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Datasheet for the decision of 13 October 2009

Case Number: T 1074/08 - 3.3.08

Application Number: 03701402.4

Publication Number: 1472353

IPC: C12N 15/31

Language of the proceedings: EN

Title of invention:
Group B streptococcus antigens

Applicant:
ID Biomedical Corporation

Opponent:
-

Headword:
Streptococcus/ID BIOMEDICAL

Relevant legal provisions:
EPC Art. 123(2), 54, 56, 83

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request - added subject-matter - no"
"Novelty - yes"
"Inventive step - yes"
"Sufficiency of disclosure - yes"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1074/08 **-** 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 13 October 2009

Appellant: ID Biomedical Corporation
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Representative: Naylor, Kathryn May
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 20 November 2007 refusing European application No. 03701402.4 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: L. Galligani
Members: F. Davison-Brunel
C. Heath

Summary of Facts and Submissions

I. European patent application No. 03 701 402 with the title "Group B Streptococcus antigens" filed as International application No. PCT/CA 03/00186 was published under No. WO 03/068813 with 30 claims. It was refused by the examining division in a decision dated 20 November 2007.

II. The decision of the examining division was taken on the grounds that the claim request then on file (claims 1 to 44 filed on 10 February 2006) did not meet the requirements of Articles 54, 56 and 84 EPC (lack of novelty and inventive step, lack of clarity).

Claim 1 of this request read as follows:

"1. An isolated polynucleotide chosen from:

(a) a polynucleotide encoding a polypeptide consisting of a sequence chosen from: SEQ ID NOS: 4, 6, 8, 10, 12, 14, 16, 18, or 20; or

(b) a polynucleotide encoding a polypeptide **having at least 70% identity** over the full length of the sequence to a polypeptide consisting of a sequence chosen from SEQ ID NOS: 4, 6, 10, 12, 14, 18, or 20 wherein the encoded polypeptide retains the ability to raise antibodies having binding specificity for Group B Streptococcus; or

(c) a polynucleotide that is complementary to the polynucleotide in (a) or (b)." (bold-type characters added by the board)

The examining division decided that the subject-matter of claim 1 was not novel as some of the polypeptides of the invention shared more than 70% identity to SEQ ID NO: 148 disclosed in document (2) (see infra). Therefore, SEQ ID NO: 148 fell within the scope of the claim. The same objection applied to claims 2, 13 to 19 and 29 to 42.
Furthermore, inventive step was denied for the subject-matter of the other claims because there no evidence had been provided that the Sip protein fragments of SEQ ID NOS: 10, 14, 16, 18 and 20 (to be used as vaccines) were immunogenic. The other Sip protein fragments SEQ ID NOS 4, 6 and 8 had been shown to be immunogenic; yet, it was not obvious that they would be any better as vaccines than the full length Sip protein disclosed in the closest prior art document (1), i.e. that they could be regarded as inventive.

III. The appellant (applicant) lodged an appeal against this decision and filed a statement setting out the grounds of appeal together with an amended set of claims (claims 1 to 31).

IV. The examining division did not rectify its decision and the case was remitted to the board of appeal (cf. Article 109(2) EPC).

V. On 10 July 2009, the board sent a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), making known its preliminary, non-binding opinion.

VI. On 28 September 2009, the appellant filed further submissions in answer to this communication together with a new main request (claims 1 to 35) and auxiliary requests 1A to 1D to replace the request on file.

VII. In a telephone conversation on 4 October 2009, the appellant was informed that the board was inclined to accept patentability of the auxiliary request 1C (claims 1 to 30) provided that the references to SEQ ID NOS: 8 and 12 were deleted from the claims as no inventive effect seemed to have been demonstrated for these specific sequences.

VIII. On 9 October 2009, the appellant sent a fax letter in answer to this telephone conversation, filing a new main request corresponding to the said auxiliary request 1C and at the same time pointing out the basis in the application as filed for acknowledging the inventive effect of SEQ ID NOS: 8 and 12.

Claims 1 and 11 of the main request (claims 1 to 30) read as follows:

"1. An isolated polynucleotide encoding a polypeptide consisting of an amino acid sequence **at least 85% identical** over the full length of the amino acid sequence chosen from: SED ID NOS: 4, 6, 8, and 12 wherein the encoded polypeptide retains the ability to raise antibodies having binding specificity for Group B Streptococcus.

