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Datasheet for the decision of 8 April 2008

Case Number:	T 1204/06 - 3.3.01			
Application Number:	01124577.6			
Publication Number:	1213294			
IPC:	C07F 9/10			
Language of the proceedings:	EN			

Title of invention:

Purifying process for phosphatidylserine

Patentee:

CHEMI S.p.A.

Opponent: Fidia Farmaceutici S.P.A.

Headword: Purification of phosphatidylserine/CHEMI

Relevant legal provisions:

EPC Art. 100(a), 114(2), 123(2) EPC R. 80

Keyword:

"Admission of late filed documents" "Interpretation of the claims - rule out interpretations which do not make technical sense" "Novelty and inventive step - yes" "Adaptation of the description - only as far as due to amendments in the claims after grant"

Decisions cited:

T 0190/99, T 0920/00, T 0197/86, T 0323/05

Catchword:

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 1204/06 - 3.3.01

DECISION of the Technical Board of Appeal 3.3.01 of 8 April 2008

Appellant: (Patent Proprietor)	CHEMI S.p.A. Via dei Lavoratori, 54 I-20092 Cinisello Balsamo (Milano) (IT)
Representative:	Pistolesi, Roberto Dragotti & Associati srl Via Marina 6 I-20121 Milano (IT)
Respondent: (Opponent)	Fidia Farmaceutici S.P.A. Via Ponte Della Fabbrica, 3/A I-35031 Abano Terme (IT)
Representative:	De Gregori, Antonella Barzano' & Zanardo Milano S.p.A. Via Borgonuovo 10 I-20121 Milano (IT)
Decision under appeal:	Decision of the Opposition Division of the European Patent Office posted 22 June 2006 revoking European patent No. 1213294 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman:	P.	Rar	nguis
Members:	С.	Μ.	Radke
	С	-P.	Brandt

Summary of Facts and Submissions

- I. The Proprietor of the patent appealed against the decision of the opposition division revoking European patent No. 1 213 294.
- II. The opposition was directed against the patent in its entirety and was based on grounds under Article 100(a) EPC (alleged lack of novelty and inventive step).
- III. Inter alia the following documents were cited during the opposition procedure:
 - (D8) S. L. Abidi, Journal of Chromatography B, vol. 717 (1998), 279-293
 - (D9) N. S. Radin, Methods in Enzymology, vol. 72 (1981), 5-7
 - (D10) P. Comfurius et al., Journal of Lipid Research Note on Methodology, vol. 31 (1990), 1719-1721
 - (D12) EP-A-0 776 976
 - (D13) Comparative tests filed by the Proprietor (now Appellant) during opposition proceedings with the letter dated 27 April 2006
 - (D15) EP-A-1 048 738
- IV. The opposition division decided that the amendments in the claims of the Main and the First and Third to Fifth Auxiliary Requests contravened the requirements of Article 123(3) EPC and rejected these requests. The Sixth Auxiliary Request was rejected for lack of clarity of the claims.

The subject-matter of the claims of the Second Auxiliary Request was deemed to be novel but not to involve an inventive step.

V. The only independent claim of said Second Auxiliary Request is claim 1 which reads as follows:

"1. Purifying process for phosphatidylserine having formula (I)

CH₂OR₁ CHOR₂ CH₂O—P(=O)—OCH₂—CH(NH₂)—COOH (I)

where R₁ e R₂, identical or different, are a C₁₀-C₃₀ acyl group; X is OH or OM, where M is chosen from the group of alkali metals, alkaline-earth metals, ammonium and alkyl ammonium, and where the serine portion is in D, L or racemic form, and preferably in L form, in which said phosphatidylserine having formula (I) is prepared by trans-phosphatidylation of phosphatidylcholines of natural or synthetic origin with serine in the presence of the enzyme D-phospholipase, comprising the extraction of said phosphatidylserine from a solution in a hydrocarbon solvent with a mixture of water and a alcohol solvent chosen among secondary and tertiary alcohols."

