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Datasheet for the decision of 12 October 2010

Case Number: T 0047/07 - 3.3.02

Application Number: 02715455.8

Publication Number: 1365841

IPC: A61P 9/00

Language of the proceedings: EN

Title of invention:
Essential N-3 fatty acids in cardiac insufficiency and heart failure therapy

Applicant:
Pfizer Italia S.r.l.

Opponent:
-

Headword:
N-3 Fatty acids in heart failure therapy/PFIZER

Relevant legal provisions:
EPC Art. 123(2), 54(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request - added subject-matter (yes)"
"Claimed subject-matter not individualised"
"Auxiliary request II - added subject-matter (yes)"
"Feature in one example not generalisable"
"Auxiliary requests I, III and IV - novelty - new use of known substance (no)"

Decisions cited:
G 0002/08, G 0005/83

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0047/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 12 October 2010

Appellant: Pfizer Italia S.r.l.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 18 August 2006 refusing European patent application No. 02715455.8 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J. Van Moer

Summary of Facts and Submissions

I. European patent application No. 02 715 455.8, filed as international application PCT/EP02/00507 on 16 January 2002 and published as WO 02/058793, was refused by a decision of the examining division on the basis of Article 97(1) EPC 1973.

II. Claim 1 of the main request before the examining division read as follows:

"Use of an essential fatty acid mixture comprising eicosapentaenoic acid ethyl ester (EPA) and docosahexaenoic acid ethyl ester (DHA) in the preparation of a medicament useful for the prevention and treatment of a heart disease chosen from cardiac insufficiency and heart failure, both chronic and acute."

III. The following document was cited *inter alia* during the proceedings before the examining division and before the board of appeal:

(1) Marchioli, R. et al.; "The results of the GISSI-Prevenzione trial in the general framework of secondary prevention"; European Heart Journal (2000), Vol. 21, No. 12, 949-952

IV. The examining division held the subject-matter of the sole request to lack novelty and not to involve an inventive step with respect to the prior art.

V. The appellant lodged an appeal against the decision of the examining division.

With letter of 10 September 2010, it filed four sets of claims as main request and as auxiliary requests I to III, replacing all previously filed requests.

The wording of claim 1 of the main request is:

"Use of an essential fatty acid mixture comprising eicosapentaenoic acid ethyl ester (EPA) and docosahexaenoic acid ethyl ester (DHA) in the preparation of a pharmaceutical preparation useful for the treatment of chronic heart failure, and wherein the preparation is for the combined therapy with another therapeutic agent selected from the group consisting of an ACE-inhibitor, an angiotensin II receptor antagonist, a diuretic, an arteriolar vasodilator, a venular vasodilator, a beta-blocker, a digitalis glycoside and mixtures thereof."

VI. A communication was sent out on 5 October 2010, *inter alia* drawing the appellant's attention to various amendments that, as examples, appeared to contravene Article 123(2) EPC. In addition, all objections raised by the examining division during the proceedings with respect to Articles 83, 84, 54 and 56 EPC, concerning all requests and all claims on file, appeared to be basically still valid.

Moreover, expressions such as "useful for" and "the preparation (medicament) is for the combined therapy with another therapeutic agent" appeared to raise problems within claims drafted in a Swiss-type second medical use format and could be read merely as

"suitable for", with consequences at least when assessing novelty.

VII. Oral proceedings took place on 12 October 2010.

At the oral proceedings, the appellant filed four sets of claims as auxiliary requests I to IV replacing all previously filed auxiliary requests.

Claim 1 of auxiliary request I differs from claim 1 of the main request in that "useful for the treatment of chronic heart failure" is replaced by "for prevention and treatment of chronic heart failure" and the text highlighted below in bold has been added. The claim reads:

"Use of an essential fatty acid mixture comprising eicosapentaenoic acid ethyl ester (EPA) and docosahexaenoic acid ethyl ester (DHA), **wherein the fatty acid mixture comprising EPA and DHA is present in a therapeutically effective amount,** in the preparation of a **pharmaceutical preparation**, wherein the **pharmaceutical** preparation is for combined therapy with another therapeutic agent selected from the group consisting of an ACE-inhibitor, **a NEP-inhibitor, an ACE/NEP-inhibitor,** an angiotensin II receptor antagonist, a diuretic, **a positive inotropic drug, a phosphodiesterase inhibitor,** an arteriolar vasodilator, a venular vasodilator, a beta-blocker, a digitalis glycoside and mixtures thereof**, for prevention and treatment of chronic heart failure**."