11. An isolated polypeptide consisting of an amino acid sequence **at least 85% identical** over the full length of the amino acid sequence chosen from: SED ID NOS: 4, 6,

8, and 12 wherein the polypeptide retains the ability to raise antibodies having binding specificity for Group B Streptococcus."
(bold-type characters added by the board)

Dependent claims 2 to 6 related to embodiments of claim 1. Claim 7 related to a complementary polynucleotide to the polynucleotide of any one of claims 1 to 6, claim 8 to a vector comprising the polynucleotide of any one of claims 1 to 6, claim 9 to a host cell transfected with said vector and claim 10 to a process for producing the polypeptide from the transfected host cells. Claim 11 concerned an isolated polypeptide consisting of an amino acid sequence **at least 85% identical** over the full length of the amino acid sequence chosen from: SED ID NOS: 4, 6, 8, and 12. Claims 12 to 15 related to embodiments of claim 11; claim 16 to a fusion polypeptide; claim 17 to a chimeric polypeptide. Claims 18, 19, 21, 22, 25 to 27 related to vaccines comprising the said polypeptides. Claims 23, 24, 28 and 29 related to the said polypeptides for prophylactic or therapeutic treatment. Claim 20 related to a method for detection of an antibody specific to Group B Streptococcus antigen making use of the polypeptides according to any one of claims 11 to 16. Claim 30 related to a kit comprising the polypeptide according to any one of claims 11 to 15.

IX. The oral proceedings scheduled for 13 October 2009 were cancelled.

X. The following documents are relevant to the present decision:

(1) : WO 99/42588 published on 26 August 1999;

(2) : WO 01/32882 published on 10 May 2001;

(3) : Database Swall Online EBI accession no. q93gj8, 1 December 2001;

(4) : Brodeur, B.R. et al., Infection and Immunity, Vol.68, No.10, pages 5610 to 5618, October 2000.

XI. The appellant's submissions may be summarized as follows:

Article 123(2) EPC; added subject-matter

The subject-matter of claims 1 to 4 finds a basis in the application as filed on page 9, lines 25 to 28 combined with the passage bridging pages 11 and 12. The subject-matter of claim 16 (fusion polypeptide) finds a basis throughout the application as filed, in particular on page 12, lines 1 and 17 to 23, page 14, lines 1 to 6 and page 16, lines 28 to 33.

The requirements of Article 123(2) EPC are fulfilled.

Article 54 EPC; novelty

The claims to polynucleotides are now limited to those polynucleotides encoding polypeptides consisting of an amino acid sequence at least 85% identical to the

specific SEQ IDs NOS: 4, 6, 8 and 12, or more. The claims to polypeptides are now limited in the same manner. Document (2) does not disclose such polynucleotides/polypeptides; in particular, SEQ ID NO 148 - considered by the examining division as novelty destroying for claim 1 then on file - does not share this percentage of identity. The claimed subject-matter is, thus, novel.

Article 56 EPC; inventive step

The now claimed subject-matter relates to polypeptides that consist of the amino acid sequences set forth in SEQ ID NOS: 4, 6, 8 or 12. The appellant surprisingly discovered that these polypeptides retain the ability to raise antibodies that bind specifically to group B Streptococcus. Thus, despite having only half of the amino acids of the Sip protein, these polypeptides provide an equivalent protection. This would not have been obvious to the skilled person before the filing date of the application as filed. Furthermore, the fractions have a number of advantages. For instance, the manufacture of a vaccine comprising a polypeptide fragment having only half the amino acids of the full length protein is technically easier, cheaper, more reliable and less wasteful in terms of resources.

The requirements of Article 56 EPC are fulfilled.

XII. The appellant requests that the decision under appeal be set aside and that the application be allowed on the basis of the main request filed on 9 October 2009.

Reasons for the decision

Main request filed on 9 October 2009
Article 123(2) EPC ; added subject-matter

1. On page 9, lines 24 to 28 of the application as filed, it is disclosed:

" Those skilled in the art will appreciate that the invention includes DNA molecules ,... that encode analogs such as mutants, variants, homologues and derivatives of such polypeptides, as described herein in the present patent application."

And, in the passage bridging pages 11 and 12, it is mentioned as regards "fragments", "analogs", "variants" or derivatives of the polypeptides of the invention identified, also on page 11, as, in particular, SEQ IDS 4, 6, 8 or 12:

"In a further embodiment, polypeptides will have greater than 80% identity. In a further embodiment, polypeptides will have greater than 85% identity. In a further embodiment, polypeptides will have greater than 90% identity. In a further embodiment, polypeptides will have greater than 95% identity. In a further embodiment, polypeptides will have greater than 99% identity."

The board considers the combination of these teachings as providing a basis for the subject-matter of claims 1 to 4, 11 to 14. It is noted that the wording used in the claims to qualify the percentage of identity

between the polypeptides is "at least ..% identical" whereas on pages 11 and 12, it is identified as "greater than ..% identity". Yet, a polypeptide which has greater than 80% identity to any one of the specific SEQ ID NOS 4, 6, 8 and 12 may have 85%, 90, 95 or 99% identity. The application as filed, thus, provides an at least implicit but unambiguous disclosure of the now claimed polynucleotides/ polypeptides.