VI. In particular, the opposition division acknowledged that the subject-matter of the claims of the Second Auxiliary Request was novel as none of the documents disclosed to extract the solution of phosphatidylserine with a mixture of water and a secondary or tertiary alcohol. Document (D12) was considered to be the closest prior art. The problem to be solved was seen as the provision of an effective process for purifying phosphatidylserine prepared by trans-phosphatidylation of phosphatidylcholines with serine in the presence of the enzyme D-phospholipase, and containing as impurities hydrophilic compounds, proteins and inorganic salts. The opposition division was of the opinion that the claims did not address such a process as they dealt with the extraction of phosphatidylserine from a hydrocarbon solution which does not work as the phosphatidylserine remained in the hydrocarbon solution and concluded that the problem posed was not solved.

Therefore, the opposition division decided that the subject-matter of the claims of the Second Auxiliary Request did not involve an inventive step.

- VII. During the appeal procedure the parties cited *inter alia* the following additional documents:
 - (D26) JP-A-05 097 874 and a translation thereof into English
 - (D27) W. W. Christie, Advances in Lipid Methology -Two, (1993), 195-213
 - (D39) D. E. Vance and J. Vance, Biochemistry of Lipids, Lipoproteins and Membranes, Elsevier, Amsterdam/NL 1991, 215-218, 290-292
- VIII. A third party filed observations in the letters dated 22 and 29 February 2008 in which the following documents were cited:

- (A1) JP-A-64-80 285 and a translation thereof into English
- (A2) N. I. Sax, Dangerous Properties of Industrial Materials, fifth edn. (1979), Van Nostrand Reinhold Company, New York/US, 648 and 663
- (A3) N. G. Andersson, Practical Process Research & Development, Academic Press, San Diego/US (2000), 2 pages without numbering
- (A4) Experimental report, 3 pages
- IX. The claims on file are
 - claims 1-13 of the Main Request,
 - claims 1-12 of the First Auxiliary Request,
 - claims 1-12 of the Second Auxiliary Request,
 - claims 1-11 of the Third Auxiliary Request,
 - claims 1-13 of the Fourth Auxiliary Request,
 - claims 1-12 of the Fifth Auxiliary Request,
 - claims 1-12 of the Sixth Auxiliary Request,
 - claims 1-11 of the Seventh Auxiliary Request,
 - all filed with the letter dated 31 March 2008.

The wording of claim 1 of the present Main Request is identical with the claim 1 of the Second Auxiliary Request rejected in the decision under appeal with the exception that "a alcohol" was replaced by "an alcohol" (see point V above).

X. The Appellant's arguments may be summarised as follows:

(a) As to the interpretation of the claims

The interpretation of the opposition division, that the claims read on a process in which the phosphatidylserine is extracted from the hydrocarbon solution - and not the polar impurities - does not make sense as phosphatidylserine is hydrophobic. The claims are to be interpreted so that they make technical sense (see T 190/99 of 6 March 2001), namely as relating to a process where the impurities are extracted from the solution of the phosphatidylserine in the hydrocarbon solvent.

(b) As to Article 123(2) EPC

The insertion of the expression "in the presence of the enzyme D-phospholipase" has its basis in the paragraph at page 2, lines 22-25 of the application as originally filed. This paragraph referred, so he argued, to the problem to be solved and thus to the claimed invention.

(c) As to novelty

He argued that document (D8) referred in chapter 2.1.2 to the extraction of a biological tissue with a mixture of hexane and isopropanol, whereas the present claims taught the extraction of phosphatidylserine prepared by the reaction of phosphatidylcholines with serine in the presence of D-phospholipase. He deemed that this specific disclosure in document (D8) could not be combined with the general statement in this document that phosphatidylserine could also be synthesized by an enzymatic exchange reaction in which a base group was replaced by serine (see page 280, lines 1-4 of the right column). (d) As to inventive step

The Appellant considered document (D12) to represent the closest prior art. The problem to be solved in view of (D12) was to reduce the amount of the impurities in the product. The comparative tests (D13), so he argued, showed that this problem was indeed solved. The documents of the prior art could not render the subject-matter claimed obvious as

- document (D15) suggested to purify
 the phosphatidylserine merely by washing with
 water;
- documents (D8) and (D9) only disclosed
 the extraction of tissues with a mixture of hexane
 and isopropanol, and
- neither documents (D26) and (D27) disclosed that the extraction with a solvent mixture containing a secondary or tertiary alcohol instead of a primary one could be advantageous.

