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**Datasheet for the decision  
of 12 December 2014**

**Case Number:** T 1144/10 - 3.3.01

**Application Number:** 95810125.5

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**IPC:** A61K31/195, A61K31/20,  
A23L1/30, A23L1/305, A61P37/00,  
A61P43/00

**Language of the proceedings:** EN

**Title of invention:**  
Compositions for improving the immune response

**Patent Proprietor:**  
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**Opponent:**  
N.V. Nutricia

**Headword:**  
Immunostimulatory diet/NESTEC

**Relevant legal provisions:**  
EPC Art. 56, 113(1)  
EPC R. 115(2)  
RPBA Art. 15(3)

**Keyword:**

Inventive step (no), obvious combination of prior art teaching  
Oral proceedings in absence of both parties



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Case Number: T 1144/10 - 3.3.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.01**  
**of 12 December 2014**

**Appellant:**  
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**Decision under appeal:**

**Decision of the Opposition Division of the  
European Patent Office posted on 26 March 2010  
revoking European patent No. 0674902 pursuant to  
Articles 101(2) and 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman** A. Lindner  
**Members:** L. Seymour  
L. Bühler

## Summary of Facts and Submissions

- I. The appeal lies from the decision of the opposition division revoking European patent No. 0 674 902.
- II. The decision was based on a main request (claims as granted), and an auxiliary request filed with letter dated 23 December 2009.

Claim 1 as granted reads as follows:

"1. The use of

(a) omega-3 polyunsaturated fatty acids, and

(b) L-arginine or L-ornithine in free amino acid or salt form or a mixture thereof, and

(c) omega-6 polyunsaturated fatty acids,

in the manufacture of an immunostimulatory pre-operative diet for post-operative stimulation of the immune system of patients subject to surgery, whereby the diet provides a daily dosage of 2 to 5g of component (a), 7.5 to 20g of component (b) and 1.5 to 5g of component (c)."

Claim 1 of the auxiliary request reads as follows:

"1. The use of an immunostimulatory effective amount of

(a) omega-3 polyunsaturated fatty acids,

(b) L-arginine or L-ornithine in free amino acid or salt form or a mixture thereof, and

(c) omega-6 polyunsaturated fatty acids,

in the manufacture of a diet for post-operative stimulation of the immune system of patients subject to surgery, wherein the diet is administered pre-operatively, and provides a daily dosage of 2 to 5g of component (a), 7.5 to 20g of component (b), and 1.5 to 5g of component (c)."

III. The following documents, cited during the opposition/appeal proceedings, are referred to below:

- (1) EP-A-0 367 724
- (2) R Tepaske et al., *The Lancet*, 2001, 358, 696 - 701
- (3) WO 90/03794
- (6) H Takeuchi et al., *World J. Surg.*, 2007, doi:10.1007/s00268-007-9219-8
- (13) M Senkal et al., *Crit. Care Med.*, 1997, 25(9), 1489 - 1496
- (14) M Senkal et al., *Arch. Surg.*, 1999, 134, 1309 - 1316

IV. In its decision, the opposition division held that the subject-matter of claim 1 of the main request lacked novelty *inter alia* with respect to document (1), based on the premise that the adjective "pre-operative" merely designated suitability of the diet for pre-operative administration.

In its analysis of inventive step of the auxiliary request, the opposition division considered document (1)

to represent the closest prior art. Since it could not be deduced from the evidence on file that pre-operative administration of the immune-enhancing composition had an additional beneficial effect over post-surgical administration, the problem to be solved was defined as lying in the provision of an alternative dosage regime for the immune-enhancing composition of document (1). The solution of pre-operative administration was considered to be obvious in view of the teaching of document (3).

- V. The appellant (patentee) lodged an appeal against this decision. Its auxiliary request filed with the statement of grounds of appeal was identical to the auxiliary request considered in the decision under appeal (cf. above points II and IV).

The appellant's arguments submitted in its statement of grounds of appeal, insofar as they are relevant to the present decision, can be summarised as follows:

The appellant submitted that the respective claims 1 of the main and auxiliary request related to subject-matter that was identical in substance.

