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D E C I S I O N
of 22 January 1996

Case Number: W 0005/95 - 3.3.4

Application Number: PCT/EP 94/02990

Publication Number: -

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Title of invention:
Novel proteins/polypeptides and cotransfection plasmids and live recombinant carriers therefor

Applicant:
Solvay Société Anonyme

Opponent:
-

Headword:
Coronavirus/SOLVAY

Relevant legal provisions:
PCT Art. 17(3)(a)
PCT Rule 13, 40.2(c)

Keyword:
"Non-unity a priori and a posteriori (yes)"

Decisions cited:
W 0013/87, G 0001/89

Headnote:
-

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Case Number: W 0005/95 - 3.3.4
International Application No. PCT/EP 94/02990

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 22 January 1996

Applicant: SOLVAY (Société Anonyme)
Rue du Prince Albert, 33
B-1050 Bruxelles (BE)

Representative: Meyers, Liliane
SOLVAY Société Anonyme
Département de la Propriété Industrielle
310, Rue de Ransbeek
B-1120-Bruxelles (BE)

Subject of the Decision: **Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicant against the invitation (payment of additional fee) of the European Patent Office (branch at The Hague) dated 27 January 1995.**

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
R. Teschemacher

Summary of Facts and Submissions

I. International patent application PCT/EP 94/02990 was filed on 7 September 1994 with forty-eight claims.

Claims 1, 7, 8, 15, 22 and 30 read as follows:

"1. A modified coronavirus S protein, wherein at least one of the A1, A2 or D antigenic regions have been modified or removed therefrom, so that said modified regions are ADE-inactive.

7. A modified coronavirus S protein, wherein the signal peptide has been deleted therefrom.

8. A substantially pure coronavirus SM protein having an amino acid sequence being substantially homologous with the amino acid sequence of Figure 1.

15. A cotransfection plasmid for cotransfection with viral DNA, said cotransfection plasmid including at least a portion of the flanking sequences of the insertion site in the viral genome to be transfected therewith, expression signals derived from RSV or HCMV and SV40 and the coding sequences for a protein of interest to be expressed by the live recombinant carrier produced by such cotransfection.

22. The cotransfection plasmid of claim 15, wherein the target protein is a coronavirus M protein.

30. A live recombinant carrier comprising FHV-1 the genome of which has DNA sequences coding for a coronavirus M protein, so that the live recombinant carrier expresses the coronavirus M protein."

Claim 10 relates generally to a process for preparing a DNA molecule encoding a modified coronavirus S protein, while claims 45 and 47 relate generally to a method for preparing a coronavirus vaccine and to a method for protecting a mammal from a coronavirus infection, respectively.

II. On 27 January 1995 the European Patent Office (EPO), acting as an International Search Authority (ISA), invited the Applicant to pay within a time limit of 30 days four additional search fees pursuant to Article 17(3)(a) and Rule 40.1 PCT and issued a partial search report on Claims 1 to 6, 12, 13, 20, 23 to 25, 35 to 44, 46, 48 and, partially, Claims 10, 14, 45 ,47 ("main invention").

III. The invitation stated that the application related to the following groups of inventions which were not linked by a single inventive concept:

1. Claims 1 to 6, 12, 13, 20, 23 to 25, 35 to 44, 46, 48 and, partially, Claims 10, 14, 45 ,47;

2. Claims 7, 11, 19, 26, 27 and, partially, Claims 10, 14, 45, 47;

3. Claims 8, 9, 21, 28, 29 and, partially, Claims 45, 47;

4. Claims 22, 30, 31 and, partially, Claims 45, 47;

5. Claims 15 to 18 and 32 to 34.

In the view of the ISA, due to the fact that coronavirus polypeptides/proteins and both cotransfection plasmids or live recombinant carriers were state of the art, there was no technical feature nor a single problem

common to the above groups of inventions which either dealt with the provision of new proteins or modified known proteins or with the provision of further expression vectors for proteins. The ISA observed that, since the following documents:

- EP-A-0 376 744
- EP-A-0 264 979
- EP-A-0 411 684
- J. Gen. Virol., 1992, Vol. 73, pages 2849 to 2862,

dealt with the live recombinant carriers carrying various forms of coronavirus proteins, the concept of preparing the individual coronavirus polypeptides by recombinant DNA technology was known and no other technical feature could provide an inventive link among the plurality of inventions.

IV. On 27 February 1995, the Applicant paid the additional fees under protest pursuant to Rule 40.2(c) PCT. In support of the protest, the Applicant submitted that:

- all claims related to proteins which were antigenically active as to stimulate the immunity of cats against coronavirus, and in particular to feline infectious peritonitis virus (FIPV);

- all claims related to vaccines including one of these antigenically-active proteins;

- all claims related to proteins that did not provoke antibody dependent enhancement (ADE) and which, being derived from the nucleic acid sequence of FIPV, had a common structure and a similar nature.

Therefore, there was one special technical feature which linked all claims of the application.

V. On 11 July 1995 the ISA issued a complete search report and communicated to the Applicant the result of its review under Rule 40.2(e) PCT which had confirmed the reasons given in the communication of 27 January 1995. The ISA disagreed with the Applicant's assertion that the claimed proteins had a common structure and pointed out that the ADE-inactivity, which had been substantiated only in respect of coronavirus S proteins, was an intrinsic feature of the M protein which was already in the state of the art. Therefore, the Applicant was invited to pay within one month the protest fee.