(e) As to documents (D39) and (A1) to (A4)

He argued that the date stamp on document (D39) showed that this document had been in the possession of the Respondent since 1992. As the document was not relevant it should not be taken into account.

Concerning documents (A1) to (A4), he concluded from the footnote on each page of the letter dated 22 February 2008 that these documents had not been filed by a third party but by the Respondent. He considered this an abuse of the procedure. XI. The arguments of the Respondent may be summarised as follows:

(a) As to the interpretation of the claims

The claim clearly reads on an extraction of the phosphatidylserine from the solution in a hydrocarbon; it thus does not need to be interpreted in view of the description.

(b) As to Article 123(2) EPC

He argued that the paragraph at page 2, lines 22-25 of the application as filed did not refer to the invention but to the prior art. The part of the application relating to the alleged invention only discloses a specific D-phospholipase having an activity of 3 KU/1.

(c) As to novelty

He argued that document (D8) was not restricted to the extraction of tissues as disclosed in chapter 2.1.2 because it mentioned that the phosphatidylserine "... can also be synthesized by an enzymatic exchange reaction in which a base group in a GPL is replaced by serine" (see page 280, lines 1-4 of the right hand column).

(d) As to inventive step

The Respondent considered that either of the documents (D10) or (D12) could represent the closest prior art.

The subject-matter claimed differed from the teaching of (D12) in that (D12) did not disclose an extraction with a solvent mixture containing water and a secondary or tertiary alcohol.

The use of water to obtain a better purification from serine was deemed to be obvious in view of (D15), (D8) or (D9), the use of isopropanol in view of document (D26) or (D27).

He presented an analogous line of argumentation starting from document (D10) and combining its teaching with the disclosure of any of the documents (D8), (D9), (D26) and (D27).

He considered the comparative tests (D13) not to be relevant as they

- did not provide a proper comparison with the closest prior art, and
- were in contradiction with the results of the examples given in the patent in suit.

(e) As to the adaptation of the description

The Respondent considered example 7 not to be in line with the amended claims.

XII. The Appellant requested

- that the documents (A1) to (A4) alleged to be filed by a third party and (D39) were not admitted to the procedure, that the decision under appeal be set aside and the patent be maintained on the basis of the Main Request or any of the First to Seventh Auxiliary Requests, all filed with the letter dated 31 March 2008.

The Respondent requested that the appeal be dismissed.

XIII. During the oral proceedings the Board informed the parties that it did not admit document (D39) while admitting documents (A1) to (A4) filed by the third party to the appeal procedure. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

- 1. The appeal is admissible
- 2. Documents (D39) and (A1) to (A4)
- 2.1 The second cover page of document (D39) bears a stamp reading as follows "FIDIA S.p.A. Biblioteca ... datà entrata" with "06.05.92" added in handwriting. This is an indication that the respective book or copies thereof have been entered into the library of the Respondent in 1992. The Respondent did not deny this.

The document was cited by the Respondent in his letter dated 14 March 2008, i.e. more than one year after his response to the statement setting out the grounds for appeal. It was cited in order to show that the transphosphatidylation could be carried out with different enzymes, e.g. with D-phospholipase or serineexchange enzyme (see the second paragraph on page 3 of said letter). This aspect is irrelevant for the subject-matter claimed which does not deal with the transphosphatidylation reaction but with the purification of the product obtained.

Consequently, the Board decided not to admit this document to the appeal procedure.

2.2 In contrast to this, document (A1) discloses the purification by solvent extraction of a phospholipid obtained by a transphosphatidylation reaction (see chapter 1, second paragraph on page 12 of the translation).

> For this reason, this document is prima facie relevant and the Board used its discretion under Article 114(2) EPC by admitting it to the proceedings together with documents (A2) to (A4) completing the line of arguments of the third party.

