

(12) **United States Patent**
Reddy(10) **Patent No.:** **US 7,491,517 B2**
(45) **Date of Patent:** **Feb. 17, 2009**(54) **METHOD OF PRODUCING
MENINGOCOCCAL MENINGITIS VACCINE
FOR NEISSERIA MENINGITIDIS SEROTYPES
A,C,Y, AND W-135**(76) Inventor: **Jeeri R Reddy**, 6817 North 97th Cir.,
Omaha, NE (US) 68122(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 51 days.(21) Appl. No.: **11/680,471**(22) Filed: **Feb. 28, 2007**(65) **Prior Publication Data**

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19, 2006.(51) **Int. Cl.***C12P 19/00* (2006.01)
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A61K 39/095 (2006.01)(52) **U.S. Cl.** **435/72**; 435/84; 435/101;
435/252.1; 435/253.6; 424/250.1(58) **Field of Classification Search** None
See application file for complete search history.(56) **References Cited****U.S. PATENT DOCUMENTS**2,844,515 A * 7/1958 Sobotka et al. 435/252.5
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Primary Examiner—Robert B Mondesi*Assistant Examiner*—Oluwatosin Ogunbiyi(57) **ABSTRACT**Methods for producing quadrivalent meningococcal menin-
gitis 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 immuno-
genic against meningococcal disease caused by *N. meningiti-*
dis A, C, Y and W-135 serogroups in sub-Saharan Africa. In
the preferred embodiment, the polysaccharides are conju-
gated 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.**18 Claims, 17 Drawing Sheets**

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**The Director of the United States
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Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

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If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

John Doll

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