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Datasheet for the decision of 9 December 2009

Case Number: T 0286/09 - 3.3.02

Application Number: 02726177.5

Publication Number: 1383514

IPC: A61K 31/702

Language of the proceedings: EN

Title of invention:
Use of a composition comprising a prebiotic for decreasing inflammatory process and abnormal activation of non-specific immune parameters

Patentee:
SOCIETE DES PRODUITS NESTLE S.A.

Opponent:
Tiense Suikerraffinaderij n.v.
N.V. Nutricia

Headword:
Prebiotic/SOCIETE DES PRODUITS NESTLE S.A.

Relevant legal provisions:
EPC Art. 54

Relevant legal provisions (EPC 1973):
-

Keyword:
"Novelty - yes - effect not disclosed in prior art"

Decisions cited:
T 0254/93, T 0409/05

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0286/09 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 9 December 2009

Appellant: (Patent Proprietor)	SOCIETE DES PRODUITS NESTLE S.A. Case postale 353 CH-1800 Vevey (CH)
Representative:	Marchant, James Ian Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks Kent TN13 1XR (GB)
Respondents: (Opponent)	Tiense Suikerraffinaderij n.v. Tervurenlaan 182 BE-1150 Brussel (BE)
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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 5 December 2008 revoking European patent No. 1383514 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 1 383 514 based on application No. 02 726 177.5 was granted on the basis of 6 claims.

Independent claim 1 as granted reads as follows:

1. Use of at least one prebiotic in the manufacture of a medicament or food or pet food composition for decreasing inflammatory process in an elderly human or elderly pet.

II. Notices of opposition were filed against the granted patent by opponent O1 and opponent O2. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC. The latter ground for opposition, i.e. Article 100(c) EPC was withdrawn during the oral proceedings before the Opposition Division.

III. The decision of the Opposition Division pronounced on 20 November 2008 revoked the patent under Article 101(3)(b) EPC.

The Opposition Division took the view that the subject-matter of claim 1 of the set of claims of the main request (set of claims as granted), of auxiliary requests 1 and 2 filed 19 September 2008, and of auxiliary request 3 filed during the oral proceedings was anticipated by the disclosure in interfering documents (7) (WO02/39834) and (8) (WO01/21008).

In particular, it considered that document (7) disclosed a composition comprising i.a. fructo-oligosaccharides and/or inulin. This composition was used in the manufacture of a functional food or medicament for the treatment of an immune condition. Further the "immune condition" was defined as ""n impaired immune response, an inflammatory condition, an inflammation, chronic disease (for example arthritis or gastritis), conditions associated with aging and leading to an increase of inflammatory response". Of these diseases all but the first one were clearly directed to inflammatory processes and the last one (conditions associated with aging and leading to an increase of inflammatory response) even made the connection between age and inflammatory processes. In addition, reference to elderly humans was clearly made in the document.

In the light of this disclosure, the Opposition Division concluded that the subject-matter of claim 1 of the main request and of auxiliary request 1 was anticipated by document (7).

As to auxiliary requests 2 to 3, the Opposition Division noted that the introduced features could not be considered as technical features in their true sense, but had to be considered as (one of) the mode of action(s).

Consequently, it considered that this feature only explained the effect achieved on the inflammatory process, which as such was obviously also achieved in document (7) when decreasing the inflammatory process.

Auxiliary request 4 filed during the oral proceedings was rejected under Article 123(2) and (3) EPC. In fact, the Opposition Division held that the introduction in claim 1 of the age interval from the example of the description constituted an unacceptable generalisation and that the deletion of the feature "decreasing inflammatory process" in claim 1 constituted a broadening of the scope of the granted claims.

Claim 1 of auxiliary request 1 before the Opposition Division reads as follows:

1. Use of at least one prebiotic in the manufacture of a medicament or food composition for decreasing inflammatory process in an elderly human.

Claim 1 of auxiliary request 2 before the Opposition Division reads as follows:

1. Use of at least one prebiotic in the manufacture of a medicament or food or pet food composition for decreasing inflammatory process in an elderly human or elderly pet, wherein said medicament or food or pet food composition decreases abnormal activation of non-specific immune parameters in the elderly human or elderly pet.

Claim 1 of auxiliary request 3 before the Opposition Division reads as follows:

1. Use of at least one prebiotic in the manufacture of a medicament or food or pet food composition for decreasing inflammatory process in an elderly human or elderly pet, wherein said medicament or food or pet

food composition decreases the phagocytic activity of granulocytes and monocytes and decreases interleukin-6 mRNA levels in peripheral blood mononuclear cells and wherein the prebiotic comprises a fructooligosaccharide, or a mixture of fructooligosaccharide and inulin.

Claim 1 of auxiliary request 4 before the Opposition Division reads as follows:

1. Use of at least one prebiotic in the manufacture of a medicament or food composition for decreasing the phagocytic activity of granulocytes and monocytes and decreasing the interleukin-6 mRNA levels in peripheral blood mononuclear cells in an elderly human aged 77 to 91 years, wherein the prebiotic comprises a fructooligosaccharide, or a mixture of fructooligosaccharide and inulin.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. With a communication dated 1 December 2009, the Board indicated its preliminary view as to novelty vis-à-vis documents (7) and (8).

