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[Continued on next page]

(54) Title: NASAL AEROSOL DELIVERY SYSTEM

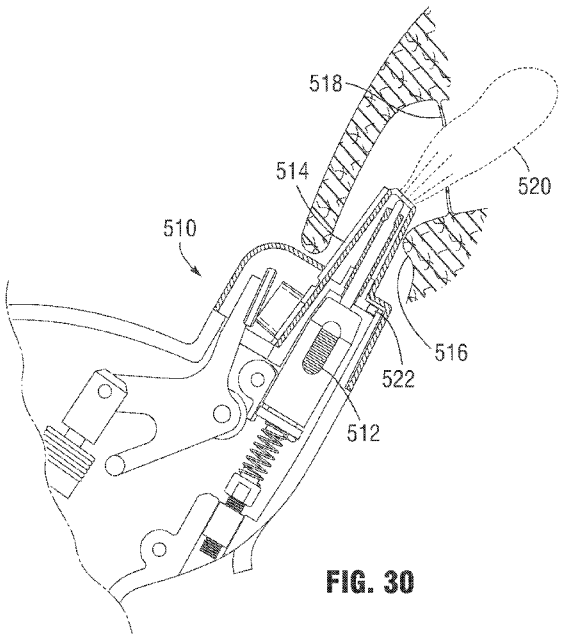


FIG. 30

(57) Abstract: A nasal delivery device (10) includes a nasal prong (14) and an activation member (22). The nasal prong can comprise an opening (16) at a top and bottom portion (18) of the prong to allow for the passage of an aerosolized treatment agent (30) through the nasal prong. The activation member can be positioned on the nasal delivery device at a location that is spaced apart from the subject's oral cavity when the nasal prong is received into the nostril (32, 38) of the subject. The activation member can be configured to detect a desired exhalation state of the subject and upon detection of the desired exhalation state, the activation member activates the delivery of the aerosolized treatment agent. The nasal delivery device comprises a handpiece (20) that can be held by a user and having an activation member for triggering the delivery of the treatment agent to a subject, and an intranasal portion or nose prong extending from the handpiece and having a dose container receiving area (58, 72) and an aerosolizing member (54, 56) to aerosolize the agent and eject an aerosolized plume into a nare of the subject. The device may comprise a vibrating-mesh nebulizer (510, 530) at a distal end of the device extending into a nare of the subject. The device may comprise an alignment device (214, 220) for improving alignment of the device with a subject to increase delivery and deposition of the agent.

WO 2014/165694 A3

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Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M11/00 A61M15/08 A61M15/00
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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 A61B

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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2011/153406 A2 (US GOV CT DISEASE CONTR & PREV [US]; CREARE INC [US]; PAPANIA MARK J [] 8 December 2011 (2011-12-08)	1,14-17
Y	paragraph [0002] - paragraph [0033] paragraph [0073] - paragraph [0074] paragraph [0077] - paragraph [0102] paragraph [0135] - paragraph [0159] figures 1-10, 16-26	2,3

Y	EP 1 977 778 A1 (MARKOS MEFAR S P A [IT]) 8 October 2008 (2008-10-08) paragraph [0001] - paragraph [0018] paragraph [0020] - paragraph [0032] figures 1-2b	2,3

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

[X] 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 application or patent 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
1 August 2014	21/10/2014

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, Fax: (+31-70) 340-3016	Aguado, Miguel

1

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/032863

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2012/205464 A1 (PARDONGE JEAN-MARC [FR]) 16 August 2012 (2012-08-16) paragraph [0001] - paragraph [0021] paragraph [0028] - paragraph [0034] figures 1-5 -----	2,3
Y	US 2008/128527 A1 (CHAN HELEN LAI WA [HK] ET AL) 5 June 2008 (2008-06-05) paragraph [0001] - paragraph [0008] paragraph [0010] - paragraph [0023] paragraph [0035] - paragraph [0042] figures 1-3 -----	2,3

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/032863

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011153406 A2	08-12-2011	CA 2801508 A1	08-12-2011
		EP 2575941 A2	10-04-2013
		US 2013072755 A1	21-03-2013
		WO 2011153406 A2	08-12-2011
EP 1977778 A1	08-10-2008	NONE	
US 2012205464 A1	16-08-2012	CN 102548667 A	04-07-2012
		EP 2490823 A1	29-08-2012
		FR 2951442 A1	22-04-2011
		JP 2013508051 A	07-03-2013
		US 2012205464 A1	16-08-2012
		WO 2011048330 A1	28-04-2011
US 2008128527 A1	05-06-2008	NONE	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-3, 14-17

A nasal delivery device comprising a handpiece and an intranasal portion with a dose container receiving area and an aerosolizing member, the device further comprising a vibrating-mesh nebulizer at the distal end of the intranasal portion.
A nasal delivery device comprising a handpiece and an intranasal portion with a dose container receiving area and an aerosolizing member, further comprising an alignment device.

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2. claims: 4, 5

A nasal delivery device comprising a handpiece and an intranasal portion with a dose container receiving area and an aerosolizing member, the device further comprising an ultrasonic actuator at least partially located in the handpiece.

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3. claims: 6-13

A nasal delivery device comprising a handpiece and an intranasal portion with a dose container receiving area and an aerosolizing member, the device further comprising a dose container to be received on or within the intranasal portion.

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4. claims: 18-20

A dose container comprising a fluid delivery member, a body member and a mesh member.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/032863

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.:
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 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 all searchable 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.:

1-3, 14-17

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.