

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Judith U. Kim
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1100 New York Avenue, N.W.
Washington, District of Columbia 20005-3934
United States of America

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

26 MAR 2013

Applicant's or agent's file reference
3229.001PC02

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US12/68589

International filing date (day/month/year)

07 December 2012 (07.12.2012)

Priority date (day/month/year)

12 May 2012 (12.05.2012)

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - G01N 33/574; B82Y 15/00; C12M 1/34 (2013.01)

USPC - 435/7.23, 287.2; 436/501

Applicant Jack Thomas Andraka

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion

11 March 2013 (11.03.2013)

Authorized officer:

Shane Thomas

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US12/68589

Box No. 1 Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - the international application in the language in which it was filed.
 - a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. This opinion has been established taking into account **the rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
 - on paper
 - in electronic form
 - b. (time)
 - in the international application as filed
 - together with the international application in electronic form
 - subsequently to this Authority for the purposes of search
4. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US12/68589

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application.

claims Nos. 5-31

because:

the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5-31 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 5-31 are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

no international search report has been established for said claims Nos. 5-31

a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit

furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13^{ter}.1(a) or (b).

See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US12/68589

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-3, 4/2, 4/3</u>	YES
	Claims	<u>NONE</u>	NO
Inventive step (IS)	Claims	<u>NONE</u>	YES
	Claims	<u>1-3, 4/2, 4/3</u>	NO
Industrial applicability (IA)	Claims	<u>1-3, 4/2, 4/3</u>	YES
	Claims	<u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 4/2 and 4/3 lack an inventive step under PCT Article 33(3) as being obvious over US 7,824,925 B2 to Wohlstadter, et al. (hereinafter 'Wohlstadter') in view of US 2010/0022026 A1 to Rump, et al. (hereinafter 'Rump').

As to claim 1, Wohlstadter discloses a sensor for detecting a molecule in a sample (photon detector (sensor) means for detecting electrochemiluminescence from the sample, column 4, lines 29-35), comprising (a) a solid support (the fibril mat is supported by another material, which may be solid; column 32, lines 29-47); (b) carbon nanotubes on a surface of the solid support (fibrils and carbon fibrils include carbon nanotubes, column 13, lines 45-54; a suspension of carbon fibrils 2301 is filtered and fibril mat 2304 collects on (the surface of) the filter membrane and/or the filter support; figure 23; column 29, lines 39-49; the filter may be used to trap the fibrils in its pores and so form a mat in which the filter acts as a support, column 30, lines 1-11); and (c) an antibody dispersed in the carbon nanotubes (an antibody that can be used in an ECL assay can be attached to one or more fibrils or a fibril mat; column 33, lines 24-30). Wohlstadter does not disclose detecting mesothelin, or wherein the antibody is capable of binding mesothelin. Rump discloses detecting mesothelin (exposing the peritoneal fluid to at least one binding agent specific for MSLN (mesothelin) to determine the level of MSLN; paragraph [0013]) and wherein the antibody is capable of binding mesothelin (the binding agent is an antibody described herein that binds to MSLN; paragraph [0015]). It would have been obvious to a person of ordinary skill in the art, at the time the invention was made, to have modified the sensor, as previously disclosed by Wohlstadter, in order to have included an antibody capable of binding and detecting mesothelin, as previously disclosed by Rump, for indicating the health of the mesothelial cell lining (Rump; paragraph [0072]) or detecting cancer (Rump; paragraphs [0075], [0076]).

As to claim 2, Wohlstadter and Rump, in combination, disclose the sensor of claim 1, and Wohlstadter further discloses wherein the solid support is a porous material (the filter may be used to trap the fibrils in its pores, so as to form a mat in which the filter acts as a support; column 30, lines 1-11).

As to claim 3, Wohlstadter and Rump, in combination, disclose the sensor of claim 2, and Wohlstadter further discloses wherein the porous material is paper (the filter may be used to trap the fibrils in its pores and so form a mat in which the filter acts as a support, column 30, lines 1-11; column 32, lines 29-47; the support may be filter paper, column 32, lines 29-47) or fabric.

As to claims 4/2 and 4/3, Wohlstadter and Rump, in combination, disclose the sensor of claims 2 and 3, and Wohlstadter further discloses wherein the carbon nanotubes are integrated into the pores of the support (the filter may be used to trap the fibrils in its pores and so form a mat in which the filter acts as a support, column 13, lines 45-54; column 30, lines 1-11; fibrils and carbon fibrils include carbon nanotubes, column 13, lines 45-54).

Claims 1-3, 4/2 and 4/3 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.