(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 October 2001 (25.10.2001)

PCT

(10) International Publication Number
WO 01/78695 A3

(51) International Patent Classification[7]: A61K 9/72, 9/14

(21) International Application Number: PCT/GB01/01751

(22) International Filing Date: 17 April 2001 (17.04.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

0009469.8	17 April 2000 (17.04.2000)	GB
00113608.4	27 June 2000 (27.06.2000)	EP

(71) Applicant *(for all designated States except US)*: **VECTURA LIMITED** [GB/GB]; University of Bath Campus, Claverton Down, Bath BA2 7AY (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **STANIFORTH, John, Nicholas** [GB/GB]; High Trees, 170 Bloomfield Road, Bath BA2 2ST (GB). **MORTON, David, Alexander, Vodden** [GB/GB]; 2nd Floor Flat, Linsley House, Beechen Cliff Road, Bath BA2 4QR (GB). **GILL, Rajbir** [GB/GB]; 7 Oak Tree Close, Trowbridge, Wiltshire BA14 9BD (GB). **BRAMBILLA, Gaetano** [IT/IT]; Via Palermo, 26/A, I-43100 Parma (IT). **MUSA, Rossella** [IT/IT]; Via Palermo, 26/A, I-43100 Parma (IT). **FERRARINI, Lorenzo** [IT/IT]; Via Palermo, 26/A, I-43100 PARMA (IT).

(74) Agents: **HUMPHREYS, Ceris, Anne** et al.; Abel & Imray, 20 Red Lion Street, London WC1R 4PQ (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
14 March 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/78695 A3

(54) Title: PHARMACEUTICAL FORMULATIONS FOR DRY POWDER INHALERS

(57) Abstract: A powder for use in a dry powder inhaler comprises: i) a fractio n of fine particle size constituted by a mixture of physiologically acceptable excipient and an additive; ii) a fraction of coarse particles; and iii) at least one active ingredient. The powder is suitable for efficacious delivery of active ingredients into the low respiratory tract of patients suffering from pulmonary diseases such as asthma. In particular, the invention provides a formulation to be administered as dry powder for inhalation which is freely flowable, can be produced in a simple way, is physically and chemically stable and capable of delivering accurate doses and/or high fine particle fraction of low strength active ingredients by using a high- or medium resistance device.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 01/01751

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/72 A61K9/14

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 7 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, PAJ, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 23485 A (CO ORDINATED DRUG DEV) 8 August 1996 (1996-08-08) cited in the application page 5, line 4 - line 16 page 15, line 11 - line 15 page 23, line 8 - line 12 example 3 figures 4A,4B ---	1-23
Y	WO 95 11666 A (CO ORDINATED DRUG DEV LTD) 4 May 1995 (1995-05-04) cited in the application page 4, line 15 - line 26 page 13, line 14 - line 20 examples --- -/--	1-23

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in 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 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	Date of mailing of the international search report
10 October 2001	18/10/2001

Name and mailing address of the ISA	Authorized officer
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	Epskamp, S

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 01/01751

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 00 28979 A (SKYEPHARMA AG) 25 May 2000 (2000-05-25) cited in the application example 2 ---	1-3,6-8, 12-16
P,X	WO 00 33789 A (R P SCHERER INC) 15 June 2000 (2000-06-15) cited in the application page 4, line 4 page 6, line 7 - line 10 examples -----	1-8,12, 14-16, 18,21-23

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 01/01751

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9623485 A	08-08-1996	AU 699131 B2	26-11-1998
		AU 4545696 A	21-08-1996
		BG 101858 A	30-04-1998
		BR 9607490 A	23-12-1997
		CA 2211874 A1	08-08-1996
		CZ 9702443 A3	14-01-1998
		EE 9700176 A	16-02-1998
		EP 0806938 A1	19-11-1997
		FI 973151 A	30-09-1997
		WO 9623485 A1	08-08-1996
		HU 9802209 A2	01-02-1999
		JP 10513174 T	15-12-1998
		NO 973502 A	30-09-1997
		NZ 300654 A	25-02-1999
		PL 321572 A1	08-12-1997
		SK 103697 A3	14-01-1998
		TR 9700722 T1	21-02-1998
		US 6153224 A	28-11-2000
		ZA 9600721 A	19-08-1996
WO 9511666 A	04-05-1995	AU 706986 B2	01-07-1999
		AU 7998194 A	22-05-1995
		CA 2174767 A1	04-05-1995
		DE 69426459 D1	25-01-2001
		DE 69426459 T2	23-08-2001
		EP 0725624 A1	14-08-1996
		ES 2153864 T3	16-03-2001
		WO 9511666 A1	04-05-1995
		JP 9507049 T	15-07-1997
		US 6221338 B1	24-04-2001
WO 0028979 A	25-05-2000	AU 6457899 A	05-06-2000
		WO 0028979 A1	25-05-2000
		EP 1131059 A1	12-09-2001
		NO 20012346 A	26-06-2001
WO 0033789 A	15-06-2000	AU 2038300 A	26-06-2000
		WO 0033789 A2	15-06-2000