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**WO 2007/011955 A3**

(54) Title: DRUG-CONTAINING IMPLANTS AND METHODS OF USE THEREOF

(57) Abstract: The present invention provides implants comprising a therapeutic drug and a polymer containing polylactic acid (PLA) and optionally polyglycolic acid (PGA). The present invention also provides methods of maintaining a therapeutic level of a drug in a subject, releasing a therapeutic drug at a substantially linear rate, and treating schizophrenia and other diseases and disorders, utilizing implants of the present invention.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/27894

**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:

--See extra 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 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.:  
Group 1, claims 1-14 and 36-48

**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 06/27894

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - A61F 2/00 (2007.01) USPC - 424/426 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) USPC: 424/426		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 424/426, 423, 422 (text search)		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PubWEST(PGPB,USPT,USOC,EPAB,JPAB); Google; PubMed Search terms: Implant, polylactic, polyglycolic, drug, rod-shaped		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/0179096 A1 (SIEGEL, S.J. ET AL) 5 December 2002 (05.12.2002) abstract; para [0009], [0011], [0014], [0019], [0021]-[0024], [0030], [0032].	1-14 and 36-48
Y	US 4,351,337 A (SIDMAN, K.R.) 28 September 1982 (28.09.1982) Fig. 2; col 10, ln 62-64; col 11, ln 10-11; col 22, ln 31-34 and 45-50.	1-14 and 36-48
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* 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 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 4 September 2007 (04.09.2007)		Date of mailing of the international search report <b>19 OCT 2007</b>
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		Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/27894

Continuation of Box 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:

Group 1, claims 1-14 and 36-48 drawn to an implantable, long term delivery system for improving medication adherence in disorders associated with a likelihood of non-compliance and methods for treating a subject for a disorder associated with a likelihood of non-compliance comprising administering to said subject a therapeutic drug in a long term delivery system.

Group 2, claims 15-35, drawn to a biodegradable implant comprising a therapeutic drug and a polymer.

Group 3, claims 49-64, drawn to a method for maintaining a therapeutic level of a therapeutic drug in a subject for a period of at least about 1 month comprising administering to said subject a set of biodegradable implants.

Group 4, claims 65-81, drawn to a method for maintaining a therapeutic level of a drug in a subject for a period of at least 3 months comprising administering to said subject biodegradable implants.

The inventions listed as Groups 1-4 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 common technical feature of the listed groups is an implantable long term drug delivery system comprising a polymer, said polymer comprising polylactic acid (PLA). However, this is not an improvement over the prior art of Ohtori et al. (US 5,501,856 A to Ohtori et al.). Ohtori et al. teaches an implantable long term drug delivery system comprising a polymer, said polymer comprising polylactic acid (PLA). Additionally, the implant and method of group 1 is not required for the biodegradable implant of group 2 or the methods of sustained drug release of group 3 and group 4.

The first named invention is claims 1-14 and 36-48 drawn to an implantable, long term delivery system for improving medication adherence in disorders associated with a likelihood of non-compliance and methods for treating a subject for a disorder associated with a likelihood of non-compliance comprising administering to said subject a therapeutic drug in a long term delivery system.