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(71) Applicants (for all designated States except US): THE TRUSTEES OF THE UNIVERSITY OF PENNSYL-VANIA [US/US]; 3160 Chestnut Street, Suite 200,

Philadelphia, PA 19104-6283 (US). VGX PHARMA-CEUTICALS, INC [US/US]; 450 Sentry Parkway, Blue Bell, PA 19422 (US).

(72) Inventors; and

- (75) Inventors/Applicants (for US only): DRAGHIA-AKLI, Ruxandra [US/US]; 5215 Starkridge Drive, Houston, TX 77035 (US). WEINER, David, B. [US/US]; 717 Beacom Lane, Merion, PA 19066 (US). YAN, Jian [CN/US]; 213 Clamar Avenue, Havertown, PA 19083 (US). LADDY, Dominick [US/US]; 1933 Christian St., Apt 2a, Philadel-phia, PA 19146 (US).
- (74) Agent: DELUCA, Mark; Pepper Hamilton LLP, 899 Cassatt Road, Berwyn, PA 19312 (US).

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- with international search report (Art. 21(3))
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(57) Abstract: An aspect of the present invention is directed towards DNA plasmid vaccines capable of generating in a mammal an immune response against a plurality of influenza virus subtypes, comprising a DNA plasmid and a pharmaceutically acceptable excipient. The DNA plasmid is capable of expressing an influenza antigen in a cell of the mammal in a quantity effective to elicit an immune response in the mammal, wherein the consensus influenza antigen comprises hemagglutinin (HA), neuraminidase (NA), matrix protein, nucleoprotein, M2 ectodomain-nucleo-proteiπ (M2e-NP), or a combination thereof. Preferably the consensus influenza antigen comprises HA, NA, M2e -NP, or a combination thereof. The DNA plasmid comprises a promoter operably linked to a coding sequence that encodes the consensus influenza antigen. Additionally, an aspect of the present invention includes methods of eliciting an immune response against a plurality of influenza virus subtypes in a mammal using the DNA plasmid vaccines provided.



### INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/83281

| A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A01N 43/04; A61K 31/70 (2009.01) USPC - 514/44 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(8): A01N 43/04; A61K 31/70 (2009.01) USPC: 514/44  |   |   |                                |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 514/44, 424/206.1, 424/209.1, 424/210.1  |   |   |                                |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PubWest, Google Scholar, Google Patent: DNA, vaccine, plasmid, mammal, immune response, influenza, NP-em2, pharmaceutically acceptable, promoter, sequence, concentration, mg/ml, leader sequence, muscle tissue, polyadenylation, IgG leader sequence, c-terminal, electroporation |   |   |                                |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT   |   |   |                                |
| Category* Citation of  | Citation of document, with indication, where appropriate, of the relevant passages  |   | Relevant to claim No.          |
|  | US 2006/0024670 A1 (LUKE et al.) 02 Feb 2006 (02.02.2006); para [0020], [0022], [0070], [0083], [0086], [0200], [0211], [0244], [0254], [0255], |   | 1, 39                          |
| Y [0063], [0066], [02  |   |   | 2-3, 34-36, 40-41              |
| Y US 2006/0165684  | US 2006/0165684 A1 (UTKU) 27 Jul 2006 (27.07.2006); para [0042], [0086]   |   | 2, 40                          |
| Y US 5,908,780 A (   | Y US 5,908,780 A (JONES) 01 Jun 1999 (01.06.1999); col 12, ln 26-36   |   | 3, 41                          |
| Y US 7,262,045 B2 (SCHWARTZ et al.) 28 Aug 2007 (28.08.3   |   | 3.08.2007); col 46, ln 44-67  | 34-36                          |
|  |   |   |                                |
| Further documents are listed in the continuation of Box C.   |   |   |                                |
| * Special categories of cited documents:  "A" document defining the general state of the art which is not considered to be of particular relevance  "I" 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  |   |   | cation but cited to understand |
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| "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)  |   | step when the document is taken alone  "Y" document of particular relevance; the claimed invention cannot be          |                                |
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| "P" document published prior to<br>the priority date claimed   | the international filing date but later than  | "&" document member of the same patent  | family                         |
| Date of the actual completion of the international search 11 May 2009 (11.05.2009)   |   | Date of mailing of the international search report  2 2 MAY 2009  |                                |
| Name and mailing address of the ISA/US   |   | Authorized officer:<br>Lee W. Young   |                                |
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### INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/83281

| Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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:   |  |  |  |
| 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:   |  |  |  |
| Claims Nos.: 4-33, 37, 38, and 42-52 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).   |  |  |  |
| Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)   |  |  |  |
| This International Searching Authority found multiple inventions in this international application, as follows:  |  |  |  |
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| 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 additional fees, this Authority did not invite payment of additional fees.   |  |  |  |
| 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.:  |  |  |  |
| Remark on Protest  The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.  The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.  No protest accompanied the payment of additional search fees. |  |  |  |