Main Request

- 3. Interpretation of the claims
- 3.1 The paragraph under dispute of present claim 1 is the following:

"comprising the extraction of said phosphatidylserine from a solution in a hydrocarbon solvent with a mixture of water and an alcohol solvent chosen among secondary and tertiary alcohols."

- 3.2 In the decision under appeal, the opposition division had interpreted the respective paragraph in claim 1 as granted to mean that "... the phosphatidylserine is extracted into the water/polar organic phase which we know is not the case in practice." (see the third paragraph under point VI).
- 3.3 In practice, so the opposition division stated in the decision under appeal, the phosphatidylserine remains in the hydrocarbon phase whereas the impurities are extracted into the water/polar organic phase, namely the water/alcohol phase (see the second paragraph under point VI; see also page 3, lines 14-18 of the application as originally filed).

Hence, it is apparent that the interpretation of present claim 1 outlined under point 3.2 above and shared by the Respondent, namely an interpretation that clings strictly to the wording, is unrealistic.

3.4 The claims are, however, directed to the person skilled in the art who will rule out interpretations which are illogical or do not make technical sense (see T 190/99 of 6 March 2001, point 2.4 of the reasons; and T 920/00 of 16 June 2003, point 2.1 of the reasons).

The person skilled in the art will realise from reading claim 1 that the phosphatidylserine to be purified is rather hydrophobic due to the two $C_{10}-C_{30}$ acyl groups R_1 and R_2 (see formula (I) depicted in the claim). In contrast to this, any unreacted serine (the chemical

formula of which is derivable from formula (I) as being HOCH₂-CH(NH₂)-COOH) is a hydroxy functional amino acid and thus very hydrophilic. Therefore, it is immediately evident to the person skilled in the art that the hydrophobic phosphatidylserine remains in the hydrophobic hydrocarbon solvent whereas hydrophilic impurities like serine will enter into the hydrophilic water/alcohol phase during the extraction.

Hence, the person skilled in the art will rule out the interpretation outlined in paragraph 3.2 above and will interpret the paragraph cited under 3.1 above as relating to the extraction of a <u>solution of</u> the phosphatidylserine in a hydrocarbon solvent with a mixture of water and an alcohol solvent chosen among secondary and tertiary alcohols, where phosphatidylserine remains in the hydrocarbon solvent whereas hydrophilic impurities will enter into the water/alcohol phase.

3.5 It is to be noted that the preceding point 3.4 relates to the interpretation of claim 1 as such and not in the light of the description (see point XI(a) above).

4. Article 123 EPC

4.1 The Respondent claimed that the insertion of the expression "in the presence of the enzyme Dphospholipase" into claim 1 had no proper basis in the application as filed because the paragraph on page 2, lines 22-25 of the application related to the prior art and not to the claimed invention. 4.1.1 Said paragraph reads as follows:

"Therefore, there is always the problem related to the availability of an effective purifying process for phosphatidylserines prepared by trans-phosphatidylation of phosphatidylcholine with serine in presence of the enzyme D-phospholipase, and containing as impurities hydrophilic compounds, proteins and inorganic salts."

This is the last paragraph of the chapter "STATE OF THE ART" and is immediately followed by the heading "SUMMARY OF THE INVENTION".

- 4.1.2 Hence, this paragraph discloses the problem to be solved by the subject-matter claimed.
- 4.1.3 Consequently, the amendment under dispute merely brings the claimed process in line with the technical problem to be solved and does not introduce subject-matter extending beyond the content of the application as filed.
- 4.2 Apart from that, present claim 1 is based in claims 1,7 and 15 of the application as originally filed.
- 4.3 Claims 2 to 11 have their basis in original claims 2 to 4 and 8 to 14; claims 12 has its basis in page 3, lines 14-16 of the description, and claim 13 in page 3, lines 19-20 of the description as originally filed.
- 4.4 The scope of the only independent claim has been amended with respect to claim 1 as granted in that

- the polar solvent organic solvent is now specified to be selected from secondary and tertiary alcohols, and
- it is indicated how the phosphatidylserine to be purified in the present process has been manufactured.

