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D E C I S I O N
of 28 November 2003

Case Number: T 0098/01 - 3.3.4

Application Number: 90905020.5

Publication Number: 0463059

IPC: C07K 14/415

Language of the proceedings: EN

Title of invention:
Allergenic proteins from ragweed and uses therefor

Patentee:
IMMULOGIC PHARMACEUTICAL CORPORATION, et al

Opponent:
ALK-ABELLO A/S

Headword:
Allergenic proteins/IMMULOGIC PHARMACEUTICAL CORPORATION, et al

Relevant legal provisions:
EPC Art. 123

Keyword:
"Main request: added subject-matter (yes)"
"First auxiliary request: added subject-matter (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0098/01 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 28 November 2003

Appellant: (Proprietor of the patent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 22 November 2000 revoking European patent No. 0463059 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairwoman: U. M. Kinkeldey
Members: R. E. Gramaglia
S. C. Perryman

Summary of Facts and Submissions

I. The appeal is against the decision of the opposition division revoking European patent No. 0 463 059 (application No. 90 905 020.5), which had been opposed by the respondent (opponent) on the grounds of Articles 100(a) (Articles 54 and 56) and 100(b) EPC. The patent was granted on the basis of 24 claims for the Contracting States AT, BE, CH, DE, DK, FR, GB, IT, LI, LU, NL and SE and 22 claims for the Contracting State ES. Claims 1, 2, 10 and 15 as granted for the non-ES Contracting States read as follows:

"1. An isolated protein or peptide capable of influencing ragweed B-cell and/or T-cell responses in ragweed-sensitive individuals, the protein or peptide being selected from:

(a) *Amb a* IA free of other *Amb a* I family members and comprising at least a portion of the amino acid sequence shown in Fig. 11; or
(b) *Amb a* IB free of other *Amb a* I family members and comprising at least a portion of the amino acid sequence shown in Fig. 12; or
(c) *Amb a* IC free of other *Amb a* I family members and comprising at least a portion of the amino acid sequence shown in Fig. 13; or
(d) *Amb a* ID free of other *Amb a* I family members and comprising at least a portion of the amino acid sequence shown in Fig. 14,

for use in therapy, prophylaxis or diagnosis.

2. A composition capable of influencing B-cell and/or T-cell responses in ragweed-sensitive individuals comprising defined amount(s) of one or more isolated *Amb a* I proteins or peptides, for use in therapy, prophylaxis or diagnosis.

10. A process for producing a ragweed protein/peptide allergen comprising the steps of:

(a) identifying a DNA sequence encoding the ragweed allergen which hybridizes (for example under high stringency conditions) with the DNA sequence shown in Figure 11, 12, 13 or 14;
(b) inserting the DNA identified in step (a) into an expression vector;
(c) inserting the expression vector of step (b) into a host cell;
(d) culturing the host cell of step (c) under conditions appropriate for expression of the DNA inserted in step
(b); and
(e) recovering the expressed product.

15. An isolated nucleic acid comprising a nucleotide sequence which encodes an *Amb a* IA, *Amb a* lB, *Amb a* IC or *Amb a* ID protein or peptide."

II. The reasons given for the revocation was that the wording "free of other *Amb a* I family members" or "defined amount(s) of one or more isolated *Amb a* I proteins or peptides" in claims 1 and 2, respectively, represented added subject-matter (Article 123(2) EPC). The first instance considered no other issues.

III. In a communication following the summons to oral proceedings the board expressed its preliminary non-binding opinion about the points to be discussed at the oral proceedings.

IV. As previously announced, none of the parties appeared at the oral proceedings held on 28 November 2003. The claim requests presently before the board are the Main Request filed by the appellant on 30 March 2001 and the First, Second and Third Auxiliary Requests filed on 28 October 2003. Claim 1 of the Main Request for the non-ES Contracting States, which the appellant erroneously labelled "except for ES/GR" (the Contracting State GR has not been designated upon entry in the regional phase before the EPO), read as follows:

"1. An isolated, recombinant or synthetic, protein or peptide capable of influencing ragweed B-cell and/or T-cell responses in ragweed-sensitive individuals, the protein or peptide being selected from:

(a) *Amb a* IA free of other *Amb a* I family members and comprising at least a portion of the amino acid sequence shown in Fig. 11; or
(b) *Amb a* IB free of other *Amb a* I family members and comprising at least a portion of the amino acid sequence shown in Fig. 12; or
(c) *Amb a* IC free of other *Amb a* I family members and comprising at least a portion of the amino acid sequence shown in Fig. 13; or
(d) *Amb a* ID free of other *Amb a* I family members and comprising at least a portion of the amino acid sequence shown in Fig. 14,

for use in therapy, prophylaxis or diagnosis."

