble fibers present in a daily dosage feeding composition. In its view, the "daily dosage" was not a clear distinguishing feature so that it could not be determined unambiguously whether an embodiment would infringe the patent.

Moreover, it expressed the view that only the doctor could decide as to the amount of fibers to be incorporated in a daily dosage composition. It therefore concluded that this feature also contravened

Article 52(4) EPC.

Concerning novelty, it found that documents (3) and (4) anticipated the subject-matter of claim 1 of the patent in suit, although they did not mention nutritionally complete feeding compositions, because there were in practice only two single alternatives for medical food, ie complete or not complete.

As to inventive step, it pointed out that document (5) clearly taught that the fermentation products of the fibers, ie the short chain fatty acids (SCFA), were in fact the active agents with respect to the pharmaceutical effects. As the hydrolysed and non-hydrolysed soluble fibers were fermented to the same degradation products in the cecum, the skilled person would expect the same pharmaceutical effects for the hydrolysed and non-hydrolysed soluble fibers, with the result that it would be obvious to replace the non-hydrolysed fibers in the tube-feeding compositions of document (5) with the hydrolysed fibers described in the food compositions of document (4).

The appellant filed, moreover, various documents intended to show that the hydrolysed and non-hydrolysed soluble fibers had the same pharmaceutical effects.

VII. The respondent's arguments submitted in the written procedure and oral proceedings can be summarised as follows:

In the respondent’s view, the examples of the contested patent clearly disclosed how to carry out the invention, so that the requirements of Article 83 were fulfilled.

It stressed that documents (3) and (4) were silent about any "nutritionally complete" foods. In its opinion, these documents could therefore not be novelty-destroying for the claimed subject-matter.

As to inventive step, it argued that the skilled person would not expect the hydrolysed soluble fiber to have the same pharmacological effects as the non-hydrolysed ones for two reasons, namely because they would not be fermented to the same SCFA as shown in example 1 of the contested patent and because the skilled person would believe that the pharmacological effects were linked to the specific mechanical properties of the non-hydrolysed fibers, ie their high viscosity.

The respondent filed, moreover, various documents, including documents published after the filing date of the contested patent, intended to show that the pharmaceutical effects of the fibers were related to their viscosity.

VIII. The appellant requested that the decision of the Opposition Division be set aside and that patent No. 0 483 070 be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained.

Reasons for the Decision

1. The appeal is admissible.

2. *Article 83 EPC and Article 52(4) EPC*

During the oral proceedings, the Board expressed the view that the written objections raised under Articles 83 and 52(4) EPC did not appear to be very convincing and invited the appellant to comment on these grounds further. In reply to this invitation, the appellant skipped these grounds and argued directly with its novelty objections. Under these circumstances, the Board supports the Opposition Division's conclusions in the decision under appeal in that respect.

3. *Article 123(2) and (3) EPC*

No objection under Article 123(2) and (3) EPC was raised and the Board sees no reason to differ.

4. *Novelty*

4.1 Documents (3) and (4) have been cited under Article 54 EPC as prejudicial to the novelty of the subject-matters of claims 1 and 10 of the patent in suit.

Document (4) describes a feeding composition which comprises hydrolysed soluble fiber (guar gum) which is able to undergo fermentation in the colon to produce short fatty acids in an amount such that the feeding composition provides not less than 5 g of hydrolysed soluble fiber per day (page 1, paragraph 2, page 2, lines 17 to 20).

Document (4) does not mention *expressis verbis* that the feeding composition is a **tube** feeding composition which is **nutritionally complete** and which provides from **10 to 60 grams** of hydrolysed soluble fiber per day.

The question arises whether the skilled person would nevertheless consider these features implicitly contained in the document.

In that respect, the Board notes that document (4) deals with "nutritious foods for patients in hospitals" **in general** but not with a particular type of nutritious food, ie a **tube** feeding composition which is **nutritionally complete** and which provides from **10 to 60 grams** of hydrolysed soluble fiber per day (see page 3, lines 2 and 3). In addition, as agreed by the parties during oral proceedings, only the lower value of the viscosity range disclosed in document (4) seems compatible with tube feeding and this is moreover only possible under particular conditions, namely with a feeding pump (page 1, paragraph 2).

Accordingly, the skilled person could not implicitly read into document (4) that the "nutritious foods for patients in hospitals" are in fact **tube** feeding compositions which are **nutritionally complete** and which provide from **10 to 60 grams** of hydrolysed soluble fiber per day.

In conclusion, the subject-matter of claim 1 is novel over document (4) under Article 54 EPC.

As regards the subject-matter of independent claim 10, which is a second medical use claim directed to the use of hydrolysed soluble fiber for the manufacture of a nutritionally complete feeding useful against bacterial sepsis, gut atrophy and diarrhea, the Board notes moreover that document (4) concerns only medical foods for patients suffering from diabetes and hyperlipemia

and that it is completely silent about bacterial sepsis, gut atrophy and diarrhea.