These amendments restrict the scope of the claims.

- 4.5 Consequently, the amendments in the claims do not contravene the requirements of Article 123(2) and (3) EPC.
- 5. Novelty

The Respondent's objection is based on document (D8), in particular on chapter 2.1.2 on page 281 and on page 280, lines 1-4 of the right column (see point XI(c) above).

5.1 Chapter 2.1.2 of this document discloses the extraction of a tissue with a solvent mixture of hexane with isopropanol and the washing of the solvent phase with an aqueous sodium sulphate solution.

> This chapter forms part of the section 2.1 entitled "Lipid extraction procedures", which in turn falls under the general section 2. entitled "Isolation techniques". This general section relates exclusively to the isolation from cells and tissue materials (see the first sentence of this general section).

5.2 The sentence at page 280, lines 1-4 of the right column reads as follows: "Alternatively, PS can also be synthesized by an enzymatic exchange reaction in which a base group in a GPL is replaced by serine [13]."

In this sentence, PS stands for phosphatidylserine and GPL for glycerophospholipid (see page 279, the first line of chapter 1, and page 280, left hand column, the first line below Figure 1).

This sentence, however, belongs to the general section 1 entitled "Introduction"; that means that it forms part of the general background disclosed in this document.

- 5.3 There is no direct and unambiguous information in document (D8) which would have induced the person skilled in the art to combine the specific information of chapter 2.1.2 - which is clearly restricted to the extraction of a tissue - with the general background information of chapter 1 stating that phosphatidylserine can also be synthesised by enzymatic reaction of a glycerophospholipid with serine.
- 5.4 The Respondent did not argue that the phosphatidylserine contained in the tissue extracted according to chapter 2.1.2 as such could be considered to be the product of the reaction of a phosphatidylcholine with serine in the presence of Dphospholipase. Nor has the Board a reason to raise such an argument as the type of tissue is not specified in chapter 2.1.2 and the biosynthesis of phosphatidylserine is dependent on the type of tissue

(see page 280, left column, first sentence of the bottom paragraph).

- 5.5 For these reasons the subject-matter of present claim 1 differs from the disclosure of document (D8).
- 5.6 The Board has also verified that none of the other documents cited deprive the subject-matter of claim 1 of novelty.
- 5.7 Consequently, the subject-matter of claim 1 is novel. The same applies to the subject-matter of the remaining claims of the Main Request which are all dependent of claim 1.

6. Inventive step

- 6.1 In accordance with the "problem-solution" approach consistently applied by the Boards of Appeal, it is necessary, in order to assess inventive step, to establish the closest prior art, to determine in the light thereof the technical problem which the invention addresses and successfully solves, and to examine the obviousness of the claimed solution to this problem in view of the state of the art. This approach ensures that inventive step is assessed on an objective basis and avoids an ex post facto analysis.
- 6.2 The closest state of the art is normally a prior art document disclosing subject-matter with the same objectives as the claimed invention and having the most relevant technical features in common.

6.2.1 Document (A1) discloses the production of **phosphatidyl glycerol** by reacting phosphatidyl choline with glycerol in the presence of a certain D-phospholipase and the extraction of the reaction mixture with a mixed solvent of hexane/ether/isopropanol (see the second paragraph on page 12 of the translation).

- 6.2.2 The documents (D10) and (D12) disclose the preparation of phosphatidylserine by trans-phosphatidylation of phosphatidylcholine with serine in the presence of the enzyme D-phospholipase and the purification of the product by solvent extraction. The solvent mixture employed in these extractions was chloroform/methanol in the case of document (D10) and heptane/methanol in the case of document (D12) (see (D10), page 1720, upper half of the left column; (D12), claim 10 and examples 2-4).
- 6.2.3 Of these documents, (D10) and (D12) are more relevant as they aim to purify phosphatidylserine as does the patent in suit. Document (D12) appears to be especially relevant as it discloses - in contrast to (D10) - to use a hydrocarbon, namely heptane, as a solvent during the extraction (as is required according to present claim 1).

