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**D E C I S I O N**  
**of 27 June 2006**

**Case Number:** T 0748/04 - 3.3.04

**Application Number:** 96913128.3

**Publication Number:** 0871460

**IPC:** A61K 35/78

**Language of the proceedings:** EN

**Title of invention:**

Bioactive factors of aloe vera plants

**Applicant:**

CARRINGTON LABORATORIES, INC.

**Opponent:**

-

**Headword:**

Bioactive factors of aloe vera plants/CARRINGTON

**Relevant legal provisions:**

EPC Art. 84, 111(1)

**Keyword:**

"Main request - clarity and conciseness (yes) "

"Remittal (yes) "

**Decisions cited:**

-

**Catchword:**

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Case Number: T 0748/04 - 3.3.04

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.04  
of 27 June 2006

**Appellant:** CARRINGTON LABORATORIES, INC.  
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**Representative:** Fisher, Adrian John  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 12 January 2004  
refusing European application No. 96913128.3  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chair:** U. Kinkeldey  
**Members:** G. Alt  
G. Weiss

## Summary of Facts and Submissions

- I. The appeal lies from the decision of the Examining Division refusing European patent application No. 96 913 123.3 titled "Bioactive factors of aloe vera plants" pursuant to Article 97(1) EPC.
- II. As the only ground for refusal the decision under appeal stated that all claims of the main and the only auxiliary request on file, both containing one independent and fourteen dependent claims, did not fulfil the requirement of clarity and conciseness as required by Article 84 EPC.
- III. Claim 1 of the main request read:
- "1. A method of separating bioactive Factors from aloe, said method comprising the steps of:
- (i) filtering a starting material with a coarse filter, having a pore size ranging from about 400µm to about 800µm, to give a coarsely-filtered starting filtrate, said starting material being selected from the group consisting of a crushed aloe leaf, aloe gel fillet, aloe raw gel, and dried aloe vera gel extract;
- (ii) filtering said coarsely-filtered starting filtrate with a medium filter, having a pore size ranging from about 100µm to about 400µm, to give a mediumly-filtered starting filtrate; and
- (iii) sizing said mediumly-filtered starting filtrate with a method selected from the group consisting of pH adjustment, selective precipitation, centrifugation,

ultracentrifugation, irradiation, filtration, ultrafiltration, homogenizing, and combination thereof, to provide:

- a) a microparticulate fraction containing an immune stimulating and macrophage activating Factor,
- b) a supernatant fraction containing an anti-inflammatory Factor, as well as an immune stimulating and macrophage activating Factor, and
- c) a low molecular weight fraction containing an anti-viral Factor."

Claim 1 of the auxiliary request differed from claim 1 of the main request in parts a), b) and c) which read:

- "a) a microparticulate fraction, obtainable as a pellet from centrifugation at 25,000 g for 30 minutes, said microparticulate fraction containing an immune stimulating and macrophage activating Factor,
- b) a supernatant fraction, obtainable as the supernatant from centrifugation at 25,000 g for 30 minutes, said supernatant containing an anti-inflammatory Factor, as well as an immune stimulating and macrophage activating Factor, and
- c) a low molecular weight fraction, having an average molecular weight less than 78K Daltons, said fraction containing an anti-viral Factor."

IV. The Examining Division's reasoning with regard to the main request was as follows: The starting material in

the method of independent claim 1 covered a plurality of different alternatives, namely crushed aloe leaf, aloe gel fillet, aloe raw gel, and dried aloe vera gel extract. The sizing step (iii) of claim 1 comprised a plurality of different alternatives, namely pH adjustment, selective precipitation, centrifugation, ultracentrifugation, irradiation, filtration, ultrafiltration, homogenizing, and combinations thereof without specifying for any of them precise working conditions. Finally, the fractions (and factors contained therein) to be provided by the method were not clearly defined because those terms aiming at their structural definition, i.e "microparticulate", "supernatant" and "low molecular weight", were relative terms without clear meaning, thus leaving as characterising features only functional definitions referring to some biological activities exhibited by the factors. Therefore, the Examining Division concluded firstly, that the large number of different alternatives within claim 1 due to the plurality of starting materials and the plurality of steps concerned with the method of separating the factors resulted in a lack of conciseness. The Examining Division found further that the many alternative method steps together with the undefined fractions and factors lead to a lack of clarity.

