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D E C I S I O N
of 12 November 2004

Case Number: T 0505/03 - 3.3.4

Application Number: 96939054.1

Publication Number: 0866874

IPC: C12P 7/64

Language of the proceedings: EN

Title of invention:
Process for the preparation of materials with a high content of isomers of conjugated linoleic acid

Patentee:
Loders Croklaan B.V.

Opponent:
Cognis Deutschland GmbH & Co. KG

Headword:
Conjugated linoleic acid/LODERS CROKLAAN

Relevant legal provisions:
EPC Art. 123(2), 54, 56

Keyword:
"Added subject matter (no)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
T 0939/92, T 0298/93, T 0989/93

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0505/03 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 12 November 2004

Appellant I: (Proprietor of the patent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 5 March 2003 concerning maintenance of European patent No. 0866874 in amended form.

Composition of the Board:

Chairman: M. Wieser
Members: G. L. Alt
R. Moufang

Summary of Facts and Submissions

I. The Patent Proprietors (Appellants I) and Cognis Deutschland GmbH & Co. KG (Appellants II), who claimed to be the legal successors of the Opponents Cognis Deutschland GmbH, lodged appeals against the interlocutory decision of the Opposition Division to maintain European Patent No. 0 866 874 in amended form.

Opposition was filed against the grant of the patent as a whole under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), and under Article 100(c) EPC on the ground of unallowable amendments (Article 123(2) EPC).

The Opposition Division decided that the claims of the main request before them did not meet the requirements of Article 123(2) EPC, but that the grounds for opposition did not prejudice the maintenance of the patent as amended according to the fourth auxiliary request before them (Article 102(3) EPC). Auxiliary requests 1 to 3 have been withdrawn during opposition procedure.

II. The Appellants I requested that the decision under appeal be set aside and the patent be maintained on the basis of claims 1 to 17 filed on 10 September 2004 as first auxiliary request.

The Appellants II requested that the decision under appeal be set aside and the patent be revoked.

III. Claims 1, 5 and 8 of Appellants' I only request read:

"1. Process for the preparation of materials B, containing geometrical isomers of conjugated linoleic acid moieties in a specific ratio X_B, wherein a material A, containing at least 5 wt % of geometrical isomers of conjugated linoleic acid moieties, comprising at least two different geometrical isomers L_1 and L_2 in a weight ratio $L_1:L_2 = X_A$, is subjected to at least one enzymic conversion, selected from one of the following conversions:

(i) free fatty acids as material A with:

(a) mono- or polyalcohols, or
(b) mono, -di -triglycerides, or
(c) alkylesters, or
(d) phospholipids

(ii) mono, -di - or triglycerides as material A with:

(a) water, or
(b) mono- or polyalcohols, or
(c) alkylesters, or
(d) phospholipids

(iii) phospholipids as material A with:

(a) water, or
(b) alkylesters, or
(c) other phospholipids, or
(d) mono- or polyols

(iv) alkylesters, or wax-esters as material A with:

(a) water, or
(b) mono- or polyols, or
(c) free fatty acids, or
(d) phospholipids,

wherein a lipase is applied, that has the ability to discriminate between L_1 and L_2, which conversion results in a mixture of at least two products (I) and (II), from which one is our material B and contains L_1 and L_2 in a weight-ratio X_B, X_B being at least 1.2 X_A ,wherein L_1 and L_2 are cis^9, $trans^{11}$- and $trans^{10}$, cis^{12}-conjugated linoleic acid or vice versa and the lipase is derived from Geotrichum candidum, or from Candida Rugosa, or is a phospholipase.

5. Organic material, containing at least 1 wt% of conjugated linoleic fatty acid moieties, wherein the conjugated linoleic acid moieties at least comprise the geometrical isomers cis9transll and transl0cisl2, linoleic acid as the two most abundant geometrical isomers in a weight-ratio:

$$\frac{\text{cis9trans11}}{\text{trans10cis12}} = 2{,}3 - 99$$

8. Organic materials, derived from vegetable oils, comprising at least the linoleic acid isomers with cis9transll and trans10cis12 as the two most abundant isomers, wherein these isomers are present in a weight ratio of 1.5-25, while the total amount of geometrical

isomers of conjugated linoleic acid moieties is at least 1 wt%."

