



(51) International Patent Classification:

G01N 21/03 (2006.01) G02B 21/08 (2006.01)
G01N 21/05 (2006.01)

1601 S. California Avenue, Palo Alto, CA 94304 (US).
WASSON, James, R.; 1601 S. California Avenue, Palo
Alto, CA 94304 (US).

(21) International Application Number:

PCT/US2013/052141

(74) Agents: FOX, James, A. et al.; 1601 S. California Avenue,
Palo Alto, CA 94304 (US).

(22) International Filing Date:

25 July 2013 (25.07.2013)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/675,811	25 July 2012 (25.07.2012)	US
61/676,178	26 July 2012 (26.07.2012)	US
61/766,116	18 February 2013 (18.02.2013)	US
61/802,194	15 March 2013 (15.03.2013)	US

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC,
SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(71) Applicant: THERANOS, INC. [US/US]; 1601 S. Califor-
nia Avenue, Palo Alto, CA 94304 (US).

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,

(72) Inventors: PANGARKAR, Chinmay; 1601 S. California
Avenue, Palo Alto, CA 94304 (US). MOHAN, Karan;

[Continued on next page]

(54) Title: IMAGE ANALYSIS AND MEASUREMENT OF BIOLOGICAL SAMPLES

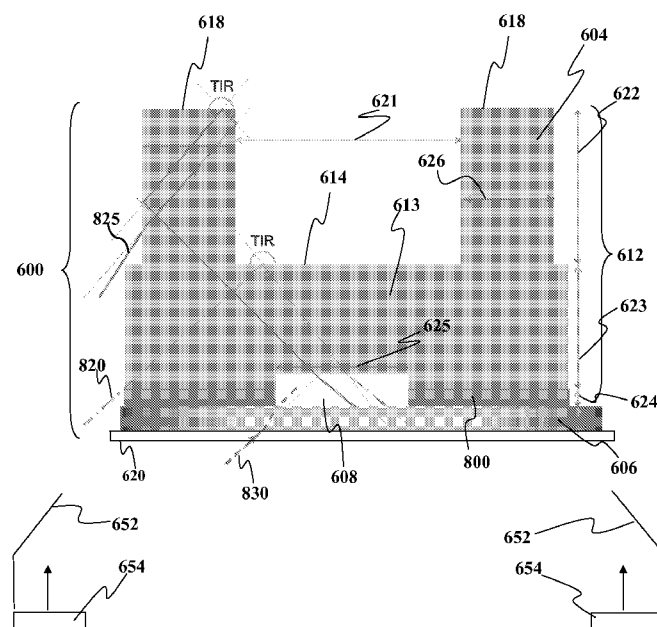


FIG. 8A

(57) Abstract: A system, cuvette (600) and method for analysing a sample such as a biological sample in which the sample is located in the sample chamber of a sample holder (600) of optically transmissive material. The sample is illuminated to provide simultaneously epi illumination and transillumination whereby the transillumination comprises light traveling from the single source (660) being reflected from at least one surface (614, 618) of the optically transmissive material of the sample holder before entering the sample. The same single source also provides the epi illumination. The light having interacted with the sample is preferably formed into an image which is analysed.



TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:

8 May 2014

Published:

— *with international search report (Art. 21(3))*

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/052141

A. CLASSIFICATION OF SUBJECT MATTER
INV. G01N21/03 G01N21/05 G02B21/08
ADD.

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)
G01N G02B

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)

EPO-Internal, WPI Data, COMPENDEX, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2001/028497 A1 (UHL RAINER [DE]) 11 October 2001 (2001-10-11) [0002]-[0010]; [0014]-[0018]; figures 1-2	1-43
Y	----- US 2010/128256 A1 (THOMSON ALASDAIR IAN [GB] THOMSON ALASDAIR IAIN [GB]) 27 May 2010 (2010-05-27) figures 1-2	1-43
Y	----- US 5 414 508 A (TAKAHASHI SATOSHI [JP] ET AL) 9 May 1995 (1995-05-09) figures 2, 4, 8, 9, 11 ----- -/-	2,7,8, 17,19, 21,22, 27,28, 30,35, 37-40,43



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" 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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

6 November 2013

Date of mailing of the international search report

24/03/2014

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Mason, William

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/052141

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:

see additional 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 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.:

1-43

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.

