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**Datasheet for the decision
of 17 April 2008**

Case Number: T 1158/07 - 3.3.04

Application Number: 03746461.7

Publication Number: 1500706

IPC: C12P 7/64

Language of the proceedings: EN

Title of invention:

Process for producing conjugated fatty acid and food/drink
obtained by the process

Applicant:

KABUSHIKI KAISHA YAKULT HONSHA

Headword:

Conjugated linoleic acid/YAKULT

Relevant legal provisions:

-

Relevant legal provisions (EPC 1973):

EPC Art.56

Keyword:

"Inventive step - (yes)"

Decisions cited:

G 0001/03, T 0019/90, T 0939/92

Catchword:

-



Case Number: T 1158/07 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 17 April 2008

Appellant:
(Applicant)

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 19 January 2007
refusing European patent application
No. 03746461.7 pursuant to Article 97(1)
EPC 1973.

Composition of the Board:

Chair: U. Kinkeldey
Members: M. Wieser
R. Moufang

Summary of Facts and Submissions

- I. The appeal was lodged by the Applicant (Appellant) against the decision of the Examining Division to refuse under Article 97(1) EPC 1973 the patent application EP 03 746 461.7 (published as EP-A-1 500 706), having the title: "Process for producing conjugated fatty acid and food/drink obtained by the process".
- II. The Examining Division decided that the subject-matter of claim 1 of the main request before them was not novel (Article 54 EPC 1973) and that the subject-matter of claim 1 of the sole auxiliary request before them did not involve an inventive step (Article 56 EPC 1973).
- III. The Board expressed its preliminary opinion in a communication dated 15 October 2007.

Oral proceedings were held on 17 April 2008.

- IV. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 5 of the main request filed at the oral proceedings.

Claim 1 of Appellant's request read as follows:

"Process for producing conjugated linoleic acid, comprising the step of conjugating linoleic acid with the use of viable cells, dead cells or a cell extract of at least one bacterium having conjugation capability selected from the group consisting of *Lactobacillus oris* ATCC 49062, *Lactobacillus pontis* ATCC 51518,

Lactobacillus pontis ATCC 51519, Lactobacillus panis JCM 11053, Bifidobacterium breve YIT 10001 (FERM BP-8205), Bifidobacterium breve ATCC 15698, Bifidobacterium breve ATCC 15701 and Bifidobacterium pseudocatenulatum ATCC 27919."

Dependent claims 2 to 5 referred to preferred embodiments of the process according to claim 1.

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

(2) WO 99/29 886

(3) EP-A-1 174 416.

(6) JAOCS, vol.79, no.2, 2002, pages 159 to 163

(8) Food Chemistry, vol.69, 2000, pages 27 to 31

(9) EP-A-1 264 893

VI. The submissions made by the Appellant, as far as they are relevant to the present decision, may be summarised as follows:

The closest prior art was represented by document (2), which was concerned with a process for producing conjugated linoleic acid (CLA) with the use of bacteria having conjugation capability. It was found that the cis-9, trans-11 isomer was the major isomer of CLA. By using the disclosed process it was possible to produce CLA wherein the cis-9, trans-11 isomer represented more than 70% of the total CLA formed, respectively wherein

the cis-9, trans-11 isomer and the trans-9, cis-11 isomer together represented 70-90% of the total CLA formed.

The problem to be solved by the present application was the provision of an improved process for the production of CLA enriched for the cis-9, trans-11 isomer, in which other CLA isomers than the cis-9, trans-11 isomer occupied 10% or less of the total CLA formed.

This problem has been solved by the process according to claim 1 using eight defined bacterial strains belonging to the genera Lactobacillus and Bifidobacterium.

The application contained experimental data showing that the posed problem has been solved by the process according to claim 1.

The subject-matter of claim 1, a process using the specifically disclosed strains which gave rise to the surprising and unexpected technical effect, could not have been derived in an obvious way from the disclosure in document (2), either alone or in combination with any other prior art document on file.

Reasons for the Decision

1. Claim 1 of the main request is based on claims 1 to 3 as originally filed. Claims 2 to 5 are based on original claims 4 to 7.

The claims are clear, concise and supported by the description.

Thus, the requirements of Article 123(2) EPC and Article 84 EPC 1973 are met.

2. The application contains a detailed description of the claimed process, including the disclosure of the separate working steps and of the various process parameters (see sections (a) to (e) in paragraphs [0038] to [0048] of the published application).

Accordingly, the application is considered to disclose the invention in a manner clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC 1973).

3. A process for producing CLA, comprising the use of the specific bacterial strains disclosed in claim 1, is not disclosed in the prior art documents on file. The subject-matter of claims 1 to 5 is therefore novel within the meaning of Article 54(1) and (2) EPC 1973.
4. For the assessment of inventive step (Article 56 EPC 1973) the Board applies the problem-and-solution approach, which, as a first step, requires the definition of the closest state of the art.
5. The Board agrees with the Appellant that document (2) represents the closest state of the art, which, as the present application, is concerned with the provision of a process for producing CLA by using bacteria having conjugation capability.

