



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : C07K 14/35, A61K 39/04, G01N 33/569</p>	<p>A3</p>	<p>(11) International Publication Number: WO 00/21983</p> <p>(43) International Publication Date: 20 April 2000 (20.04.00)</p>
<p>(21) International Application Number: PCT/DK99/00538</p> <p>(22) International Filing Date: 8 October 1999 (08.10.99)</p> <p>(30) Priority Data: PA 1998 01281 8 October 1998 (08.10.98) DK 60/116,673 21 January 1999 (21.01.99) US</p> <p>(71) Applicant (for all designated States except US): STATENS SERUM INSTITUT [DK/DK]; Artillerivej 5, DK-2300 Copenhagen S (DK).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): ANDERSEN, Peter [DK/DK]; Sparreholmvej 47, DK-2700 Brønshøj (DK). WELDINGH, Karin [DK/DK]; Nørrebrogade 224, 3. tv, DK-2200 Copenhagen N (DK). HANSEN, Christina, Veggerby [DK/GB]; 14 Conyngham Road, Victoria Park, Manchester M14 5SA (GB). FLORIO, Walter [IT/IT]; Via Carriona, 226, I-Carrara (IT). OKKELS, Li, Mei, Meng [DK/DK]; Aldershvilevej 116A, DK-2880 Bagsværd (DK). SKJØT, Rikke, Louise, Vinther [DK/DK]; Thorvaldsensvej 9, 5. sal, DK-1871 Frederiksberg C (DK). ROSENKRANDS, Ida [DK/DK]; Kastaniehaven 9, DK-3500 Vaerlose (DK).</p>	<p>(74) Agent: PLOUGMANN, VINGTOFT & PARTNERS A/S; Sankt Annæ Plads 11, P.O. Box 3007, DK-1021 Copenhagen (DK).</p> <p>(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p> <p>(88) Date of publication of the international search report: 23 November 2000 (23.11.00)</p>	
<p>(54) Title: TUBERCULOSIS VACCINE AND DIAGNOSTIC REAGENTS BASED ON ANTIGENS FROM THE <i>MYCOBACTERIUM TUBERCULOSIS</i> CELL</p>		
<p>(57) Abstract</p> <p>The present invention relates to substantially pure polypeptides, which has a sequence identity of at least 80 % to an amino acid sequence disclosed, or which is a subsequence of at least 6 amino acids thereof, preferably a B- or T-cell epitope of the polypeptides disclosed. The polypeptide or the subsequence thereof has at least one of nine properties. The use of the disclosed polypeptides in medicine is disclosed, preferably as vaccine or diagnostic agents relating to virulent <i>Mycobacterium</i>. The invention further relates to the nucleotide sequences disclosed and the nucleotide sequences encoding the disclosed polypeptides. Medical and non-medical use of the nucleotide sequences is disclosed.</p>		

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK 99/00538

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07K14/35 A61K39/04 G01N33/569

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K A61K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 16646 A (CORIXA CORP) 23 April 1998 (1998-04-23) page 2, line 7 - line 14 page 4, line 14 - line 21 page 5, line 14 - line 21 SEQ IDNO 190, 195 page 28, line 16; example 3D abstract --- -/--	1-15, 18-23

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

17 April 2000

Date of mailing of the international search report

20. 09. 00

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK 99/00538

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>EIGIMEIER AT AL: "Use of an ordered cosmid library to deduce the genomic organization of Mycobacterium leprae" MOLECULAR MICROBIOLOGY, vol. 7, no. 2, 1993, pages 197-206, XP002900965 page 197 -page 205; figure 2 abstract</p>	1-6
A	<p>---</p>	7-15, 18-23
P,X	<p>COLE S T: "Deciphering the biology of Mycobacterium tuberculosis from the complete genome sequence" NATURE, vol. 393, 11 June 1998 (1998-06-11), pages 537-544, XP002900966 abstract page 542, right-hand column, paragraph 2; table 1H</p>	1-6
P,A	<p>-----</p>	7-15, 18-23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 99/00538

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15, 18-23

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK99/00538

According to PCT Rules 13.1 and 13.2, an international application shall relate to one invention only or a group of inventions linked by one or more of the same corresponding "special technical features", i.e. features that define a contribution which each of the inventions makes over the prior art.

In the present application the following inventions have been found *à posteriori* in relation to W098/16646:

1-22. Substantially pure polypeptides with a sequence identity of at least 80% to an amino acid disclosed in SEQ ID NOs 34, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 36, 38, 75, 77 and 79 respectively (each sequence corresponding to one invention) as well as nucleotide sequences coding disclosed in SEQ ID NOs 33, 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 35, 37, 74, 76 and 78 encoding the polypeptides, which constitute 22 different inventions. These inventions also relate to the use of the polypeptides and nucleotide sequences and are disclosed in claims 1-15 and 18-23. Inventions 1-5 (sequences disclosed in SEQ ID NOs 34, 2, 4, 6, 8, and 33, 1, 3, 5, 7) have been searched.

23. An extract of polypeptides from Mycobacteria and the use of the extract for the preparation of a composition for the generation of an immune response against Mycobacterium. This invention is disclosed in claims 16-17 and has not been searched.

The special technical feature of each of the inventions 1-22 is each specific amino acid sequence. At least one of the searched sequences has been published in W098/16646 and is expected to have properties equal to the corresponding polypeptide of the application. The special technical feature of invention 23 is the extract of polypeptides obtained using a certain method. Thus, the inventions found in the application are not linked by any common special technical feature and the application lacks unity *à posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK 99/00538

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9816646 A	23-04-1998	AU 4814497 A	11-05-1998
		CZ 9901265 A	17-11-1999
		EP 0932681 A	04-08-1999
		NO 991694 A	10-06-1999
		PL 332878 A	25-10-1999
