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[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR OPTICAL DETECTION USING CAPILLARY ACTION

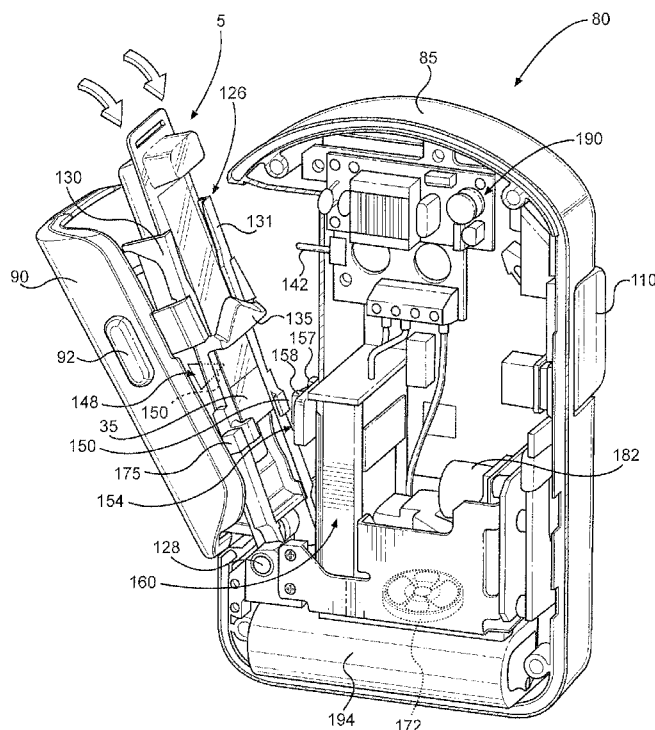


FIG. 5

(57) Abstract: A product and method for the detection
of one or more analytes in a collected sample employs
capillary action in a sample card (5) containing a sample
substrate, at least one test capsule (25) and an absorbent
pad (45). The absorbent pad (45) absorbs the contents
of the test capsule (25) and delivers the same to the
sample substrate, with the contents of the test capsule
(25) chemically reacting with at least one detection re-
agent to establish an optical indicator for the analyte(s).
The sample card (5) can be automatically tested within a
reader device (80) which supplies one or more light
sources, records and processes an optical signal pro-
duced by the chemical reaction, and outputs a test result.



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- with international search report (Art. 21(3))
- 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))

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12 June 2014

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2013/035121

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G01N 33/22 (2014.01)

USPC - 422/68.1

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) - G01N 21/00, 21/75, 21/76, 21/77, 33/22 (2014.01)

USPC - 422/68.1, 82.05, 82.07; 436/164, 165, 166, 169, 172

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

CPC - G01N 1/02, 2001/022, 2001/028, 2021/7786 (2014.02)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Orbit, Google Patents, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/0236879 A1 (EGAN et al) 29 September 2011 (29.09.2011) entire document	14-19
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Y		1-13
Y	US 2010/0184229 A1 (HAAS et al) 22 July 2010 (22.07.2010) entire document	1-13
A	US 7,629,885 B2 (DUGAN et al) 08 December 2009 (08.12.2009) entire document	1-19
A	US 2012/0211088 A1 (NELSON et al) 23 August 2012 (23.08.2012) entire document	1-19

☐ 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

"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

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2013/035121

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 Extra 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 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.:
1-19

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.

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 need to be paid.

Group I: Claims 1-19 are drawn to an analyte detection system

Group II: Claims 20-29 are drawn to a method of detecting an analyte

Group III: Claims 30-44 are drawn to a method of detecting at least one of an explosive-related analyte and a narcotic analyte

The inventions listed as Groups I through III 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 special technical features of Group I, an analyte detection system, are not found in Groups II and III; the special technical features of Group II, a method of detecting an analyte, are not found in Groups I and III; and the special technical features of Group III, method of detecting at least one of an explosive-related analyte and a narcotic analyte comprising applying specific detection reagents to the sample based on the analyte being detected, are not found in Groups I and II.

