



- (51) International Patent Classification:
C07D 209/42 (2006.01)
- (21) International Application Number:
PCT/IB2013/060614
- (22) International Filing Date:
4 December 2013 (04.12.2013)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
251/MUM/2013 29 January 2013 (29.01.2013) IN
1305/MUM/2013 4 April 2013 (04.04.2013) IN
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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, 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, IR, IS, JP, KE, KG, 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, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

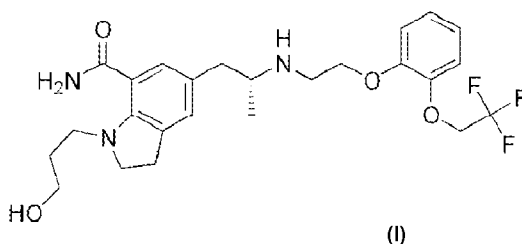
Published:

- with international search report (Art. 21(3))

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

18 December 2014

(54) Title: A NOVEL PROCESS FOR THE PREPARATION OF SILODOSIN



(57) Abstract: The present invention relates to a novel process for the preparation of Silodosin.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2013/060614

| A. CLASSIFICATION OF SUBJECT MATTER C07D209/42 Version=2014.01 | | |
|---|--|-----------------------|
| 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) C07D | | |
| 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) ORBIT, STN, IPO INTERNAL DATABASE | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| Y | WO 2011124704 A1, Ratiopharm Gmbh, 13-10-2011 Description, claim 1-3 | 1-3 |
| Y | WO 2012062229 A1, ZENTIVE K.S. , 12-05-2012, Description 1-3. | 1-3 |
| Y | JP 2006188470 B2, PHARMACEUTICALS INC, Julie F Liu, 06-09-2011 DISCRIPTION | 1-3 |
| Y | EP 1 806 340 , KISSEI PHARMACEUTICAL CO.LTD, YAMAGUCHI TOSHIAKI, 04-05-2011 DISCRIPTION | 1-3 |
| Y | CN 101302183, CHINA PHARMACEUTICAL UNIVERSITY , 29-09-2010 DISCRIPTION | 1-3 |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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 but 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 18-06-2014 | Date of mailing of the international search report 18-06-2014 | |
| Name and mailing address of the ISA/ Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075 Facsimile No. | Authorized officer Dr. Seema Telephone No. +91-1125300200 | |

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IB2013/060614

| Citation | Pub.Date | Family | Pub.Date |
|------------------------|------------|------------------------|------------|
| WO WO 2011124704 A1 A1 | 13-10-2011 | WO WO 2011124704 A1 A1 | 13-10-2011 |
| WO WO 2012062229 A1 | 18-05-2012 | WO WO 2012062229 A1 A1 | 18-05-2012 |
| JP JP 2006188470 B2 | 06-09-2011 | JP JP 2006188470 B2 | 06-09-2011 |
| EP EP 1 806 340 | 05-09-2011 | AG EP 1 806 340 | 05-09-2011 |
| CN CN 101302183 | 29-09-2010 | CN CN 101302183 | 29-09-2010 |

Continuation of Observations where unity of invention is lacking (Box III)

silidosin comprising the process of preparation of intermediate of formula C which further comprising steps (a) reacting nitro compound of formula (F) with suitable base and acid (b) Reacting ketone of formula (E) (c) hydrolysis of sulphanyl group of compound of formula (D) in presence of suitable acid.

In Conclusion , the group of claims are not linked by common or corresponding special technical feature and define three different invention not linked by a single general inventive concept. The application , hence does not meet the requirement of unity of invention as defined in Rule 13.1 and 13.2 PCT.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2013/060614

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:
The inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:
Group 1: Claim 1-3 relate to process for preparation of Silodosin formula 1 comprising use of sulphinamide of formula (IV) for diastereoselective reductive amination of ketone of formula (V).
Group 2: Claim 4-6 relate to a process for preparation of silodosin of formula (1) reaction of compound of formula (VI) with any suitable base and subsequently with any suitable acid to give compound of formula (V).
Group 3: Claim 7-17 relate to relate to process for preparation of

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.:
Claim No. 1-3

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.