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(54) Title: SCREENING TEST AND PROCEDURE USING SKIN PATCHES

(57) Abstract: Marker compounds indicative of variations in physiological conditions, genetic defects or disease states have been found to be present in spocrine sweat and, in many conditions, these markers are present in apocrine sweat in elevated levels when compared to blood. These markers are collected and/or detected in apocrine sweat and used as an indicator that a disease state or particular physiological condition exists. A skin patch, wipe or electronic detector for vapors released from spocrine sweat are used to indicate the existence of a disease state or changing physiological condition. The patch or wipe can include in monoclonal antibodies or other chemical compounds that can indicate the presence of specific markers. This may include indicators that render visible, the existence of a reaction between the monoclonal antibody or chemical compound and the marker compound to indicate the existence of the condition being tested for. Various different disease states can be detected including, but not limited to heart disease, cancer, autoimmune disease, viral or bacterial disease, renal disease, drug intoxication and other systemic illnesses. Fertility for conception and histocompatibility for organ transplantation of individuals should also be detectable.

## INTERNATIONAL SEARCH REPORT

Internal Application No  
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<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7 G01N33/52 G01N33/94 G01N33/74 G01N33/574		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) IPC 7 G01N		
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 practical, search terms used) EMBASE, BIOSIS, EPO-Internal, WPI Data, PAJ		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 891 649 A (CALIFORNIA INTSITUTE OF TECHNOLOGY) 6 April 1999 (1999-04-06) column 3, line 10 -column 4, line 60 figures 1-4	1-5
Y	the whole document	6-32
X	US 6 042 543 A (REGENST OF THE UNIVERSITY OF MINNESOTA) 28 March 2000 (2000-03-28) column 1, line 58 -column 2, line 51 column 3, line 61 -column 4, line 5	1-5
A	the whole document	6-32
X	EP 0 811 847 A (BOEHRINGER MANNHEIM) 10 December 1997 (1997-12-10) abstract	1-5
A	page 2, line 38 -page 4, line 39 the whole document	6-32
	-/--	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in 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 document 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  22 April 2003		Date of mailing of the international search report  02/05/2003
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  Thumb, W

## INTERNATIONAL SEARCH REPORT

 Inter Application No  
 PCT/US 01/44319

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 737 442 A (HISAMITSU PHARMACEUTICALS CO. INC.) 16 October 1996 (1996-10-16) page 4, line 23 - line 39 page 7, line 43 - page 8, line 15	6-19
A	the whole document	1-5, 20-32
Y	----- BALABANOVA S ET AL: "Detection of drugs in sweat!" BEITRAGE ZUR GERICHTLICHEN MEDIZIN. AUSTRIA 1990, vol. 48, 1990, pages 45-49, XP009009462 ISSN: 0067-5016 the whole document	6-12, 20-25
Y	----- US 5 944 662 A (SUDORMED, INC.) 31 August 1999 (1999-08-31) the whole document	1-32
Y	----- US 4 868 106 A (KONISHIROKU PHOTO INDUSTRY CO., LTD.) 19 September 1989 (1989-09-19) the whole document	1-32
A	----- DE 299 02 593 U (GENZYME VIROTECH GMBH) 26 August 1999 (1999-08-26) the whole document -----	12, 19, 32

INTERNATIONAL SEARCH REPORT

Int'l application No.  
PCT/US 01/44319

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 6-32  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
- 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 II Observations where unity of invention is lacking (Continuation of item 2 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 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.:

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

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

1. Claims: 1-12 (part); 13-19

A method for diagnosing a mammalian body for the existence of cancer comprising collecting liquid or vapour from apocrine gland secretions and providing means for indicating the presence of a cancer marker compound; means for performing the method.

2. Claims: 1-12 (part); 20-25

A method for diagnosing an individual for use of drugs comprising collecting liquid or vapour from apocrine gland secretions and providing means for indicating the presence of the chemical component or a metabolite of the drug; means for performing the method.

3. Claims: 1-12 (part); 26-32

A method for diagnosing an individual for cardiac disease comprising collecting liquid or vapour from apocrine gland secretions and providing means for indicating the presence of marker compound indicative of cardiac disease; means for performing the method.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box I.1

Although claims 6-32 are directed to a diagnostic method practised on the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

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Continuation of Box I.1

Claims Nos.: 6-32

Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body

## INTERNATIONAL SEARCH REPORT

Information on patent family members

Internation Application No

PCT/US 01/44319

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Information on patent family members

Inter | Application No

PCT/US 01/44319

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DE 29902593	U	15-07-1999	DE 29902593 U1	15-07-1999