2. Claims 5, 6 and 15 find a basis in the figures of the application as filed. Claims 7 to 10 correspond to originally filed claims 2g, 12, 14 and 15. Claim 16 finds a basis on eg page 12, lines 17 to 23. Claims 17 to 30 correspond to originally filed claims 20 to 30. In some of the claims (eg claims 18 and 19, corresponding to originally filed claim 21), the term "vaccine" has replaced the term "pharmaceutical composition". A basis for the vaccine is found eg on page 19, lines 5 to 7 of the application as filed.

3. In the board's judgment, the requirements of Article 123(2) EPC are fulfilled.

Article 54 EPC: novelty

4. Four documents were identified in the search report as relevant to the patentability of the present invention. Documents (1), (2) and (4) are concerned with developing vaccines against group B Streptococcus. All of them disclose specific, potentially immunogenic polypeptides. None of these have sequences which consist of SEQ ID NOS 4, 6, 8 or 12 nor do they have sequences presenting a percentage of identity to the

SEQ ID NOS 4, 6, 8 or 12 ranging from at least 85% to at least 99%. Document (3) is an excerpt from a database on line showing a partial sequence of the Sip protein from which the now claimed polypeptides are derived. Yet, this sequence is different from that of the claimed polypeptides. The subject-matter of claims 1 to 6, 11 to 15 is, thus novel. In the same manner, the subject-matter of claims 7 to 10, 16 to 30 which are dependent on either claims 1 to 6 or claims 11 to 15 enjoys novelty.

5. The requirements of Article 54 EPC are fulfilled.

Article 56 EPC: inventive step

6. Document (2) is a patent application relating to fragments of group B Streptococcus cell surface associated or secreted proteins which may be immunogenic and, therefore, useful in the prevention or treatment of Group B Streptococcus infections (see page 4, first full paragraph). In this document, one of the many sequences which are disclosed (SEQ ID NO 148) derives from the Sip protein. But its immunogenicity is not shown.

Document (4) is a publication relating to the identification of the Group B Streptococcus Sip protein which elicits cross-protective immunity. In this respect, document (4) appears to correspond to document (1) (a patent application) although the two documents do not exactly describe the same data, (compare, for example, Figure 5 of document (4) with Figure 10 of document (1) or Figure 6 of document (4) with Table 5 of document (1)).

Document (1) is a patent application which discloses group B Streptococcus polypeptides which may be immunogenic (page 6). A preferred embodiment is the Sip protein (SEQ ID NOS 39 and 44) comprising 434 or 409 amino acids depending on the presence/absence of a 25 amino acid residues leader peptide. The Sip protein is shown to be conserved amongst the various Group B streptococci (example 10) as well as to trigger an immune response in mice (Tables 3 and 4) and to confer protection against various experimental Group B Streptococcus infections (Table 5). In the board's judgment, document (1) is the closest prior art.

7. Starting from the teachings of document (1), the problem to be solved can be defined as the provision of further polypeptides capable of conferring protection against Group B Streptococcus infections.

8. As a solution, the claims propose the Sip protein fragments consisting of SEQ ID NOS 4, 6, 8 and 12 and polypeptides having sequence identity thereto which remain able to raise antibodies having binding specificity for Group B Streptococcus. Table 5 in the patent in suit demonstrates that the required effect is indeed achieved, ie. that the polypeptides SEQ ID NOS 4, 6, 8 and 12 (respectively identified as Дsip-2, Дsip-3, Дsip-4 and Дsip-6, see the relationship between the two on pages 4 and 5) elicit protection against group B Streptococcus strain C 388/90. It is noted by comparing these data to those provided in Table 5 of document (1) - reporting the ability of the full-length Sip protein to elicit protection against the same C 388/90 streptococcal strain - that the protecting effect of

the fragments (60% to 88% surviving mice) is about as good as or better than that of the full length Sip protein (80% surviving mice).

9. This is a result which the skilled person would have had no reasons to expect. Furthermore, precisely because the specific fragments are smaller than the protein, they are advantageous, possibly safer and more reliable when producing the corresponding vaccines.

10. For these reasons, inventive step is acknowledged to the claimed polypeptides/polynucleotides encoding them as well as to any corresponding vaccines, uses, methods of use and kit containing them. The requirements of Article 56 EPC are fulfilled.

Article 83 EPC; sufficiency of disclosure

11. As the claimed polypeptides/polynucleotides encoding them are defined by their sequences, there should be no difficulty in isolating and producing them. The claimed uses are those normally expected in the medical field. In the absence of any evidence to the contrary, the board accepts that at the priority date, it would have been possible to put them into practice without undue burden. The requirements of Article 83 EPC are fulfilled.

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 with the order to grant a patent on the basis of claims 1 to 30 filed as main request on 9 October 2009 and a description and figures to be adapted thereto.

The Registrar | The Chairman

A. Wolinski | L. Galligani