On page 5, lines 3 to 6, document (2) discloses that, in order to establish whether or not a particular bacterial strain is useful for the purpose of its invention, strains in question can be tested by a skilled person for its ability to produce CLA from linoleic acid according to a test procedure described in the section "Materials and Methods" starting on page 8 of document (2).

A few lines further down on page 5 it is reported that, surprisingly and contrary to other results disclosed in the prior art, it has been found that the ability to produce CLA is "strain-dependent".

Document (2) discloses that the cis-9, trans-11 isomer, which is considered to be the most important isomer in biological activity, was the major isomer of the produced CLA. In the experimental part of the document it is shown, that, by using the disclosed strains, it was possible to produce CLA wherein the cis-9, trans-11 isomer represented more than 70% of the total CLA formed (page 5, lines 27 to 33), respectively wherein the cis-9, trans-11 isomer and the trans-9, cis-11 isomer together represented 70-90% of the total CLA formed (page 10, lines 19 to 22 and page 13, lines 2 to 5).

6. The problem to be solved by the present application was to provide an improved process for the production of CLA enriched for the cis-9, trans-11 isomer, in which other CLA isomers than the cis-9, trans-11 isomer occupied 10% or less of the total CLA formed (see paragraph [0052] of the published application).

7. In order to decide whether the requirements of Article 56 EPC 1973 are met, it has to be examined if the problem underlying the application has indeed been solved by the subject-matter claimed, and if the claimed solution involves an inventive step.

If a claim comprises non-working embodiments, this may have different consequences, depending on the circumstances. If a technical effect is expressed in a claim and thereby constitutes a real technical feature, there may be lack of sufficient disclosure (Article 83 EPC 1973). Otherwise, if the effect, in the present case the reduction of CLA isomers other than cis-9, trans-11, is not expressed in a claim but rather is part of the problem to be solved, it may be a question of whether a given problem is solved by all embodiments falling under the claim which results in a problem of inventive step (cf decision of the Enlarged Board of Appeal G 1/03, OJ EPO 2004, 413, point (2.5.2) and T 939/92, OJ EPO 1996, 309).

8. Examples 2 and 8 of the present application describe processes using *Bifidobacterium breve* YIT 10001 (FERM BP-8205) wherein 96% or more of the produced CLA is the cis-9, trans-11 isomer (see paragraphs [0068] and [0087] of the published application).

Example 3 discloses that *Lactobacillus oris* ATCC 49062 when producing CLA as described in example 1, selectively produces only the cis-9, trans-11 isomer (see paragraph [0069] and figure 1).

Example 7 describes the production of CLA by *Lactobacillus pontis* ATCC 51518. It is shown that all

the produced CLA consists of the cis-9, trans-11 isomer (see paragraph [0084]).

According to table 3, last line, CLA produced by *Bifidobacterium pseudocatenulatum* ATCC 27919 entirely consists of the cis-9, trans-11 isomer.

9. The Board notes that results in the form of experimental data which show that the technical problem underlying the present application has indeed been solved, have been provided for four of the eight strains specified in claim 1.

According to established case law of the Boards of Appeal, the extent of the monopoly conferred by a patent should correspond to and be justified by the technical contribution to the art. This general principle of law also applies to decisions under Article 56 EPC 1973, because everything covered by a legally valid claim has to be inventive (see Case Law of the Boards of Appeal, 5th Edition 2006, Chapter I.D.1).

The Board is aware of decision T 939/92 (*supra*) containing fundamental rulings on broad claims in the field of chemistry. The Board in case T 939/92 held that in view of the state of the art the technical problem which the patent in suit addressed was provision of further chemical compounds with herbicidal activity. It was necessary for all the claimed compounds to possess this activity. The question as to whether or not such a technical effect was achieved by all the chemical compounds covered by such a claim might properly arise under Article 56 EPC, if this

technical effect turned out to be the sole reason for the alleged inventiveness of these compounds. The Appellants' submission that the test results contained in the description showed that **some** of the claimed compounds were indeed herbicidally active could not be regarded as sufficient evidence to lead to the inference that substantially **all** the claimed compounds possessed this activity. In such a case the burden of proof rested with the appellants. The requirements of Article 56 EPC had not therefore been met.

10. Claim 1 of the main request of the application underlying decision T 939/92 referred to a triazole sulphonamide defined by its formula, which contained three residues designated (R1), (R2) and (R3). A list of possible substituents for each of these three residues is indicated in the claim, which also included three provisos. Thus, the claim, although not referring to an indefinite number of compounds, encompassed a large group of compounds whose exact size could not be judged at first sight. Moreover, as stated in detail in point 2.6.2 of decision T 939/92, the Appellant's own submissions with regard to several prior art documents on file were such, that a person skilled in the art would have been unable to predict on the basis of his general knowledge that all claimed compounds would have herbicidal activity.

