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Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv)) for US only

Published:

— with international search report

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18 January 2007

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.

(54) Title: EXPANDABLE GASTRIC RETENTION DEVICE

(57) Abstract: The present application concerns gastric retention devices formed from compositions comprising polymeric materials, such as polysaccharides, and optional additional materials including excipients, therapeutics, and diagnostics, that reside in the stomach for a controlled and prolonged period of time.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/04668

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61K 9/14(2006.01),9/48(2006.01),9/52(2006.01),9/54(2006.01)

USPC: 424/451,457,458,463,489

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. : 424/451, 457, 458, 463, 489

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)
WEST

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 2004/0219186 A1 (AYRES) 04 November 2004 (04.11.2004), pages 3-7.	1-20, 26-29, 133 and 135-139
A	US 5,766,623 (AYRES et al.) 16 June 1998 (16.06.1998), see reference	1-20, 26-29, 133 and 135-139
A	US 6,207,197 B1 (ILLUM et al.) 27 March 2001 (27.03.2001), see entire reference.	1-20, 26-29, 133 and 135-139
A	US 2002/0128251 A1 (STORM et al.) 12 September 2002 (12.09.2002), see entire reference.	1-20, 26-29, 133 and 135-139



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	"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
"E"	earlier application or patent published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

18 August 2006 (18.08.2006)

Date of mailing of the international search report

18 OCT 2006

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/04668

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.: 1-20,26-29,133 and 135-139

- 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/US05/04668

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, claims 1-20, 26-29 and 135-139 are drawn to a gastric retention device comprising a gel within an ingestible capsule.

Group II, claims 21-25 and 30-68 are drawn to a compressed device.

Group III, claims 69-82, 123-133 and 140 are drawn to method of making the device.

Group IV, claims 83-92, 101-109, 134 and 141-144 are drawn to a method for using a gastric retention device.

Group V, claims 93-100 and 110-119 are drawn to a method of appetite suppression.

Group VI, claims 120-122 are drawn to a vaginal administration device.

The inventions listed as Groups I-VI 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: they do not share the same essential elements that define the "special technical feature" necessary to specify a contribution over the prior art. The element common to all the groups is gastric retention device, which is known in the art and, therefore, cannot be said to be the special technical feature, which makes a contribution over the prior art. All other elements differ from each other, *e.g.*, the method of making the device, the method of using the device, and device for vaginal administration, each of which is known in the pharmaceutical art. Thus, these claims lack the corresponding special technical features necessary to link them together to fulfill the Unity of Invention requirement.