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- (54) Title: ASSAYS WITH PRIMARY CELLS

- (57) Abstract: Systems, including methods, apparatus, compositions, and kits, for performing assays with primary cells.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/30176

<p>A. CLASSIFICATION OF SUBJECT MATTER</p> <p>IPC(8) : G01N 33/53 US CL : 435/7.1</p> <p>According to International Patent Classification (IPC) or to both national classification and IPC</p>																						
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) U.S. : 435/7.1</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched</p> <p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)</p>																						
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <thead> <tr> <th>Category *</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>US 2002/0197656 (Li et al) 26 December 2002 (26.12.2002), Abstract, Section 0053; 0058; 0133)</td> <td>1-4, 6-13, 16-18 and 41</td> </tr> <tr> <td>X</td> <td>Mohr et al. Microarray as Cancer keys: An array of possibilities J. Clin. Oncology 2002 Vol. 20, page 3165-3175, Whole document, especially page 3172-3172.</td> <td>1-4, 7-13, 17-18 and 41</td> </tr> <tr> <td>Y</td> <td>US 6534307 (Muraca et al.) 18 March 2003 (18.03.2003), whole document</td> <td>5, 14-15</td> </tr> <tr> <td>Y</td> <td>US 20030017445 (Berg et al) 23 June 2003 (23.06.2003), whole document</td> <td>37-40</td> </tr> </tbody> </table>			Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X	US 2002/0197656 (Li et al) 26 December 2002 (26.12.2002), Abstract, Section 0053; 0058; 0133)	1-4, 6-13, 16-18 and 41	X	Mohr et al. Microarray as Cancer keys: An array of possibilities J. Clin. Oncology 2002 Vol. 20, page 3165-3175, Whole document, especially page 3172-3172.	1-4, 7-13, 17-18 and 41	Y	US 6534307 (Muraca et al.) 18 March 2003 (18.03.2003), whole document	5, 14-15	Y	US 20030017445 (Berg et al) 23 June 2003 (23.06.2003), whole document	37-40					
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<p><input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.</p>																						
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<p>Date of the actual completion of the international search</p> <p>22 August 2005 (22.08.2005)</p>		<p>Date of mailing of the international search report</p> <p>05 APR 2006</p>																				
<p>Name and mailing address of the ISA/US</p> <p>Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230</p>		<p>Authorized officer</p> <p><i>Valerie Bell-Hamouf</i> Jacob Cheu</p> <p>Telephone No. (572) 272-1600</p>																				

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/30176

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)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. 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 an additional fee, this Authority did not invite payment of any additional fee.
 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.: 1-18 and 37-41
- Remark on Protest The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/30176

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are 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 appropriate additional examination fees must be paid.

Group I, claim(s) 1-18, 37-41, drawn to a method of testing potential modulators of primary cells and a kit thereof.

Group II, claim(s) 19-32, 37-41, drawn to a method of testing potential modulators of primary cells and a kit thereof, with a special technical feature of selecting a subset of the potential modulators for further analysis based on the effects of detection.

Group III, claim(s) 33-41, drawn to testing potential modulators of primary cells and a kit thereof, with a special technical feature of isolating from a plurality of human subjects and connecting each set to one or more particles.

Group IV, claim(s) 42-74, drawn to a method of assaying primary cells, with a special technical feature of selecting a compartment configured to hold a volume of fluid and having a support surface configured to support the volume.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The instant invention directs to a method and kit thereof to test and assess potential modulators of primary cells.

Baker et al. (US 2002/0165179) teach in vitro toxicology assessment for potential modulator. Baker et al. teach that the in vitro toxicology assay can be performed on the *primary cells (freshly isolated), primary cells, or transformed cells* (See section 0202-0203). Baker et al. teach that such in vitro assay provides the advantage of rapid screening for multiple cell cultures, or various primary cell types (See section 0203). Therefore, the group I invention is disclosed under Baker et al. reference.

Furthermore, according to PCT rule 13.2, unit of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. All the groupings are direct to the use of primary cells for assaying modulator, but each group has different special technical feature not shared by other group. Thus, the instant invention, groups I-V, suffers lack of unity under PCT rule 13.2.