11. Contrary to this, claim 1 of the present application refers to a process using one of a group of eight specified bacterial strains. The application contains experimental proof that the technical effect, which is the sole reason for the inventiveness of the claimed process, is achieved by four of these eight strains. In

addition, the Board is not aware of any prior art document that would lead a skilled person to the prediction that said effect cannot be achieved by all eight strains encompassed by claim 1.

Accordingly, decision T 939/92 (*supra*), which referred to a different technical situation, cannot be applied in the present case.

12. In decision T 19/90 (OJ EPO 1990, 476), point (3.3) of the reasons, the Board decided on the quality of evidence required in order to decide that embodiments falling within the scope of a broad claim do not work. The competent Board came to the conclusion that serious doubts substantiated by verifiable facts are required. Although decision T 19/90 in this point was concerned with the examination of the requirements of Article 83 EPC, the present Board, bearing in mind that the question if a claim comprises non-working embodiments may have different consequences, depending on the circumstances (see point (7) above), is of the opinion that the criteria elaborated in decision T 19/90 have to be applied also in the present case.

The Board concludes that no such evidence meeting the criteria established by the case law of the Boards of Appeal (cf decision T 19/90 *supra*), is on file, and assumes that the problem underlying the present application, as defined in point (6) above, has been solved over the scope of claim 1.

13. It remains to be examined if the claimed solution involves an inventive step.

Document (2), representing the closest state of the art, discloses a process for the production of CLA with the use of bacterial strains, wherein the cis-9, trans-11 isomer represents more than 70% of the total CLA formed, or wherein the cis-9, trans-11 isomer and the trans-9, cis-11 isomer together represent 70-90% of the total CLA formed. Moreover, the document teaches the skilled man that, in order to find further useful bacterial strains having conjugation capability, he should follow the screening method disclosed on page 8 onwards.

However, no bacterial strain is disclosed which is capable to solve the technical problem underlying the present application (see point (6) above).

14. Document (3) is concerned with the production of conjugated fatty acid esters in order to overcome the problem of strong bitterness and astringency of free conjugated fatty acids (see paragraph [0007]). Document (3) is not concerned with the production of CLA enriched for the cis-9, trans-11 isomer.

Document (6), also referring to CLA production from linoleic acid by lactic acid bacteria, reports in the abstract on page 159, that the resulting CLA was a mixture of CLAs wherein the "cis-9, trans-11 (or trans-9, cis-11)" amounted to 38% of total CLA.

Document (8) investigates the effect of the addition of various sugars on the formation of the cis-9, trans-11 isomer of CLA by different bacterial strains.

Document (9) refers in claim 2 to a process for producing CLA by cultivating a bacterium of the genus Bifidobacterium, wherein the CLA is the cis-9, trans-11 isomer. The preferred strain, Bifidobacterium breve 2258, is said to be able to convert 46% (0.23 mg/ml) of 0.5 mg/ml linoleic acid into "other fatty acids, preferentially the cis-9, trans-11 CLA isomer followed by cis-9-C 18:1 (oleic acid) and a peak of unidentified fatty acids, which most likely is another CLA isomer, although confirmation of this requires further study. The amount of cis-9, trans-11 CLA produced was 0.136 mg/ml, and the unidentified fatty acids accounted for 0.03 mg/ml." (see paragraph [0018]).

Thus, the cis-9, trans-11 isomer of CLA represented about 82% of the total CLA formed.

15. The Board does not exclude that a skilled person trying to solve the problem underlying the present application would make use of the screening method disclosed in document (2). The application of this method will result in the provision of strains having the ability to convert linoleic acid into CLA in an obvious way, **but** it does not allow to draw a conclusion concerning the expectation of success to isolate specific bacterial strains to be used in a process for the production of CLA enriched for the cis-9, trans-11 isomer, in which other CLA isomers than the cis-9, trans-11 isomer occupy 10% or less of the total CLA formed. It is not the theoretical possibility to isolate a strain by applying a known screening method, but the actual provision of specific strains for achieving a defined technical effect, not disclosed in

the prior art, which establishes elements of surprise justifying acknowledgement of an inventive step.

16. The Board therefore is convinced that the subject-matter of claim 1 cannot be derived in an obvious way from the disclosure in document (2), either alone or in combination with any other document on file belonging to the state of the art according to Article 54(2) EPC 1973.

The subject-matter of claim 1, as well as of dependent claims 2 to 5, involves an inventive step and meets the requirements of Article 56 EPC 1973.

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 grant a patent on the basis of the following documents:

Claims 1 to 5 of the main request filed at the oral proceedings;

Pages 2 to 13 (including page 3a) of the adapted description filed at the oral proceedings;

Figure 1 as originally filed.

Registrar:

Chair:

P. Cremona

U. Kinkeldey