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**Datasheet for the decision  
of 4 September 2008**

**Case Number:** T 1039/04 - 3.3.01

**Application Number:** 01986685.4

**Publication Number:** 1330450

**IPC:** C07D 339/04

**Language of the proceedings:** EN

**Title of invention:**

Process for the production of R(+) $\alpha$ -lipoic acid

**Applicant:**

LABORATORIO CHIMICO INTERNAZIONALE S.p.A.

**Opponent:**

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**Headword:**

R(+) $\alpha$ -lipoic acid/LABORATORIO CHIMICO INTERNATZIONALE

**Relevant legal provisions:**

EPC Art. 82, 113(1)

EPC R. 103

**Relevant legal provisions (EPC 1973):**

EPC Art. 109, 111

EPC R. 67

**Keyword:**

"Substantial procedural violation (yes)"

"Reimbursement of the appeal fee (yes)"

**Decisions cited:**

G 0003/03, T 0951/92, J 0010/07

**Catchword:**

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Case Number: T 1039/04 - 3.3.01

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.01  
of 4 September 2008

**Appellant:** LABORATORIO CHIMICO INTERNAZIONALE S.p.A.  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 13 April 2004  
refusing European application No. 01986685.4  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

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

## Summary of Facts and Submissions

- I. This appeal lies from the decision of the examining division to refuse the European application No. 01 986 685.4 stemming from the PCT application EP01/11575 for lack of unity of claim 1 under Article 82 EPC.
- II. The appellant submitted with the statement of grounds of appeal a new set of claims and contested the decision of the department of the first instance, in particular, for substantial procedural violation of Article 113(1) EPC.
- III. The department whose decision is contested has considered the appeal to be admissible and well founded and it rectified its decision under Article 109(1) EPC. The filed request for reimbursement of the appeal fee could not be allowed and the case was referred to the Board of Appeal.
- IV. Claim 1 of the set of claims of the PCT application as originally filed read as follows:
- "1. Process for the synthesis of R(+) $\alpha$ -lipoic acid comprising the following stages:
- a) salifying of racemic thioctic acid with R(+) $\alpha$ -methylbenzylamine (FEA), wherein the molar ratio FEA/racemic thioctic acid is between 0.45 and 0.70;
- b) separation by filtration of the crystallized diastereoisomeric salt of R(+) $\alpha$ -lipoic acid-R(+) $\alpha$ -methylbenzylamine ;
- c) purification by re-crystallization of the diastereoisomeric salt of R(+) $\alpha$ -lipoic acid-R(+) $\alpha$ -

methylbenzylamine, wherein the re-crystallization solvent consists of a mixture of non-polar/polar solvents, the polar solvent being maximum 20% by volume of the mixture, and the temperature of dissolution of the salt is between 50 and 75°C;

d) separation of the diastereoisomeric salt to obtain R(+) $\alpha$ -lipoic acid by reaction of said salt with acids selected from the group consisting of aliphatic hydroxy-carboxylic acids having 3 to 6 carbon atoms and aqueous phosphoric acid with a dilution between 2 and 10% by weight."

- V. In the IPER, the International Preliminary Examining Authority considered that document (1), i.e. US-A-5 281 722, was the closest prior art and the subject-matter of claim 1 differed there from in that a certain type of acid was selected (hydroxy-carboxylic acid or phosphoric acid), that a ratio between polar and non-polar solvent was given and that a dissolution temperature was specified.

However, the technical features common to the two groups of inventions, which established novelty over document (1), were the ratio between polar and non-polar solvent and the dissolution temperature in the recrystallisation step. The use of a mixture of a polar and a polar solvent for recrystallization at a temperature between 50 and 75°C were usual measures applied for recrystallization of organic compounds. Therefore, these features, although not explicitly mentioned in document (1), could not be regarded as special technical features (Rule 13.2 PCT), defining the contribution which each of the claimed inventions made over the prior art.

Accordingly, the two processes according to claim 1 relating either to the use of a hydroxy-carboxylic acid or the use of phosphoric acid (step d) were not linked by a general inventive concept, and did not fulfil the requirement of unity of invention (Rule 13.1 PCT).

VI. In the first communication of the examining division of the EPO, the objection of lack of unity raised by the IPEA was maintained (Article 82 EPC) by direct reference to the IPER (see point V above).

VII. In response, the applicant pointed out that the contribution made by the claimed process vis-à-vis the prior art resided in the combination of the steps c) and d) wherein particular conditions were used which made it possible to obtain at the same time an increase in the final yield of the product and a simplification of the process.