Starting from document (1) as closest prior art, the appellant defined the problem to be solved as finding a method for providing a patient with an improved immune system so that resistance to infection would be improved upon surgery. The claimed diet, when administered pre-operatively, had been shown to cause a different medical effect in comparison to when it was administered post-operatively, with the result that immune and metabolic function was maintained at or above pre-operative levels for a period that lasted well beyond surgical intervention. This was supported by the data disclosed

in post-published documents (2), (6), (13) and (14). This effect could not have been predicted from the cited prior art. The teaching that could be derived from document (3) was that compositions comprising omega-6 fatty acids could be administered prior to burning to enhance the immune system response and resistance to infection, but that it would have been important not to use omega-3 polyunsaturated fatty acids (PUFAs) prior to surgery, since this would produce an adverse result. There was therefore no reason why a skilled person would consider combining the teaching of documents (1) and (3). Moreover, there was no suggestion in the cited documents that would inevitably lead a skilled person to the specific ranges claimed in the patent in suit.

VI. With its letter of response, the respondent (opponent) filed counterarguments, which, insofar as they are relevant to the present decision, can be summarised as follows:

The respondent agreed with the finding of the opposition division that the wording of claim 1 of the main request was such that pre-operative administration was not required.

Moreover, the respondent contested the appellant's analysis of inventive step, since document (3) taught that immune response and resistance to infection could be improved pre-operatively by altering the diet of a patient. Contrary to the appellant's contention, there was nothing in document (3) that taught not to use omega-3 PUFAs.

VII. Oral proceedings were held before the board on 12 December 2014. Both the appellant and respondent

did not attend, as announced with letters dated 30 September 2014 and 10 December 2014, respectively.

The appellant (patent proprietor) requested in writing that the decision under appeal be set aside and that, as its main request, the patent be maintained as granted, or, alternatively, that the patent be maintained on the basis of the claims of the auxiliary request filed with the statement of grounds of appeal.

The respondent (opponent) requested in writing that the appeal be dismissed.

At the end of the oral proceedings, the decision of the board was announced.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Oral proceedings were held in the absence of the parties (cf. above point VII). Pursuant to Rule 115(2) EPC, if a party duly summoned to oral proceedings before the European Patent Office does not appear as summoned, the proceedings may continue without that party. Reference is further made to Article 15(3) of the Rules of Procedure of the Boards of Appeal, which stipulates that the Board shall not be obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case. Therefore, the present decision could be taken at oral proceedings, based on the written submissions of the parties (Article 113(1) EPC).



3. *Main request - Inventive step (Articles 52(1), 56 EPC)*

3.1 Claim 1 of the patent in suit is drafted as a second medical use claim in a "Swiss-type" format and relates to the use of three components, namely, omega-3 PUFAs, L-arginine or L-ornithine, and omega-6 PUFAs, in specified daily amounts, in the manufacture of an immunostimulatory pre-operative diet for post-operative stimulation of the immune system of patients subject to surgery. A reading of "pre-operative" as designating a mere suitability, as argued by the respondent, would render this feature effectively redundant. In the board's view, the only technically meaningful way of construing the superposition of the adjectives "pre-operative" and "post-operative" in context is that the former feature defines the timing of the intake of the diet in question, and it is in this sense that it is construed in the analysis below.

3.2 The board considers, in agreement with the parties, that document (1) represents the closest prior art.

Document (1) discloses immunostimulatory compositions comprising arginine or ornithine, omega-3 PUFAs, and omega-6 PUFAs (page 2, lines 45 to 54). The most preferred omega-6 PUFA is linoleic acid (page 3, line 43). The amount of arginine component is such as to allow a daily administration of, most preferably, 15 to 22 g; ornithine may be substituted on a 1:1 molar ratio for arginine (page 3, lines 3 to 9). The amount of omega-3 PUFAs to be administered corresponds to a daily supply of, most preferably, 0.15 to 10.0 g (page 3, lines 35 to 39). The amount of omega-6 PUFAs to be administered corresponds to a daily supply of, most preferably, 0.5 to 10 g (page 3, lines 48 to 49). These preferred ranges (cf. also claim 6) are exemplified in

the form of composition A, which comprises 18.75 g of arginine, and, for example, 3.6 g of omega-6 PUFA, and 3.0 g of omega-3 PUFA (see page 6, lines 1 to 24). The amount of linoleic acid in this composition is typically 2.5 to 4.5 g (page 6, line 18).

