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Bezeichnung der Erfindung: Pharmaceutical compositions  
Title of invention:  
Titre de l'invention :

Klassifikation / Classification / Classement : A61K 31/425

**ENTSCHEIDUNG / DECISION**

vom / of / du 23. 12. 1986

Anmelder / Applicant / Demandeur : EFAMOL

Patentinhaber / Proprietor of the patent /  
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Art. 84

Kennwort / Keyword / Mot clé :

"Clarity of the term 'physiologically functional' (positive)"

Leitsatz / Headnote / Sommaire

Europäisches  
Patentamt  
Beschwerdekammern

European Patent  
Office  
Boards of Appeal

Office européen  
des brevets  
Chambres de recours



Case Number : T 139/85

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.1  
of 23 December 1986

**Appellant :** EFAMOL LIMITED  
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**Representative :** Caro, William Egerton  
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**Decision under appeal :** Decision of Examining Division 001 of the European  
Patent Office dated 09.01.85 refusing European  
patent application No. 81 300 867.9 pursuant to  
Article 97(1) EPC

**Composition of the Board :**

**Chairman :** K. Jahn  
**Member :** F. Antony  
**Member :** G. Paterson

### Summary of Facts and Submissions

- I. European patent application No. 81 300 867.9, filed on 3 March 1981, claiming British priority of 14 March 1980 and published on 7 October 1981 under publication number 37 175 was refused by a decision of the Examining Division 001 on 18 October 1984, dispatched 9 January 1985. The decision was based, for the Contracting States BE, CH, DE, FR, GB, IT, LI, LU, NL, SE, on fourteen claims submitted 28 August 1984, without Claim 15 filed 3 November 1983, which the Examining Division apparently assumed had been dropped; and, for the Contracting State AT, on twelve claims equally submitted 28 May 1984.

Of the claims for the Contracting States other than Austria, independent Claims 1 and 15 read (after correction of a spelling error):

- "1. A pharmaceutical composition comprising gamma-linolenic acid and/or dihomogamma-linolenic acid or a physiologically functional salt, ester or other derivative thereof, and thioproline, alone or in an acceptable pharmaceutical vehicle.
15. A pharmaceutical pack comprising the materials set out in any preceding claim presented separately, or one or more separately and others together, but for conjoint administration."

The only independent claim of the set for Austria, Claim 1, read:

- "1. The use of gamma-linolenic acid and/or dihomogamma-linolenic acid or a physiologically functional salt, ester or other derivative thereof, together with

thioproline, alone or in an acceptable pharmaceutical vehicle, for the method of producing a pharmaceutical composition for treatment of cancer."

- II. The reason for the refusal was that, in the view of the Examining Division, the requirements of Article 84 EPC as regards clarity were not met insofar as the term "physiologically functional ... other derivatives thereof" was concerned. While Rule 29(1) EPC requires the claim to define the subject-matter in terms of technical features, the chemical nature of the claimed "other derivative" was obscure in itself and also when the description was consulted; once unclear, it could not be rendered clear by qualifying it as "physiologically functional" or by the subsequent mentioning of examples of other derivatives. This objection applied equally to Claim 1 of the AT set.
- III. On 1 March 1985 the Applicants (Appellants) filed a Notice of Appeal against the above decision, paying the prescribed fee. The Grounds of Appeal were submitted on 26 April 1985, together with a complete specification and claims containing numerous detailed amendments as set out on pages 4 to 5 of the Grounds of Appeal. Further amendments were submitted on 18 November 1986, following a telephone conversation between the Rapporteur and the Appellants' representative.
- IV. While Claim 1 of both sets of claims still reads as set forth in section I hereinabove, the set for Contracting States other than Austria now contains two further independent claims, reading as follows (taking into consideration a correction in Claim 15 agreed over the telephone on 26 November 1986).

- "14. The use of gamma-linolenic acid and/or dihomo-gamma-linolenic acid or a physiologically functional salt, ester or other derivative thereof and of thioproline in the manufacture of a product for the conjoint treatment of cancer.
15. A pharmaceutical pack comprising the materials set out in any preceding claim including at least the two essential components set out in Claim 1 presented separately, or one or more separately and others together, but for conjoint administration."
- V. The Appellants argue that the same kind of wording has been accepted in five other European Patents granted to them, and that such wording is not unfairly broad and is wholly clear; other derivatives exist and are easily identifiable as suitable. Nothing in the EPC forbids functional claim language. To deny coverage for "physiologically functional" derivatives other than salts and esters would deprive the Appellants of meaningful protection. They therefore request that the impugned decision be set aside and that a patent be granted on the basis of the present two sets of claims. They further request refund of the Appeal Fee.

#### Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC; it is, therefore, admissible,
2. There can be no formal objection to the present claims under Article 123(2) EPC. The same applies to all but one of the amendments proposed for the description on 26 April 1985. For most of these, this is so clearly recognizable that it requires no explanation. The amendment to page 9,

line 22, is justified in view of page 6, lines 23 to 24, and the one to page 12, line 3, in view of page 11, lines 8 et seq., of the original documents.

The Board is not satisfied as to the justification, under Article 123(2) EPC, of the proposed substitution of "8,11,14-eicosatrienoic acid" for "5,8,11-eicosatrienoic acid" in the reaction scheme on page 2: The cited pages from Fieser and Fieser "Organic Chemistry" do not show the correct structure, and the further explanations in the enclosures to the Appellants' letter dated 17 November 1986 are no conclusive proof. The Board, therefore, makes use of the authorization by the Appellants to totally delete the said term (Appellants' letter received 18 November 1986, last three lines of second paragraph). This deletion brings about no restriction of scope.

3. Before judging on the clarity of the objected term "... other derivative", it must first be decided whether or not, on its proper construction, this is strictly qualified by the attribute "physiologically functional", or whether it could possible cover any derivative other than salts and esters, irrespective of whether such "other" derivative is or is not "physiologically functional" (the said attribute possibly referring only to the salts and esters).
  - 3.1. Grammatically, if "physiologically functional" was to refer only to "salt" and "ester", the whole phrase would have to read "a physiologically functional salt or ester or another derivative". The enumeration of "... salt, ester or other derivative" immediately following "a physiologically functional ..." would certainly suggest that the latter attribute relates to each of the three following nouns. In the Board's judgement, this is the proper construction of this term.

- 3.2. Furthermore, the case history shows that all derivatives to be covered were to be "physiologically functional": The original Claim 1 referred, without specifying salts or esters, to just a "physiologically functional derivative" of either gamma-linolenic or dihomogamma-linolenic acid. It was only after the Examining Division objected to the clarity of the expression "physiologically functional derivative" that the Applicants tried to overcome this objection by referring, at first, in the claims submitted 3 November 1983, to those derivatives specified in the original documents -salts and esters -and, following these, to "other" physiologically "acceptable" derivatives; and after this was not accepted they took resort to the terms of present Claim 1. Hence it is clear that the Appellants have at all times sought to cover all "physiologically functional" derivatives -irrespective of their chemical nature (salts, esters or "others") - and conversely, that the attribute "physiologically functional" refers to the "other" derivatives as well as to the salts and esters.
- 3.3. Accordingly, the allowability of the term "other derivatives", under the clarity requirements of Article 84 EPC and otherwise, must not be viewed in isolation, but only with respect to the whole term "physiologically functional ... other derivative". Moreover, as the complete expression "physiologically functional salt, ester or other derivative" is intended to cover physiologically functional salts, physiologically functional esters and physiologically functional "other" derivatives ("other" meaning all others), it has no meaning different from the original "physiologically functional derivative" and should be judged accordingly, without regard to the word "other". The

question then is simply whether it is permissible to define a derivative solely by the term "physiologically functional".

4. The term "physiologically functional" is, of course, itself a functional feature. The Examining Division has - correctly - not objected to this term to the extent it is being applied to salts and esters.
  - 4.1. This Board has decided in its recent decision T 68/85 "Synergistic Herbicides/Ciba-Geigy" dated 27 November 1986 (to be reported in the Official Journal):

"Functional features defining a technical result are permissible in a patent claim if, from an objective viewpoint, such features cannot otherwise be defined more precisely without restricting the scope of the invention, and if these features provide instructions which are sufficiently clear for the expert to reduce them to practice without undue burden, if necessary with reasonable experiments" (English translation of official Headnote in German language).
  - 4.2. The afore-quoted criteria are met, in the present case, by the term "physiologically functional", irrespective of whether it applies to salts, to esters or to "other" derivatives (or simply to "derivatives" in general):
    - 4.2.1. It is extremely difficult, if not impossible, to find a specific chemical term or plurality of terms defining all those derivatives - existing and yet to be synthesized - of gamma-linolenic and of dihomogamma-linolenic acid which are "physiologically functional", i.e. which - in the context of the invention - have the same physiological function as the free acids, e.g. by being convertible in the body thereto. Certainly is it impossible, as the examples of amides and phospholipids



prove (Appellants' letter received 3 November 1983, page 2, third paragraph), to find an enumeration of such terms which is also permissible under Article 123(2) EPC. Accordingly, the Board sees no way in which the functional feature "physiologically functional" could "otherwise be defined more precisely without (unduly) restricting" the claim.

4.2.2. The said feature is also "sufficiently clear for the expert to reduce (it) to practice without undue burden"; for the expert clearly understands its meaning (cf. preceding paragraph 4.2.1), and if in doubt with respect to a particular derivative whether it is "physiologically functional", he can without undue burden, i.e. by means of reasonably simple experiments, determine this.

4.3. Accordingly, in the Board's judgement, the term "physiologically functional", when applied to "derivatives" or "other derivatives" (i.e. derivatives other than salts and esters) meets the clarity requirements of Article 84 EPC in the context of the present invention.

