

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

D E C I S I O N
of 2 July 2002

Case Number: T 1091/00 - 3.3.2

Application Number: 91903945.3

Publication Number: 0515460

IPC: A23L 1/054

Language of the proceedings: EN

Title of invention:

Docosahexaenoic acid, methods for its production and compounds containing the same

Patentee:

MARTEK CORPORATION

Opponent:

OmegaTech, Inc.
Aventis Research & Technologies GmbH
Monsanto Company
Nagase Biochemicals, Ltd.

Headword:

Edible oil/MARTEK CORPORATION

Relevant legal provisions:

EPC Art. 123(2), 100(b), 54, 111(1)

Keyword:

"Main request - added matter (no) - basis in the application as filed"

"Sufficiency of disclosure (yes) - respondent's misinterpretation of the product's features"

"Novelty (no) - "obtainable" not a limiting feature over the prior art"

"First auxiliary request - added matter (no) basis in the application as filed"

"Novelty (yes) - features of the product claim and of the process claims not to be found in the available prior art"

Decisions cited:

-

Catchword:

-



Case Number: T 1091/00 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 2 July 2002

Appellant:
(Proprietor of the patent)

MARTEK CORPORATION
6480 Dobbin Road
Columbia
MD 21045 (US)

Representative:

Mercer, Christopher Paul
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

Respondent 01:
(Opponent 01)

OmegaTech, Inc.
4090 Nautilus Court North Suite 208
Boulder
Colorado 80301 (US)

Representative:

Mallalieu, Catherine Louise
D. Young & Co.
21 New Fetter Lane
London EC4A 1DA (GB)

Respondent 02:
(Opponent 02)

Aventis Research & Technologies GmbH
Industriepark Höchst K 801
D-65926 Frankfurt am Main (DE)

Representative:

Ahrens, Gabriele, Dr.
Jasperallee 1A
D-38102 Braunschweig (DE)

Respondent 03:
(Opponent 03)

Monsanto Company
800 North Lindbergh Boulevard
St. Louis
Missouri 63166 (US)

Representative:

Ruffles, Graham Keith
MARKS & CLERK
57-60 Lincoln's Inn Fields
London WC2A 3LS (GB)

Respondent 04: Nagase Biochemicals, Ltd
(Opponent 04) 1-17 Shinmachi 1-chome Nishi-ku
Osaka 550-0013 (JP)

Representative: Schlich, George William
Mathys & Squire
European Patent Attorneys

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 30 October 2000
revoking European patent No. 0 515 460 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: J. Riolo
S. U. Hoffmann

Summary of Facts and Submissions

- I. European patent No. 0 515 460 based on application No. 91 903 945.3 was granted on the basis of 22 claims.

Independent claim 1 as granted read as follows:

"1. A single cell-edible oil characterized in that docosahexaenoic acid (DHA) makes up at least 15% of the oil by weight, preferably at least 20%, more preferably at least 30% and most preferably at least 35%."

- II. Four notices of opposition were filed against the granted patent.

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step and under Article 100(b) for insufficiency of disclosure.

The following documents were *inter alia* cited during the proceedings.

(2) J. Protozool. 17(2), 213-219, 1970

(4) Biochimica and Biophysica Acta, 316, 56-65, 1973

(10) WO-A-8900606

(11) Novel Microbial Products for Medicine and Agriculture, chapter 28, 253-259, 1989.

- III. The decision of the Opposition Division pronounced on 12 October 2000 revoked the patent under Article 102(1) EPC.

The Opposition Division held that neither the set of claims of the main request nor the sets of claims of the auxiliary requests 1 and 2 met the requirements of the EPC.

It first considered that the objections pursuant to Article 100(b) EPC raised by opponents 01, 02 and 04 did not bring into question the sufficiency of the disclosure of the patent in suit, so that it concluded that the requirements of this Article were fulfilled.

However, regarding novelty, the Opposition Division was of the opinion that the oil extract described in document (4) anticipated the subject-matter of the independent main product claim of the main, first and second auxiliary requests.

Accordingly, the patent in suit did not comply with Article 54 EPC.

- IV. The appellant (patentee) lodged an appeal against the said decision.
- V. With its letter dated 22 May 2002, respondent 03 withdrew its opposition.

Respondent 01 submitted its written arguments on 29 October 2001. With its faxed letter on 6 June 2002, respondent 01 informed the Board that it would not attend the oral proceedings.

Respondent 04 did not intervene during the appeal proceedings.

VI. Oral proceedings were held before the Board on 2 July 2002 during which a main request as well as subsidiary requests 1 and 2 were submitted by the appellant in substitution for all previous requests as the basis for remittal to the first instance.

During the oral proceedings the appellant withdrew its former written request for reimbursement of the appeal fee for a substantial procedural violation.

Independent product claim 1 of the main request corresponds to independent claim 1 as granted, wherein the oil has been defined as being "obtainable from a unicellular organism by hexane extraction" and wherein the docosaehaenoic acid (DHA) content has been restricted to a value of "at least 35%".

Dependent product claim 2 corresponds to dependent claims 2 as granted. The two alternatives of product claim 3 as granted have been split into dependent claims 3 and 4 in the main request.

Process claim 5 corresponds to process claim 4 as granted, restricted to the preparation of an oil having at least 20% DHA and wherein the reference to the product claims has been deleted. It reads:

"5. A method of producing a single cell edible oil wherein DHA makes up at least 20% of said oil by cultivating a microorganism capable of producing the said single cell oil in a fermenter to achieve a cell density of at least about 10 grams biomass per litre of a nutrient solution, harvesting the biomass and recovering the single cell oil from the biomass, wherein the microorganism is a dinoflagellate and the

microorganism is induced to produce the single cell oil at a concentration of at least about 1.5 grams per litre of nutrient solution by imposition of a stationary phase."

Dependent process claims 8 to 14 correspond respectively to dependent claims 6 to 12 as granted. Moreover, the restriction to a DHA of at least 20% in dependent claim 14 has been deleted.

The two alternatives of process claim 5 as granted have been split into dependent claims 6 and 7 in the main request.

The set of claims of the first auxiliary request corresponds to the set of claims of the main request, wherein the word "directly" has been introduced into claim 1 before the term "obtainable".

VII. The appellant submitted that the restriction of claim 1 to the hexane extract from a unicellular organism and to a DHA content of at least 35% in the extracted oil rendered the claimed product novel over the available prior art.

It also argued that process claim 5 was novel as none of the prior art disclosed cultivating a dinoflagellate at a biomass density of at least 10 g/L to provide an oil yield of at least 1,5 g/L. In that respect, it filed a declaration of one of the inventors of the patent in suit to support this view.

VIII. Respondent 02 contested the admissibility of the newly filed sets of claims under Article 123(2) EPC. In its opinion, the restriction of the independent process

claims in the three sets of claims to the production of an oil wherein DHA makes up at least 20% contravened Article 123(2) EPC because said feature was disclosed in claim 12 as granted in combination with the process features (a) to (g) and not with the features of this process claim.

It also contested the introduction of the word "directly" into the product claim of the first auxiliary request as, in its view, no basis was to be found in the application as originally filed.

Concerning the sufficiency of the disclosure in relation with the newly filed product claim, respondent 02 argued that this claim encompassed any unicellular organism as starting material. In its opinion the claim could not be performed in its full scope as the description of the patent in suit as originally filed gave only a single example of microorganisms, ie *cryptothecodinium cohnii*, a marine dinoflagellate. Moreover, having regard to the prior art documents, such as documents (2) and (11), it was obvious that not all microorganism and not even all marine dinoflagellates contained DHA. In addition, according to document (11), the amount of DHA in *cryptothecodinium cohnii* and in the other studied dinoflagellate was in any case lower than 35%.

Finally, it also stressed that the working examples of the description as filed did not mention the weight % of DHA obtained by the hexane extraction so that no way of carrying out the invention as claimed was given in the application as filed.

It also contested the sufficiency of disclosure of the

independent process claim, putting forward that it merely recited producing a biomass of at least 10 grams per litre and a single cell oil at a concentration of at least 1.5 grams per litre without providing the means to achieve it.

As to the novelty of the product claim 1, respondent 02 was of the opinion that the term "being obtainable by hexane extraction" was not a restriction on the claimed oil. Accordingly, any prior art oil containing more than 35% DHA, such as for instance the oil described in document (10), was novelty destroying for this claim.

Respondent 01 shared this view in its written submissions.

Concerning the independent process claim, respondent 02 maintained that the growth conditions described in documents (4) and (10) anticipated the preparation method according to said claim.

During the oral proceedings, respondent 02 asked the Board to examine inventive step for all the appellant's requests without remitting the case to the first instance.

IX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution.

Respondent 02 requested that the appeal be dismissed.

With its letter on 6 June 2002, respondent 01 wrote that "upon reviewing the submissions made in this appeal, it does seem more appropriate to remit the case

back to the Opposition Division for further consideration".

Reasons for the Decision

1. The appeal is admissible.
2. *Main request*
- 2.1 Articles 123(2) and (3) EPC

The only objection under Article 123(2) maintained by respondent 02 against this set of claims concerns the restriction of the independent process claim 5 to the production of an oil wherein DHA makes up at least 20% by weight.

In that respect, the Board notes that, according to the corresponding process claim as granted (ie, former claim 4), said process was directed to the production of an oil according to claim 1, ie wherein DHA makes up at least 15%, 20%, 30% or 35% by weight.

Moreover, said feature is also disclosed as such in process claim 23 as originally filed and in the description, for instance on page 14, line 16.

Accordingly, the argument put forward by respondent 02 that said restriction contravened Article 123(2) EPC because said feature was disclosed in claim 12 as granted in combination with the process features (a) to (g) and not with the features of this process claim does not hold.

No other objections under Article 123 EPC were raised by respondent 02 during the oral proceedings and by respondent 01 in its written submissions and the Board sees no reason to differ.

2.2 Article 100(b) EPC

The Board agrees with the Opposition Division's arguments and conclusion as to the sufficiency of disclosure.

Concerning the further points against the product claim 1 brought up by respondent 02 during the oral proceedings, the Board observes that the product claim 1 does not claim a unicellular organism but merely an edible oil which is primarily characterized by its DHA content. The fact that it is obtainable from a unicellular organism does not imply that the microorganism constitutes a mandatory feature of the claim.

Accordingly, the fact that documents (2) and (11), two documents describing the DHA content of various microorganisms, show that some unicellular organisms and even some dinoflagellates contain no or little DHA does not bring the feasibility into ((2) page 215, Table 2; (11) page 254, Table 1).

In that respect, it is moreover pointed out that the unicellular organisms having a lower content of DHA are also good candidates as starting material for extracting the claimed edible oil since claim 1 does not exclude additional process steps after the hexane extraction, so that a subsequent concentration of the hexane extract up to a content of DHA of at least 35%

by weight is also encompassed by this claim.

Finally, as to the question whether the amount of DHA in the hexane extracts of the working examples of the contested patent is at least 35% by weight, the Board has no reason to doubt that the appellant's statement that this amount is indeed greater than 35% by weight is not correct.

As these examples were in the application as originally filed as an illustration of the claimed invention, the Board considers that it is the task of the respondent to provide evidence for its allegations to the contrary.

Concerning the respondent's argument of insufficiency of disclosure against the independent process claim by putting forward that the claim merely recites producing a biomass of at least 10 grams per litre and a single cell oil at a concentration of at least 1.5 grams per litre without providing the means to achieve it, the Board would point out that it is the European patent as a whole including the description and its examples which must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

In that respect, the respondent did not introduce any element to show that the information given in the application and in particular in the examples was not sufficient to that end.

Accordingly, the Board concludes that the requirements of Article 100(b) EPC are fulfilled

2.3 Novelty

Document (10) has been cited as prejudicial to the novelty of the subject-matter of claim 1 of the patent in suit.

Document (10) discloses in example 1 experimental growth conditions to be applied for the production of various microorganisms such as microalgae as well as extraction procedures to be applied in order to get a lipid fraction containing a sufficiently high concentration of Omega-3 fatty acids (ie a mixture of DHA and EPA (eicosapentanoic acid)) to be useful in nutrition and medicine. The description of this document mentions the marine dinoflagellate *cryptothecodinium cohnii* as the only example of microalgae and states that the Omega-3 fatty acids may constitute as much as 10 to 50% of the total fatty acid fraction (page 5, line 24 and page 8, last paragraph).

Claim 1 of the contested patent is a product claim characterized by the following features:

- (a) a single cell edible oil
- (b) wherein DHA makes up at least 35% of the oil by weight
- (c) said oil being obtainable from a unicellular organism by hexane extraction.

As to feature (c) the Board observes that this feature is an open feature which does not exclude any previous or further processing steps apart from hexane extraction. Therefore it does not *per se* confer any

distinguishing feature over any prior art oil.

Accordingly, the only relevant features for the assessment of novelty remain the features (a) and (b).

Whereas it is clear that document (10) discloses single cell (*cryptothecodinium cohnii*) oils which are edible since the total lipid extract is intended to be used in nutrition and pharmacy, this document is silent about the precise content of DHA in the total lipid extract.

Having regard to the fact that the only marine dinoflagellate disclosed in the patent in suit is the same as the one envisaged in document (10) (ie *cryptothecodinium cohnii*), the Board has, in the absence of any evidence to the contrary, no reason to doubt than the DHA content in document (10) must be the same, namely above 35% by weight.

Accordingly, the Board concludes that the subject-matter of claim 1 of the patent in suit is anticipated by the disclosure in document (10).

The Board does not agree with the appellant's submission that claim 1 is novel merely because the value of more than 35% DHA cannot be found in document (10).

In fact, it was the choice of the appellant to seek to establish novelty over the prior art by means of this unusual parameter. It is therefore its task to demonstrate that the prior art does not fulfil this condition.

For the reasons given above, the Board also does not

accept that novelty over the prior art can be achieved by the open wording "obtainable ... by hexane extraction".

Finally, although the Board is also of the opinion that the chloroform extract of example 1 as such cannot be regarded as "edible", it remains convinced that the mention of its intended use in nutrition and pharmacy renders this disclosure novelty destroying since it implicitly inevitably implies to the skilled person the required additional step of getting rid of the toxic solvents. The appellant moreover did not contest that chloroform has been used as a solvent for the preparation of various food products such as coffee or vanillin.

In conclusion, the subject-matter of claim 1 of the main request is not novel under Article 54 EPC. There is therefore no need to examine the other claims.

3. *First auxiliary request*

3.1 Articles 123(2) and (3) EPC

The only objection under Article 123(2) raised by respondent 02 against this set of claims concerns the introduction of the word "directly" in claim 1 before the term "obtainable".

In that respect, the Board notes that all the examples of the description as originally filed describe the production of an oil which is directly obtainable by hexane extraction without further processing steps.

Moreover, it clearly appears from the description as originally filed that "additional processing steps... can be performed if required or desirable for a particular application", in other words further steps are merely optional (page 12, lines 29 to 31).

Accordingly, the argument put forward by respondent 02 that said restriction to the product "directly" obtainable by hexane extraction contravened Article 123(2) EPC because it has no support in the application as originally filed does not hold.

No other objections under Article 123 EPC were raised and the Board sees no reason to differ.

3.2 Novelty

Contrary to the main request, claim 1 is now directed to the product "directly" obtainable from a unicellular organism by hexane extraction. There is now a clear restriction to the claimed oil for the skilled person. In fact, the present wording implies that the amount of at least 35% of DHA must already be present in the extracted **neutral** lipid fraction of the unicellular organism in order for the technical feature c) of the product claim to be fulfilled.

Accordingly, document (10), which only describes the total lipid fraction (ie a mixture of polar lipids and other non-lipid components as well as neutral lipids) is not novelty destroying.

Indeed, the hexane extraction used in the process of preparation of the oil leads to a complex composition of lipids which is now different in any case from the

extract obtained with polar solvents.