Dependent claims 2 to 4 referred to preferred embodiments of the process according to claim 1. Dependent claims 6, 7, 9 and 10 related to preferred embodiments of the organic material according to claims 5 and 8 respectively. Claims 11 to 17 concerned blends, food products, animal feed, food supplements and pharmaceutical products containing the organic material of claims 5 to 10, or organic material obtainable by the process of claims 1 to 4.

IV. The Board expressed their preliminary opinion in a communication dated 3 June 2004.

Oral proceedings were held on 12 November 2004.

V. The following documents are referred to in this decision:

(1) J. Food Comp. Anal., vol. 5, 1992, pages 185 to 197

(2) EP-A-0 442 558

(3) WO-A-90/09 110

(4) Biocatalysis, vol. 3, 1990, pages 277 to 293

VI. The submissions made by the Appellants I as far as they are relevant for the present decision may be summarised as follows:

Novelty of the organic materials of claims 5 and 8 was not anticipated by the disclosure in document (1), which referred to a new analytical method for determining geometrical isomers of conjugated linoleic acid (CLA) in food products.

Neither the subject-matter of claim 1, which was based on a combination of claims 1, 2, 3 and 7 of the claims as granted, nor of claims 5 and 8, was obvious over prior art documents (1), (2) and (4) either if taken alone or in any combination. None of these documents referred to an enzymatic method for changing the weight ratio of the cis9trans11 (c9t11) and trans10cis12 (t10c12) geometrical isomers of conjugated linoleic acid (CLA), or to products thereof. Both isomers were known to be effective for different purposes, as was confirmed by post-published documents.

VII. The submissions made by the Appellants II as far as they are relevant for the present decision may be summarised as follows:

Claim 5 lacked novelty over the disclosure in document (1).

Claim 1 could be considered to be inventive only, if it permitted achieving an effect which stood in causal connection with its technical features. However, no technical use or effect was known at the filing date for t10c12 CLA. Any reference to an effect of t10c12 CLA for specific purposes mentioned in the patent in suit, was pure allegation and not supported by facts or experimental data. Documents cited by the Appellants I

in favour of such effect were late filed and had to be disregarded.

Claims 5 and 8 suffered from the same drawback, as no effect had been shown for the organic materials containing c9t11 and t10c12 CLA in the specific weight ratios disclosed. These weight ratios were chosen arbitrarily and a so called "Scheinmerkmal".

Moreover, the process according to claim 1 was not inventive in the light of prior art documents (1) and (2) or (4).

Starting from document (1) as closest prior art, the problem to be solved was seen in the provision of organic material enriched with regard to c9t11 CLA. The skilled person would have been encouraged to aim at this goal as document (1) disclosed that c9t11 CLA was the biologically active form of CLA. Both, documents (2) and (4) disclosed the necessary technical tool to solve this problem, namely a lipase from Geotrichum candidum being highly specific for C_{18} fatty acids with a cis-9 double bond.

Likewise document (2) could be seen as closest state of the art. The method disclosed therein differed from the subject-matter of claim 1 only in so far as a different starting material was used, namely saturated and unsaturated fatty acids instead of a mixture of geometrical isomers of CLA. The skilled person, knowing from document (1) that c9t11 CLA was the biologically active form of CLA, would have been encouraged to amend the teaching of document (2) by using this different starting material, and would have had a reasonable

expectation of success, as document (2) in the passage bridging pages 2 and 3 states that the specificity of the disclosed lipase is not dependent on any specific residue following the cis-9 double bond.

Reasons for the Decision

Admissibility of the appeal of Appellants II

1. Together with their notice of appeal, the Appellants II have filed documentary evidence according to which they are the legal successor of the original opponents. In view of this evidence which was not contested by Appellants I, the Board is satisfied that the opponent status was transferred to Appellants II. Thus the appeal of Appellants II is admissible.