Accordingly, claim 10 is also novel over document (4) under Article 54 EPC as, beside the feature of being nutritionally complete, the above-mentioned therapeutical effects are not disclosed in this document.

4.2 The appellant emphasised that nutritionally complete foods for enteral feeding were well-known and in widespread clinical use, as shown in document (5) (page 204, left column, lines 21 to 27, page 208, left column, lines 1 and 2).

It therefore concluded that the skilled person would read the disclosure in document (4) referring to "nutritious foods for patients in hospitals" as involving precisely a nutritionally complete enteral feeding composition.

It is true that nutritionally complete enteral feeding compositions are a kind of nutritious food which belongs to the "nutritious foods for patients in hospitals". There are however many other types of such medical nutritious foods depending on the nutritional deficiencies and associated diseases to be corrected in the patients. Moreover, not every patient in hospitals needs enteral feeding for ingesting foods.

Accordingly, the Board is convinced that the skilled person could not understand this general definition given in document (4) as inevitably meaning that the food must be nutritionally complete and suitable for tube feeding.

He could, accordingly, even less read in document (4) that the food must provide from 10 to 60 grams of hydrolysed soluble fiber per day.

As to claim 10, the appellant referred to the passage in document (4) which recited that, compared to non-hydrolysed soluble fiber, the hydrolysed soluble fiber retained the same excellent characteristics of **improving the physiological function of the digestive tract** and concluded that the skilled person would accordingly consider this disclosure to anticipate the use of hydrolysed soluble fiber for preventing bacterial sepsis, gut atrophy and diarrhea.

It is also true that the disclosure in document (4), namely that the hydrolysed soluble fiber retained the same excellent characteristics of improving the physiological function of the digestive tract, might encompass the specific beneficial therapeutical effects mentioned in claim 1. It is however the Rule for the assessment of novelty that a generic or conceptual disclosure does not anticipate specific or individualised items.

Accordingly, beside the feature requiring the food to be nutritionally complete, the specific therapeutical effects mentioned in claim 10 must also be regarded as a novel feature over the generic disclosure in document (4).

As document (3) does not contain any additional technical information compared to document (4), the above findings also hold good over this document.

5. *Inventive step*

5.1 The contested patent relates to tube enteral foods which contain hydrolysed soluble fiber useful for preventing bacterial sepsis, gut atrophy and diarrhea (page 2, lines 3 and 4, claims 1 and 10).

Document (5) discloses completely balanced enteral foods and reviews the various arguments published in the scientific literature about the dispute concerning the need of dietary (non-hydrolysed) fibers in artificial enteral nutrition (page 204, left column, line 21, to right column, line 4; page 204, right column, lines 4 to 11; page 207, right column, last paragraph).

Document (5) teaches that soluble fibers, which are able to undergo fermentation in the colon to produce SCFA, act as antidiarrhea agents *via* a mechanism involving the SCFA fermentation products (page 206, lines 5 to 7).

This document moreover shows that these fermentation products of soluble fibers also seem to play a role in stimulating mucosal proliferation, which prevents the mucosal atrophy of the colon (page 206, lines 33 to 40). Document (7) confirms these findings and discusses the beneficial consequences of this intestinal mucosa SCFA trophic effect with respect to the prevention of sepsis (page 105S, left column, lines 7 to 9, page 105S, right column, lines 30 to 36).

In summary, document (5) discloses that the active components in the colon with respect to the prevention of diarrhea, gut atrophy and sepsis are apparently not the soluble fibers *per se* but their fermentation products, namely the SCFA.

Not disclosed in this document is the use of **hydrolysed** fiber in enteral foods to this end.

The Board agrees with the parties that document (5) can be regarded as the closest prior art.

5.2 Accordingly, the problem to be solved by the subject-matter of claim 1 of the patent in suit as against document (5) can only be seen in the provision of an alternative tube-feeding composition (which prevents bacterial sepsis, gut atrophy and diarrhea). Both parties agreed with this definition of the problem to be solved over document (5) during the oral proceedings.

5.3 This problem is solved by providing a tube feeding composition comprising hydrolysed soluble fibers which are able to undergo fermentation in the colon to produce SCFA (short chain fatty acid) and, in the light of the description and examples of the patent in suit, the Board is satisfied that the problem has been solved. During the oral proceedings, the respondent pointed out that the term “comprising” used in claim 1 of the patent in suit clearly meant that non-hydrolysed fibers could also be present with the hydrolysed fibers.

5.4 Thus, the question to be answered is whether the proposed solution, ie adding the particular fiber of claim 1 to the prior-art enteral food compositions, would have been obvious to the skilled person faced with the problem defined above in the light of the prior art.

In that respect, document (4) describes a **hydrolysed**

soluble fiber (guar gum) and teaches its use in nutritious foods for patients in hospitals.