So, it is evident that document (D12) - and not (D10) - represents the closest prior art (see point XI(d) above).

6.2.4 More specifically, this document discloses a process for making phosphatidylserine by reacting phosphatidylcholine with serine in the presence of D-phospholipase in a water/organic solvent diphasic

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system (see claims 1 and 3). Phosphatidylserine may be purified from other phospholipids by selective extraction of the respective calcium salt with a heptane/methanol mixture (see claim 10). It can be further purified by crystallisation from heptane/acetone (see claim 11).

- 6.3 According to paragraph [0011] of the patent in suit the problem posed was to provide "an effective purifying process for phosphatidylserines prepared by transphosphatidylation of phosphatidylcholine with serine in presence of the enzyme D-phospholipase, and containing as impurities hydrophilic compounds, proteins and inorganic salts."
- 6.4 It is now to be determined whether or not or to which extent this problem was indeed solved by the claimed subject-matter with respect to document (D12) as the closest prior art.
- 6.5 It was controversial between the parties whether or not the comparative tests (D13) are relevant for assessing the problem solved (see point X(d) and the last paragraph of point XI(d) above).
- 6.5.1 This document discloses in Trial 1 the reaction of a product containing phosphatidylcholine, namely Epikuron 200, in toluene with L-serine in the presence of D-phospholipase. In Trial 3, 200 ml of the reaction mixture in toluene was extracted with a mixture of 100 ml of water and 100 ml of methanol and the phosphatidylserine was isolated from the toluene fraction, whereas in trial 4 the procedure of Trial 3

was repeated with the exception that the methanol was replaced by 100 ml of the secondary alcohol isopropanol.

6.5.2 It is evident that Trial 4 was in accordance with present claim 1 interpreted as outlined in the third paragraph of point 3.4 above.

Trial 3 is not in accordance with present claim 1 in that the primary alcohol methanol was employed (instead in the secondary alcohol isopropanol), namely the alcohol employed in the extraction disclosed in the closest prior art (D12).

6.5.3 The Respondent argued that document (D13) provided no proper comparison with respect to the closest prior art because a higher amount of D-phospholipase was used in Trial 1 as compared to the examples of document (D12).

> However, the teaching of (D12) neither limits the concentration of D-phosholipase nor specifies any preferred concentration range for this enzyme. A higher concentration of the enzyme than specified in the examples of document (D12) is thus still within the preferred teaching of this document.

6.5.4 Moreover, it is evident from point 6.5.2 above that Trials 3 and 4 only differ by the type of alcohol solvent used during the extraction, i. e. by one of the features which distinguish the subject-matter of present claim 1 over the disclosure of document (D12).

These Trials thus provide a proper comparison of the subject-matter claimed with the closest prior art (see

T 197/86, OJ EPO 1989, 371, point 6.1.3 of the reasons).

- 6.5.5 The last page of document (D13) shows that the phosphatidylserine obtained in the comparative Trial 3 contains much more L-serine and phospholipase D than the one obtained in Trial 4.
- 6.5.6 The Respondent argued that this finding was in contradiction with the results of the examples of the patent in suit, especially in view of the results of tests 1 and 4 listed in Table 1 and of examples 2 and 4.

However, the relative amounts of the solvents used in examples 2 and 4 as well as in tests 1 and 4 of the patent in suit differ. Therefore these examples and tests provide no reliable comparison so that no effect caused by the type of alcohol used can be derived therefrom.

- 6.5.7 Hence, trials 3 and 4 of document (D13) demonstrate that the subject-matter of present claim 1 indeed solves the problem mentioned under point 6.3 above in view of the closest prior art.
- 6.6 Then it has to be determined whether or not the person skilled in the art would have solved this problem in view of the prior art as a whole by means of the features of present claim 1, namely by extracting the solution of the phosphatidylserine in a hydrocarbon solvent with a mixture of water and an alcohol solvent chosen among secondary and tertiary alcohols.

6.6.1 Document (D12) does not give any hint that the phosphatidylserine might be extracted with any solvent system other than heptane/methanol (see page 4, lines 5-8 and the examples). So, this document as such cannot render the subject-matter of present claim 1 obvious.