- V. Concerning the auxiliary request the Examining Division held that a line of argumentation corresponding to those raised with regard to the main request applied to claims 1 and also dependent claims 2 to 15 because the further features incorporated into part a), b) and c) did not help to define clearly the products to be obtained.

- VI. With the statement setting out the grounds of appeal two amended sets of claims, a main and an auxiliary request were filed.
- VII. The Board sent two communications. In the second one the appellant was informed about the Board's preliminary view that claim 1 of the amended main request did not comply with the clarity-requirement of Article 84 EPC. The Board however indicated that claim 1 of the auxiliary request did not seem to suffer from this objection.
- VIII. In reply the appellant filed an amended main request to replace the main request on file. Claims 1 and 2 of this request read:

"1. A method of separating bioactive Factors from aloe, said method comprising the steps of:

(i) filtering a starting material with a coarse filter, having a pore size ranging from 400µm to 800µm, to give a coarsely-filtered starting filtrate, said starting material being crushed aloe leaf, aloe gel fillet, aloe raw gel or aloe vera gel extract;

(ii) filtering said coarsely-filtered starting filtrate with a medium filter, having a pore size ranging from 100µm to 400µm, to give a mediumly-filtered starting filtrate;

(iii) sizing said mediumly-filtered starting filtrate with centrifugation at 20,000 to 150,000 g for a period greater than 10 minutes up to 48 hours, to provide:

(a) a microparticulate fraction as a pellet, said microparticulate fraction containing an immune stimulating and macrophage activating Factor, and

(b) a supernatant fraction as a supernatant, said supernatant fraction containing an anti-inflammatory Factor, as well as an immune stimulating and macrophage activating Factor.

2. The method of claim 1, wherein said sizing step further comprises sizing said mediumly-filtered starting filtrate with size exclusion chromatography, to provide a low molecular weight fraction, having an average molecular weight of less than 78K Daltons, said low molecular weight fraction containing an anti-viral Factor."

IX. The appellant's arguments submitted during the written proceedings as far as they are relevant to the present decision were as follows:

The mere fact that four different starting materials were allowed in the claimed method did not render the skilled person unable to determine the matter for which protection was sought.

It was clear to the reader what the microparticulate and supernatant fractions were because they were the inevitable result of carrying out the process.

The fact that a claim covered different possibilities did not render it in concise.

X. Requests

The appellant requested that the decision of the Examining Division be set aside and that a patent be granted on the basis of the Main Request filed with the letter of 9 February 2006.

Oral proceedings were requested in the event that the Board proposed to refuse the application.

**Reasons for the Decision**

1. The main request considered in the decision under appeal and the main request before the Board differ in the following respects:

- Part (iii) of claim 1 reads *"sizing said mediumly-filtered starting filtrate with centrifugation at 20,000 to 150,000 g for a period greater than 10 minutes up to 48 hours, to provide:"* instead of *"sizing said mediumly-filtered starting filtrate with a method selected from the group consisting of pH adjustment, selective precipitation, centrifugation, ultracentrifugation, irradiation, filtration, ultrafiltration, homogenizing, and combination thereof, to provide:"*.

Hence, claim 1 in part (iii) is restricted to a single sizing method under defined conditions.

- Part (a) of claim 1 of the main request is formulated as *"a microparticulate fraction as a pellet, said microparticulate fraction containing an*



*immune stimulating and macrophage activating Factor, and"* (emphasis added by the board) and not, as in the main request before the Examining Division "*a microparticulate fraction containing an immune stimulating and macrophage activating Factor*". Part (b) reads "*a supernatant fraction as a supernatant, said supernatant fraction containing an anti-inflammatory Factor, as well as an immune stimulating and macrophage activating Factor.*" instead of "*a supernatant fraction containing an anti-inflammatory Factor, as well as an immune stimulating and macrophage activating Factor, and"* (emphasis added by the board).