Amendments and Clarity - Articles 123(2), 123(3) and 84 EPC

2. Claim 1 of the request of Appellants I is a combination of claims 1, 2 and 5 as originally filed, respectively of claims 1, 2, 3 and 7 as granted. Claim 5 is a combination of claims 6 and 8 as originally filed and corresponds to claim 8 as granted. Claim 8 is based on claim 9 and page 6, lines 4 to 5 as originally filed and corresponds to claim 11 as granted. Claims 2 to 4, 6, 7 and 9 to 17 are identically contained in the claims as originally filed and as granted.

Consequently, claims 1 to 17 meet the requirements of Articles 123(2) and 123(3) EPC. Appellants II have not raised any objection in this respect.

The amendments to the claims do not give rise to an objection under Article 84 EPC.

Novelty - Article 54 EPC

3. Claim 5 was the only claim attacked under Article 54 EPC because of lack of novelty in the light of the disclosure in document (1).

4. The claim refers to organic material containing at least 1 wt% CLA moieties, comprising at least c9t11 and t10c12. The two geometrical isomers are present in a weight ratio of 2,3:1 to 99:1.

5. Document (1) discloses in tables (1) to (7) the content of "conjugated dienoic isomers of linoleic acid" in commercially available foodstuff. None of the analysed samples contained at least 1 wt% CLA, in fact the highest values determined were 0,88 +/-0,051 wt% (in strained lamb, table (7)), 0,71 +/-0,008 wt% (in brick cheese, table (2)) and 0,7 +/-0,029 wt% (in condensed milk, table (3)). Besides the total CLA content all tables indicate the content of the cis9trans11 isomer, expressed in % of the total CLA. Table (4) only, referring to the analysis of oils and fats, discloses the content of the t10c12 isomer. The weight ratio of c9t11 to t10c12 found in the seven analysed samples ranges from 1,03:1 (sunflower) to 1,175:1 (olive).

6. Thus, the organic material according to claim 5 is not disclosed in document (1). The same applies to the material according to claim 8, which is derived from vegetable oil and comprises the two isomers in a weight ratio of 1:1,5 to 1:25.

The subject-matter of the claims of Appellants' I request is therefore novel and meets the requirements of Article 54 EPC.

Inventive step - Article 56 EPC

7. Document (1) discloses that CLA has been shown to be anticarcinogenic in several animal models (abstract). Page 185, last paragraph discloses that "[T]he c-9,t-11 CLA isomer (Fig. 1) **is believed** to be the active form because **apparently** only this isomer is incorporated into the phospholipid fraction of tissues of animals fed a mixture of CLA isomers (Ha *et al.*, 1990)", (emphasis added by the Board). This statement is repeated on page 193, second paragraph.

The document discloses a method for determining the content of c9t11 CLA isomer by HPLC analysis in samples of commercially available foodstuff. The preparation of the internal standard, pure c9t11 CLA isomer, is described on pages 186 to 187. CLA is synthesized according to a modified method of the American Oil Chemists' Society and additionally isomerised by an isomerase from Buryrivibrio fibrisolvens. Methyl derivatization of the internal standard and of the CLA in the samples is described on pages 187 to 188. Special care is taken to keep isomerisation of the CLA during derivatization at a low level.

The results of HPLC analysis are shown in tables (1) to (7), showing the total CLA content in mg/g and the c9t11 content of the samples in % of total CLA. Table (4) only, referring to the analysis of oils and fats,

additionally discloses the t10c12 CLA content of eight analysed samples.

8. According to Appellants II, document (1) shows that at the priority date of the patent in suit c9t11 CLA was the only isomeric form of CLA known to be biologically active. No useful property of t10c12 CLA isomer was known. The statement on page 2, line 36 of the patent, stating that the effectiveness of the two isomers for specific purposes are different and that it is therefore highly desirable to have the opportunity to make CLAs, wherein the ratio c9t11/t10c12 can be chosen freely, depending on the conditions applied during the process, is not substantiated by facts or any experimental data. This cannot be cured by reference to post-published prior art, showing such properties which are useful to solve a technical problem.

Appellants II stressed that the issue of inventive step cannot be decided without regard to the solution of a technical problem. The skilled person at the priority date of the patent in suit had no reason to consider the provision of a method according to claim 1, or products according to claims 5 and 8, as they were not known to have a technical effect which can be used to solve a technical problem.