Claim 1 of auxiliary request II contains the text "wherein the content of EPA+DHA in the mixture is about

84 % by weight" instead of the text "wherein the fatty acid mixture is present in a therapeutically effective amount," and reads (differences with respect to auxiliary request I are in bold):

"Use of an essential fatty acid mixture comprising eicosapentaenoic acid ethyl ester (EPA) and docosahexaenoic acid ethyl ester (DHA), **wherein the content of EPA+DHA in the mixture is about 84 % by weight,** in the preparation of a pharmaceutical preparation, wherein the pharmaceutical preparation is for combined therapy with another therapeutic agent selected from the group consisting of an ACE-inhibitor, a NEP-inhibitor, an ACE/NEP-inhibitor, an angiotensin II receptor antagonist, a diuretic, a positive inotropic drug, a phosphodiesterase inhibitor, an arteriolar vasodilator, a venular vasodilator, a beta-blocker, a digitalis glycoside and mixtures thereof, for prevention and treatment of chronic heart failure."

Claim 1 of auxiliary request III reads like claim 1 of auxiliary request I, with "pharmaceutical preparation" replaced by "medicament" and the text ", wherein the fatty acid mixture comprising EPA and DHA is present in a therapeutically effective amount," deleted.

Claim 1 of auxiliary request IV reads as follows (text added to claim 1 of auxiliary request III highlighted in bold):

"Use of an essential fatty acid mixture comprising eicosapentaenoic acid ethyl ester (EPA) and docosahexaenoic acid ethyl ester (DHA), **wherein the**

content of EPA+DHA in the mixture is about 85 % by weight, in the preparation of a medicament, wherein the medicament is for combined therapy with another therapeutic agent selected from the group consisting of an ACE-inhibitor, a NEP-inhibitor, an ACE/NEP-inhibitor, an angiotensin II receptor antagonist, a diuretic, a positive inotropic drug, a phosphodiesterase inhibitor, an arteriolar vasodilator, a venular vasodilator, a beta-blocker, a digitalis glycoside and mixtures thereof, for prevention and treatment of chronic heart failure**, and wherein the essential fatty acid mixture is administered by an oral route at a dose ranging from about 0.7 g and about 1.5 g daily**."

All these auxiliary requests were admitted into the proceedings.

VIII. The arguments of the appellant in both the written and oral proceedings may be summarised as follows:

With respect to Article 123(2) EPC, a restriction to one of the three diseases originally disclosed, namely chronic heart failure out of "a heart disease chosen from cardiac insufficiency and heart failure, both chronic and acute" was allowable. "Treatment" had replaced "prevention and treatment" because prevention related to persons not yet suffering from the disease they were at risk of contracting, which was not possible at the same time as the treatment of the disease once contracted. Since such a meaning of the "and" between "prevention" and "treatment" was contradictory, the appellant was entitled to restrict the claim to "treatment" alone. Finally, the list of other therapeutic agents for combined therapy had

merely been shortened by removing agents not normally used in heart therapy nowadays.

All these amendments were inevitable and necessary corrections which were not in breach of Article 123(2) EPC.

In so far as the board had indicated concerns with respect to Article 123(2) EPC in connection with the reference to "about 84 % by weight content" of EPA+DHA in the essential fatty acid mixture, this percentage was disclosed under "formulation 1" as one of the examples for gelatin capsules and as such was generalisable to the teaching of claim 1 of auxiliary request II, in particular since this content was indicated as an "about" percentage.

Concerning the provisions of Article 54(2) EPC, in document (1) only the treatment of patients with recent myocardial infarction was disclosed, and chronic heart failure was not indicated. Usually the heart compensated for deficiencies caused by myocardial infarction and there was neither chronic heart failure automatically after infarction nor a necessary development of such disease from the mentioned compensation work of the heart.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with letter of 10 September 2010 or in the alternative on the basis of auxiliary requests I to IV filed at the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. The amended claims filed by the appellant as auxiliary requests I to IV represent an attempt to overcome the objections raised in the communication of the board and during the oral proceedings. Consequently, they are admitted into the proceedings.

3. *Second medical use claim in Swiss-type format under EPC 2000 in force since 13 December 2007 (Article 54(5) EPC)*

The application in suit was filed on 16 January 2002 and is still pending. Therefore, according to Article 1 No. 1 and 3 of the decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000 (OJ EPO 2007, 197), revised Articles 53(c), 54(4) and (5) EPC apply to it since it was pending on 13 December 2007 when EPC 2000 entered into force.