V. Claims 1, 2, 9 and 14 of Auxiliary Request 1 read as follows:

"1. An isolated, recombinant or synthetic, protein or peptide capable of influencing ragweed B-cell and/or T-cell responses in ragweed-sensitive individuals, the protein or peptide being selected from:

(a) *Amb a* IA and comprising at least a portion of the amino acid sequence shown in Fig. 11; or
(b) *Amb a* IB and comprising at least a portion of the amino acid sequence shown in Fig. 12; or
(c) *Amb a* IC and comprising at least a portion of the amino acid sequence shown in Fig. 13; or
(d) *Amb a* ID and comprising at least a portion of the amino acid sequence shown in Fig. 14,

for use in therapy, prophylaxis or diagnosis.

2. A composition capable of influencing B-cell and/or T-cell responses in ragweed-sensitive individuals comprising defined amount(s) of one or more isolated, recombinant or synthetic, *Amb a* I proteins or peptides, for use in therapy, prophylaxis or diagnosis, the protein or peptides being selected from

(a) *Amb a* IA comprising at least a portion of the amino acid sequence shown in Fig. 11; or

(b) *Amb a* IB comprising at least a portion of the amino acid sequence shown in Fig. 12; or

(c) *Amb a* IC comprising at least a portion of the amino acid sequence shown in Fig. 13; or

(d) *Amb a* ID comprising at least a portion of the amino acid sequence shown in Fig. 14.

9. A process for producing a recombinant ragweed protein/peptide allergen capable of influencing ragweed B-cell and/or T-cell responses in ragweed-sensitive individuals comprising the steps of:

(a) identifying a DNA sequence encoding the ragweed allergen which hybridizes (for example under high stringency conditions) with the DNA sequence shown in Figure 11, 12, 13 or 14;
(b) inserting the DNA identified in step (a) into an expression vector;
(c) inserting the expression vector of step (b) into a host cell;
(d) culturing the host cell of step (c) under conditions appropriate for expression of the DNA inserted in step
(b); and
(e) recovering the expressed product.

14. An isolated nucleic acid comprising a nucleotide sequence which encodes an *Amb a* IA, *Amb a* IB, *Amb a* IC or *Amb a* ID protein or peptide capable of influencing ragweed B-cell and/or T-cell responses in ragweed-sensitive individuals wherein the nucleotide sequence is selected from the nucleotide sequences shown in Figures 11, 12, 13 or 14 or a functional equivalent thereof."

VI. The submissions in writing by the appellant, insofar as they are relevant to the present decision, can be summarized as follows:

Main request
Article 123(2)(3) EPC
Claim 1

- Recombinant protein or peptide production was disclosed in the published WO application as filed on page 33, line 18-ff.

- The wording "free of other *Amb a* I family members" had a basis in the application as in Figure 16 (see also page 16, lines 16 to 19) and Figure 20 (see also page 9, lines 1 to 4) of the application as filed, showing that the *Amb a* I proteins produced in transformed E. coli were free from any other *Amb a* I proteins.

Claim 2

- Any therapeutic composition had of necessity "defined amount(s)" of the components. Therefore no added subject-matter or broadening of the scope of protection could be seen.

First Auxiliary Request

- The wording "free of other *Amb a* I family members" had been deleted from claim 1 in view of the term "recombinant", which necessarily taught that the protein or peptide will be "free of other *Amb a* I family members".

VII. The appellant (patentee) had requested in writing that the decision under appeal be set aside and that the patent be maintained on the basis of the Main Request filed on 30 March 2001 or the First, Second or Third Auxiliary Requests filed on 28 October 2003

and remittal to the opposition division.

The respondent (opponent) had requested in writing that the appeal be dismissed.