The immunostimulatory compositions are suitable for use in patients who suffer from depressed host defence mechanisms, for example, as a result of post-surgical trauma (page 4, lines 51 to 54). Post-operative administration of composition A is disclosed in example 3.

- 3.3 In view of the closest state of the art, it must now be determined which problem the claimed invention addresses and successfully solves.

In its statement of grounds of appeal, the appellant relied on documents (2), (6), (13) and (14) to support its submission that the claimed diet, when administered pre-operatively caused a different medical effect in comparison to when it was administered post-operatively.

However, the data disclosed in these documents is not considered to be relevant for the following reasons:

Document (2) is only concerned with pre-operative administration of an oral immune-enhancing nutritional supplement (see page 696, summary).

Document (6) provides a comparison between post- and **peri**-operative immunonutrition. In the former case, the regimen was received during 14 days after surgery, and in the latter, 5 days before surgery and 14 days after surgery (page 2161, right-hand-column, second paragraph, groups B and C, respectively). This comparison is not

considered to be pertinent, since it does not reflect the impact of the distinguishing feature of the invention, namely, of **pre**-operative as opposed to post-operative administration (cf. decision under appeal, page 9, first paragraph).

Document (13) only relates to post-operative immunonutrition (see page 1489, abstract), and document (14) to peri-operative immunonutrition (see page 1310 (third paragraph)).

Therefore, none of these documents provide a valid comparison between pre- and post-operative immunonutrition.

As is well established in the case law of the boards of appeal, alleged but unsupported differences cannot be taken into consideration in respect of the determination of the problem to be solved.

- 3.4 The problem to be solved in the light of the closest state of the art is therefore defined as lying in the provision of an alternative method for improving the immune response of patients upon surgery.

The solution proposed in claim 1 relates to a use characterised in the pre-operative administration of the immunostimulatory diet.

Having regard to the experimental results reported in Example 2 of the patent in suit, the board is satisfied that the problem has been solved.

- 3.5 It remains to be investigated whether the proposed solution is obvious to the skilled person in the light of the prior art.

The skilled person faced with the above-mentioned problem would have been aware of other documents relating to immunostimulatory diets, such as document (3). This document teaches that, prior to an operative procedure, the immune response system of a patient can be improved by providing the patient with a diet very high in linoleic acid (see page 2, lines 19 to 23, and claim 1). Further lipid components are not excluded (page 5, lines 16 to 24), and the diet may contain arginine (page 4, line 22 to page 5, line 5).

In view of the fact that the diets containing large amounts of omega-6 PUFAs, and specifically linoleic acid, are also envisaged in document (1) (cf. above point 3.2), it is concluded that the skilled person would have been prompted by document (3) to contemplate administration of the diets according to document (1) prior to surgery as a solution to the problem posed, thus arriving at the subject-matter claimed without the exercise of inventive skill.

- 3.6 The board cannot accept the appellant's submission that document (3) teaches away from the use of omega-3 PUFAs in the diets disclosed. The appellant referred in this context to the experimental results disclosed in Table I of document (3), and in particular to the entries relating to MaxEPA (pages 11, 12). However, it is noted that the composition MaxEPA not only contains omega-3 PUFAs, but additionally 28% palmitic acid and 18% oleic acid (see page 9, line 26 to page 10, line 3). Therefore, for this reason alone, no conclusion can be reached from Table I as to a potential detrimental effect of omega-3 PUFAs. Indeed, no statement to this effect is to be found in document (3).

An inventive step also cannot be linked to the claimed ranges of daily dosages of components, in view of the fact that compositions falling within these ranges are already disclosed in the closest prior art document (1) (cf. above point 3.2).

3.7 Consequently, the appellant's main request is rejected for lack of inventive step of claim 1.

4. *Auxiliary request - Inventive step (Articles 52(1), 56 EPC)*

The appellant did not submit any additional arguments in favour of inventive step for this request. The board agrees with the appellant's submission that the amended claim 1 relates to subject-matter that is identical in substance to that of claim 1 of the main request (cf. above point 3.1). The considerations concerning claim 1 of the main request, as set out above in point 3, therefore apply equally.

Consequently, the appellant's auxiliary request is also rejected for lack of inventive step of claim 1.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated