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**Datasheet for the decision
of 4 May 2012**

Case Number: T 1539/10 - 3.3.09
Application Number: 02024238.4
Publication Number: 1298199
IPC: A23L 1/03, C12N 1/14, C12N 1/00
Language of the proceedings: EN

Title of invention:

Process for the heterotrophic production of microbial products with high concentrations of omega-3 highly unsaturated fatty acids

Applicant:

MARTEK BIOSCIENCES CORPORATION

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 76(1), 123(2), 84

Relevant legal provisions (EPC 1973):

-

Keyword:

"Amendments - added subject-matter (no)"
"Clarity - claims (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1539/10 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 4 May 2012

Appellant:
(Applicant)

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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 1 February 2010
refusing European patent application
No. 02024238.4 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: W. Sieber
Members: M. O. Müller
R. Menapace

Summary of Facts and Submissions

I. European patent application No. 02024238.4, which is a divisional application from the earlier application No. 93923347.4 in the name of Omegatech, Inc. (now Martek Biosciences Corporation), was refused by decision of the examining division issued in writing on 1 February 2010.

II. The examining division's decision was based on the amended claims filed with letter of 15 May 2008, claim 1 of which read as follows:

"1. A process for culturing microorganisms of the order Thraustochytriales for the production of lipids, the process comprising:

culturing the microorganisms of the order Thraustochytriales in a culture medium having a chloride concentration of less than 3 grams of chloride per liter of said culture medium, wherein less than 25% of the sodium in the fermentation medium is supplied as sodium chloride and wherein the microorganisms have a cell aggregate size of less than 100 microns."

The examining division held that claim 1 did not meet the requirements of Article 76(1) EPC as the parent application as filed

- disclosed the microorganisms "Thraustochytrium and Schizochytrium" rather than "microorganisms of the order Thraustochytriales" as referred to in claim 1; and
- required the presence of a non-chloride sodium salt, contrary to claim 1.

- Objections under Article 76(1) EPC were also raised against various dependent claims.
- III. On 15 March 2010, the appellant (applicant) filed a notice of appeal against the above decision and paid the prescribed fee on the same day. A statement setting out the grounds of appeal was filed on 28 May 2010 together with a main request and auxiliary requests A, A', B to H, I and I'.
- IV. On 28 September 2011, the appellant was summoned to oral proceedings. In the annex to the summons, the board raised several objections under Articles 76(1) and 84 EPC against the requests then on file.
- V. In its response dated 3 April 2012, the appellant submitted a main and an auxiliary request. The only difference between these requests was that claim 1 of the main request still referred to microorganisms "of the order Thraustochyriales" whereas claim 1 of the auxiliary request referred the microorganisms "Thraustochytrium or Schizochytrium". By its letter of 30 April 2012, the appellant asked whether any outstanding issues could be dealt with on the telephone in order to avoid oral proceedings.
- VI. On 2 May 2012, the board's outstanding objections were communicated to the appellant on the phone. Minutes of the telephone conversation were sent to the appellant on the same day. The board maintained its objection concerning the reference to the order Thraustochytriales in claim 1 of the main request. As regards the auxiliary request, the objections concerned

the wording "for the production of omega-3 highly unsaturated fatty acids (HUFA)" (Article 76(1) EPC) and the term "highly unsaturated" (Article 84 EPC) in claim 1, the order of dependent claims 3 and 4 (Article 84 EPC), claims 6-8 (Articles 76(1) and 84 EPC), the wording "Schizochytrium replicate by successive bipartition" in claim 9 (Article 76(1) EPC), the step of recovering the omega-3 HUFA in claim 15 and the term "said non-chloride source of sodium" in claim 18.

VII. By its letter of 3 May 2012, the appellant withdrew its previous main and auxiliary requests and filed a new main request containing 15 claims, which read as follows:

"1. A process for growing microorganisms Thraustochytrium, Schizochytrium or mixtures thereof, the process comprising:
culturing the microorganisms Thraustochytrium, Schizochytrium or mixtures thereof in a culture medium having a chloride concentration of less than 3 grams of chloride per liter of said culture medium, wherein the culture medium comprises non-chloride containing sodium salts and less than 25% of the sodium in the fermentation medium is supplied as sodium chloride."

