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D E C I S I O N
of 13 February 2002

Case Number: T 0750/98 - 3.3.4

Application Number: 90901397.1

Publication Number: 0449958

IPC: A61K 39/095

Language of the proceedings: EN

Title of invention:
Meningococcal class I outer-membrane protein vaccine

Patentee:
AMERICAN CYANAMID COMPANY, et al

Opponent:
Aventis Pasteur

Headword:
Outer-membrane protein/CYANAMID

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes)"

Decisions cited:
G 0009/92

Catchword:
-

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Case Number: T 0750/98 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 13 February 2002

Respondent: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 11 May 1998 concerning maintenance of European patent No. 0 449 958 in amended form.**

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
S. C. Perryman

Summary of Facts and Submissions

I. The appeal was lodged by the patent proprietors against the interlocutory decision of the opposition division issued on 11 May 1998 whereby the European patent No. 0 449 958, which had been opposed by one party under Article 100(a) to (c) EPC, was maintained in amended form on the basis of the seventh auxiliary request on file in the two versions for all designated contracting states except Spain (non-ES states) and for ES, this being the only request considered to meet all the EPC requirements.

In its decision, the opposition division indicated also that the opponents' request for an apportionment of costs in their favour was justified.

Claims 15 to 17 of the request allowed by the opposition division for the non-ES states read as follows:

"15. An antigenic conjugate, consisting of an oligopeptide containing an epitope of a meningococcal Class I outer-membrane protein, conjugated to a carrier protein or epitope thereof, provided that the carrier protein is not ß-galactosidase, wherein the epitope is selected from the group consisting of: QPQVTNGVQGN, PPSKSQP, QAANGGASG, YYTKDTNNNLTL, YYTKNTNNNLTL, YYTKDTNNNL, YYTKNTNNNL, HFVQQTPQSQP and HYTRQNNTDVF."

"16. An antigenic conjugate of claim 15, wherein the antigen carrier protein is a bacterial toxin, CRM or epitope thereof."

"17. A genetic fusion peptide or protein, consisting of

an oligopeptide containing an epitope of a meningococcal Class I outer-membrane protein fused to a carrier protein, peptide or epitope thereof, provided that the carrier protein is not ß-galactosidase, wherein the epitope is selected from the group consisting of: QPQVTNGVQGN, PPSKSQP, QAANGGASG, YYTKDTNNNLTL, YYTKNTNNNLTL, YYTKDTNNNL, YYTKNTNNNL, HFVQQTPQSQP and HYTRQNNTDVF."

II. The opponents filed a notice of appeal, but did not pay the appeal fee. Nor did they file a statement of grounds of appeal.

III. With the statement of grounds of appeal, the appellants withdrew the first to sixth auxiliary requests and maintained only the main request as submitted before the opposition division. They did not challenge the finding of the opposition division as regards the apportionments of costs.

IV. The respondents (opponents) did not reply to the statement of grounds of appeal.

V. On 9 January 2002, the board issued a communication with an outline of the points to be discussed and a provisional view on some of the issues.

VI. On 14 January 2002, the appellants filed a main request and four auxiliary requests. On 30 January 2002, they filed auxiliary request 1a.

VII. Oral proceedings took place on 13 February 2002.

The respondents, which had informed the board by letter dated 28 January 2002 of their intention not to attend

the hearing, were not represented.

The appellants filed as a sole request a new set of claims for the non-ES states in replacement of all the previous requests on file.

Claims 1 to 14 and 18 to 35 of this request for the non-ES states as well as claims 1 to 27 for ES were as allowed by the opposition division. Claims 15 to 17 for the non-ES states read as follows:

"15. An antigenic conjugate, comprising a carrier protein or an epitope thereof, to which is conjugated a fragment of a meningococcal Class 1 outer-membrane protein having a molecular weight of 25kd or less containing an epitope selected from the group consisting of: QPQVTNGVQGN, PPSKSQP, QAANGGASG, YYTKDTNNNLTL, YYTKNTNNNLTL, YYTKDTNNNL, YYTKNTNNNL, HFVQQTPQSQP and HYTRQNNTDVF, provided that the carrier protein is not ß-galactosidase."

"16. An antigenic conjugate of claim 15, wherein the antigen carrier protein is a bacterial toxin, CRM or epitope thereof."