VI. Oral proceedings were held before the Board on 9 December 2009.

A new main request was filed during the oral proceedings.

Independent Claim 1 of the set of 6 claims of the main request reads as follows:

1. Use of at least one prebiotic in the manufacture of a medicament for decreasing inflammatory process in an elderly human.

VII. The appellant argued that, as the disclosure of document (8) was confined to the nutrition of pets, this document no longer came into consideration as potentially novelty-destroying in respect of the main request filed during the oral proceedings since it concerned the treatment of a different group of patients, namely elderly humans.

As to document (7), it submitted that this document taught the person skilled in the art that the overall composition disclosed in the description might be effective in the prevention or treatment of an immune condition including conditions associated with aging and leading to an increase of inflammatory responses.

Although this composition included a prebiotic (inulin and an FOS (fructooligosaccharide)), there was no teaching that the prebiotic as such had the effect of alleviating the condition in question.

On the contrary the person skilled in the art reading D7 would not have been able to tell which of the essential components of the composition of document (7) was having the effect of alleviating the condition and the most likely conclusion that he would draw was that all components were essential, i.e. in as much as there

was an effect producing an alleviation of the condition it was the combined effect of all of the components.

VIII. With respect to claim 1 of the main request filed during the oral proceedings, respondent 2 (opponent 2) argued that the term "medicament" was not clear as it could also be something different from a food composition, contrary to what was described in the specification, and because the alternative concerning the preparation of a food composition present in claim 1 as granted was deleted.

The objection of lack of novelty vis-à-vis document (8) was not maintained by the respondents during the oral proceedings.

They did however, submit that claim 1 of the main request lacked novelty in view of Document (7), for the reasons given below.

As FOS and inulin were the only specifically named ingredients in the passage describing the essence of the invention in document (7), whereas other named ingredients were identified on a higher level of aggregation, each necessarily comprising a very large number of alternatives, the skilled person would have understood that the technical effects of the mixture as a whole were directly linked to at least the specifically identified ingredient. Thus, document (7) disclosed that FOS and/or inulin were useful for decreasing inflammatory process in an elderly human.

Furthermore, the selection of one element of a list could not be regarded as novel. In fact, the list of

elements in this case was the list of the ingredients of the composition, consisting of a source of protein, a source of carbohydrate, a source of fat, a probiotic lactic acid bacterium and FOS and/or inulin. The selection made therefrom was the selection of FOS and/or inulin from a single list, which according to established case law did not confer novelty.

Referring to Technical Board of Appeal Decision T 254/93 (OJ 1998, 285), which ruled that the mere explanation of an effect obtained when using a compound in a known composition, even if the effect was not known to be due to this compound in the known composition, could not confer novelty to a known process if the skilled person was already aware of the occurrence of the desired effect, respondent 2 (opponent 2) further argued that novelty could not be acknowledged in the present case either, as it was similar.

In that respect, it requested the referral of the matter to the Enlarged Board of Appeal in the case the Board intended to deviate from T 254/93 in its decision.

IX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the main request submitted during the oral proceedings or any of the auxiliary requests 2 to 4 (renumbered 1 to 3) filed on 7 December 2009.

The respondents (opponents O1 and O2) requested that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.

2. *Main request*

2.1 Admissibility of the main request filed during the oral proceedings.

Claim 1 of this set of claims differs from claim 1 of the set of claims as granted only in that it has been restricted to one of the alternatives encompassed by claim 1, namely the preparation of a medicament for elderly humans.

As this amendment was made in response to an objection made in relation to decision T 409/05, cited for the first time by respondent 2 (opponent 2) in its letter dated 4 December 2009, the Board considers that the request is not late filed as the appellant had in fact no opportunity to react properly beforehand since the objection was not previously known to him. Moreover, the respondents did not contest the admissibility of this request and the amendment does not delay the procedure since it merely amounts to the deletion of alternatives.

Accordingly, the set of claims of the main request presented during the oral proceedings may be introduced into the proceedings.

2.2 Article 84 EPC

The objection of lack of clarity raised by respondent 2 during the oral proceedings, namely that the term "medicament" in claim 1 was not clear, cannot be accepted by the Board as the subject-matter of claim 1 of this request was already in claim 1 of the granted patent as such, so that clarity cannot be objected to in the present case as it is not a ground for opposition.

The fact that the alternative in granted claim 1 relating to the preparation of a food composition was deleted is irrelevant in that respect since both alternatives, namely the preparation of a medicament and the preparation of a food composition, were independent alternatives.

2.3 Novelty

In the light of the different group of patients defined in claim 1 of the main request(i.e. humans vs pets), the novelty objection vis-à-vis document (8) was not maintained by the respondents and the Board sees no reason to differ.