"2. The process of claim 1, wherein the culture medium comprises sodium sulfate providing a sodium concentration in a range of from 1.0 g/L to 50.0 g/L."

"3. The process of claim 2, wherein the culture medium comprises sodium sulfate providing a sodium concentration in an amount between 1.0 g/L and 25 g/L."

"4. The process of claim 3, wherein the culture medium comprises sodium sulfate providing a sodium concentration in a range of from 2.0 g/L to 25 g/L."

"5. The process of any preceding claim, wherein a source of chloride comprises sodium chloride."

"6. The process of any preceding claim, wherein the Schizochytrium replicate by successive bipartition and by forming sporangia which release [sic] zoospores."

"7. The process of any preceding claim, wherein the Thraustochytrium replicate by forming sporangia and releasing zoospores."

"8. The process of any preceding claim, comprising culturing the microorganisms at a temperature from 5°C to 48°C and a pH from pH 5.0 to pH 11.0."

"9. The process of any preceding claim, wherein the culture medium comprises between 60 mg and 120 mg of chloride per liter of culture medium."

"10. The process of any preceding claim, wherein a non-chloride source of sodium comprises sodium sulfate."

"11. The process of any preceding claim, wherein the culturing produces a yield of biomass per sugar of 50% or greater."

"12. The process of any preceding claim, further comprising the step of extracting omega-3 highly

unsaturated fatty acids containing four or more double bonds from the microorganisms."

"13, The process of any preceding claim, wherein said culture medium has a chloride concentration of less than 500 milligrams of chloride per liter of said culture medium."

"14. The process of any preceding claim, wherein said culture medium has a chloride concentration of less than 250 milligrams of chloride per liter of said culture medium."

"15. The process of any preceding claim, wherein said non-chloride containing sodium salt is selected from the group consisting of soda ash, sodium carbonate, sodium bicarbonate, sodium sulfate and mixtures thereof."

VIII. On 4 May 2012, oral proceedings were held before the board. The appellant maintained the main request filed by letter of 3 May 2012 as its sole request.

IX. So far as relevant to the present proceedings, the appellant's arguments can be summarized as follows:

One issue about which the board still felt a need for discussion was whether the process of claim 1 of growing *Thraustochytrium*, *Schizochytrium* or mixtures thereof was disclosed in the parent application as filed in combination with the concentration requirements of this claim, as disclosed on page 9 of the parent application as filed.

In this respect, the appellant pointed out that the process of claim 1 of growing *Thraustochytrium*, *Schizochytrium* or mixtures thereof was disclosed on page 2, lines 16-22 of the parent application as filed and that subsequent thereto, specific reference was made to a low chloride content and a low proportion of sodium chloride. On the basis of this reference, it was evident that the concentration requirements disclosed on page 9 of the parent application as filed applied to the process disclosed on page 2 of the parent application as filed.

A further issue addressed by the board during the oral proceedings was whether claim 5, which requires sodium chloride to be present in the culture medium, was based on the parent application as filed. In this regard, the appellant explained that this requirement was implicitly present in the parent application as filed, e.g. on page 2, lines 20-24.

- X. The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of claims 1-15, filed as main request with letter of 3 May 2012.

Reasons for the Decision

- 1. The appeal is admissible.

2. *Amendments - Article 76(1) EPC*

2.1 The process of claim 1 no longer refers to the growing of microorganisms of the order Thraustochytriales for the production of omega-3 highly unsaturated fatty acids (HUFA). In particular, claim 1 refers to

- (a) A process for growing microorganisms Thraustochytrium, Schizochytrium or mixtures thereof, the process comprising: culturing the microorganisms Thraustochytrium, Schizochytrium or mixtures thereof in a culture medium wherein the culture medium comprises non-chloride containing sodium salts;
- (b) with the culture medium having a chloride concentration of less than 3 grams of chloride per liter of said culture medium; and
- (c) wherein less than 25% of the sodium in the fermentation medium is supplied as sodium chloride (see point VII above for the exact wording of claim 1).

