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kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,

DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
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RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ,
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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))*

Published:

— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments (Rule 48.2(h))*

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

31 October 2013

(54) Title: CORE SHEATH DRUG DELIVERY DEVICES

(57) Abstract: It relates to a device comprising (a) a core comprising polyurethane; (b) a sheath comprising ethylene vinyl acetate copolymer, said sheath substantially or completely surrounding said core; and (c) one or more active pharmaceutical ingredients dissolved or dispersed in said core and/or said sheath; and to a process for its preparation.



INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2013/052855

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 additional 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 an 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.:

1-5, 8, 15-18, 21

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/EP2013/052855

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/00 A61K47/32 A61K47/34 A61K31/00 A61P15/18
A61F6/06

ADD.

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)

A61K A61F

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)

EPO-Internal, BIOSIS, EMBASE, FSTA, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/061963 A2 (ORGANON NV [NL]; INTERVET INT BV [NL]; DRIANCOURT MARC-ANTOINE [FR]; D) 29 May 2008 (2008-05-29)	1-3,5,8, 15-18,21
Y	page 3, line 33 - page 4, line 5 page 5, line 10 - page 7, line 7 page 10, lines 15-19	4
Y	----- EP 1 732 520 B1 (ORGANON NV [NL]) 24 June 2009 (2009-06-24) cited in the application page 2, paragraph 0012 - page 3, paragraph 0016 -----	4



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 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

18 June 2013

Date of mailing of the international search report

09/09/2013

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2013/052855

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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			PE	01272006 A1	15-03-2006
			TW	I290837 B	11-12-2007
			US	2007141102 A1	21-06-2007
			WO	2005089723 A1	29-09-2005

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5, 8, 15-18, 21

A device comprising: (a) a core comprising polyurethane; (b) a sheath substantially or completely surrounding said core, said sheath comprising ethylene vinyl acetate copolymer; and (c) one or more active pharmaceutical ingredients dissolved or dispersed in said core and/or said sheath; wherein the active pharmaceutical ingredients are present in the core in a concentration below its saturation concentration.

2. claims: 6, 7, 9-12(completely); 13, 14(partially)

A device comprising: (a) a core comprising polyurethane; (b) a sheath substantially or completely surrounding said core, said sheath comprising ethylene vinyl acetate copolymer; and (c) one or more active pharmaceutical ingredients dissolved or dispersed in said core and/or said sheath; wherein the estrogen is ethinyl estradiol.

A device comprising: (a) a core comprising polyurethane; (b) a sheath substantially or completely surrounding said core, said sheath comprising ethylene vinyl acetate copolymer; and (c) one or more active pharmaceutical ingredients dissolved or dispersed in said core and/or said sheath; wherein the progestin is etonogestrel.

A device comprising: (a) a core comprising polyurethane; (b) a sheath substantially or completely surrounding said core, said sheath comprising ethylene vinyl acetate copolymer; and (c) one or more active pharmaceutical ingredients dissolved or dispersed in said core and/or said sheath; wherein the progestin is levonorgestrel.

3. claim: 19

A device comprising: (a) a core comprising polyurethane; (b) a sheath substantially or completely surrounding said core, said sheath comprising ethylene vinyl acetate copolymer; and (c) one or more active pharmaceutical ingredients dissolved or dispersed in said core and/or said sheath; wherein the device is a vaginal ring.

4. claim: 20

A device comprising: (a) a core comprising polyurethane; (b) a sheath substantially or completely surrounding said core, said sheath comprising ethylene vinyl acetate copolymer; and (c) one or more active pharmaceutical ingredients dissolved or dispersed in said core and/or said sheath; wherein the pharmaceutical ingredients are encapsulated prior to incorporation into the device.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210