2.3.1 Document (7) discloses a composition which comprises a source of protein, a source of carbohydrate, a source of fat, a probiotic lactic acid bacterium and additionally FOS (fructo-oligosaccharides) and/or inulin. This composition is used in the manufacture of a functional food or a medicament for the prevention or treatment of an immune condition, particularly in elderly patients. Such condition is further defined as

including *inter alia* "conditions associated with aging and leading to an increase of inflammatory responses" (page 1, lines 17 and 18, page 2, line 32 to page 3, line 2; page 3, lines 15 to 17, and lines 26 to 28).

Thus, document (7) disclosed the administration of a composition including among others a prebiotic (FOS and/or inulin) to persons (by implication elderly persons) with an immune condition associated with aging and leading to an increase of inflammatory responses. It does not however disclose that the prebiotic as such, or any other ingredient of the composition, has any effect *per se* in alleviating the condition.

This is to be contrasted with the subject-matter of claim 1, which concerns the effect of a prebiotic for decreasing the inflammatory process. This effect of the prebiotic is moreover shown in the description of the patent is suit which includes a report of a study where the diet of elderly persons was supplemented by a prebiotic (FOS) and a clear effect was observed in terms of decreasing the inflammatory process that could only be attributed to the FOS.

Accordingly, the subject-matter of claim 1 of the main request is novel vis-à-vis document (7).

2.3.2 The Board does not agree with the respondents' submissions that the skilled person reading document (7) would deduce that FOS and/or inulin were the active ingredients merely because they were specifically mentioned in the composition, whereas the other ingredients were mentioned in more generic terms, or because they would arrive at that conclusion by default

since they know that fat and protein are there as bulk food and the prebiotic for preventing diarrhea (page 6, lines 10 to 14), so that the remaining ingredients, namely the probiotic FOS and/or inulin, must be the ones having the effect of decreasing inflammatory process.

In fact, document (7) discloses on page 8, lines 5 to 7, that FOS and inuline "may" be added to the composition and that they provide up to 5% of the energy of the composition.

Thus, contrary to the respondents' view, in the light of the above passage in document (7), the skilled person can only conclude that the overall composition disclosed in the description is effective in the prevention or treatment of an immune condition, including conditions associated with aging and leading to an increase of inflammatory responses, since each ingredient taken alone plays a different role in the compositions which has no link with inflammatory process.

As to the argument relating to selecting from a single list of ingredients, the Board cannot agree with the respondents either.

In fact, as discussed above, document (7) does not disclose a list of several ingredients having each an effect on the inflammatory process, but a composition of several ingredients wherein the effect can only be understood as being the result of the combined effect of all of the ingredients.

Finally, the present situation is to be distinguished from the one in T 254/93.

Indeed, in T 254/93, contrary to the present case, the prior art formulation comprises two ingredients, namely a corticosteroid, well-known for inducing skin atrophy, and a retinoid. Moreover, it was accepted that skin atrophy induced by corticosteroids was accompanied by such strong symptoms that the fact that skin atrophy did not occur when using this prior art composition containing the second ingredient, namely the retinoid, could not be overlooked by the medical practitioner.

Under these circumstances, the Board decided that, although not mentioned *expressis verbis* in the prior art , the effect of the retinoid on the prevention of skin atrophy caused by corticosteroids could not be regarded as novel **because the skilled person was already aware of the occurrence of the desired effect,** i.e. he knew from the prior art that the retinoid must have had the effect of preventing skin atrophy (point 4.8).

The present situation is different since, as discussed above, the skilled person could not be already aware of the occurrence of the desired effect, i.e. the skilled person could not know from the prior art that the prebiotic had an effect on inflammatory process because the prior art advocated the use of the prebiotic for a specific purpose, namely to "provide up to 5% of the energy of the composition" (page 8, lines 5 to 7).

The request to refer a question of law to the Enlarged Board of Appeal (see point VIII, last paragraph, of the

facts and submissions above) does not need to be considered since in the present case no contradiction to decision T 254/93 occurs since the situation underlying the present case can be distinguished from the situation forming the basis for the decision T 254/93 (see above).

3. *Remittal to the department of first instance*

3.1 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of a case. The essential function of an appeal is to consider whether the decision 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.

In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party solely upon one particular issue which is decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

3.2 The observations made above apply in full to the present case. The Opposition Division decided that claim 1 was not patentable on the grounds of lack of

novelty over documents (7) and (8), but disregarded the essential issues of sufficiency of disclosure (Article 83 EPC), novelty (Articles 52(1), 54 EPC) vis-à-vis the remaining prior art documents, and inventive step (Articles 52(1), 56 EPC). These issues, however, formed, *inter alia*, the basis for the requests that the patent be revoked in its entirety and must therefore be considered as essential substantive issues 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 Opposition Division for further prosecution on the basis of the set of claims of the main request filed by the appellant during the oral proceedings.

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 on the basis of the main request submitted during the oral proceedings.

The Registrar The Chairman

C. Eickhoff U. Oswald