According to Enlarged Board of Appeal decision G 0002/08 dated 19 February 2010 (OJ EPO 10/2010, 458), a second medical use claim may no longer be in the "Swiss-type" format (instituted by decision G 0005/83, OJ EPO 1985, 64) once three months have elapsed as from publication of G 0002/08 in the Official Journal, the purpose of this time limit being to enable future applicants to comply with this new situation (final paragraph of headnote to G 0002/08).

Therefore, the claims of the current requests in the Swiss-type format are accepted by the board.

4. *Claim 1 of the main request; original disclosure (Article 123(2) EPC)*

4.1 Claim 1 as originally filed relates to

- prevention and
- treatment

of three different diseases namely
a heart disease chosen from

- cardiac insufficiency,
- chronic heart failure, and
- acute heart failure.

In addition, original claim 13, referring to original claim 2 which itself refers to original claim 1, concerns a list of

- eleven therapeutic agents

for the combined therapy, used each alone or in mixture with another one.

4.2 Claim 1 of the main request essentially relates to

- treatment of
- chronic heart failure
- in combined therapy with another therapeutic agent selected from the restricted group consisting of seven agents.

4.3 Nothing in the wording of the claims as originally filed links the disease "chronic heart failure" specifically to "treatment" in combined therapy with another therapeutic agent selected from a restricted group consisting of seven agents instead of eleven.

Nor is such a link supplied by any text in the description as originally filed.

Accordingly, the teaching of claim 1 of the main request cannot be regarded as individualised and thus is not recognisable as such in the application as originally filed.

4.4 As a consequence, the teaching of claim 1 of the main request represents an unallowable extension of the content of the application as originally filed (Article 123(2) EPC).

5. *Claim 1 of auxiliary request II; original disclosure (Article 123(2) EPC)*

This claim concerns the percentage "about 84%" relating to "formulation 1" as one of the examples for gelatin capsules. However, compared to the introduction to both examples beginning on page 7, line 11 of the description as originally filed ("Gelatin capsules: According to the methods known from pharmaceutical technique, capsules are prepared with the following composition and containing 1 g of active ingredient (85% EPA-DHA) in each capsule") and taking into account that the second example in fact contains 85% EPA-DHA, 840 mg of EPA-DHA contained in the capsules of the first example appear to represent an uncertainty or

even mistake in this particular dosage rather than a generalisable teaching.

In addition, nowhere else in the whole application as originally filed is any dosage of 84% EPA-DHA in relation to the overall fatty acid mixture ("active ingredient") disclosed.

Therefore, the subject-matter as claimed in auxiliary request II extends the content of the application as originally filed and is in breach of Article 123(2) EPC.

6. *Claims 1 of auxiliary requests I, III and IV;*

6.1 *Original disclosure (Article 123(2) EPC)*

The subject-matter of these claims can be derived from claims 1, 2 and 13 as originally filed, in combination with page 5, lines 24 to 29 of the application as originally filed, or together with original claim 5 and original claim 9.

6.2 *Clarity and sufficient disclosure (Articles 83 and 84 EPC)*

Whether the broadly functional definition of other therapeutic agents "for combined therapy" with the essential fatty acid mixture (e.g. angiotensin II receptor antagonist, diuretic or beta-blocker) ultimately raises problems with respect to these articles of the EPC did not have to be decided, since the subject-matter of the remaining requests was in any case anticipated by the state of the art in this respect.

Concurrently used therapeutic agents in a combined therapy were disclosed in document (1), a scientific publication, in the same way as in the application in suit.

6.3 *Novelty (Article 54(2) EPC)*

6.3.1 *Auxiliary request I*

The subject-matter of claim 1 of auxiliary request I essentially relates to the

- use of an essential fatty acid mixture comprising eicosapentaenoic acid ethyl ester (EPA) and docosahexaenoic acid ethyl ester (DHA)
- in the preparation of a pharmaceutical preparation,
- for combined therapy with another therapeutic agent, e.g. an angiotensin II receptor antagonist
- for prevention and treatment of
- chronic heart failure.

Document (1) discloses the

- use of an essential fatty acid mixture comprising eicosapentaenoic acid ethyl ester (EPA) and docosahexaenoic acid ethyl ester (DHA) (see page 949, left-hand column, second paragraph, lines 13 to 17)
- in the preparation of a pharmaceutical preparation (*loc. cit.*),
- for combined therapy with another therapeutic agent, e.g. an inhibitor of angiotensin-converting enzyme (see page 949, left-hand column, second paragraph,

lines 23 to 26; in particular line 25 to 26; wherein "inhibitor of angiotensin-converting enzyme" in this context is the same as "angiotensin II converting inhibitor" which in turn is used synonymously with "angiotensin II receptor antagonists", as can be seen in the description of the application in suit, page 4, line 30)

- for (secondary) prevention of (see document (1), page 951, left-hand column, second paragraph, lines 3 to 7)
- myocardial infarction (see document (1), page 949, left-hand column, second paragraph, lines 8 to 9 together with lines 17 to 21, in particular lines 20 and 21).