Accordingly, the Board is satisfied that the skilled person faced with the problem as defined above under 5.2 would prepare the tube-feeding composition according to the contested patent without inventive activity just by combining the teachings of documents (4) and (5) since he would also expect the **hydrolysed** soluble fiber of document (4) to be further degraded and fermented in the colon into the therapeutically active SCFA thus providing the same effect as the non-hydrolysed fibers of the prior art, especially since the wording of claim 1 of the contested patent does not exclude the presence of non-hydrolysed fibers (see under 5.3).

5.5 The Board does not agree with the arguments submitted by the respondent that there was a disincentive to use hydrolysed soluble fiber.

Among the various documents filed by the respondent to that end only documents (11) and (20) belong to the state of the art. The disclosure of the other documents cannot be taken into account to establish whether the skilled person would have been diverted from using hydrolysed soluble fibers since he could not have been aware of their content at the priority date of the contested patent.

Document (11) discloses that a particular fiber, namely a mucilaginous fiber, has proven to be efficient in treating diarrhea by absorbing sufficient water to solidify the stool and slowing the transit time (page 194, lines 32 to 40).

This document thus merely teaches that hydrophilic bulk laxatives have a beneficial effect on diarrhea *via* a mechanism which is based on their mechanical properties.

However, this document neither contradicts nor invalidates the teaching of document (5) that, as far as soluble fermentable fibers are concerned, a different mechanism is involved which cannot be based on the water-holding property since the bacterial breakdown of these fibers in the large intestine is nearly complete (page 205, left column, last complete paragraph, lines 1 to 8).

As to document (20), the Board notes that this document does indeed teach that viscosity appears to be an important property of dietary fibers, in particular of guar fiber, that is related to its action in reducing prostaglandial glycaemia (page 1394, right column, last sentence; summary, lines 10 to 12).

This teaching does not however concern the therapeutical effects of the patent in suit, ie the prevention of bacterial sepsis, gut atrophy and diarrhea. In addition, there is nothing in the file which could suggest that the skilled person would consider the effects shown in relation to diabetic treatment to be also valid for the above-mentioned different medical indications.

Moreover, document (4), which was published more than 20 years after document (20) teaches precisely the contrary. In fact, hydrolysed guar gum is disclosed therein as retaining “the same excellent characteristics of lowering the blood sugar content”

and as being "particularly suitable as medical food for patients suffering form diabetes".

In addition, as shown under point 5.1, document (5) contains information which strongly suggests that the active components are not the soluble fibers *per se* but their fermentation products, the SCFA, with the result that the skilled person would not pay any particular attention to the viscosity of the fiber, any more than he would in the case of soluble fibers which undergo fermentation in the colon.

Accordingly, the Board is convinced that there is no disincentive preventing the skilled person from using non-hydrolysed fiber and expecting the effects of hydrolysed soluble fibers disclosed in document (5) to remain.

Nor does the Board accept the argument that document (5) taught away from using hydrolysed soluble fiber, since it suggested adding non-gelling fibers such as soy fibers as an alternative solution to the non-hydrolysed gel-forming fibers.

It is, in fact, true that document (5) indicates, on the one hand, that the addition of gel-forming fibers such as non-hydrolysed guar gum to liquid formula diets for enteral feeding is problematic because of their high viscosity and, on the other hand, that no tube blockage has been reported with soy fibers (page 207, left column, lines 10 to 13; page 207, right column, last paragraph, lines 7 to 9).

Document (5) is however a scientific Article which reviews the relevant literature dealing with the

addition of dietary fibers to liquid formula diets. The purpose of such an Article is primarily to give a sound and objective view of what is known and what has been achieved in the art by previous authors, rather than to suggest a technical solution to a given technical problem.

Accordingly, the skilled person reading document (5) remains completely free to use alternatives other than that referred to in this document such as the alternative of using the less viscous hydrolysed soluble guar gum fibers described in document (4).

Finally, as to the respondent's submission that the skilled person would have expected a different SCFA profile to be produced in the colon if hydrolysed fibers were used instead of non-hydrolysed fibers, with the result that the skilled person could not expect to have the same pharmacological effects, the Board notes that this consideration is not substantiated. There is indeed nothing on file which shows that different SCFA profiles would lead to different therapeutical effects. It must therefore be assumed that a different amount of a given SCFA in the SCFA profile would merely lead to a different degree of the same therapeutical effect. In that respect, comparative example 1 of the contested patent does not moreover show such a drastic difference in the amount of butyric acid obtained when hydrolysed or non-hydrolysed fibers are fermented. Thus, non-hydrolysed pectin, for instance, provides only about 25% less butyric acid when compared to hydrolysed pectin.

5.6 In the light of these facts, the Board can only conclude that the subject-matter of claim 1 does not

involve an inventive step as required by Article 56 EPC.

Since claim 1 of the only set of claims under consideration is not allowable, there is no need for the Board to consider the remaining claims.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Townend P. Lançon