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D E C I S I O N
of 29 April 2004

Case Number: T 0485/99 - 3.3.2

Application Number: 95810125.5

Publication Number: 0674902

IPC: A61K 31/195

Language of the proceedings: EN

Title of invention:
Method of improving the immune response

Patentee:
Novartis Nutrition AG

Opponent:
-

Headword:
Method of improving the immune response/NOVARTIS

Relevant legal provisions:
EPC Art. 111(1)

Keyword:
"Lack of discussion of the main issue concerning the novelty of the therapy - remittal"

Decisions cited:
T 0056/97, T 0233/96

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0485/99 **-** 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 29 April 2004

Appellant: Novartis Nutrition AG
Monbijoustrasse 118
CH-3007 Bern (CH)

Representative: Zumstein, Fritz, Dr.
Patentanwälte
Dr. F. Zumstein,
Dipl.-Ing. F. Klingseisen
Bräuhausstrasse 4
D-80331 München (DE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 10 December 1998 refusing European application No. 95810125.5 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. Ortega Plaza
P. Mühlens

Summary of Facts and Submissions

I. European patent application No. 0 674 902 based on application No. 95 810 125.5 was filed with 7 use claims and 2 product claims. During the oral proceedings before the examining division the claims were amended to a set of claims relating to 6 use claims.

Claim 1 read as follows:

"The use of (a) omega-3 PUFAs (Component(a)) and (b) L-arginine or L-ornithine in free amino acid or salt form or a mixture thereof (Component (b)), 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 5 g of Component (a) and 7.5 to 20 g of Component (b)."

II. The following documents were cited *inter alia* during the proceedings:

(1) EP-A-367 724

(2) EP-A-567 433

(3) US-A-4 752 618

(5) US-A-4 981 844

(6) M. D. Peck, the Journal of Trauma, vol. 30, No 4, 445-452, 1990

(7) R. Tepaske, The Lancet, vol. 358, 696-701, 2001.

III. The appeal lies from a decision of the examining division refusing the patent application under Article 97(1) EPC.

IV. The examining division considered that the subject-matter claimed in the main request (set of claims filed during the oral proceedings before the first instance) lacked an inventive step (Article 56).

In particular, the examining division considered that document (5) represented the closest prior art. The difference was the use of omega-3 PUFAs in the place of omega-6 PUFAs.

It defined the problem as the provision of immunostimulating compositions for pre-operative use which have a post-operative effect.

The solution concerned the use of (a) omega-3 PUFAs and (b) L-arginine or L-ornithine in free amino acid or salt form or a mixture thereof.

In the examining division's view the solution was obvious in the light of the prior art document (3), since it disclosed the use of omega-3 PUFAs and arginine or ornithine as active ingredients in immunostimulatory compositions. Document (3) further disclosed that such compositions could be administered prior to challenge of the immune system.

The examining division further cited document (2) which contained a reference to document (5). It considered that the skilled person would have been bound to combine these documents with document (3).

V. A communication from the Board was sent on 7 July 2003, in response to which the claims were amended.

VI. With letter of 22 April 2004, two sets of claims were filed as main and auxiliary requests.

Claim 1 of the main request reads:

"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 5 g of Component (a) and 7.5 to 20 g of Component (b) and 1.5 to 5 g of component (c)."

Claim 1 of the auxiliary request additionally contains the following passage at the end of the claim:
"... and wherein the omega-3 polyunsaturated fatty acids (a) are in the form of fish oil and the omega-6

polyunsaturated fatty acids (c) are in the form of safflower oil, sunflower oil, soya oil, cotton oil, or corn oil."

VII. The appellant lodged an appeal against said decision and supported it with arguments in its grounds of appeal.

VIII. Oral proceedings were held on 29 April 2004. The board raised the point of novelty vis-à-vis the contents of document (1) and stressed the following:
In the board's opinion, the compositions as defined in claim 1 of the main request were known from document (1) which disclosed compositions comprising arginine, omega-3 polyunsaturated fatty acids (PUFAs) and omega-6 PUFAs. The amounts for the daily dosage disclosed in document (1) overlapped with those appearing in the claim and on page 6 Example A disclosed specifically a dosage of 1500 cc falling within the claimed ranges. The use disclosed in document (1) for the compositions was immunostimulatory. Therefore, the only feature remaining in the claim was the pre-operative administration, since the patients fully overlapped with those of document (1) in view of the fact that the immuno status of a patient is relative to several factors such as age and condition not defined in the claim.