While the active essential fatty acid mixture und the medication are in fact identical, the disease is not described in identical words.

However, as was undisputedly stated during the oral proceedings, after myocardial infarction of some severity - and the patients in the GISSI-Prevenzione trial at least had to be clinically known in order to be recruited - necrotic tissue is present in the heart, meaning that the rest of the tissue has to work harder to achieve the same output as before, which at least in the long-term perspective is necessary to meet the needs of the patient who has suffered the infarction.

Thereby, the risk that chronic heart failure will develop cannot be excluded. Chronic heart failure is defined in the application in suit as being

"characterized by clinical signs and symptoms secondary to the inadequate response to the body metabolic requirements" because of the heart's "inability in keeping a stroke adequate to the metabolic requirements of the tissues or maintaining the stroke volume by a high filling pressure". "This condition could occur acutely or have a chronic course (see description as originally filed, page 2, lines 1 to 3)."

Since - also undisputedly - prevention means that the pharmaceutical preparation as claimed has to be administered before the disease starts in the patient at risk of contracting this disease, patients with recent myocardial infarction are exactly in the situation where as a consequence of the results of the GISSI-Prevenzione trial medication with an essential fatty acid mixture comprising eicosapentaenoic acid ethyl ester (EPA) and docosahexaenoic acid ethyl ester (DHA) is to be started.

In turn, while administering the claimed pharmaceutical preparation to patients with recent myocardial infarction - as was done in the GISSI-Prevenzione trial - the claimed teaching is inevitably anticipated, since prevention of chronic heart failure is in fact achieved.

6.3.2 *Auxiliary request III*

The single difference to claim 1 of the auxiliary request I is the use of the word "medicament" instead of the term "pharmaceutical preparation".

Thus, the same argumentation applies for this request as for auxiliary request I and it too is anticipated.

6.3.3 *Auxiliary request IV*

The only additional features with respect to auxiliary request III are

– wherein the content of EPA+DHA in the mixture is about 85% by weight,

and

– wherein the essential fatty acid mixture is administered by an oral route at a dose ranging from about 0.7 g and about 1.5 g daily.

Both features are anticipated in the teaching of document (1), since daily doses of the claimed essential fatty acid mixture "as a 1 g capsule containing 850 mg eicosapentaenoic acid and docosahexaenoic acid as ethyl esters" were administered there (see page 949, left-hand column, second paragraph, lines 13 to 17).

This administration concerns the oral route (capsule), a dose between about 0.7 g and about 1.5 g daily (1 g) and an 85% by weight content of EPA+DHA in the mixture (850 mg of 1 g).

Thus, again, the same argumentation applies for this request as for auxiliary request I.

7. *Further arguments of the appellant*

7.1 The appellant argued that he was entitled to restrict to "treatment" alone since "prevention and treatment" was contradictory.

However, even if the board were to refrain from reading "for prevention and treatment" as a short form of "for a disease selected from prevention and treatment" which usually is accepted, the only amendment following from this argumentation is to replace the word "and" by "or". There is absolutely no need to prefer either "prevention" or "treatment" when dismissing one of the terms in order to remove the alleged contradiction. Thus, the choice of "treatment" is arbitrary and not inevitable; the latter being necessary for allowability of this choice in the context of the other amendments of the subject-matter as claimed.

7.2 A similar argumentation applies to the amendment of the list of other therapeutic agents for combined therapy.

Since there is no real need to adjust this list to a new perception of agents normally used in heart therapy nowadays, the amendment is arbitrary and not inevitable; it is not allowable in the context of the subject-matter as claimed.

7.3 The use of the word "about" together with "84% by weight content" of EPA+DHA in the essential fatty acid mixture may under certain circumstances include 85%, but the focus of the examples and even the whole application as originally filed was on 85%. Therefore, a generalisation of incidentally mentioned 84% on the

whole subject-matter of the application is not allowable.

8. The board concludes that the subject-matter of claims 1 of the main request and auxiliary request II of the application in suit was not originally disclosed in the application as originally filed (Article 123(2) EPC) and the subject-matter of claims 1 of the auxiliary requests I, III and IV is anticipated by the teaching of document (1) (Article 54(2) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald