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**Datasheet for the decision
of 23 February 2011**

Case Number: T 0779/09 - 3.3.01

Application Number: 02002360.2

Publication Number: 1231213

IPC: C07F 9/10

Language of the proceedings: EN

Title of invention:

Procedure for the preparation of pure phosphatides and their use in the cosmetic, pharmaceutical and alimentary fields

Patentee:

FIDIA FARMACEUTICI S.p.A.

Opponent:

CHEMI SPA

Headword:

Preparation of pure phosphatides/FIDIA FARMACEUTICI S.P.A.

Relevant legal provisions:

EPC Art. 123(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Added subject-matter - (yes) - subject-matter not originally disclosed"

Decisions cited:

-

Catchword:

-



Case Number: T 0779/09 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 23 February 2011

Appellant: FIDIA FARMACEUTICI S.p.A.
(Patent Proprietor) Via Ponte della Fabbrica 3-A
I-35031 Abano Terme (Padova)

Representative: Coletti, Raimondo
Barzanò & Zanardo Milano S.p.A.
Via Borgonuovo, 10
I-20121 Milano (IT)

Respondents: CHEMI SPA
(Opponent) Via dei Laboratori 54
I-20092 Cinisello Balsamo, Milano (IT)

Representative: Pistolesi, Roberto
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Via Marina 6
I-20121 Milano (IT)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 26 January 2009
revoking European patent No. 1231213 pursuant
to Article 102(1) EPC.

Composition of the Board:

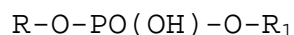
Chairman: P. Ranguis
Members: J.-B. Ousset
C.-P. Brandt

Summary of Facts and Submissions

- I. The appellant (patentee) lodged an appeal against the decision of the opposition division which revoked the European patent No. 1 231 213.
- II. The opposition division revoked the patent, because the subject-matter of claims 9, 10, 12-14 of the main request were not novel vis-à-vis document (7) (EP 776 976) and document (2) (EP 1048738). First auxiliary request was considered as not involving an inventive step in view of document (2) as the closest prior art in combination with documents (5) (Nakajima et al. Biotech. and Bioeng. Chemistry (1973), 37(7), 1667-72) and document (14) (Chiaki Ogino et al.; J. Biochem. (1999), 125, 263-9).
- III. With its statement setting out the grounds of appeal the appellant submitted a main request and three auxiliary requests which claims 1 read as follows:

Claim 1 of the main request read as follows:

"1. A process for the preparation of phosphatides with high yields of products and a high degree of purity, having the formula (I):



wherein R is diacylglycerol and R₁ is an alcoholic group which process comprises:

reacting a phosphatide of the formula (II):

R-O-PO(OH)-O-R₂, wherein R means as above and R₂ is

CH₂-CH₂-NH₂ and/or CH₂-CH₂-N(CH₃)₃, with a primary or secondary alcohol with a chain length of between C₂ to C₄, possibly substituted by one or more polar groups selected from the group consisting of amino, hydroxy and carboxy, in a single aqueous phase in the presence of phospholipase D with transphosphatidyltion activity produced from a *Streptomyces hachijoense* strain, wherein the phosphatide with the formula (I) is

- (a) phosphatidylethanolamine, phosphatidylhomoserine, phosphatidylhydroxyproline, phosphatidylglycerol or
- (b) phosphatidylserine;

said process being further characterized in that it is carried out by one single reaction step and one single precipitation step, using a purified fraction of phospholipase D from *Streptomyces hachijoense* strain, with a complete conversion of the substrate when the phosphatide of formula (I) is phosphatidylserine."

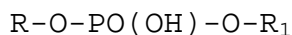
Claim 1 of the first auxiliary differs from claim 1 of the main request in that the feature "...purified on an anionic and cationic exchange resin and further eluted at pH 6.2 from the cationic exchange resin..." was introduced before the feature "...with a complete conversion of the substrate when the phosphatide of formula (I) is phosphatidylserine."

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the feature "...purified on an anionic and cationic exchange resin and further eluted at pH 6.2 from the cationic exchange

resin, and in an acetate buffer at pH 5.6..." was introduced before the feature "...with a complete conversion of the substrate when the phosphatide of formula (I) is phosphatidylserine."

Claim 1 of the third auxiliary request read as follows:

"1. A process for the preparation of phosphatides with high yields of products and a high degree of purity, having the formula (I):



wherein R is diacylglycerol and R₁ is an alcoholic group which process comprises:

reacting a phosphatide of the formula (II):

R-O-PO(OH)-O-R₂, wherein R means as above and R₂ is CH₂-CH₂-NH₂ and/or CH₂-CH₂-N(CH₃)₃, with a primary or secondary alcohol with a chain length of between C₂ to C₄, possibly substituted by one or more polar groups selected from the group consisting of amino, hydroxy and carboxy, in a single aqueous phase in the presence of phospholipase D with transphosphatidylase activity produced from a *Streptomyces hachijoense* strain, wherein the phosphatide with the formula (I) is

- (c) phosphatidylethanolamine, phosphatidylhomoserine, phosphatidylhydroxyproline, phosphatidylglycerol or
- (d) phosphatidylserine;

said process being further characterized in that it is carried out by one single reaction step and one single precipitation step, using a purified fraction of phospholipase D from *Streptomyces hachijoense* strain, purified on an anionic and cationic exchange resin and further eluted at pH 6.2 from the cationic exchange resin, and in an acetate buffer at pH 5.6, and, when the phosphatide of formula (I) is phosphatidylserine, with a complete conversion of the substrate to produce a phosphatidylserine with a titer of 95% and phosphatidic acid with a titer of 5%, using as substrate, a pure lecithin having a phosphatidylcholine content of 95%."

IV. As far as they are relevant for the present decision, the appellant's arguments can be summarized as follows:

- Basis of the amendments was to be found in the description as filed (see page 3, lines 11 to 17 and page 4, lines 14 to 15).

V. The respondent (opponent) argued as follows:

- The absence of the expression "100% aqueous environment" in connection with the expression added to claim 1 of each request, namely "...one single reaction and one single precipitation step..." contravened Article 123(2) EPC.

VI. With a communication accompanying the summons to oral proceedings, the board informed the parties that the objections of the respondent, in particular as far as Article 123(2) EPC was concerned, appeared relevant and that the appeal was likely to be dismissed.

- VII. With a letter of 23 December 2010, the appellant informed the board that it will neither be present nor represented at the oral proceedings scheduled on 23 February 2011.
- VIII. In view thereof, the board cancelled the invitation to oral proceedings.
- IX. The appellant requested that the decision of the opposition division of 26 January 2009 be set aside and that the patent in suit be maintained either on the basis of the main request or on one of the three auxiliary requests filed on 15 May 2009 with its statement setting out the grounds of appeal.
- X. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

All requests

2. Amendments
 - 2.1 In claim 1 of the main request as well as in claim 1 of auxiliary requests 1 to 3, the expression "...one single reaction step and one single precipitation step..." has been added in the characterizing part of the process of claim 1.

2.2 The appellant pointed out that a basis for such an amendment was present in the description as originally filed (see page 3, lines 11 to 17).

The said expression is actually mentioned on page 3, line 17 of the description as originally filed but characterizes a process which is run in a 100% aqueous environment (see page 3, line 14 of the description as originally filed). The nature of the solvent is not mentioned in the process claimed in claim 1 of the respective requests. Therefore, the claimed subject-matter of claim 1 of all the requests on file encompasses not only processes in which the solvent is 100% aqueous but also processes in which the solvent is different.

Neither the appellant nor the board could find in the description as originally filed a basis for a process as claimed in claim 1 of all the requests on file which is run in **one single reaction step and one single precipitation** in presence of a solvent different from water.

2.3 Therefore, all the requests currently on file contravene the requirements of Article 123(2) EPC and are to be rejected.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

M. Schalow

P. Ranguis