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(51) International Patent Classification ⁶ : A61K 9/00, 31/565	A3	(11) International Publication Number: WO 98/50016 (43) International Publication Date: 12 November 1998 (12.11.98)
(21) International Application Number: PCT/IE98/00033 (22) International Filing Date: 7 May 1998 (07.05.98) (30) Priority Data: S970333 7 May 1997 (07.05.97) IE (71) Applicant (for all designated States except US): GALEN (CHEMICALS) LIMITED [IE/IE]; Belgard Road, Tallaght, Dublin 24 (IE). (72) Inventors; and (75) Inventors/Applicants (for US only): PASSMORE, Clare [GB/GB]; 108 Malone Road, Belfast (GB). GILLIGAN, Claire [GB/GB]; 17 Orpen Park, Belfast (GB). (74) Agents: O'CONNELL, Maura et al.; F. R. Kelly & Co., 9 University Street, Belfast BT7 1NA (GB).		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> (88) Date of publication of the international search report: 4 February 1999 (04.02.99)
(54) Title: INTRAVAGINAL DRUG DELIVERY DEVICES FOR THE ADMINISTRATION OF TESTOSTERONE AND TESTOSTERONE PRECURSORS		
(57) Abstract <p>The invention relates to an intravaginal shell or core drug delivery device suitable for administration to the human or animal female. The device comprises testosterone or a testosterone precursor in a polymer matrix, surrounded by a sheath, and is capable of releasing the testosterone or testosterone precursor in a substantially zero order pattern on a daily basis for at least three weeks. The device is intended to restore circulating testosterone levels to normal physiological range or to induce supratherapeutic testosterone levels.</p>		

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INTERNATIONAL SEARCH REPORT

Internal Application No

PCT/IE 98/00033

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K9/00 A61K31/565

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)

IPC 6 A61K

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3 920 805 A (ROSEMAN THEODORE J) 18 November 1975 see the whole document ---	1,2,5-8
Y	WO 96 19196 A (GALEN CHEMICALS LTD ;MCCLAY ALLEN (GB)) 27 June 1996 see the whole document ---	1,2,5-8
A	US 4 449 980 A (MILLAR THOMAS D ET AL) 22 May 1984 -----	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

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- "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

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"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

18 November 1998

Date of mailing of the international search report

25/11/1998

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IE 98/00033

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 7,8
because they relate to subject matter not required to be searched by this Authority, namely:
Remark: Although claim(s) 7,8
is(are) directed to a method of treatment of the human/animal
body, the search has been carried out and based on the alleged
effects of the compound/composition.
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 II Observations where unity of invention is lacking (Continuation of item 2 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 an additional fee, this Authority did not invite payment
of any additional fee.
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.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 98/00033

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