Since the claim was a second medical use claim, the board pointed out that the main issue to be assessed was whether the therapy or indication was different from that disclosed in document (1).

IX. With respect to the novelty issue the appellant denied that the broader ranges for omega-3 and omega-6 PUFAs of document (1) could be taken as novelty-destroying for the smaller ranges appearing in the claims. With respect to arginine it acknowledged a certain overlap. With respect to Example A it doubted that it referred to a daily dosage since this was not explicitly stated. Additionally, there were differences in the patients to be treated. The patients subject to surgery did not yet have an infection according to the application in suit, whereas the patients from document (1) suffered from depressed host mechanisms and already had an infection.

The appellant pointed to document (7), page 701, in order to show with a certain plausibility that applying the diet before or after surgery there is a different metabolism. The diet according to the application in suit led to a better preservation of renal function. Different clearance of diet implies different absorption of diet, which means the diet creates a different physiological state.

X. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution.

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 The late-filed sets of claims were admitted into the proceedings since they do not essentially differ from the set of claims already on file and can be regarded as a reply to the arguments on file.

2. The appellant stated the basis for the amendments introduced in the claims in the originally filed description. The board is satisfied that the requirements of Article 123(2) EPC are met.

3. *Remittal to the department of first instance*

3.1 The set of claims on which the first-instance decision was based and the sets of claims before the board during the oral proceedings relate exclusively to so-called "second (further) medical use" or "Swiss-type" claims.

Such form of claims was allowed for the first time by the parallel decisions G 1/83, G 5/83 and G 6/83 (OJ EPO 1985, 60, 64, 67). In accordance with the principles recognised in these decisions a specific format was allowed for a further medical indication, i.e. the use of a substance, already known as a medicament, for the manufacture of a medicament for the treatment of an illness or disease not previously treated by means of that substance (G 5/83, especially reasons, point 17, second paragraph).

This, did not exclude the possibility of deriving a second or further medical indication (a new therapeutic application) of a substance or composition, already known as a medicament, likewise from some other previously unknown feature (other than treatment of a

different illness or disease) associated with the use of that substance or composition in a method for the medical treatment of the human or animal body. In this connection reference is made to board of appeal case law, for example as summarised in "Case Law of the Boards of Appeal of the European Patent Office", 2002, I C, 5.2.2.

3.2 It is also to be noted that the basic structure of a second medical use claim could be formally built up from of three blocks corresponding to the following:
(a) the use of a compound or composition
(b) for the manufacture of a medicament
(c) for a therapy.

In the present case the appellant has argued that the medicament is novel (concerning the daily dosage for the diet).

3.3 In this respect the board wishes to point out that it is indeed not necessary for the novelty of the subject-matter claimed in claims drafted as second medical use claims to rely upon a novel therapy. The compound (or composition) or the medicament may be novel.

However, having regard to document (1), the board cannot agree with the appellant's position in this respect.

3.4 Document (1) discloses immunostimulatory compositions comprising arginine or ornithine, omega-3 polyunsaturated fatty acids (PUFAs) and omega-6 PUFAs (page 2, lines 45 to 51).

The amount of arginine component is such as to allow a daily administration of, most preferably, 15 to 22 grams (page 3, lines 7 to 8).

The amount of omega-3 PUFAs to be administered corresponds to a daily supply, most preferably of 0.15 to 10 grams (page 3, lines 38 to 39).

The amount of omega-6 PUFAs to be administered corresponds to a daily supply, most preferably of 0.5 to 10 grams (page 3, lines 49).

Example A on page 6 corresponds to a unit dosage of 1500 cc. It discloses a composition having 18.75 g arginine, 3.6 g omega-6 PUFAs and 3.0 g omega-3 PUFAs. These specific amounts fall within the ranges defined in claim 1 of the main request.