Groups I through III share the technical features of an analyte detection system comprising: a. a sample card including: a housing, a sample substrate onto which a sample is collected, at least one test capsule containing a liquid to be delivered to a collected sample, an absorbent pad to collect the liquid from the at least one test capsule after the liquid is released and to deliver the liquid to the sample substrate, one or more detection reagents contained in at least one of the at least one test capsule, the sample substrate, and the absorbent pad, and an identifying mark indicating a sample card type; and b. a reader device including: a housing with a card carrier to receive the sample card, a card rupture mechanism configured to release the liquid in the test capsule after a sample card has been inserted into the card carrier, a light assembly, an optical reader configured to: read the identifying mark in indicating the sample card type such that the system conducts an analysis protocol specific to the sample card type, and read an optical signal produced by reaction of the collected sample and the one or more detection reagents, a signal processor for determining a test result based on the optical signal, and a communication system for conveying the test result and a method of detecting at least one of an explosive, a narcotic, organophosphates and gunshot residue analyte. However, these technical features do not represent a contribution over the prior art.

Specifically, US 2011/0236879 A1 to Egan et al. teach an analyte detection system (abstract) comprising: a. a sample card (Fig. 3; Para. [0131], ...Test Device...) including: a housing (Fig. 3, 306 and 312; Para. [0135], ...the Test Device upper 306 and lower housing 312...), a sample substrate onto which a sample is collected (Fig. 3, 309 and 310; Paras. [0131];[0132];[0134], ...aperture/port 302,—provides an opening through which a sample from the SCD flows...compartment 307 that may be in fluid communication with the aperture, which aperture is in the fluid communication with a wicking substrate 309...sample mixture through the wicking pad and into the test strip 310...), at least one test capsule containing a liquid to be delivered to a collected sample (Fig. 3, 309; Para. [0132], the compartment can comprise one or more subcompartments 308 that contain one or more solution(s)...), an absorbent pad to collect the liquid from the at least one test capsule after the liquid is released and to deliver the liquid to the sample substrate (Fig. 3, 311, Para. [0137], ...absorbent substrate 311...; Para. [0135]), one or more detection reagents contained in at least one of the at least one test capsule, the sample substrate, and the absorbent pad (Para. [0134], ...such a solution can function as a wash or chase buffer, mobilizing or enhancing mobilization of the processed sample mixture...such liquid solutions can comprise was buffer, saline or any desired solution...in some embodiments, such a solution can comprise reagents, enzymes, labels or chemical compounds...; Fig. 3; Para. [0132]), and an identifying mark indicating a sample card type (Para. [0135], ...the Test Device upper 306 and lower housing 312 can comprise identity labels 303 and 305, which identify and correspond to an identical identify label on the SCD and can also identify the lot number of the Test Device...); and b. a reader device (Fig. 4; Para. [0154], ...Test Device is then inserted into a reader 400... Paras. [0185]-[0188]) including: a housing with a card carrier to receive the sample card (Fig. 4; Para. [0154], ...movable tray 402...; Paras. [0185]-[0188]), a card rupture mechanism configured to release the liquid in the test capsule after a sample card has been inserted into the card carrier (Para. [0132], ...Subcompartments in the context of the Test Device can be made of a pierceable, puncturable, breakable (e.g. ampule) or depressible bladder...additional force is applied to the...compartment 308...; Para. [0134]; Paras. [0154]-[0157]), a light assembly (Paras. [0185]-[0192]), an optical reader (Para. [0034], ...read by an optical reader...) configured to: read the identifying mark in indicating the sample card type such that the system conducts an analysis protocol specific to the sample card type (Paras. [0185]-[0188]; [0195]), and read an optical signal produced by reaction of the collected sample and the one or more detection reagents (Paras. [0185]-[0188];[0194];[0195];[0134]), a signal processor for determining a test result based on the optical signal (Paras. [0185]-[0188];[0194];[0195]), and a communication system for conveying the test result (Paras. [0185]-[0188];[0195]).

Further, US 7,629,885 B2 to Dugan et al. teach a method of detecting at least one of an explosive, a narcotic, organophosphates and gunshot residue analyte (Abstract, ...collect threat sample from subjects entering a venue, with the samples being screened for a threat signature, such as explosives...; Col. 3, Lines 36-47, ...an explosive substance...).

The inventions listed in Groups I through III therefore lack unity under Rule 13 because they do not share a same or corresponding special technical feature.