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Published:

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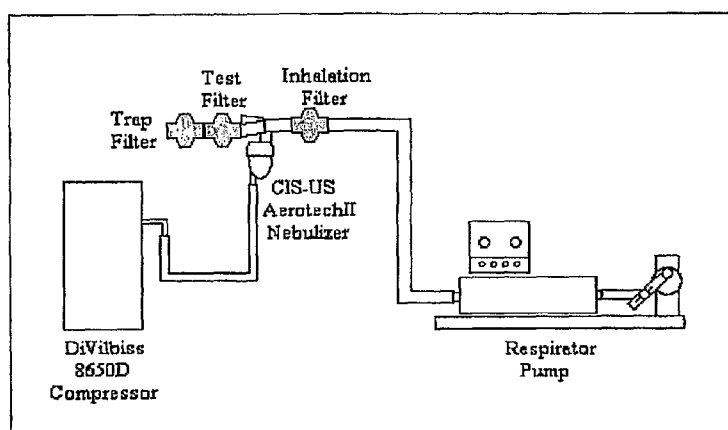
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[Continued on next page]

(54) Title: SYSTEM FOR DELIVERING NEBULIZED CYCLOSPORINE AND METHODS OF TREATMENT

Equipment Setup for the Exhalation Filter Challenge



(57) Abstract: Systems comprising a pressurized delivery device and a formulation of cyclosporine coupled to an exhalation filter or trap that is capable of preventing cyclosporine from escaping into the local environment are provided. An apparatus for use in the system comprises either an exhalation filter and a pressurized delivery device, wherein the exhalation filter is capable of providing high filter efficiency and maintaining low filter resistance after usage with the formulation, or a trap which provides a means for expired gas to be released into a solvent chamber containing a solvent with a high affinity for cyclosporine. These systems may be used to treat patients with pulmonary disorders, organ transplant patients such as lung transplant patients, and other immune-related disorders.



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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/004861

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/10

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)

A61M

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/006901 A1 (IACONO ALDO T [US]) 17 January 2002 (2002-01-17) cited in the application	1-4,8-10
Y	paragraph [0019] paragraph [0073]	28
A	US 4 824 451 A (VOGT CLIFFORD M [US] ET AL) 25 April 1989 (1989-04-25) column 3, line 21 - line 44	1,3,4,9, 10
A	US 2004/147433 A1 (KEEP MARCUS [US] ET AL) 29 July 2004 (2004-07-29) paragraph [0037] paragraph [0060]	1,8,12, 14-19
A	WO 03/053404 A (SHERMAN BERNARD CHARLES [CA]) 3 July 2003 (2003-07-03) page 22, line 1 - page 23, line 36	1,8, 12-19
-/--		

☒ 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 doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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- *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

2 November 2007

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/004861

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 533 409 A (WELLCOME FOUND [GB]) 24 March 1993 (1993-03-24) column 10, line 44 - column 12, line 13 -----	28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/004861

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.: 22-27
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
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:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an 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.:

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-11

an apparatus, comprising:
A) a pressurised delivery device
B) an exhalation filter/trap
and
further features of the filter B)

2. claims: 1 + 8 + 12-21

an apparatus, comprising:
A) a pressurised delivery device
B) an exhalation filter/trap
and
different compositions of the liquid formulation to be
nebulised

3. claim: 28

a method for selecting an exhalation filter (B) for a system
comprising:
C) a compressor
D) a rotary pump
E) an inhalation filter
F) a trap filter
G) a nebuliser containing liquid
(arrangement capable of simulating breathing)
the method comprising the steps of:
- running the system for an amount of time
- measuring the effects on properties of the filter
- assigning suitability of the filter based on the measured
properties

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/004861

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