- 6.6.2 Documents (D8), (D9) and (D27) relate to the extraction of phosphatidylserine from **tissues** with hexane/isopropanol (see (D8), chapter 2.1.2 on page 281; see (D9), the title, the first sentence of the article and chapters 5 and 6; see (D27), the title and chapter C starting on page 197, in particular page 198, the fifth paragraph in the right hand column). Therefore, they deal with the isolation and not with the purification of the isolated phosphatidylserine (Note that document (D8) recommends chromatographic purification procedures in chapter 2.2 to be performed after the extractions disclosed in chapter 2.1; document (D27) teaches in chapter D on page 199 to purify the product by further extracting it with hexane/chloroform or with chloroform/methanol). Hence, these documents do not give any indication to the person skilled in the art that it might be worthwhile to modify the extraction process disclosed in document (D12) in order to solve the problem posed.
- 6.6.3 Document (D15) discloses to remove serine from phosphatidylserine by washing the solid product with water (see paragraph [0028]). There is no indication in this document which could have led the person skilled in the art to replace the methanol solvent in document (D12) by a mixture of water and a secondary or tertiary alcohol.

6.6.4 Document (D26) teaches dissolution of a phospholipid in a non-polar solvent, such as hexane or heptane, and extraction of the solution with a water containing polar solvent (see claim 1 and paragraph [0008]). As polar solvents, primary alcohols (methanol, ethanol) and a secondary one (isopropanol), as well as acetone, are mentioned as being equally well suited, while ethanol is used in the examples.

> Hence, this document does not give any indication to the person skilled in the art that the extraction with a secondary alcohol (like isopropanol) or a tertiary one rather than with methanol could yield a purer product.

6.7 Thus document (D12) can neither as such nor in combination with any of the documents (D8), (D9), (D15), (D26) or (D27) render the subject-matter of claim 1 obvious. Moreover, the Board is not aware of any other document more relevant for assessing inventive step.

For this reason, the subject-matter of claim 1 of the Main Request is based on an inventive step. The same holds for dependent claims 2 to 13.

6.8 Hence, no grounds under Article 100 EPC nor any other provisions of the EPC prejudice the maintenance of the patent based on the claims of the Main Request.

Auxiliary Requests

 As the Main Request is allowable there is no need to deal with the auxiliary requests.

8. Adapted description

The Board has verified that the amended pages of the description properly adapt the description to the amended claims as far as amendments in the claims were made with respect to the claims as granted.

The Respondent claimed that example 7 was not in line with the wording of claim 1 which requires the extraction of a solution of the phosphatidylserine "in a hydrocarbon solvent with a mixture of water and an alcohol solvent chosen among secondary and tertiary alcohols."

This requirement was part of the wording of claim 1 as granted so that the discrepancy alleged by the Respondent was present in the patent in suit as granted.

Rule 80 EPC determines that the description of a European patent may only be amended to the extent " ... that the amendments are occasioned by a ground of opposition under Article 100, ...".

An alleged discrepancy between the claims and the description of the patent as granted cannot, however, be subsumed under a ground of opposition under Article 100 EPC with the effect that an amendment in the description in order to remove this alleged discrepancy is not admissible under Rule 80 EPC (see T 323/05 of 9 August 2007, point 3 of the reasons).

Therefore, there is no reason to further adapt the description to the claims, no matter whether or not the wording of claims 1 is in line with example 7.

9. Remittal to the department of first instance (Article 111(1) EPC)

In the present case, the Board cannot decide on the maintenance of the patent as amended because the prerequisites according to Rule 82(2), second sentence, are not yet fulfilled.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the department of first instance with the order to maintain the patent as amended in the following version:

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- Claims: Nos. 1 to 13 according to the Main Request filed with the letter of 31 March 2008;
- Description: Pages 2 and 6 as granted and pages 3,
 4 and 5 as amended during the oral proceedings
 before the board of appeal.

The Registrar:

The Chairman:

M. Schalow

P. Ranguis