9. According to established case law of the Boards of Appeal the existence of a technical problem and its solution is an essential requirement for the acknowledgement of an inventive step (cf decision T 939/92, OJ EPO 1996, 309; point 2.4.1 of the reasons for the decision).

The answer to the question what a skilled person would have done in the light of the state of the art depends in large measure on the technical result he had set out to achieve. In other words, the notional "person skilled in the art" is not to be assumed to seek to perform a particular act without some concrete technical reason: he must, rather, be assumed to act not out of idle curiosity but with some specific technical purpose in mind (T 939/92, supra; point 2.4.2).

10. In the context of the definition of a technical problem and its solution, the Board in case T 939/92 (supra) came to the conclusion that for some compounds falling under the broad wording of the claims, the alleged technical effect was not credible. The Board decided that in such a situation the underlying problem was the minimalist one, namely the mere provision of further chemical compounds as such, regardless of their likely useful properties (T 939/92, supra; point 2.5). The competent Board found in point 2.5.3 of T 939/92 that the solution of this problem by arbitrarily chosen compounds does not meet the requirements of Article 56 EPC.

11. In case Appellants' II assertion were correct, that no technical effect was known for t10c12 CLA, the consequence, when following the reasoning of decision T 939/92 would not be that no problem could be formulated in the present case, but that a less ambitious problem had to be formulated whose solution may not involve an inventive step.

12. The present Board, however does not consider that the reasoning of decision T 939/92 is applicable in the present case as it referred to a different technical situation. Contrary to Appellants' II argument, the Board is convinced that, at the priority date of the patent in suit, an application of t10c12 CLA was known, which was recognized to give rise to a technical effect.

13. Document (3) (the corresponding European patent EP 41 101 is acknowledged on page 1, paragraph [0002] of the patent in suit) discloses the use of active forms of CLA, selected from 9,11-octadecadienoic acid and the 10,12-octadecadienoic acid, active isomers, esters, salts and derivatives thereof for preserving products by preventing oxidation, quenching singlet oxygen and inhibiting mould growth (claim 2). Document (3) discloses on page 17 that t10c12 is the predominantly produced isomeric form of 10,12-CLA.

14. Thus, the disclosure in the prior art documents (1) and (3) can be summarised as follows:

While it is assumed that c9t11 is the anticarcinogenic active form of CLA (document (1)), other useful activities of CLA (preventing oxidation, quenching singlet oxygen, inhibiting mould growth) are attributed to both, the c9t11 and t10c12 isomers (document (3)).

Thus, the effectiveness of the two isomers for specific purposes is known to be different, as stated on page 2, line 36 of the patent in suit.

Consequently, the Board is of the opinion that the provision of a process to make CLAs wherein the ratio

of the two isomers in question can be chosen freely, and of new CLA-compositions produced thereby, constitutes a technical problem. The skilled person at the claimed priority date, had a technical purpose to investigate for a solution to this problem.

For these reasons Appellants' II argument, namely that the claims lack an inventive step because they do not provide a solution to a technical problem, must fail.

15. Following another line of argumentation, Appellants II stated that the claimed subject-matter lacked an inventive step, as it was obvious in the light of the disclosure in documents (1), (2) and (4).

In accordance with the problem and solution approach, the Boards of Appeal in their case law have developed certain criteria for identifying the closest prior art providing the best starting point for assessing inventive step. It has been repeatedly pointed out that this should be a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i. e. requiring the minimum of structural modifications (cf Case Law of the Boards of Appeal of the European Patent Office, 4th Edition 2001, chapter I.D.3). Ideally that purpose or objective should be something already mentioned in the prior art document as a goal worth achieving (cf decision T 298/93 of 19 December 1996, point (2.2.2) of the reasons for the decision).

The purpose or objective of claim 1 of the patent in suit is the provision of a process for changing the

weight ratio of the two geometrical CLA isomers c9t11 and t10c12 in a starting material. Claims 5 and 8 refer to novel products (see item (2) to (5) above) which, according to the description, can be obtained by this process.

