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(54) Title: PHARMACEUTICAL AEROSOL FORMULATIONS FOR PRESSURIZED METERED DOSE INHALERS COMPRISING A SEQUESTERING AGENT

(57) Abstract: Aerosol solution formulation for use in an aerosol inhaler which comprises at least one active ingredient selected from a group consisting of 20-ketosteroids and quinolinone derivatives, a propellant containing a hydrofluoroalkane, and a cosolvent, stabilized by addition of a specific amount of a sequestering agent.



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INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61K9/12 A61K9/72 A61K47/02 A61K31/573 A61K31/58
 A61K31/4704

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

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, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 466 594 A (CHIESI FARMACEUTICI S.P.A) 13 October 2004 (2004-10-13) paragraph [0001] paragraphs [0015] - [0019] paragraph [0022] paragraphs [0034], [0035] paragraph [0038] paragraphs [0042], [0043] paragraphs [0048], [0049] claims 1-5,7,8,11-15 ----- -/--	1-14,16, 18-22

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	"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 document 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 8 June 2006	Date of mailing of the international search report 05.10.2006
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Marchand, Petra
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INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2006/001287

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>EP 1 157 689 A (CHIESI FARMACEUTICI S.P.A) 28 November 2001 (2001-11-28) cited in the application paragraph [0001] paragraph [0010] paragraphs [0015] - [0018] paragraph [0022] paragraphs [0034], [0035] paragraph [0038] paragraphs [0042], [0043] paragraphs [0048], [0049] claims 1-4,10-12</p> <p style="text-align: center;">-----</p>	1-14,16, 18-21
A	<p>WO 01/89480 A (CHIESI FARMACEUTICI S.P.A; LEWIS, DAVID; GANDERTON, DAVID; MEAKIN, BRI) 29 November 2001 (2001-11-29) cited in the application claims 1,2,5,8,9</p> <p style="text-align: center;">-----</p>	1-14, 16-22
Y	<p>WO 00/78286 A (3M INNOVATIVE PROPERTIES COMPANY) 28 December 2000 (2000-12-28) cited in the application page 1, line 7 - line 11 page 3, line 3 - page 5, line 13 page 7, line 4 - page 10, line 3 examples 5-10 claims 1-16,21,22,25,28</p> <p style="text-align: center;">-----</p>	1-14, 17-21
Y	<p>WO 96/40042 A (RHONE-POULENC RORER PHARMACEUTICALS INC; WON, CHONG, MIN; STROHBECK, C) 19 December 1996 (1996-12-19) page 1, line 15 - line 17 page 3, line 7 - line 17 page 9, line 24 - page 10, line 3 page 10, line 23 - page 11, line 20 page 12, line 23 - page 13, line 19 claims 1-9,14,15</p> <p style="text-align: center;">-----</p>	1-14, 17-21
Y	<p>WO 94/13262 A (JAGER, PAUL, D; KONTRY, MARK, J; NAGEL, JURGEN, H) 23 June 1994 (1994-06-23) cited in the application page 1, line 5 - line 16 page 3, line 7 - line 16 page 4, line 19 - page 5, line 11 page 6, line 15 - page 7, line 2 page 7, line 24 - page 8, line 2 page 10, line 10 - line 11 page 10, line 17 - line 25 claims 1-5,7-11,13,39,40</p> <p style="text-align: center;">-----</p> <p style="text-align: center;">-/--</p>	1-14, 17-21

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2006/001287

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/074024 A (CHIESI FARMACEUTICI S.P.A; DAVIES, REBECCA, JAINE; GANDERTON, DAVID; L) 12 September 2003 (2003-09-12) page 1, lines 4,5 page 12, lines 5-23 page 13, lines 2-9 page 14, lines 9-16 page 16, lines 10-13 page 16, line 27 - page 16, line 10 claims 1,8-13,16,19,20,22 -----	11-14, 16,18-21
A	US 2003/165435 A1 (FREUND BERNHARD ET AL) 4 September 2003 (2003-09-04) paragraph [0001] paragraphs [0033] - [0035] paragraphs [0037], [0038] paragraph [0042] - paragraph [0051] tables 2-4 claims 1-3,5,6,9,10,13-16 -----	1-14, 16-22
A	WO 01/07014 A (CHIESI FARMACEUTICI S.P.A; MALVOLI, CHIARA; GARZIA, RAFFAELLA; BRAMBI) 1 February 2001 (2001-02-01) page 1, line 1 - line 10 page 5, line 17 - page 7, line 19 page 11, line 8 - line 21 page 11, line 26 - line 27 page 12, line 6 - line 13 examples 1-3 claims 1,3-9 -----	1-14, 16-22

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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.:

1-12 (in part), 13, 14, 16

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-12 (in part), 13 (completely), 14 (completely), 16 (completely), 17-21 (in part), and 22 (completely)

aerosol formulations comprising a 20-ketosteroid, a liquefied HFA propellant, an alcoholic cosolvent, and a sequestering agent selected from phosphoric acid and sulfuric acid; use of phosphoric acid or sulfuric acid to stabilize the active ingredient in said formulations; pressurized metered dose inhalers comprising said formulations; and a method of filling an aerosol inhaler

2. claims: claims 1-12 (in part), 15 (completely), and 17-21 (in part)

aerosol formulations comprising a quinolinone derivative, a liquefied HFA propellant, an alcoholic cosolvent, and a sequestering agent selected from phosphoric acid and sulfuric acid, provided that when the active ingredient is 8-hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methyl ethyl]amino]ethyl]]-2(1H)-quinolinone or its hydrochloride salt the sequestering agent is not phosphoric acid; use of phosphoric acid or sulfuric acid to stabilize the active ingredient in said formulations; and pressurized metered dose inhalers comprising said formulations

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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International application No

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