2.1.1 Feature (a) of claim 1 is disclosed on page 2, lines 16-22 of the parent application as filed, which reads as follows:

"The present invention is directed to a new process for growing the microflora Thraustochytrium, Schizochytrium, and mixtures thereof, which includes the growing of the microflora in a culture medium containing non-chloride containing sodium salts, particularly including sodium sulfate."

2.1.2 Feature (b) of claim 1 is disclosed on page 9, lines 14-18 of the parent application as filed:

"It has been surprisingly found that microflora of the present invention can be grown at chloride concentrations of less than about 3 g/l, more preferably less than about 500 mg/l, more preferably less than about 250 mg/l and more preferably between about 60 mg/l and about 120 mg/l ..." (emphasis added by the board);

and in claim 12 of the parent application as filed:

"The process of claim 1, wherein said culture medium has a chloride concentration of less than about 3 grams of chloride per liter of culture medium."

2.1.3 Feature (c) of claim 1 is disclosed on page 9, lines 3-8 of the parent application as filed:

"More particularly, a significant portion of the sodium requirements of the fermentation are supplied as non-chloride containing sodium salts. For example, less than about 75% of the sodium in the fermentation medium is supplied as sodium chloride, more preferably less than about 50% and more preferably less than about 25%".

2.1.4 Feature (a) of claim 1 (process for growing Thraustochytrium and/or Schizochytrium as disclosed on page 2, lines 16-22) is clearly linked in the parent application as filed to features (b) and (c) of claim 1 (concentration requirements disclosed on page 9). In

particular, this link is present in the parent application as filed in the sentence directly subsequent to the disclosure of feature (a) (process for growing Thraustochytrium and/or Schizochytrium), which sentence reads as follows:

"More particularly, a significant portion of the sodium requirements of the fermentation are supplied as a non-chloride containing sodium salt (implying a low proportion of or no sodium chloride). The present process is particularly useful in commercial production because the chloride content in the medium can be significantly reduced, thereby avoiding the corrosive effects of chloride on fermentation equipment" (emphasis and insertion in brackets added by the board) (page 2, lines 22-28 of the parent application as filed).

On the basis of this sentence, the skilled person would clearly deduce that the process of growing Thraustochytrium and/or Schizochytrium (feature (a) of claim 1) is to be carried out in a culture medium with a low proportion of sodium chloride and a reduced chloride content. It would thus be clear to the skilled person that the low proportion of sodium chloride and the reduced chloride content as quantified on page 9 of the parent application as filed (features (b) and (c) of claim 1) refer to the process of growing Thraustochytrium and/or Schizochytrium as disclosed on page 2 (feature (a) of claim 1).

2.2 Claims 2-4 require the culture medium to comprise sodium sulfate providing a sodium concentration in a

range of from 1.0 g/L to 50.0 g/L, between 1.0 g/L and 25 g/L and from 2.0 to 25 g/L, respectively. This is based on page 10, lines 3-8 of the parent application as filed ("The concentration of sodium sulfate is effective to meet the salinity requirements of the microflora, preferably the sodium concentration is (expressed as g/l of Na) is [sic] greater than about 1.0 g/l, more preferably between about 1.0 g/l and about 50.0 g/l and more preferably between about 2.0 g/l and about 25 g/l.").

- 2.3 Claim 5 requires the source of chloride to comprise sodium chloride. This represents one of the two possibilities clearly implied by page 2, lines 22-24 of the parent application as filed (see the insertion by the board ("implying a low proportion of or no sodium chloride") in the passage quoted in point 2.1.4 above).
- 2.4 Claim 6, which requires the Schizochytrium to replicate by successive bipartition and by forming sporangia which release zoospores is based on page 11, lines 5-6 of the parent application as filed ("Schizochytrium replicate by successive bipartition and by forming sporangia which release zoospores.").
- 2.5 Claim 7, which requires the Thraustochytrium to replicate by forming sporangia and releasing zoospores, is based on page 11, lines 7-8 of the parent application as filed ("Thraustochytrium, however, replicate only by forming sporangia and releasing zoospores.").
- 2.6 Claim 8, which requires the microorganisms to be cultured at a temperature from 5°C to 48°C and a pH

