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(71) Applicant: **ABBOTT DIABETES CARE INC.** [US/US]; 1420 Harbor Bay Parkway, Suite 290, Alameda, California 94502 (US).

(72) Inventors: **MCCANLESS, Jonathan D.**; 2003 Myrtle St, Unit B, Oakland, California 94607 (US). **OUYANG, Tianmei**; 18660 Devon Ave, Saratoga, California 95070 (US). **OJA, Stephen M.**; 120 State St, Apt 4, Reno, Nevada 89501 (US). **OJHA, Yagya Raj**; 834 San Antonio Avenue, Apt E, Alameda, California 94501 (US). **OZEL, Rifat Emrah**; 3555 Calvin Avenue, San Jose, California 95124 (US). **FOX, Cade B.**; 777 El Camino Real, Apt 10, Burlingame, California 94010 (US). **LIU, Zenghe**; 2815 Sea View Pkwy, Alameda, California 94502 (US). **FELDMAN, Benjamin J.**; 2164 Blake Street, Berkeley, California 94704 (US).

(74) Agent: **BODENSTEIN, Matthew S.** et al.; Sterne, Kessler, Goldstein & Fox P.L.L.C, 1101 K Street NW, 10th Floor, Washington, District of Columbia 20005 (US).

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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:
22 August 2024 (22.08.2024)

(54) Title: BIOSENSORS WITH HYDROPHILIC POLYURETHANE MEMBRANES

(57) Abstract: The present disclosure provides an analyte sensor comprising a working electrode, a sensing layer disposed on at least a portion of the working electrode, and a hydrophilic polyurethane membrane overcoating at least the sensing layer, wherein the hydrophilic polyurethane is aliphatic, aromatic, or both aliphatic and aromatic. The hydrophilic polyurethane membrane limits the transport of mass to the sensing layer without the need to be crosslinked. With such membrane, the analyte sensor can provide consistent analyte measurements over a temperature range of about 22-42 °C. The present disclosure is further related to a method of forming an analyte sensor comprising providing a working electrode, disposing a sensing layer on at least a portion of the working electrode, and coating at least the sensing layer with a hydrophilic polyurethane membrane, wherein the hydrophilic polyurethane is aliphatic, aromatic, or both aliphatic and aromatic.

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INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61B 5/145, C12Q 1/00 (2024.01)
ADD. C08G 18/32 (2024.01)

CPC - INV. A61B 5/145, A61B 5/14532, C12Q 1/005, C12Q 1/006
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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)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,322,063 A (Allen et al.) 21 June 1994 (21.06.1994) Col 1 ln 5-8; Col 5 ln 7-11; Col 5 ln 16-21; Col 5 ln 28-31; Col 5 ln 44-47; Fig. 2	1-4 ---- 5
Y	US 2021/0079216 A1 (Mitsui Chemicals, Inc.) 18 March 2021 (18.03.2021) Para [0001]; [0008]; [0041]	5
A	US 6,350,524 B1 (Lee et al.) 26 February 2002 (26.02.2002) entire document	1-5
A	US 9,014,774 B2 (Abbott Diabetics Care Inc.) 21 April 2015 (21.04.2015) entire document	1-5

☐ 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
"D" document cited by the applicant in the international application
"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	Date of mailing of the international search report
06 May 2024	JUN 21 2024
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. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 24/10721

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.: 6-46, 51-57, and 60-61
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 sheets)

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.:
1-5

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/US 24/10721

Continuation of Box No. III Observations where unity of invention is lacking

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 searched, the appropriate additional search fees must be paid.

Group I: Claims 1-5 directed toward an analyte sensor comprising a working electrode, a sensing layer disposed on at least a portion of the working electrode, and a hydrophilic polyurethane membrane overcoating at least the sensing layer, wherein the hydrophilic polyurethane is aliphatic, aromatic, or both aliphatic and aromatic.

Group II: Claims 47-50 and 58-59 directed toward a method of manufacturing an analyte sensor, the method comprising: (i) dip-coating a working electrode configured for detecting an analyte in a solution comprising a polyurethane or a copolymer comprising a polyurethane and a solvent system.

The inventions listed as Groups I-II 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:

Special Technical Features:

Group I requires an analyte sensor comprising a sensing layer disposed on at least a portion of the working electrode and a hydrophilic polyurethane membrane, not required by Group II.

Group II requires a method of manufacturing an analyte sensor, the method comprising: (i) dip-coating a working electrode in a solution comprising a polyurethane or a copolymer comprising a polyurethane and a solvent system, not required by Group I.

Common Technical Features:

Groups I-II share the common technical feature of an analyte sensor comprising a working electrode; a sensing layer, and a polyurethane membrane overcoat. However, these shared technical features do not represent a contribution over prior art, because the shared technical feature is anticipated by US 5,322,063 A to Allen et al. (hereinafter Allen).

Allen discloses an analyte sensor (Col 1 ln 5-8 invention relates to homogeneous membranes composed of hydrophilic polyurethanes that are useful in the fabrication of electrochemical glucose sensors) comprising a working electrode (Col 5 ln 7-11 Fig. 2 Sensor 10 includes a distal portion 11 in which are located sensor elements 12-14 which are connected through leads 15 to contacts 16. Typical sensing elements would be a counter electrode 12, working electrode 13 and reference electrode 14), a sensing layer (Col 5 ln 16-21 In this type of sensor, glucose oxidase is also provided in the area adjacent the sensor elements, and catalyzes the reaction of glucose and oxygen. This, or a subsequent reaction, is monitored by the sensing elements, and a determination of glucose present in the surrounding subcutaneous tissue may thereby be obtained; Col 5 ln 28-31 Glucose oxidase 19 is deposited on the working electrode and all three sensor/electrodes are then covered with a membrane), and a polyurethane membrane overcoat (Col 5 ln 44-47 The membrane of the invention is formed from a hydrophilic polyurethane. Polyurethane is a thermoplastic polymer produced by the condensation reaction of a polyisocyanate and a hydroxyl-containing material; Col 5 ln 28-31 Glucose oxidase 19 is deposited on the working electrode and all three sensor/electrodes are then covered with a membrane).

As the shared technical features were known in the art, they cannot be considered common technical features that would otherwise unify the groups. Therefore, Groups I-II lack unity under PCT Rule 13.

Item 4 continued: Claims 6-46, 51-57 and 60-61 are unsearchable claims because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).