16. Document (2) discloses a new lipase from Geotrichum candidum, which is extremely specific for 9-cis fatty acids. In the passage bridging pages 2 and 3 it is mentioned that the specificity of the enzyme is not influenced by the kind of hydrocarbon groups following the 9-cis double bond, which may be saturated, unsaturated, branched or even contain cyclic radicals or hydroxy or epoxy groups. Most preferred fatty acid residues are found to comprise oleic and linoleic acid residues (page 4, lines 14 to 15). CLA is not mentioned in document (2).

17. A fatty acid specific lipase from Geotrichum candidum being specific for C_{18} fatty acids with a cis-9 double bond is also disclosed in document (4), page 278, second full paragraph. This review article referring to lipase-catalyzed reactions for modifications of fats and other lipids, does not mention CLA.

18. Appellants II, starting from the disclosure in document (2), identified the problem underlying claim 1 to be solved as providing a different use for the lipase from Geotrichum candidum by using a different starting material, namely a mixture of c9t11 and t10c12 CLA instead of a mixture of saturated and unsaturated fatty acids.

The present invention is concerned with CLA and its beneficial effects for humans and animals (see first sentence of the description). As document (2) (as well as document (4)) does not even mention this chemical substance, it cannot serve as the most promising springboard towards the invention according to established case law of the Boards of Appeal (see item (15) above). Thus, an argument on lack of inventive step (Article 56 EPC) of the claimed subject-matter, starting from document (2) as closest state of the art, must fail.

19. Neither document (1) or (3), which in fact are the only cited prior art documents published before the filing date of the patent which concern CLA, mention the possibility of changing the weight ratio of c9t11/t10c12 CLA isomer in a sample and accordingly do not give an indication towards a method for achieving such goal.

20. Consequently, as none of the cited prior art documents discloses subject-matter conceived for the same purpose or aiming at the same objective as claims 1, 5 and 8 of the patent in suit, a document relating to the same or closely related technical field has to be considered as best starting point for evaluating the inventive merits of the invention (cf decision T 989/93 of 16 April 1997, point (12) of the reasons for the decision).

21. Document (1), contrary to document (3), refers to the weight ratio of c9t11/t10c12 CLA isomer (see table (4)). Therefore, the Board comes to the conclusion that it is objectively the closest prior art which was available

to the skilled person for the subject-matter of all claims of Appellants' I request.

22. Starting from the disclosure in document (1) the problem to be solved by the patent in suit is seen in the provision of a process for changing the weight ratio of the two geometrical CLA isomers c9t11 and t10c12 in a starting material and the provision of organic materials containing the two isomers in such changed weight ratio.

The Board is convinced that this problem has been solved by the process according to claim 1 and the materials according to claims 5 and 8.

23. Appellants II argue that a skilled person, reading in document (1) that c9t11 is **believed** to be the active CLA isomer, would have been encouraged to change the weight ratio of c9t11/t10c12 in the analysed foodstuff to the favour of the c9t11 isomer and would thus arrive at the claimed subject-matter, namely the process of claim 1 and the organic materials of claims 5 and 8, in an obvious way.

The Board cannot agree. Document (1) is concerned with analytical methods and does not contain any information that would encourage the skilled reader to modify the composition of the analysed samples. At best, a skilled person trying to improve the quality of human and animal alimentation, could derive from the teaching in document (1) the use of those foodstuffs which contain a high concentration of c9t11 CLA isomer.

Alternatively, the skilled reader could consider producing pure c9t11 CLA according to page 186 to 187 of document (1).

24. The skilled person would have had no reason to combine the teaching of document (1) with either of documents (2) or (4), which do not even mention the molecule of interest, namely CLA.

25. The Board finds that the process of claim 1, as well as the novel materials according to claims 5 and 8, cannot be derived in an obvious way from the disclosure in the cited prior art documents, either if taken alone or in any combination.

Thus, claims 1 to 17 meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form on the basis of the following documents:

   Description:
   pages 2, 5 to 16 of the patent specification;
   pages 3 and 4 filed at the oral proceedings.

   Claims 1 to 17 filed on 10 September 2004 as first auxiliary request.

The Registrar: The Chairman:

P. Cremona M. Wieser