"17. A genetic fusion peptide or protein, comprising a carrier protein, peptide or epitope thereof, to which is fused a fragment of a meningococcal Class 1 outer-membrane protein having a molecular weight of 25kd or less containing an epitope selected from the group consisting of: QPQVTNGVQGN, PPSKSQP, QAANGGASG, YYTKDTNNNLTL, YYTKNTNNNLTL, YYTKDTNNNL, YYTKNTNNNL, HFVQQTPQSQP and HYTRQNNTDVF, provided that the carrier protein is not ß-galactosidase."

New pages 3a and 3b of the description adapted to the claim request were also filed.

VIII. The appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 35 submitted as new sole request for all designated Contracting States except ES at oral proceedings on 13 February 2002, Claims 1 to 27 for ES as maintained by the opposition division and the description and drawings as maintained by the opposition division except for pages 3a and 3b submitted at oral proceedings on 13 February 2002 being substituted for pages 3a and 3b referred to in the decision of the opposition division.

Reasons for the Decision

1. By not paying the appeal fee, the opponents, who had filed a notice of appeal, did not challenge the decision of the opposition division. Under Article 108 EPC their appeal is deemed not to have been filed.

2. As the patent proprietors are the sole appellants, the claims as maintained by the opposition division are not subject of the appeal (cf G 9/92, OJ EPO 1994, 875). Consequently, as in the sole request on file claims 1 to 14 and 18 to 35 for the non-ES states and claims 1 to 27 for ES are identical to those allowed by the opposition division, they may not be challenged. Thus, the appeal is limited to the examination of claims 15 to 17 for the non-ES states (cf Section VII above).

3. As regards the formal admissibility of these claims, it is noted that their scope is narrower than that of the

corresponding granted claims 17 to 20, independent claim 17 and 18 thereof not being limited to conjugates containing the specific epitopes now recited in the claims. Moreover, the feature "a fragment of a meningococcal Class 1 outer-membrane protein having a molecular weight of 25kd or less" is supported by the application as filed which explicitly refers to such a feature on page 10, lines 11 to 15 (N.B.the designations Class I and Class 1 are equivalent and interchangeably usable). Thus, the said claims comply with the requirements of Article 123(2)(3) EPC.

4. The claim formulation now adopted for claims 15 to 17 had never been put forward before the opposition division which was confronted either with a broader version not limited by the feature "a fragment of a meningococcal Class 1 outer-membrane protein having a molecular weight of 25kd or less" which broader version was rejected for lack of inventive step having regard to document (1) (Infection and Immunity, November 1987, pages 2734 to 2740) or with a version directed to an antigenic conjugate or fusion protein "consisting" of an oligopeptide containing one of the recited epitope sequences, which was allowed (cf Section I above).

5. The set of claims allowed by the opposition division includes product claim 6 which is directed to a "Substantially purified fragment of Class I outer-protein of Neisseria meningitidis the fragment having a molecular weight of about 25 kD or less and containing continuos or discontinuos epitopes with bactericidal antibodies against N. meningitidis, wherein the epitopes are located in surface loops of meningococcal Class I outer-membrane proteins in the area of amino acids 24-34 and 176-187". It is noted that the epitopes

whose specific sequence are recited in the claims at issue are precisely in that area. This logically means that, according to the ratio decidendi of the opposition division, a fragment of Class 1 outer-protein of Neisseria meningitidis having a molecular weight of about 25 kD or less and containing the nine specific epitopes listed in the claims at issue complies with all the requirements of the EPC, in particular it involves an inventive step. This finding may not be challenged (cf point 2 above) in relation to claim 6, but in any case the board agrees with the reasons stated for this finding.

6. If such a fragment is patentable, then on the same reasoning an antigenic conjugate or a fusion protein containing it has to be considered patentable. This is precisely the subject-matter of the claims at issue which can therefore be allowed.

7. There are no objections to new pages 3a and 3b of the description which have been adapted to the new set of claims.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside apart from the apportionment of costs in favour of the respondent opponent.

2. The case is remitted to the first instance with the order to maintain the patent on the basis requested by

the appellants.

The Registrar: The Chairperson:

P. Cremona U. Kinkeldey