VIII. The board gave its decision at the end of oral proceedings on 28 November 2003.

Reasons for the Decision

1. The appeal is admissible.

Main Request
Claim 2
Article 123(2) EPC

2. Claim 29 as originally filed read "A therapeutic composition comprising an allegenic peptide of Amb a I", but this does not mention well defined amounts of this, or that they are isolated: this originally filed claim is broad enough to cover naturally found mixtures of Amb a I. This claim thus does not by itself provide a basis for claim 2 as granted.

3. On page 30 of the application as filed it is stated at lines 22 to 25 that "Through use of the peptides of the

present invention, allergen preparations of consistent, well defined composition and biological activity can be made and administered for therapeutic purposes". On page 31 of the application as filed it is stated at lines 16 to 21 "...a peptide of the present invention (e.g., one having all or a portion of the amino acid sequence of a peptide derived from the DNA insert of Clone Amb a IA, Clone Amb a IB, Clone Amb a IC. . .or their full cDNAs)". Originally filed claim 12, and the description relating to Figures 14 and 16 indicate that Amb a ID is to be considered as in this same category. These passages provide a basis for a claim limited to recombinant or synthetic proteins having at least a portion of the protein sequence shown in Figures 11, 12, 13 or 14, but not for claim 2 as granted which refers to any isolated Amb a I proteins, including ones isolated from natural sources. Thus claim 2 as granted does not comply with Article 123(2) EPC, and the Main Request must be refused.

First Auxiliary Request
Article 123(2)(3) EPC
Claim 1

4. The added feature "recombinant or synthetic" finds a basis in the published WO application as filed on page 33, lines 18 to 21 and on page 33, line 31 to page 34, line 1, relating to the recombinant or synthetic production of the claimed proteins/peptides. Compared with claim 1 as granted, this amendment does not extend the scope of the claim since the isolated recombinant or synthetic protein will of necessity be free from other Amb a I family members. Thus the claim satisfies the requirements of Article 123(2)(3) EPC.

Claim 2

5. The added language over granted claim 2 "recombinant or synthetic" has already been dealt with under point 4 supra.

6. Claim 2 of the First Auxiliary Request finds a basis in the passages already quoted in point 3 above, as it is now limited, compared to claim 2 as granted, to recombinant or synthetic peptides "of the present invention" for which on page 30 of the application as filed it was suggested that they are present in a consistent well defined composition which requires that they be present in defined amounts.

7. The added language over granted claim 2 "the protein or peptides being selected from

(a) *Amb a* IA comprising at least a portion of the amino acid sequence shown in Fig. 11; or

(b) *Amb a* IB comprising at least a portion of the amino acid sequence shown in Fig. 12; or

(c) *Amb a* IC comprising at least a portion of the amino acid sequence shown in Fig. 13; or

(d) *Amb a* ID comprising at least a portion of the amino acid sequence shown in Fig. 14"

finds a basis in claim 12 as filed.

Claim 9

8. Claim 9 differs from granted claim 10 in that the wording "capable of influencing B-cell and/or T-cell responses in ragweed-sensitive individuals" has been added. This language finds a basis in claim 2 as filed. As for the added feature "recombinant", it has already been dealt with under point 4 supra.

Claim 14

9. Claim 14 differs from granted claim 15 by the addition of the features "capable of influencing B-cell and/or T-cell responses in ragweed-sensitive individuals" already dealt with under point 8 supra and "wherein the nucleotide sequence is selected from the nucleotide sequences shown in Figures 11, 12, 13 or 14 or a functional equivalent thereof" to be found in claims 20 and 21 as filed.

10. Moreover, none of the amendments vis-à-vis the granted claims results in any broadening of the scope of protection. Therefore, the claims of Auxiliary Request I fulfil the requirements of Article 123(2)(3) EPC.

Remittal

11. The first instance considered no issue other than Article 123 EPC. Therefore, the board deems it appropriate to have the remaining issues investigated by the first instance in order to know whether there are any objections at all in this respect and, if there are, what the basis for these objections is. Thus the

board exercises its power under Article 111(1) EPC to remit the case to the first instance for further prosecution.

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 on the basis of the First Auxiliary Request submitted on 28 October 2003.

The Registrar: The Chairwoman:

P. Cremona U. M. Kinkeldey