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(71) Applicant (for all designated States except US): **AC-**

**CENTIA BIOPHARMACEUTICALS, INC.** [US/US];  
324 South Hyde Park Avenue, Suite 350, Tampa, FL  
33606 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **O'DONNELL,**  
**Francis, E.** [US/US]; 865 Longboat Club Rd., Longboat  
Key, FL 34228 (US). **DEROO, Donald** [US/VU]; 38  
Greenleaf Farms Road, Newton, CT 06470 (US).

(74) Agents: **LADWIG, Glenn, P.** et al.; Saliwanchik, Lloyd  
& Saliwanchik, P.o. Box 142950, Gainesville, FL  
32614-950 (US).

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HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR,  
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,  
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MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR),  
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(54) Title: MUCOSALLY NON-IRRITATIVE LIQUID AMPHOTERICIN B FORMULATIONS AND METHODS FOR  
TREATING NON-INVASIVE FUNGUS-INDUCED MUCOSITIS

(57) Abstract: The present invention is directed to liquid compositions and methods for non-irritatively treating and preventing non-invasive fungus-induced mucositis. Specifically, the invention involves liquid compositions including a mucosally non-irritative mixture of amphotericin B and a pharmaceutically acceptable carrier. Such compositions can be non-irritatively mucoadministered to prevent, reduce, or eliminate chronic non-invasive fungus-induced mucositis conditions. In some embodiments, the compositions are stored in a sealed container under an inert gas atmosphere (e.g., nitrogen) prior to mucoadministration, which provide enhanced stability. Other aspects of the invention are sealed containers containing a liquid composition comprising a mucosally non-irritative mixture of amphotericin B; a pharmaceutically acceptable carrier; and an inert gas headspace, such as pure, medical grade nitrogen.



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## INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/US2009/033832****A. CLASSIFICATION OF SUBJECT MATTER***A61K 31/7048(2006.01)i, A61K 9/08(2006.01)i, A61K 47/02(2006.01)i, A61P 31/10(2006.01)i*

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)

IPC8 as above

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)  
eKOMPASS, Google patent, Google**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 0101955 A1 (JANSSEN PHARMACEUTICA et al) 11 January 2001 See abstract, page 2 lines 14-24, page 5 lines 23-26, claims	1-4, 9-10, 14-23
X	US 5389373 A (Davis, S.S. et al) 14 February 1995 See col.2 lines 37-54, examples, claims	1-4, 9-10, 14-23
A	EP 202837 A1 (SMITHKLINE BECKMAN CO.) 26 November 1986 See the whole document	1-4, 9-10, 14-23
A	WO 2007140614 A (TOUTOUNCHI, C.) 13 December 2007 See the whole document -----//-----	1-4, 9-10, 14-23



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 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 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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

23 SEPTEMBER 2009 (23.09.2009)

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Name and mailing address of the ISA/KR

Korean Intellectual Property Office  
Government Complex-Daejeon, 139 Seonsa-ro, Seo-  
gu, Daejeon 302-701, Republic of Korea

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Authorized officer

KIM, YONG

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**INTERNATIONAL SEARCH REPORT**

International application No.

**PCT/US2009/033832****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.: 38-83  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 38-83 pertain to methods for treatment of the human by therapy, as well as diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
2. ☒ Claims Nos.: 6, 8, 12, 36, 44, 57, 58, 81  
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:  
Claims 6, 8, 12, 36, 44, 57, 58, 81 are singularly dependent claim which depends from multiple dependent claim. The referring of these claims is unclear. Thus, claims 6, 8, 12, 36, 44, 57, 58, 81 are unsearchable because they fail to comply with the prescribed requirements to such an extent that a meaningful search could not be carried out under Article 34(4)(a)(ii) of the
3. ☒ Claims Nos.: 5,7,11,13,24-35,37-39,41-43,45-56,59-67,69,71-76,80,82,83  
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:

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 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.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2009/033832**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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