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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, 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, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- 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:

6 December 2012

(54) Title: TESTOSTERONE UNDECANOATE COMPOSITIONS

(57) Abstract: The present disclosure is drawn to pharmaceutical compositions and oral dosage forms containing testosterone undecanoate, as well as related methods of treatment. In one embodiment, the oral dosage form can include a therapeutically effective amount of testosterone undecanoate and a pharmaceutically acceptable carrier. The dosage form can be formulated such that, when measured using a USP Type II apparatus in 1000 mL of 8 wt% Triton X-100 in water at 37C and 100 rpm, the oral dosage form releases at least 20% more testosterone undecanoate after the first 120 minutes than an equivalent dose testosterone undecanoate containing oral dosage form without the pharmaceutically acceptable carrier.



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A. CLASSIFICATION OF SUBJECT MATTER*A61K 47/48(2006.01)i, A61K 9/16(2006.01)i, A61K 9/14(2006.01)i, A61K 31/568(2006.01)i, A61K 31/138(2006.01)i*

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: A61K 47; A61K 31; A61K 9

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)

eKOMPASS(KIPO internal), PUBMED

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010-0173882 A1 (GILIYAR CHANDRASHEKAR et al.) 08 July 2010	1-33,41-43,45,47
Y	See claims 1-2,4,6-7,11-17,21-24 and paragraphs [0004],[0036],[0042]-[0045],[0054],[0055],[0061]	44,46
Y	Stuart N Seidman et al. Testosterone replacement therapy for hypogonadal men with SSRI-refractory depression. Journal of Affective Disorders. 1 March 1998, Vol. 48, Issue 2-3, pages 157-161 See abstract and introduction	44,46
A	US 2008-0317844 A1 (DUDLEY ROBERT E. et al.) 25 December 2008 See whole document	1-33,41-47
A	US 2005-0287203 A1 (H. NIJS DE et al.) 29 December 2005 See whole document	1-33,41-47

 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 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

26 SEPTEMBER 2012 (26.09.2012)

Date of mailing of the international search report

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Name and mailing address of the ISA/KR

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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.: 34-40
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 34-40 pertain to methods for treatment or diagnostic of the human body by therapy, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
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:

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 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

Information on patent family members

International application No.

PCT/US2011/064495

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010-0173882 A1	08.07.2010	AU 2010-203457 A1 CA 2744266 A1 EP 2373295 A2 JP 2012-514653 A WO 2010-081032 A2	15.07.2010 15.07.2010 12.10.2011 28.06.2012 15.07.2010
US 2008-0317844 A1	25.12.2008	AU 2006-236564 A1 AU 2011-201422 A1 CA 2604943 A1 CN 101217963 A0 EP 1871384 A2 JP 2008-537960 A KR 10-2008-0009201 A US 8241664 B2 WO 2006-113505 A2	26.10.2006 14.04.2011 26.10.2006 09.07.2008 02.01.2008 02.10.2008 25.01.2008 14.08.2012 26.10.2006
US 2005-0287203 A1	29.12.2005	None	