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(71) Applicant (for all designated States except US): **THER-  
AQUEST BIOSCIENCES, LLC** [US/US]; 146 MEDI-  
NAH DRIVE, Blue Bell, PA 19422-3212 (US).

(71) Applicant and

(72) Inventor: **BABUL, Najib** [US/US]; 146 MEDINAH  
DRIVE, Blue Bell, PA 19422-3212 (US).

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**Declarations under Rule 4.17:**

- as to applicant's entitlement to apply for and be granted a  
patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the  
earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

**Published:**

- with international search report
- before the expiration of the time limit for amending the  
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For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: METHODS OF PREVENTING THE SEROTONIN SYNDROME AND COMPOSITIONS FOR USE THEREFOR

(57) Abstract: The present invention is directed to pharmaceutical compositions and the use thereof for preventing or minimizing the intensity of the serotonin syndrome. The present invention is directed at a method of preventing or minimizing the intensity of the serotonin syndrome in humans which comprises administering proserotonergic agents and serotonin surge protectors, wherein said concurrent administration reduces or prevents serotonin excess, which is the cause of the serotonin syndrome. The present invention is also directed to pharmaceutical compositions comprising proserotonergic agents and serotonin surge protectors useful for carrying out the method of the present invention.



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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/42962

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A01N 37/18 (2007.01)

USPC - 514/620

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)

USPC - 514/620

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
 USPC: 514/27, 165, 218, 620, 456, 406, 471, 569, 23, 459; 424/725 (see search terms below)  
 IPC(8): A01N 37/18(2007.01)

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

PGPB, USPT, USOC, EPAB, JPAB. Search terms: controlled-release, sustained-release, drug abuse, serotonin syndrome, formulation, Cmax, Tmax, AUC

## 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 2004/0132826 A1 (HIRSH et al.) 8 Jul 2004 (08.07.2004) para 0005, 0006, 0009, 0013, 0019, 0046-0079, 0088, 0093	1-4, 54-57, 108 ----- 5, 58
Y	US 5,968,551 A (OSHLACK et al.) 19 Oct 1999 (19.10.1999) esp col 2 line 54-col 3 line 4; col 6 line 55- col 7 line 8	5, 58

☐ Further documents are listed in the continuation of Box C.


\* 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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

13 April 2007 (13.04.2007)

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Name and mailing address of the ISA/US

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Authorized officer:

Lee W. Young

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/42962

## 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.: 6-53 and 59-107  
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 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.:

### 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.