The second document cited by the respondents as novelty destroying is document (4).

This document is an academic study concerning the environmental factors which may influence DHA biosynthesis. It discloses chloroform/methanol extracts of *crypthecodinium cohnii* which are first fractionated into neutral and polar lipid fractions and subsequently further fractionated to obtain, among other things, a triglyceride fraction (pages 57 to 58, "Lipid extraction and fractionation").

The highest DHA content in the triglyceride fraction (ie a subfraction of the neutral fraction) is disclosed in Figure 7 of this document and it amounts to about 30% DHA.

These figures were not contested by the respondents neither in writing nor during the oral proceedings.

Accordingly, the subject-matter of claim 1 and its dependent claims 2 to 4 is novel over document (4) as well.

The respondent's argument that document (4) anticipates the subject-matter of claim 1 because its scope is identical to the scope of the main request cannot be followed by the Board for the reasons given in the first paragraph under 3.2.

It remains now to examine whether the subject-matter of the independent process claim 5 fulfils the requirements of novelty as well.

Document (4) discloses in Table 1 growth conditions wherein a maximum concentration of $3,39 \cdot 10^9$ cells/L of *cryptothecodinium cohnii* has been reached after a 4 day stationary phase.

Document (10) describes growth conditions wherein the maximum amount of carbon source mentioned in example 2 is 5 g/L glucose.

Having regard to the calculation provided by the appellant with its letter dated 2 June 2002 showing that the maximum biomass reached under the growth conditions of documents (4) and (10) are respectively 2,35 g/L and 3 g/L, the Board concludes that the process of claim 5, which requires a biomass of at least 10 g/L to be achieved, is novel over said prior art.

Moreover, the respondents did not contest these values neither in writing nor during the oral proceedings.

The respondent's argument that the C/N ratio in document (10) is the same as in the patent in suit and that another carbon source may be present, namely yeast extract (1 g in example 2), does not change the fact that a biomass of 10 g/L cannot be achieved under the conditions disclosed in document (10).

Accordingly, the subject-matter of claim 5 and its dependent claims 6 to 14 is novel over the documents (4) and (10) cited against the novelty of the process claims.

4. *Remittal*

The rejection, by the Board, of the present main request and its findings in relation to the present first auxiliary request under Articles 123(2)(3), 83 and 54 EPC are *res judicata*.

Although Article 111(1) EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should preferably be given the opportunity to have two readings of the important elements of the case. The essential function of an appeal in *inter partes* proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally referred back, if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is taken into consideration by the boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against a party and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first instance department for consideration of the undecided issues.

The observations and comments made above apply fully to the present case. The Opposition Division decided that claim 1 was not patentable on the grounds of lack of novelty but left out the essential issue of inventive step (Articles 52(1), 56 EPC). This issue, however, forms, *inter alia*, the basis for the requests of the

respondents that the patent be revoked in its entirety and must therefore be considered as an essential substantive issue in the present case.

Thus, in view of the above considerations the Board has reached the conclusion that, despite respondent 02's procedural request presented during the oral proceedings, in the circumstances of the present case, it is necessary to remit the case to the Opposition Division for further prosecution on the basis of the set of claims of the first auxiliary request filed during the oral proceedings.

The decision of remittal has been taken in the absence of respondent 01. Respondent 01 had to expect that the appellant would amend the claims during oral proceedings in order to overcome possible or already raised objections. As it appears from 2.1 and 3.1 above, the new limitations to the claims were foreseeable. As to the others, attention has been paid to the written submissions of the parties.

In accordance with Article 113(1) EPC, respondent 01 was given an opportunity to present its comments as it was duly summoned to the oral proceedings. The fact that it decided not to make use of this opportunity cannot lead to an extension or prolongation of its procedural right.

In response to the summons to oral proceedings, respondent 01 opted, in the end, for the remittal of the case to the first instance (see point IX). Remittal does not imply the end of the procedure and respondent 01 will have the opportunity to give its view on the issue of inventive step which remains to be decided by

the first instance.

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 for further prosecution.

The Registrar:

The Chairman:

A. Townend

P. A. M. Lançon