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(54) Title: INFLUENZA VACCINE

(57) Abstract: The invention provides a monovalent influenza vaccine comprising a low dose of egg-derived influenza virus antigen from an influenza virus strain that is associated with a pandemic outbreak or has the potential to be associated with a pandemic outbreak, in combination with an aluminium adjuvant. The invention also provides vaccine kits comprising a combination of a parenteral and a mucosal influenza vaccine, wherein the combined dose of antigen is no more than the conventional antigen dose. Also provided are methods for preparing the vaccines.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K39/145 A61P31/12

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 A61K

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)

WPI Data, MEDLINE, EPO-Internal, BIOSIS, SCISEARCH, EMBASE, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KISTNER O ET AL: "DEVELOPMENT OF A VERO CELL-DERIVED INFLUENZA WHOLE VIRUS VACCINE" DEVELOPMENTS IN BIOLOGICAL STANDARDIZATION, CH, BASEL, vol. 98, 1999, pages 101-110, XP000909542 cited in the application the whole document ---	1-9, 17-20, 25
A	WO 94 19013 A (SMITHKLINE BEECHAM CORP ; SMITHKLINE BEECHAM BIOLOG (BE); DILLON SU) 1 September 1994 (1994-09-01) claims 1,6,8,9 ---	
A	US 5 149 531 A (YOUNGNER JULIUS S ET AL) 22 September 1992 (1992-09-22) abstract ---	12, 26
	-/--	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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- *&* document member of the same patent family

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INTERNATIONAL SEARCH REPORT

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PCT/EP 00/09509

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>LU XIUHUA ET AL: "A mouse model for the evaluation of pathogenesis and immunity to influenza A (H5N1) viruses isolated from humans." JOURNAL OF VIROLOGY, vol. 73, no. 7, July 1999 (1999-07), pages 5903-5911, XP002162397 ISSN: 0022-538X abstract page 5910, left-hand column, paragraph 3</p>	<p>1-10, 17-20</p>
A	<p>GUARNACCIA S ET AL: "COMPARATIVE IMMUNOGENICITY-REACTOGENICITY DOSE-RESPONSE STUDY OF INFLUEZA VACCINE" ANNALS OF ALLERGY,US,AMERICAN COLLEGE OF ALLERGY AND IMMUNOLOGY,, vol. 65, no. 3, 1990, pages 218-221, XP000887044 ISSN: 0003-4738 the whole document</p>	
T	<p>WO 00 15251 A (BAXTER AG ;BARRETT NOEL (AT); KISTNER OTFRIED (AT); MUNDT WOLFGANG) 23 March 2000 (2000-03-23) the whole document</p>	
P,X	<p>WO 00 47222 A (BAXTER AG ;BARRETT NOEL (AT); KISTNER OTFRIED (AT); DORNER FRIEDRI) 17 August 2000 (2000-08-17) the whole document</p>	<p>1-10, 12-20, 25,26</p>

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. l. Application No

PCT/EP 00/09509

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9419013 A	01-09-1994	AP 431 A	15-11-1995
		AU 6141094 A	14-09-1994
		CA 2156525 A	01-09-1994
		CN 1124013 A	05-06-1996
		EP 0684838 A	06-12-1995
		JP 8506592 T	16-07-1996
		MX 9401225 A	31-08-1994
		SI 9400085 A	30-09-1994
<hr/>			
US 5149531 A	22-09-1992	AU 8193191 A	23-01-1992
		WO 9200097 A	09-01-1992
<hr/>			
WO 0015251 A	23-03-2000	AU 5720099 A	03-04-2000
<hr/>			
WO 0047222 A	17-08-2000	AT 19499 A	15-12-2000
		AU 2525300 A	29-08-2000
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