

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
19 May 2005 (19.05.2005)

PCT

(10) International Publication Number
WO 2005/045058 A3

(51) International Patent Classification⁷: **G01N 27/26**,
33/537

(21) International Application Number:
PCT/US2004/035079

(22) International Filing Date: 25 October 2004 (25.10.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/515,094 27 October 2003 (27.10.2003) US

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(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, 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, IT, 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 December 2005

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.



WO 2005/045058 A3

(54) Title: DETECTING HUMAN ANTI-THERAPEUTIC ANTIBODIES

(57) Abstract: The invention provides a method for detecting the presence of anti-therapeutic antibody antibodies in a patient being treated with a therapeutic antibody. In one aspect of the invention, the invention is implemented by the following steps: (i) providing a first therapeutic antibody having a molecular tag attached thereto by a cleavable linkage, the molecular tag having one or more predetermined separation characteristics; (ii) providing a second therapeutic antibody having a cleavage-inducing moiety attached thereto, the cleavage-inducing moiety having an effective proximity; (iii) combining in an assay mixture the sample, the first therapeutic antibody, and the second therapeutic antibody under condition such that the first and second therapeutic antibodies form a complex with an anti-therapeutic antibody wherein the cleavable linkage of the first therapeutic antibody is within the effective proximity of the cleavage-inducing moiety of the second therapeutic antibody and molecular tags are released; and (iv) separating from the assay mixture and detecting the released molecular tags to determine the presence or absence of anti-therapeutic antibodies in the sample.

INTERNATIONAL SEARCH REPORT

International application No

PCT/US04/35079

<p>A. CLASSIFICATION OF SUBJECT MATTER</p> <p>IPC(7) : G01N 27/26, 33/537</p> <p>US CL : 204/450, 451; 435/7.1, 7.5, 965, 971; 436/536, 537, 538</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)</p> <p>U.S. : 204/450, 451; 435/7.1, 7.5, 965, 971; 436/536, 537, 538</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>EAST: PHOTOCLEAV\$4 NEAR2 (BOND\$4 OR LINK\$4)</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>Y</td> <td>US 4,945,042 A (GEIGER et al) 31 July 1990. See col. 9, line 9-col. 10, line 22.</td> <td>1-11</td> </tr> <tr> <td>Y</td> <td>US 6,027,890 A (VAN NESS et al) 22 February 2000. See col. 33, line 52-col. 36, line 22; col. 45, line 41-col. 46, line 29; col. 58, line 67, line 11.</td> <td>1-11</td> </tr> <tr> <td>Y</td> <td>US 6,127,526 A (BLANK) 03 October 2000. See col. 6, lines 1-22.</td> <td>8-11</td> </tr> <tr> <td>Y</td> <td>US 6,627,400 A (SINGH et al) 30 September 2003. See col. 5, line 31-col. 13, line 13.</td> <td>1-7</td> </tr> <tr> <td>Y</td> <td>KHAZABELI, M.B. et al. Phase I trial of multiple large doses of murine monoclonal antibody CO17-1a. II. Pharmacokinetics and immune response. Jour. National Cancer Inst., 1988, Vol. 80, pages 937-942. See paragraph spanning cols.1-2 of page 938.</td> <td>1-11</td> </tr> </tbody> </table>			Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	Y	US 4,945,042 A (GEIGER et al) 31 July 1990. See col. 9, line 9-col. 10, line 22.	1-11	Y	US 6,027,890 A (VAN NESS et al) 22 February 2000. See col. 33, line 52-col. 36, line 22; col. 45, line 41-col. 46, line 29; col. 58, line 67, line 11.	1-11	Y	US 6,127,526 A (BLANK) 03 October 2000. See col. 6, lines 1-22.	8-11	Y	US 6,627,400 A (SINGH et al) 30 September 2003. See col. 5, line 31-col. 13, line 13.	1-7	Y	KHAZABELI, M.B. et al. Phase I trial of multiple large doses of murine monoclonal antibody CO17-1a. II. Pharmacokinetics and immune response. Jour. National Cancer Inst., 1988, Vol. 80, pages 937-942. See paragraph spanning cols.1-2 of page 938.	1-11		
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<p>Date of the actual completion of the international search</p> <p>19 August 2005 (19.08.2005)</p>		<p>Date of mailing of the international search report</p> <p>28 OCT 2005</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</p> <p>Facsimile No. (703) 305-3230</p>		<p>Authorized Officer</p> <p>David A. Saunders, PhD</p> <p>Telephone No. 571-272-0507</p> 																				