Comparative example 6 of the patent application was, in that respect, referred to, wherein the R(+) $\alpha$ -lipoic acid-R(+) $\alpha$ -methylbenzylamine salt was dissolved in a toluene/methanol mixture comprising a percentage of the polar solvent of 35% at 45°C. It was not possible to re-crystallize the diastereoisomeric salt since it did not precipitate. This example showed the criticality of the ratio between the two solvents. The comparative example attached to this response also showed that by using toluene as the crystallisation solvent, it was not possible to obtain an optical purity equivalent to that obtained in example 1.

Together with the response a new set of claims was submitted. Claim 1 reads as follows:

"1. Process for the synthesis of R(+) $\alpha$ -lipoic acid comprising the steps of:

a) salifying of racemic thioctic acid with R(+) $\alpha$ -methylbenzylamine (FEA), wherein the molar ratio FEA/racemic thioctic acid is between 0.45 and 0.70;

b) separation by filtration of the crystallized diastereoisomeric salt of R(+) $\alpha$ -lipoic acid-R(+) $\alpha$ -methylbenzylamine ;

c) purification by re-crystallization of the diastereoisomeric salt of R(+) $\alpha$ -lipoic acid-R(+) $\alpha$ -methylbenzylamine;

d) separation of the diastereoisomeric salt to obtain R(+) $\alpha$ -lipoic acid by reaction of said salt with an acid;

characterised in that in step c) the re-crystallization solvent consists of a mixture of non-polar/polar solvents, the polar solvent being maximum 30% by volume of the mixture, and the temperature of dissolution of the salt is between 50 and 75°C, and in step d) the acid is selected from the group consisting of aliphatic hydroxy-carboxylic acids having 3 to 6 carbon atoms and aqueous phosphoric acid with a dilution between 2 and 10% by weight."

VIII. In its decision, the examining division considered that in the proposed combination of steps c) and d), the only feature common to both groups, was the step c), namely the use of a certain mixture of non-polar/polar solvents for the purification by recrystallization of the diastereoisomeric salt and the dissolution temperature of the salt between 50 and 70°C.

The said process step c) could not be regarded as a special technical feature for the following reasons:

The appellant had admitted that only the combination of steps c) and d) yielded the alleged improvement and that the acid used in the step d) was a critical parameter. Furthermore, the applicant had mentioned that the conditions used in step c) were among the conditions usually employed for the re-crystallisation of organic compounds.

Document (1), when describing the solvents for recrystallizing the diastereoisomeric salt pairs, referred to pure solvents or homogeneous mixtures of them. Preferred solvents were toluene, acetic acid ethyl ester and cyclohexane. In view of this teaching, the generic features according to the present step c) could not be regarded as special technical feature defining the contribution of the claimed invention over the prior art.

In this context, the arguments presented by the applicant concerning the improvements achieved by the recrystallisation solvents could not be accepted. All the examples involved as recrystallization solvent a mixture of methanol in toluene, whereas the solvents were very broadly defined in the claims. It was, therefore, not credible, that all recrystallisation solvents encompassed by the generic definition of the claims, yielded an improvement over the examples of document (1) (see point 1.3 of the decision).

Consequently, the only features common to the two groups of inventions designated in reaction step c), did not represent a special technical feature as required by Rule 30(1) EPC and the present claim 1 did not fulfil the requirement of Article 82 EPC.

IX. With the statement of grounds of appeal, the appellant filed a new set of claims (see point II above) and requested the reimbursement of the appeal fee for substantial procedural violation.

The following arguments were submitted as far as the request for reimbursement is concerned.

In the first official communication, the examining division had raised an objection of lack of unity on the ground that the conditions of recrystallisation used in step c) belonged to the common general knowledge and therefore were not inventive.

On the contrary, the decision of refusal of the application was based;

firstly, on the fact that the applicant had allegedly himself admitted in the letter of reply that the conditions of step c) did not contribute to the results obtained by the process of the invention,

secondly, in claim 1, the conditions of recrystallisation were defined too broadly and, therefore, it was not credible that all of them led to the claimed improvement over the process disclosed in document (1).



However, it had never been admitted that the conditions used in step c) were among the conditions usually employed for the recrystallisation of organic compounds. The citation of sentences only partially and, especially, out of context completely distorted their original meaning. Moreover, the decision to refuse was based on reasons very different from the objection communicated with the first communication, namely that it was not credible that all the solvents encompassed in Claim 1 led to the alleged improvement. The applicant had thus been deprived of his right under Article 113(1) EPC to be afforded an opportunity to comment upon such reasons. Decision T 951/92 was cited in that respect.

