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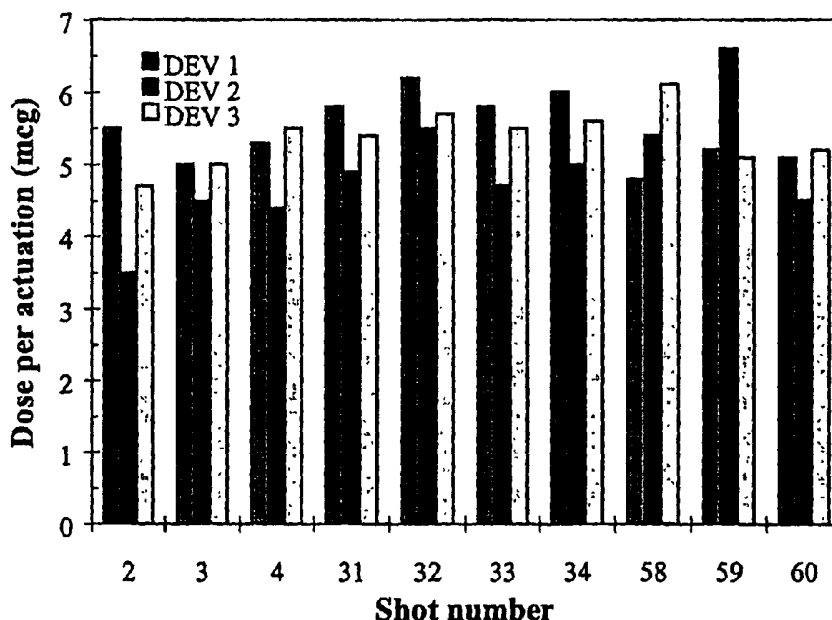
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[Continued on next page]

(54) Title: INHALATION COMPOSITION



(57) Abstract: The invention provides a dry powder inhalation composition comprising medicament particles and a mixture of lactose particles with a VMD of between about 70 and about 120 microns and a diameter of less than 250 microns, the mixture being characterized in that up to 96% by weight of the lactose particles are less than 150 microns in diameter and wherein up to 25% by weight of the lactose particles are less than 5 microns in diameter. The compositions provide for a more accurate, uniform and consistent dispersion when used with, for example, a multidose dry powder inhaler. Also disclosed are methods for use of the compositions of the invention.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

*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.*

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**INTERNATIONAL SEARCH REPORT**

International application No.  
PCT/US03/26385

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC(7) : A61K 31/65, 31/045, 9/14, 31/075, 31/56, 31/135, 47/26  
 US CL : 514/360, 169, 171, 177, 178; 424/489  
 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)  
 U.S. : 514/360, 169, 171, 177, 178; 424/489

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)  
 PGPB,USPT,USOC,EPAB,JPAB,DWPI

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/0041164 A1 (VERKERK et al.) 15 November 2001 (15.11.2001), see the entire document, especially paragraphs 0008-0011 on pages 1-2, and all claims.	1-8
A,E	US 6,645,466 B1 (KELLER et al.) 11 November 2003 (11.11.2003).	1-8

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 application or patent 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		
"P" document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search 17 January 2004 (17.01.2004)	Date of mailing of the international search report <b>15 MAR 2004</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Sabiha N. Qazi <i>Jayce Brubaker</i> Telephone No. <b>571-272-1600</b>

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/26385

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claim 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.  Claim Nos.: 9-12  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 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.  
 No protest accompanied the payment of additional search fees.