Moreover, since in composition A it is stated that the composition has 1 kcal/cc the dosage corresponds to 1500 kcal, which is a common daily dosage. Hence the board is convinced that composition A illustrates one specific example for a daily dosage falling within claim 1 of the main request.

For the reasons given above the board considers that document (1) anticipates the compositions and medicament underlying claim 1 of the main request.

3.5 Document (1) also discloses that the immunostimulatory compositions are suitable for use in patients who suffer from depressed host defence mechanisms, e.g. in patients who suffer from depressed host defence mechanisms as a result of post-surgical trauma, cancer,

chemotherapy radiation therapy, sepsis, trauma, burns, immunosuppressive drug therapy, malnutrition and transfusion induced immunosuppression (page 4, lines 51 to 54).

Document (1) also discloses that "the administration of the composition ... allows to maintain, restore and enhance the immune function where desired." (page 4, lines 56 to 58).

Further, document (1) also discloses that "such compositions may accordingly be employed to enhance a depressed host defence mechanism, to restore a normal immune function in a human with a deficient immune response, to enhance the development of the immune system in a developing human, (and) to enhance a senescent immune system of a human" (page 5, lines 1 to 4).

It should be pointed out that claim 1 does not define the immunological status of the patients to be treated, this being of a relative nature since it depends on patient age and condition.

3.6 From the point of view of the wording of claim 1 it has to be said that the only feature remaining with respect to document (1) is the fact that the intake of the diet is pre-operative.

Therefore, it remains to be investigated whether the pre-operative therapy as defined in the claim, which also deals with post-operative **immunostimulation**, can be distinguished from the therapy disclosed in document (1) by a different medical (physiological)

effect due to this pre-operative administration and thus whether it relates to a functional feature leading to the therapeutic indication in the sense of G 5/83 or not.

If it does not, the use defined in such a way might restrict the medical practitioner's freedom when treating his patients (see T 56/97, unpublished in the Official Journal, points 2-2.5). Pre- or post-operative administration of the diet would then constitute methods for treatment of the human body and could thus not be regarded as patentable inventions under Article 52(4) EPC.

3.7 With respect to a possible novel therapeutic indication the appellant has argued that the group of patients treated with the pre-operative diet could be distinguished from those treated with the post-operative diet.

It is clear that the patients before and after the operation are different, however, in the board's opinion, the question raised is whether the physiological status of the patients caused by the pre-operative diet is different.

At present, this cannot be established.

Accordingly, it would be necessary to demonstrate that a different physiological status is achieved for the patients when treated pre-operatively which leads to a new functionality linked to the therapeutic indication (see T 233/96, unpublished in the Official Journal, points 8.6 and 8.7).

3.8 As already set out, the first-instance decision is based on a set of claims only comprising Swiss-type use claims. However, the first-instance decision is silent about the assessment of the novelty of these use claims in the sense laid out above. When assessing the novelty, it is necessary to analyse the claim wording and look for all the features of the claim and compare them with the state of the art. Therefore, in the present case, the main issue, i.e. whether the therapy under the aspect of physiological status of the patient does serve to bring novelty to the subject-matter claimed, has not been discussed by the first-instance department. The board considers this is a major issue given the circumstances of the case.

3.9 The appellant has requested remittal of the case in order not to be deprived of the right to have the issues assessed by two instances.

3.10 The crucial question of the present case not having been dealt with by the appealed decision, the Board decides to make use of its discretionary power under Article 111(1) EPC to remit the case to the first instance to have this complex point dealt with by two instances.

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.

The Registrar: The Chairman:

A. Townend U. Oswald

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Appellant: Novartis Nutrition AG
Monbijoustrasse 118
CH-3007 Bern (CH)

Representative: Zumstein, Fritz, Dr.
Patentanwälte
Dr. F. Zumstein,
Dipl.-Ing. F. Klingseisen
Bräuhausstrasse 4
D-80331 München (DE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 10 December 1998 refusing European application No. 95810125.5 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. Ortega Plaza
P. Mühlens

In application of Rule 89 EPC the Decision given on 29 April 2004 is hereby ordered to be corrected as follows:

Page 7, para 3.2, line 3 the word "of" is to be deleted.

The Registrar: The Chairman:

A. Townend U. Oswald