ABSTRACT

The invention relates to a new crystalline forms of tiotropium bromide, processes for preparing them and their use for preparing a pharmaceutical composition for the treatment of respiratory complaints, particularly for the treatment of COPD (chronic obstructive pulmonary disease) and asthma.
A. CLASSIFICATION OF SUBJECT MATTER

INV. C07D451/10 A61K31/46 A61P11/06

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 practical, search terms used)

EPO-Internal, WPI Data, BEILSTEIN Data, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>WO 03/000265 A (BOEHRINGER INGELHEIM PHARMA KG; SIEGER, PETER; WERTHANN, ULRIKE) 3 January 2003 (2003-01-03) claims 1,2,10,11</td>
<td>1-53</td>
</tr>
</tbody>
</table>

[ ] 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 document but published on or after the international filing date

*L* document which may throw doubt on validity (claim(s)) or which is cited to establish the publication date of another document or other reason (as specified)

*C* 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.

**S** document member of the same patent family

Date of the actual completion of the International search

2 August 2006

Date of mailing of the International search report

22.12.2006

Name and mailing address of the ISA/Authorized officer

European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-(70) 240-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Seelmann, Ingo
Box 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 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 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.:

   see annex

Remark on Protest
☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2004)
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1(part), 35-37(part), 38, 53(part)
   subject-matter relating to tiotropium bromide anhydride

2. claims: 1(part), 2, 35-37(part), 44, 53(part)
   subject-matter relating to tiotropium bromide 1,4-dioxane solvate

3. claims: 1(part), 3, 35-37(part), 40, 53(part)
   subject-matter relating to tiotropium bromide ethanol solvate

4. claims: 1(part), 4, 35-37(part), 39, 53(part)
   subject-matter relating to tiotropium bromide methanol solvate

5. claims: 1(part), 5-7, 35-37(part), 46, 53(part)
   subject-matter relating to tiotropium bromide anisol solvate

6. claims: 1(part), 8-10, 26-28, 35-37(part), 42, 51, 53(part)
   subject-matter relating to tiotropium bromide n- or tert.-butanol solvate

7. claims: 1(part), 11-16, 35-37(part), 48, 49, 53(part)
   subject-matter relating to tiotropium bromide DMF or DMA solvate

8. claims: 1(part), 17-19, 35-37(part), 41, 53(part)
   subject-matter relating to tiotropium bromide isopropanol solvate

9. claims: 1(part), 20-22, 35-37(part), 45, 53(part)
   subject-matter relating to tiotropium bromide solvate, 2-propanediol
10. claims: 1(part), 23-25, 35-37(part), 52, 53(part)

subject-matter relating to tiotropium bromide pyridine solvate

---

11. claims: 1(part), 29-31, 35-37(part), 43, 50, 53(part)

subject-matter relating to tiotropium bromide THF solvate

---

12. claims: 1(part), 32-34, 35-37(part), 47, 53(part)

subject-matter relating to tiotropium bromide THP solvate

---
<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
<th>Publication date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>US 2004228806 A1</td>
<td>18-11-2004</td>
</tr>
<tr>
<td>WO 03000265 A</td>
<td>03-01-2003</td>
<td>AT 337006 T</td>
<td>15-09-2006</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BG 108440 A</td>
<td>31-08-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BR 0210537 A</td>
<td>22-06-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2450961 A1</td>
<td>03-01-2003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CN 1529294 A</td>
<td>11-08-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CZ 20040120 A3</td>
<td>12-05-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DK 1401445 T3</td>
<td>27-11-2006</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EA 5813 B1</td>
<td>30-06-2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EE 200400029 A</td>
<td>15-04-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1401445 A1</td>
<td>31-03-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HR 20031066 A2</td>
<td>30-04-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HU 0400333 A2</td>
<td>28-12-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2005504015 T</td>
<td>10-02-2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MX PA03011718 A</td>
<td>06-12-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NZ 530690 A</td>
<td>27-05-2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PL 364489 A1</td>
<td>13-12-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SK 522004 A3</td>
<td>08-06-2004</td>
</tr>
</tbody>
</table>