VI. The protest fee was paid by the Applicant on 2 August 1995.

Reasons for the Decision

1. The protest is admissible.

2. According to Rule 13.1 PCT, the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. If the ISA considers that the claims lack this unity, it is empowered, under Article 17(3)(a) PCT, to invite the Applicant to pay additional fees.

3. Lack of unity may be directly evident **a priori**, i.e. before the examination of the merits of the claims in comparison with the state of the art revealed by the search (cf., for example, decision W 13/87 of 9 August 1988). Alternatively, having regard to decision G 1/89 of the Enlarged Board of Appeal, dated 2 May 1990 (OJ EPO 1991, 155), the ISA is also empowered to raise an objection **a posteriori**, i.e. after having taken the

prior art revealed by the search into closer consideration. This practice is laid down in the PCT Search Guidelines, Chapter VII,9 (PCT Gazette 30/1992, 14025) which are the basis for a uniform practice of all International Searching Authorities. The Enlarged Board of Appeal indicated that such consideration represented only a provisional opinion on novelty and inventive step which was in no way binding upon the authorities subsequently responsible for the substantive examination of the application (point 8.1. of the Reasons for the decision). In point 8.2 of the Reasons, the Enlarged Board mentioned that such invitation to pay additional fees should always be made "with a view to giving the Applicant fair treatment" and should only be made in clear cases.

4. The claims of the present application may be grouped in the following way:

(i) groups 1 and 2 are concerned with the provision of **a modified coronavirus S protein** (cf., in particular Claims 1 and 7, respectively), group 1 being in particular concerned with the provision of **a modified, ADE (antibody dependent enhancement)-inactive coronavirus S protein** (cf. Claim 1);

(ii) group 3 relates to the provision of **coronavirus SM protein in substantially pure form** (cf. Claim 8);

(iii) group 4 is concerned with the preparation of **live recombinant carriers expressing the coronavirus M protein** (cf. Claim 30);

(iv) group 5 relates to the preparation of **live recombinant carriers expressing a protein of interest** (cf. Claim 15).

5. There is no technical relationship involving one or more of the same or corresponding **special technical feature** among the above groups of inventions referred to under (i) to (iv). It is apparent from the present description (cf. pages 3 and 4) that the quoted groups of inventions relate to **different** objects which are not necessarily interrelated from the technical point of view. The fact that, as submitted by the Appellant, the above claims relate to vaccines including antigenically-active coronavirus proteins derived from the nucleic acid sequence of FIPV does not per se constitute a "special technical feature" in the meaning of Rule 13 PCT, i.e. a technical feature defining the contribution which each of the said groups of invention, considered as a whole, makes over the prior art. This is because, on the one hand, it is manifest that the background art - as mentioned also in the present description (cf. pages 2 and 3) - already dealt with the preparation by recombinant DNA techniques of vaccines including coronavirus proteins, in particular from FIPV. Thus, for example, the problem of the provision of the coronavirus SM protein in substantially pure form is technically independent from the problem of providing a modified coronavirus S protein as well as from the provision of live recombinant carriers expressing the coronavirus M protein. Further, the provision of a cotransfection plasmid according to Claim 15 is not necessarily linked to the problem of expressing the one or the other coronavirus protein (S, M or SM) in a live recombinant carrier as many other known ways can lead thereto. On the other hand, neither the ADE-inactivity nor the FIPV origin are technical features which always necessarily characterise the subject-matter of the claims of the

said groups of inventions, also when the said claims are interpreted in the light of the description. Consequently, in the Board's judgement, the groups of inventions referred to under (i) to (iv) lack unity already **a priori**.

6. As stated above, the groups 1 and 2 are concerned with the provision of **a modified coronavirus S protein**, group 1 being in particular concerned with the provision of **a modified ADE (antibody dependent enhancement)-inactive coronavirus S protein**. The performing of a structural modification on the known coronavirus S protein would constitute **a priori** the "special technical feature" providing the link between group 1 and 2. However, the examination of the prior art shows that structural modifications of the coronavirus S protein are disclosed e.g. in document WO 92/08487. This document relates inter alia to the preparation by recombinant DNA techniques of various fragments of coronavirus S protein to be used as vaccines (cf. pages 3 to 4). Among them, fragments are disclosed that, due to their primary structure, necessarily fall within the definition of both present Claim 1 (removal from coronavirus S protein of at least one of the A1, A2 or D antigenic regions and, consequently, of the regions responsible for ADE-activity) and present Claim 7 (deletion of the signal peptide from coronavirus S protein). Therefore, both these claims lack novelty having regard to the quoted document (1). Under these circumstances groups 1 and 2 are left **a posteriori** without a common inventive concept. No other "special technical feature" in the sense of Rule 13.2 is available to link the two groups so as to form a single general inventive concept.

7. For the foregoing reasons, in the Board's judgement, the international application does not comply with the requirement of Rule 13.1 PCT and the invitation to pay the additional fees was justified.

Order

For these reasons it is decided that:

The protest according to Rule 40.2(c) PCT is dismissed.

The Registrar: The Chairwoman:

L. McGarry U. Kinkeldey