

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
10 February 2005 (10.02.2005)

PCT

(10) International Publication Number
WO 2005/011520 A3

(51) International Patent Classification⁷: **A61B 5/05**, 5/00

(21) International Application Number:
PCT/US2004/023454

(22) International Filing Date: 21 July 2004 (21.07.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/490,009 25 July 2003 (25.07.2003) US

(71) Applicant (for all designated States except US): **DEX-COM, INC.** [US/US]; 5555 Oberlin Drive, San Diego, CA 92121 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **PETISCE, James, R.** [US/US]; 3789 Torrey View Court, San Diego, CA 92130 (US). **TAPSAK, Mark, A.** [US/US]; 247 Asbury

Road, Orangeville, PA 17859 (US). **SIMPSON, Peter, C.** [US/US]; 1236 Stratford Court, Del Mar, CA 92014 (US). **CARR-BRENDEL, Victoria** [US/US]; 3735 Grillo Court, Pleasanton, CA 94566 (US).

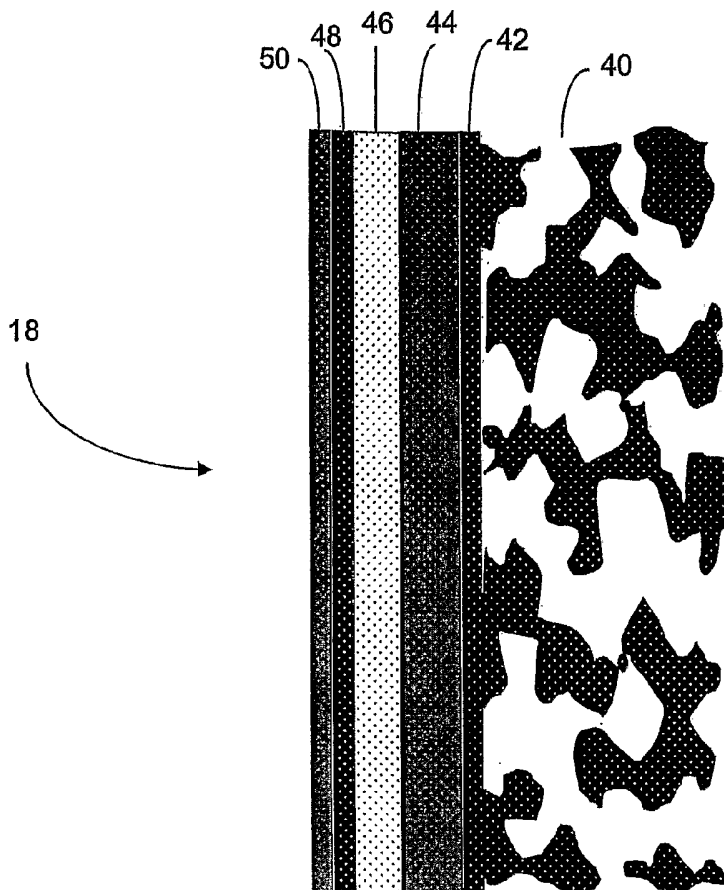
(74) Agent: **HART, Daniel**; Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, CA 92614 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH,

[Continued on next page]

(54) Title: OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES



(57) Abstract: The present invention relates generally to systems and methods for increasing oxygen availability to implantable devices. The preferred embodiments provide a membrane system (18) configured to provide protection of the device from the biological environment and/or a catalyst for enabling an enzymatic reaction, wherein the membrane system includes a polymer formed from a high oxygen soluble material. The high oxygen soluble polymer material is disposed adjacent to an oxygen-utilizing source on the implantable device so as to dynamically retain high oxygen availability to the oxygen-utilizing source during oxygen deficits. The membrane system (18) can include a cell disruptive domain (40), a cell impermeable domain (42), a resistance domain (44), an enzyme domain (46), an interference domain (48), and an electrolyte domain (50) adjacent to the electrochemically reactive surfaces. Membrane systems of the preferred embodiments are useful for implantable devices with oxygen-utilizing sources and/or that function in low oxygen environments, such as enzyme-based electrochemical sensors and cell transplantation devices.



GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:

15 December 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/23454

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 05/05, 05/00

US CL : 600/345, 309

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)

U.S. : 600/345-366, 309, 372, 373, 377, 395

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)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 6,721,587 B2 (GOUGH) 13 April 2004 (13.04.2004), column 4, line 57, column 6, line 15-66.	1-12
---		-----
Y		13
Y	US 5,882,494 A (VAN ANTWERP) 16 March 1999 (16.03.1999), Abstract and claim 1.	13
A	US 4,650,547 A (GOUGH) 17 March 1987 (17.03.1987), Abstract.	1

☐ 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

"E" earlier application or patent 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

21 September 2005 (21.09.2005)

Date of mailing of the international search report

19 OCT 2005

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. (703) 305-3230

Authorized officer

Navin Natnithithadha

Telephone No. (571) 272-2415

Sheila H. Venev
Paralegal Specialist
Tech. Center 3700

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/23454

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:
Please See Continuation 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 any 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.: 1-13

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/US04/23454

BOX 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 examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-13, drawn to an electrochemical sensor for determining a presence or a concentration of an analyte in a fluid.

Group II, claim(s) 14-21, drawn to an analyte sensing device configured for implantation into a tissue of a host.

The inventions listed as Groups I and 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: the lack the same special technical feature of an electrochemical sensor comprising a working electrode.