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Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

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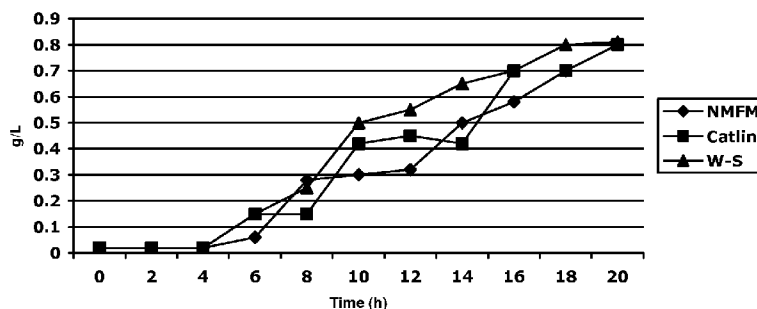
- with international search report

[Continued on next page]

(54) Title: METHOD OF PRODUCING MENINGOCOCCAL MENINGITIS VACCINE FOR NEISSERIA MENINGITIDIS SEROTYPES A,C,Y, AND W-135

Method of producing Meningococcal meningitis vaccine for Neisseria meningitidis serotypes A, C, Y, W - 135.

**Dry Biomass Production in 100 Liter
Bioreactor Average of Neisseria meningitidis
serotypes A,C,Y,W-135.**



(57) Abstract: Methods for producing quadrivalent meningococcal meningitis polysaccharide and conjugate vaccines for serotypes A, C, Y and W-135 disclosed. *Neisseria meningitidis* fastidious medium was designed to maximize the yield of capsular polysaccharides and generate minimal cellular biomass and endotoxin in a short duration of fermentation. The crude polysaccharides are isolated, purified, and mechanically depolymerized by sonication. These purified polysaccharides were found in human clinical trials to be safe and immunogenic against meningococcal disease caused by *N. meningitidis* A, C, Y and W-135 serogroups in sub-Saharan Africa. In the preferred embodiment, the polysaccharides are conjugated to carrier proteins of diphtheria or tetanus toxoid to an average molecular size of 5100 to 9900 Daltons and provide broad spectrum protection to humans of all ages. Accelerated polysaccharide production and the efficacy of the resulting vaccine are demonstrated.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2007/064536

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. *C12N 1/20* (2006.01) *A61K 39/095* (2006.01)
 US Cl. 435/253.6 424/250.1

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)

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 practicable, search terms used)
 WPIDS, CAPLUS, MEDLINE: Neisseria, medium, media, mops, morpholinopropanesulphonic acid, manganese sulfate, MnSO₄, nicotinamide adenine dinucleotide, nad, vitamin b12, cobalamin, cyanocobalamin

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	AJELLO, G.W., et al., "Trans-Isolate Medium: a New Medium for Primary Culturing and Transport of Neisseria meningitidis, Streptococcus pneumoniae, and Haemophilus influenzae", Journal of Clinical Microbiology, 1984, Vol. 20, No. 1, pages 55-58 Whole article	1-27
A	US 6 555 333 B1 (EVALLE) 29 April 2003 Whole specification	1-27
A	EP 0 489 392 (BECTON DICKINSON AND COMPANY) 22 January 1997 Whole document	1-27

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Further documents are listed in the continuation of Box C

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See patent family 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 application or patent 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

"&" document member of the same patent family

Date of the actual completion of the international search
 3 October 2007

Date of mailing of the international search report

04 FEB 2008

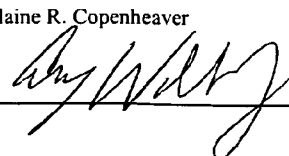
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2007/064536

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. These particulars are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
US	6555333	EP	1362909		
EP	0489392	AU	87969/91	CA	2055973
		JP	5041975	NO	914764
				FI	915713
				NZ	240659
END OF ANNEX					