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Torrance, CA 90505 (US). **YAO, Qiang**; 11121 Garfield Avenue, Culver City, CA 90230 (US).

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(74) Agents: **GAGALA, Bruce, M.** et al.; Leydig, Voit & Mayer, Ltd., Two Prudential Plaza, Suite 4900, 180 N. Stetson Av., Chicago, IL 60601-6780 (US).

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(71) Applicant: **AMERICAN BIOSCIENCES, INC.**  
[US/US]; 2730 Wilshire Boulevard, Suite 110, Santa Monica, CA 90403 (US).

(72) Inventors: **DESAI, Neil, P.**; 2730 Wilshire Boulevard, Suite 110, Santa Monica, CA 90403 (US). **YANG, Andrew**; 4309 Rio Hondo Avenue, Rosemead, CA 91770 (US). **CI, Sherry, Xiaopei**; 1987 San Salvatore Place, San Marino, CA 91108 (US). **DE, Tapas**; 10927 Palms Boulevard, Apr. 2, Los Angeles, CA 90034 (US). **TRIEU, Vuong**; 2739 Wilshire Boulevard, Suite 100, Santa Monica, CA 90403 (US). **SOON-SHIONG, Patrick**; 11718 Barrington Court #311, Los Angeles, CA 90049 (US). **BEALS GRIM, Bridget**; 23939 Ocean Avenue, Apt. 205,

WO 2004/052401 A3

(54) Title: COMPOSITIONS AND METHODS OF DELIVERY OF PHARMACOLOGICAL AGENTS

(57) Abstract: The present invention relates to a pharmaceutical composition comprising a pharmaceutical agent and a pharmaceutically acceptable carrier, which carrier comprises a protein, for example, human serum albumin and/or deferoxamine. The human serum albumin is present in an amount effective to reduce one or more side effects associated with administration of the pharmaceutical composition. The invention also provides methods for reducing one or more side effects of administration of the pharmaceutical composition, methods for inhibiting microbial growth and oxidation in the pharmaceutical composition, and methods for enhancing transport and binding of a pharmaceutical agent to a cell.

## INTERNATIONAL SEARCH REPORT

International Application No

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**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 7 A61K47/18 A61K47/42 A61K47/48

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, MEDLINE, EMBASE

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92/07259 A (BIOMED FRONTIERS INC) 30 April 1992 (1992-04-30) page 6, lines 10-13 page 12, lines 16-22 page 18, lines 30-35 claims 1,13 -----	1-36
X	MEIJS W E ET AL: "A Facile Method for the Labeling of Proteins with Zirconium Isotopes" NUCLEAR MEDICINE AND BIOLOGY, ELSEVIER SCIENCE PUBLISHERS, NEW YORK, NY, US, vol. 23, no. 4, 1 May 1996 (1996-05-01), pages 439-448, XP004051812 ISSN: 0969-8051 page 441, left-hand column, lines 3-6,8-14,35-37,53 - right-hand column, line 19 ----- -/-	1-36

Further documents are listed in the continuation of box C.

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
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- \*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

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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

Authorized officer

Villa Riva, A

## INTERNATIONAL SEARCH REPORT

International Application No  
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 425 319 A (OMOMO YOSHIRO ET AL) 10 January 1984 (1984-01-10) abstract claims; examples	1-36
X	US 5 990 153 A (WOOD JOHN G ET AL) 23 November 1999 (1999-11-23) claims 3,4	1-36
E	WO 2004/007520 A (CINI JOHN K ; MEDAREX INC (US); NAGI ATHENA D (US)) 22 January 2004 (2004-01-22) abstract page 2, lines 19-22 examples; tables 2,3	37-50
X	EP 0 227 593 A (HOSPITAL FOR SICK CHILDREN) 1 July 1987 (1987-07-01) the whole document	37-50
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X	US 4 645 660 A (TAKAHASHI KEIETSU ET AL) 24 February 1987 (1987-02-24) claims; example 1	37-50
A	HALLIWELL B: "PROTECTION AGAINST TISSUE DAMAGE IN VIVO BY DESFERRIOXAMINE: WHAT IS ITS MECHANISM OF ACTION?" FREE RADICAL BIOLOGY AND MEDICINE, ELSEVIER SCIENCE, XX, vol. 7, no. 6, 1989, pages 645-651, XP001058483 ISSN: 0891-5849 the whole document	37-50
X	VICTOR TUAN GIAM CHUANG ET AL: "PHARMACEUTICAL STRATEGIES UTILIZING RECOMBINANT HUMAN SERUM ALBUMIN" PHARMACEUTICAL RESEARCH, NEW YORK, NY, US, vol. 19, no. 5, May 2002 (2002-05), pages 569-577, XP009007551 ISSN: 0724-8741 the whole document, in particular Introduction and Fig. 2	51-84
X	US 5 916 596 A (MAGDASSI SHLOMO ET AL) 29 June 1999 (1999-06-29) cited in the application column 6, lines 10-18, 37-44 example 1	51-84

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 439 686 A (SOON-SHIONG PATRICK ET AL) 8 August 1995 (1995-08-08) cited in the application abstract; examples column 2, line 64 – column 3, line 26 column 5, lines 45-65 column 6, lines 42-49 -----	51-84
X	WO 00/23117 A (GEN HOSPITAL CORP) 27 April 2000 (2000-04-27) page 12, line 19 – page 14, line 21 claims 1,20-25 -----	85-93
X	EP 0 544 292 A (BOEHRINGER MANNHEIM GMBH) 2 June 1993 (1993-06-02) abstract page 2, lines 44-57 page 3, lines 22-43 examples -----	85,87, 89-93
X	US 6 310 039 B1 (KRATZ FELIX) 30 October 2001 (2001-10-30) abstract column 2, lines 13-30 column 3, line 63 – column 4, line 9 claims -----	85-93
X	US 6 204 054 B1 (SUTTON ANDREW DEREK ET AL) 20 March 2001 (2001-03-20) abstract column 1, line 52 – column 2, line 4 column 4, lines 52-57 examples 3,4 claims -----	85,87-93

## INTERNATIONAL SEARCH REPORT

International application No.  
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### Box I Observations where certain claims were found unsearchable (Continuation of item 1 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:  

Although claims 19-36, 64-76, 85-90 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compositions.
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 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:

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 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.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box I.1

Although claims 19-36, 64-76, 85-90 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compositions.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

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