- from 5.0 to 11.0, is based on page 12, lines 1-9 of the parent application as filed ("Growth of the strains by the invention process can be effected at any temperature conducive to satisfactory growth of the strains; for example, between about 5°C and about 48°C, preferably... The strains will grow over a pH range from 5.0-11.0 with a preferable range of about 6.0-8.5.").
- 2.7 Claim 9, which requires the culture medium to comprise between 60 mg and 120 mg of chloride per liter of culture medium, is based on page 9, lines 14-18 of the parent application as filed (see the passage quoted in point 2.1.2 above).
- 2.8 Claim 10, which requires the non-chloride source of sodium to comprise sodium sulphate, is based on the passage on page 2, lines 16-22 of the parent application as filed (see the passage quoted in point 2.1.1 above).
- 2.9 Claim 11, which requires the culturing process to produce a yield of biomass per sugar of 50% or greater, is based on page 9, lines 19-20 of the parent application as filed ("...while still attaining high yields of biomass per sugar of about 50% or greater").
- 2.10 Claim 12, which requires the process to comprise the step of extracting omega-3 highly unsaturated fatty acids ("HUFAs") containing four or more double bonds from the microorganisms, is based on
- page 12, lines 16-17 ("Similarly, extracted omega-3 HUFAs can be used as a feed or food supplement.")

and also page 13, line 3 ("extracted omega-3 HUFAs") in conjunction with

- page 8, lines 1-3 of the parent application as filed ("The nomenclature "highly unsaturated fatty acid" means a fatty acid with 4 or more double bonds.").
- 2.11 Claims 13 and 14, which require the culture medium to have a concentration of chloride per litre of culture medium of less than 500 and of less than 250 milligrams, respectively, are based on page 9, lines 14-18 of the parent application as filed (see the passage quoted in point 2.1.2 above).
- 2.12 Claim 15, which requires the non-chloride source of sodium to be selected from the group consisting of soda ash, sodium carbonate, sodium bicarbonate, sodium sulphate and mixtures thereof, is based on page 9, lines 25-28 of the parent application as filed ("Non-chloride containing sodium salts can include soda ash (a mixture of sodium carbonate and sodium oxide), sodium carbonate, sodium bicarbonate, sodium sulfate and mixtures thereof,...").
- 2.13 The claims of the main request thus meet the requirements of Article 76(1) EPC.

3. *Amendments - Article 123(2) EPC*

All the passages from the description of the parent application as filed that have been cited above are present in identical form in the description of the present divisional application as filed. Furthermore,

the upper limit of the chloride concentration in the culture medium, as disclosed in claim 12 of the parent application as filed, is equally present in claim 2 of the present divisional application as filed. Consequently, in the same way as for Article 76(1) EPC, the requirements of Article 123(2) EPC are met.

4. *Amendments - Article 84 EPC*

- 4.1 In view of the fact that claim 1 no longer contains a reference to microorganisms for the production of omega-3 highly unsaturated fatty acids, no objections under Article 84 EPC arise against claim 1.

In claim 12, the only remaining claim referring to omega-3 highly unsaturated fatty acids, the term "highly unsaturated" has been defined as "containing four or more double bonds", which is why this claim meets the requirements of Article 84 EPC as well.

- 4.2 All the other objections raised by the board in the telephone conversation of 2 May 2012 (see point VI above) have also been met. In particular the order of claims 3 and 4 has been reversed and the term "said non-chloride source of sodium" in claim 15 has been replaced by the term "said non-chloride containing sodium salt".

- 4.3 The board is therefore satisfied that the claims of the main request meet the requirements of Article 84 EPC.

5. *Remittal*

The remaining requirements of the EPC have not yet been dealt with by the examining division. To allow a full examination of these requirements at two levels, the board has decided to exercise its discretion under Article 111(1) EPC to remit the case to the examining division for further prosecution, in line with the appellant's request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of claims 1-15, filed as main request with the letter of 3 May 2012.

The Registrar:

The Chairman:

G. Röhn

W. Sieber