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/052141

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/043301 A1 (MANTELE WERNER [DE] ET AL MAENTELE WERNER [DE] ET AL) 2 March 2006 (2006-03-02) figure 2 -----	4,5,32, 33
Y	JP 2007 127449 A (OLYMPUS CORP) 24 May 2007 (2007-05-24) figure 8 -----	6,9,34, 36
A	US 6 088 097 A (UHL RAINER [DE]) 11 July 2000 (2000-07-11) figures 11, 13-14 -----	1-43
A	US 3 854 044 A (STAY B ET AL) 10 December 1974 (1974-12-10) figure 2 -----	1-43

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/052141

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2001028497 A1	11-10-2001	DE 10017823 A1 US 2001028497 A1	18-10-2001 11-10-2001
US 2010128256 A1	27-05-2010	AU 2008273926 A1 CA 2688625 A1 CN 101688828 A EA 201000088 A1 EP 2012110 A1 EP 2162726 A1 US 2010128256 A1 WO 2009007699 A1	15-01-2009 15-01-2009 31-03-2010 30-06-2010 07-01-2009 17-03-2010 27-05-2010 15-01-2009
US 5414508 A	09-05-1995	JP H05240774 A US 5414508 A	17-09-1993 09-05-1995
US 2006043301 A1	02-03-2006	AT 336718 T AU 2003224036 A1 CA 2480739 A1 DK 1493019 T3 EP 1493019 A2 EP 1715327 A2 JP 4638153 B2 JP 2005530986 A US 2006043301 A1 WO 03083458 A2	15-09-2006 13-10-2003 09-10-2003 18-12-2006 05-01-2005 25-10-2006 23-02-2011 13-10-2005 02-03-2006 09-10-2003
JP 2007127449 A	24-05-2007	NONE	
US 6088097 A	11-07-2000	DE 19801139 A1 US 6088097 A	15-07-1999 11-07-2000
US 3854044 A	10-12-1974	GB 1382081 A US 3854044 A	29-01-1975 10-12-1974

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-43

A system, cuvette and method for analyzing a sample such as a cell in a sample holder comprising optically transmissive material providing trans-illumination, by means of light traveling within said material, to the sample following at least one reflection from at least one surface of said optically transmissive material.

2. claims: 44, 45

A method for the measurement of a component of interest in cells of a cellular population in a sample, comprising quantitative measurement of a marker present in cells to determine the amount of cells, adding an amount of a cell marker which binds specifically to a component of interest, assaying the cells to determine the amount of the component of interest.

3. claims: 46, 47

A method for focusing a microscope comprising mixing a sample with a reference particle of known size, visualizing the reference particle with a microscope and focusing the microscope using the position of the reference particle or the sharpness of the image.

4. claims: 48, 49

A method of identifying a cell by assaying cells to determine the presence, amount or size of cell surface antigen, additionally assaying the cell nuclear size or shape as well as the quantitative cell light scatter so as to permit identification of the cell from the combination of the above three parameters.

5. claim: 50

A system for imaging a sample comprising objects which scatter light, the system comprising a sample holder, an illuminating light source, an objective lens and a further lens for collecting and focusing light scattered at a plurality of scatter angles onto an aperture whereby only a portion of light at said scatter angles passes the aperture.

6. claims: 51-58

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A system for imaging a sample, comprising a light source, a sample vessel and a stage having a sample vessel receiver having an optically transparent surface which is engaged by a sample vessel interface whereby the interface conforms to the optically transparent surface to prevent light distortion.