5. The Board agrees with the Examining Division's statement (paragraph 7 of part II of the impugned Decision, page 7, referring to item 1.3 on page 3 of the Official Action dated 30 March 1984) that the claimed subject-matter is novel and involves an inventive step: None of the cited references anticipates all features of the invention, and the experimental evidence given on pages 8 and 9 of the Applicants' letter received 3 November 1983 renders it plausible that the problem of the invention - enhanced inhibition of the growth of malignant cells - is unexpectedly solved by the synergistic combination of Claim 1. This claim is, therefore, patentable.

6. Independent Claims 14 and 15 of the set for Contracting States other than Austria are based on the same inventive concept as Claim 1. The above considerations on the clarity of the term "physiologically functional" and on the substantive patentability requirements (novelty, inventive step) are therefore equally applicable to them. As to the form of these claims, Claim 14 corresponds to the claim form held allowable in the Decision of the Enlarged Board of Appeal Gr. 05/83 of 5 December 1984 (OJ 3/1985, 64); while Claim 15 corresponds to the claim form held allowable in this Board's Decision T 9/81 of 25 January 1983 (OJ 9/1983, 372).

There being no objection as to form either, Claims 14 and 15 are, therefore, also allowable.

Claims 2 to 13 of the set for Contracting States other than Austria relate to preferred embodiments of the subject-matter of Claim 1 and are thus equally allowable.

7. The appeal is therefore allowed.
8. In the second paragraph of item 5 on page 6 of the impugned Decision, the Examining Division has left it undecided whether the set of claims for Austria needs further amendment.
  - 8.1. In item 8 on page 5 of its Official Action dated 30 March 1984, the Examining Division had stated :
    - (i) that the objections to the set for the other Contracting States applied *mutatis mutandis* to the one for Austria; and

- (ii) that the phrase "The use of Claim 1" in Claim 2 did not seem to make sense.

In order to overcome the second objection, the Applicants had, in the fresh set of claims submitted on 28 May 1984, substituted "set out in Claim 1" for "of Claim 1" making abundantly clear what in the Board's view was already sufficiently intelligible from the previous version. Up to this point, there having been no further changes in the passage concerned, the claims for Austria need no further amendment.

8.2. It is not for the EPO to judge any objection under Austrian law, in view of that country's reservations under Article 167(2) EPC, to the set of claims for that country. All that the EPO has to judge is whether these claims are allowable under the European Patent Convention as a whole.

8.2.1. Claim 1 of the set of claims for Austria, apart from immaterial minor differences, corresponds to allowable Claim 14 of the set for the other Contracting States and is, therefore, also patentable.

8.2.2. Claims 2 to 12 of the set of claims for Austria after correction of an obvious error agreed with the Appellants over the telephone ("the quinoline derivative" instead of "quinocrine" in the third line of Austrian Claim 11) correspond to the allowable claims with identical numbering for the other Contracting States and are thus equally patentable.

8.3. The claims for Austria therefore need no further amendment.

9. The Appellants request refund of the Appeal Fee because "the Examining Division failed to take duly into account the material available to it at the time the decision was made, particularly the prior accepted cases" (emphasis added, see paragraph 5.2 on page 20 of Appeal Grounds submitted 26 April 1985).
  - 9.1 According to Rule 67 EPC, "the reimbursement of appeal fees shall be ordered ... where the Board of Appeal deems an appeal to be allowable, if such reimbursement is equitable by reason of a substantial procedural violation".
  - 9.2 This Board has allowed the appeal because it does not agree with the Decision of the Examining Division on the substantive question as to the allowability of the claims having regard to the provisions of Art. 84 EPC. However, in the Board's view, there was no procedural violation by the Examining Division in the present case. For this reason, reimbursement of the appeal fee cannot be ordered.

Order

For these reasons,

it is decided that:

1. The impugned decision is set aside.
2. The case is remitted to the first instance with an order to grant a patent on the basis of the following documents:

- set of claims for Contracting States other than Austria: Claims 1 to 13 submitted 26 April 1985, subject to correction of the spelling of "pharmaceutical" in line 1 of Claim 1 and of "diiodohydroxyquin" in line 3 of Claim 5;


Claims 14 and 15 submitted 18 November 1986, subject to correction of "compounds" in line 3 of Claim 15, to read "components";

- set of Claims for Austria: Claims 1 to 12 submitted 26 April 1985, subject to correction of "quinochrine" in line 3 of Claim 11 to read "the quinoline derivative";

- Description: pages 1, 3, 4 and 6 to 12 submitted 26 April 1985;

pages 2 and 5 submitted 18 November 1986, subject to deletion from the reaction scheme on page 2 of "(8,11,14-eicosatrienoic acid)" and transfer to the site thereof of the term "dihomo-gamma-linolenic acid (DGLA)" from the preceding line.

3. Reimbursement of the appeal fee is refused.

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