### ${\bf (19)}\ World\ Intellectual\ Property\ Organization$

International Bureau



## ) | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1881 | 1

## (43) International Publication Date 30 June 2005 (30.06.2005)

**PCT** 

# (10) International Publication Number WO 2005/059161 A3

(51) International Patent Classification:

 A61K 38/00 (2006.01)
 C12N 7/02 (2006.01)

 C07H 21/04 (2006.01)
 C12Q 1/68 (2006.01)

 C12N 7/00 (2006.01)
 C12Q 1/70 (2006.01)

(21) International Application Number:

PCT/US2004/042475

(22) International Filing Date:

17 December 2004 (17.12.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data: 60/529,772 17 December 2003 (17.12.2003)

(71) Applicant (for all designated States except US): INTRA-LYTIX, INC. [US/US]; The Warehouse at Camden Yards, 323 West Camden Street, Suite 675, Baltimore, MD 21201 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SULAKVELIDZE, Alexander [US/US]; c/o INTRALYTIX, INC., The Warehouse at Camden Yards, 323 West Camden Street, Suite 675, Baltimore, MD 21201 (US). SOZHAMANNAN, Shanmuga [US/US]; c/o INTRALYTIX, INC., The Warehouse at Camden Yards, 323 West Camden Street, Suite 675, Baltimore, MD 21201 (US). VOELKER, LeRoy [US/US]; c/o INTRALYTIX, INC., The Warehouse at Camden Yards, 323 West Camden Street, Suite 675, Baltimore, MD 21201 (US).

- (74) Agent: NAKAMURA, Dean; GRAY CARY LLP, 1625 Massachusetts Avenue, N.W., Suite 300, Washington, DC 20036 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, 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, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

#### **Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 8 June 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHODS FOR EVALUATION A BACTERIOPHAGE PREPARATION

(57) Abstract: A quality assurance/quality control paradigm for bacteriophage is provided.



### INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/42475

| A. CLA<br>IPC 8;  | SSIFICATION OF SUBJECT MATTER<br>A61K 38/00( 2006.01);C07H 21/04( 2006.01);C12<br>2006.01)<br>A61K 38/00( 2006.01);C07H 21/04( 2006.01);C12<br>2006.01)   | , , , , , , , -   | , , ,                            |  |
|---|---|---|----------------------------------|--|
| USPC: 435/5,6,235.1,239;536/23.72;530/344 According to International Patent Classification (IPC) or to both national classification and IPC |   |   |                                  |  |
| B. FIEL   | DS SEARCHED   |   |                                  |  |
| Minimum documentation searched (classification system followed by classification symbols) U.S.: 435/5, 6, 235.1, 239; 536/23.72; 530/344    |   |   |                                  |  |
| 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) WEST, Medline  |   |   |                                  |  |
| C. DOC  | UMENTS CONSIDERED TO BE RELEVANT  |   |                                  |  |
| Category *  | Citation of document, with indication, where a  | ppropriate, of the relevant passages  | Relevant to claim No.            |  |
| <i>ت</i> Y  | LAEMMLI Cleavage of structural proteins during th<br>T4. Nature. (15 Aug 1970) Vol. 227, No. 5259, pp. 6  |   | 1-4                              |  |
| Υ -   | STRATAGENE Catalog, 1999, pg. 96  |   | 1-4                              |  |
| Y   | YANISCH-PERRON et al. Improved M13 phage cloning vectors and host strains: nucleotide sequences of the M13mp18 and pUC19 vectors. Gene. (1985) Vol.33, No. 1 pp:103-19.   |   | 1-4                              |  |
| Υ _   |   |   |                                  |  |
| Y   | Y SWINTON et al. Replacement of the deoxycytidine residues in Rhizobium bacteriophage RL38JI DNA. FEBS letters, (1985 May 20) Vol. 184, No. 2, pp. 294-8.   |   | 1-4                              |  |
| Υ -   | MANIATIS et al. Molecular Cloning: A Laboratory (1982) pp. 68-69.   | Manual. Cold Spring Harbor Laboratory   | 4                                |  |
| Further   | documents are listed in the continuation of Box C.  | See patent family annex.  |                                  |  |
|   | pecial categories of cited documents:  t defining the general state of the art which is not considered to be of   | "T" later document published after the interdate and not in conflict with the application principle or theory underlying the invention      | tion but cited to understand the |  |
| particular relevance  |   | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step |                                  |  |
| "L" documen   | plication or patent published on or after the international filing date<br>t which may throw doubts on priority claim(s) or which is cited to<br>the publication date of another citation or other special reason (as | when the document is taken alone  "Y" document of particular relevance; the cli   | aimed invention cannot be        |  |
| specified) "O" document   | )<br>t referring to an oral disclosure, use, exhibition or other means  | considered to involve an inventive step combined with one or more other such obeing obvious to a person skilled in the                      | locuments, such combination      |  |
| "P" documen   | t published prior to the international filing date but later than the ate claimed   | "&" document member of the same patent fa   |                                  |  |
|   | ctual completion of the international search  | Date of mailing of the international search   | report                           |  |
|   | 06 (17.03.2006)   | 12 APR 2006   |                                  |  |
| Name and mailing address of the ISA/US  Mail Stop PCT, Attn: ISA/US   |   | Authorized officer Smulb Som  |                                  |  |
| Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450  |   | Telephone No. (703) 272-1600  |                                  |  |
|   | . (571) 273-3201  |   |                                  |  |

Form PCT/ISA/210 (second sheet) (April 2005)

### INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/42475

| 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:   |  |  |
| 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 No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)                                     |   |  |  |
|  | ional Searching Authority found multiple inventions in this international application, as follows: ontinuation Sheet  |  |  |
| 1.   | As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.  As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.  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. Remark on   | 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.: 1-4  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.   |  |  |

Form PCT/ISA/210 (continuation of first sheet(2)) (April 2005)

|  | International application No.   |  |  |
|--|---|--|--|
| INTERNATIONAL SEARCH REPORT  | PCT/US04/42475  |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
| BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACK! This application contains the following inventions or groups of inventions which are   | e not so linked as to form a single general inventive   |  |  |
| concept under PCT Rule 13.1. In order for all inventions to be examined, the appro   | priate additional examination fees must be paid.  |  |  |
| Group 1, claims 1-4, drawn to a method of assuring identity of a bacteriophage preparation.  |   |  |  |
| Group 2, claim 5, drawn to a method of preparing a lytic bacteriophage preparation.  |   |  |  |
| Group 3, claim 6, drawn to a phage.  |   |  |  |
| This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.                   |   |  |  |
| In order for more than one species to be examined, the appropriate additional exami  | nation fees must be paid. The species are as follows:   |  |  |
| Each of the Lists of claim 6.  |   |  |  |
|  |   |  |  |
| The inventions listed as Groups 1-3 do not relate to a single general inventive concerthey lack the same or corresponding special technical features for the following reas a single inventive concept because each is directed to different results, have different | sons: Each of the methods (Groups 1 and 2) do not have  |  |  |
| The species listed above do not relate to a single general inventive concept under PC species lack the same or corresponding special technical features for the following n  | CT Rule 13.1 because, under PCT Rule 13.2, the easons: each of the Lists is a different organism. |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |
|  |   |  |  |