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- (71) **Applicant:** BASF SE [DE/DE]; 67056 Ludwigshafen (DE).
- (71) **Applicant (for MN only):** BASF (CHINA) COMPANY LIMITED [CN/CN]; 300 Jiangxinsha Road, Shanghai 200137 (CN).
- (72) **Inventors:** WALK, Tilmann B.; Lessingstrasse 15, 14532 Kleinmachnow (DE). RAVENZWAAY, Bennard van; Rheinstrasse 6, 67122 Altrip (DE). MELLERT, Werner; Alte Ziegelei 9, 67454 Haßloch (DE). FABIAN, Eric; Siegbertstrasse 3, 67346 Speyer (DE). STRAUSS, Volker; Karl-Räder-Allee 21D, 67098 Bad Dürkheim (DE). KAMP, Hennie; Kirchheimbolander Strasse 9, 67294 Bischheim (DE). WIEMER, Jan C; Henningsdorfer Str. 139a, 13503 Berlin (DE). LOOSER, Ralf; Hauptstrasse 2, 13158 Berlin (DE). HEROLD, Michael Manfred; Quitzowstrasse 87, 10551 Berlin (DE). PROKOUDINE, Alexandre; Eschengraben 101, 13189 Berlin (DE).
- (74) **Agent:** DICK, Alexander; Herzog Fiesser & Partner, Patentanwälte, Dudenstrasse 46, 68167 Mannheim (DE).
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- Published:**  
— 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))
- (88) **Date of publication of the international search report:** 31 October 2013



(54) **Title:** MEANS AND METHODS FOR ASSESSING LIVER DISORDERS

(57) **Abstract:** The present invention pertains to the field of diagnostics for liver disorders and toxicological assessments for risk stratification of chemical compounds. Specifically, it relates to a method for diagnosing liver disorders. It also relates to a method for determining whether a compound is capable of inducing such liver disorders in a subject and to a method of identifying a drug for treating liver disorders. Furthermore, the present invention relates to a device and a kit for diagnosing liver disorders.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2013/051862

## A. CLASSIFICATION OF SUBJECT MATTER

See the Extra Sheet

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: A61B5/-; A61B19/-; A61K31-; A61P-

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)

EPODOC, WPI, CNPAT, CNKI, ISI web of Science: biomarker, liver, disorder, disease, diagnos-, metabonomic-, identify, compound

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JOHN, C. L. et al., Metabonomics and its role in drug development and disease diagnosis Expert Rev. Mol. Diagn. Vol.4, No.2, Pages 189-199, 2004	3-20
X	THIERRY, P. et al., The diagnostic value of biomarkers(SteatoTest) for the prediction of liver steatosis., Comparative Hepatology Vol.4, No.10, 23. Dec. 2005	3-20
X	WU, Y.B. et al., Duo Zhong Sheng Hua Zhi Biao Lian He Jian Ce Zai Gan Bing Zhen Duan Zhong De Ying Yong. J Med. Theor. & Prac., Vol.23, No.3, Pages 327-328, Mar. 2010	3-20

Further documents are listed in the continuation of Box C.

See patent family annex.

<p>* Special categories of cited documents:</p> <p>“A” document defining the general state of the art which is not considered to be of particular relevance</p> <p>“E” earlier application or patent but published on or after the international filing date</p> <p>“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)</p> <p>“O” document referring to an oral disclosure, use, exhibition or other means</p> <p>“P” document published prior to the international filing date but later than the priority date claimed</p>	<p>“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</p> <p>“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</p> <p>“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</p> <p>“&amp;” document member of the same patent family</p>
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Date of the actual completion of the international search  
08 Jul.2013(08.07.2013)

Date of mailing of the international search report  
**22 Aug. 2013 (22.08.2013)**

Name and mailing address of the ISA/CN  
The State Intellectual Property Office, the P.R.China  
6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China  
100088  
Facsimile No. 86-10-62019451

Authorized officer  
**WANG Kewei**  
Telephone No. (86-10)62413746

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2013/051862

## 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.: 1, 2, 4(part)-9(part), 16  
because they relate to subject matter not required to be searched by this Authority, namely:  
See Extra Sheet.
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:

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 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 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/IB2013/051862

**Continuation of: Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

The subject matter of claims 1 and 16 is attributed to a method for diagnosis of human or animal disease and does not meet the criteria set out in Rules 39.1(iv) PCT. Claims 2 and 4 (part)-9 (part) refer to claim 1. They also do not meet the criteria set out in Rules 39.1(iv) PCT.

The search report is made on the basis of the following subject matter for claim 16: the use of at least one biomarker selected from any one of 1, 2, 3a, 3b, 4a, 4b, 7a, 7b, 7c or 7d or detection agent for the said biomarker in the manufacture of an agent for diagnosing a liver disorder in a subject.

**Continuation of: A. CLASSIFICATION OF SUBJECT MATTER**

A61B 5/00 (2006.01) i

A61B 19/00 (2006.01) i