The decision to refuse was issued in violation of Articles 113(1) and 96(2) EPC.

- X. The appellant requested the reimbursement of the appeal fee.

### **Reasons for the Decision**

1. The appeal is admissible and the board of appeal is competent to deal with the appeal and to decide on the request (see G 3/03, OJ EPO 2005, 344).
2. In the present case, the sole question before the Board is whether the decision of the department of the first instance has deprived the applicant of its right to be heard under Article 113(1) EPC and thus whether the reimbursement of the appeal fee is equitable by reason of a substantial procedural violation in the

proceedings before the department of the first instance according to Rule 67 EPC 1973.

2.1 The present patent application was pending before the entry into force of the EPC 2000. Rule 103 EPC 2000 corresponding to Rule 67 EPC 1973 with some draft changes remains dependent of Articles 109 and 111 EPC. From 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, it can be inferred that Articles 109 and 111 EPC of the revised version should not be applied to pending patent applications at the date of entry in force of the revised Convention. Therefore, according to Article 7, paragraph 2, of the Act revising the European Patent Convention of 29 November 2000, Articles 109 and 111 EPC 1973 should be applied. Consequently, Rule 67 EPC 1973 is to be considered in the current case (J 10/07, to be published in the OJ EPO, point 7).

2.2 Article 113(1) EPC states that the decisions of the European patent Office "may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments".

2.3 In the context of the examining procedure under Articles 96 and 97 EPC, Article 113(1) EPC is intended to ensure that before a decision refusing an application for non-compliance with a requirement of the EPC is issued, the applicant has been clearly informed of the essential legal and factual reasons on which the finding of non-compliance is based, so that he knows in advance of the decision both that the

application may be refused and the legal and factual reasons why the application may be refused; furthermore, before issue of a decision, the applicant must have a proper opportunity to comment upon such reasons, and if he wishes, to give counter-arguments and reasoning in support of the allowance of the application, and/or to propose amendments to the application so as to avoid refusal of the application.

Thus the term "grounds or evidence" in Article 113(1) EPC should not be narrowly interpreted. In particular, in the context of examination procedure the word "grounds" does not refer merely to a ground of objection to the application in the narrow sense of a requirement of the EPC which is considered not to be met. The word "grounds" should rather be interpreted as referring to the essential reasoning, both legal and factual, which leads to refusal of the application. In other words, before a decision is issued an applicant must be informed of the case which he has to meet, and must have an opportunity of meeting it (see T 951/92, OJ EPO 1996, 53, point 3(v) of the reasons)".

- 2.4 In the board's judgment, the examining division, in its decision, did not contest that an improvement was provided by the use of specific mixture of methanol and toluene but contested **for the first time** that this improvement could be credibly acknowledged over the whole claimed area. This constitutes a considerable shift in the reasoning with respect to the objection raised in the first communication. The applicant could not be aware of such an objection before the decision of refusal of the department of the first instance and has thus not had the opportunity to present comments on

the grounds relied upon by the contested decision. Therefore, the principle of the right to be heard enshrined in Article 113(1) EPC has been violated.

- 2.5 The board also notes that the right to be heard has also been infringed given that the decision of the examining division was also substantially based on arguments which, though supplied by the applicant in support of his case, have been used against him to produce an effect on which he had not an opportunity to make observations (see points VIII and IX above).

Indeed, the reasoning of the examining division that the step c) belonged to usual measures is based on the fact that the applicant itself has allegedly admitted it in its response. In the board's judgement, for an instance of the EPO to use some sentences of a line of argumentation against the applicant itself **without having informed him beforehand** also amounts to a substantial procedural violation. Indeed, an argumentation cannot be interpreted in a sense contrary to what is intended by the applicant without his being informed beforehand that such an interpretation can be made by the instance in charge of the case. The board observes that in its statement of grounds of appeal the appellant has strongly contested the interpretation of the examining division.

- 2.6 Since the appeal is allowable, in the sense that the board grants the appellant's request and due to the causal link between the appellant's right to be heard and the necessity of the appeal, the appeal fee is to be reimbursed.

**Order**

**For these reasons it is decided that:**

The appeal fee shall be reimbursed.

The Registrar

The Chairman

M. Schalow

P. Ranguis