Thus, due to the distinction between "pellet" and "supernatant", the amendments clarify that the two fractions are the direct result of the centrifugation step.

- Part (c) of claim 1 of the main request before the Examining Division "*a low molecular weight fraction containing an anti-viral Factor*" is made to claim 2 (see section VIII above).

By this amendment it is made clear that if the mediumly-filtered starting filtrate obtained by step (ii) is subjected to size exclusion chromatography instead of centrifugation as claimed in claim 1, a low molecular weight fraction containing an anti-viral Factor is obtained.

2. Claim 1 contains the further amendment that one of the starting materials is "*aloe vera gel extract*" whereas it was "*dried aloe vera gel extract*" in the main

request before the Examining Division (emphasis added by the board). This amendment appears not to have been made in connection to the grounds for refusing the application. It will therefore not be considered in this decision, but will have to be dealt with by the Examining Division during further prosecution (see below).

3. In a first line of argumentation the Examining Division found that the main request lacked clarity because, in view of the many options for starting materials, the many alternative methods for sizing (step (iii) of the claim) and given that the fractions to be obtained were defined in an unclear way, the reader of the claim was not in a position to determine in which way the method was to be carried out. The second line of argumentation was that the many alternative ways of performing the method covered by the claim lead to a lack of conciseness.
  
4. Claim 1 of the present main request is directed to a method of separating bioactive factors from aloe. It comprises at least the three steps (i), (ii) and (iii). In the first step, four different types of starting materials may be used, crushed aloe leaf, aloe gel fillet, aloe raw gel or aloe vera gel extract. A method for obtaining each of them is, in the Board's view either self-explanatory (crushed aloe leaf), or indicated in the description (page 9, lines 24 et seq.; page 10, lines 5 et seq; page 10, lines 10 et seq.). The three method steps (i), (ii) and (iii) are to be performed in series, i.e. without any intermediate steps. This latter feature can be inferred from the way in which the claim is formulated, namely, in that the

end product of step (i) and (ii), respectively, is used as the starting product of step (ii) and (iii), respectively. The immediate and only products of the centrifugation step referred to in part (iii) of the claim - this interpretation is imposed by the term "to provide" at the end of step (iii) - are "a microparticulate fraction as a pellet" and "a supernatant fraction as a supernatant", both containing factors with a certain biological activity. Hence, the claim relates to methods in which each one of four alternative starting materials may be subjected to a fixed sequence of three method steps resulting in a pellet and a supernatant containing factors with biological activity.

5. The definition of a feature or subject-matter is clear if it is comprehensible to the skilled person without ambiguity. In the Board's judgement, it follows from the observations above that this is the case here. Consequently, claim 1 defines the matter for which protection is sought in a clear way.
6. The same is true for claim 2 indicating that sizing by size exclusion chromatography to obtain low molecular weight fraction is an alternative way of treating the mediumly-filtered material obtained in step (ii) and also indicating, by inclusion of a specific molecular weight value "less than 78K Daltons" what is meant by "low molecular weight" and for the remaining claims 3 to 12 of the main request.
7. Moreover, given the restriction of the claims, the Board considers that objection of lack of conciseness has also become obsolete with regard to all claims.

8. Consequently, the amended claims meet the requirement of clarity and conciseness of Article 84 EPC.

*Remittal*

9. In view of the major amendments and in view of the fact that the decision under appeal only gave reasons as to why the subject-matter of the claims was not allowable for lack of clarity and conciseness pursuant to Article 84 EPC, the Board deems it appropriate to exercise its power under Article 111(1) EPC and to remit the case to the Examining Division for further examination of whether the amended claims comply with the requirements of the EPC. During the further prosecution it seems to be of importance to firstly examine the claims with regard to the requirements of Article 123(2) EPC and moreover, Article 84 EPC relating to the requirement of support.

*Oral proceedings*

10. In view of the above findings oral proceedings, requested as an auxiliary measure in the event that the Board envisaged refusal of the application, are not necessary.

**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 for further prosecution on the basis of claims 1 to 12 of the Main Request filed with the letter dated 9 February 2006.

Registrar:

Chair:

P. Cremona

U. Kinkeldey