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(54) Title: COMPOSITIONS AND METHODS TO IMPROVE THE THERAPEUTIC BENEFIT OF SUBOPTIMALLY ADMINISTERED CHEMICAL COMPOUNDS INCLUDING SUBSTITUTED HEXITOLS SUCH AS DIANHYDROGALACTITOL AND DIACETYLDIANHYDROGALACTITOL

(57) Abstract: The present invention describes methods and compositions for improving the therapeutic efficacy of therapeutic agents previously limited by suboptimal therapeutic performance by either improving efficacy as monotherapy or reducing side effects. Such methods and compositions are particularly applicable to substituted hexitols such as dianhydrogalactitol and diacetyl-dianhydrogalactitol.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 11/48031

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A01N 31/00 (2011.01)

USPC - 514/738

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)

USPC: 514/738

IPC(8): A01N 31/00 (2011.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC: 514/724;514/811 (SEE SEARCH TERMS BELOW)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST:PGPB, USPT, USOC, EPAB, JPAB

GOOGLE: SCHOLAR/PATENTS: Diacetyldianhydrogalactitol hexitol anhydride reduce side effects dosing regimen phenotype genotype diluent solvent systems Dianhydrogalactitol chemosensitizer chemopotentiator chemotherapy combinations immunostimulators

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No:
X --- Y	US 2009/0318561 A1 (DAVIS et al) 24 December 2009 (24.12.2009) para [0009];[0012];[0015]-[0017]; [0026];[0027];[0037];[0030];[0042];[0043];[0060]-[0067];[0095];[0101];[0102];[0111]-[0114];[0120];[0125];[0129];[0130];[0135];[0144];[0145];[0162];[0168];[0209];[0215]	1-4;161-162 5-160;163-197
Y	KERPEL-FRONIUS et al. Relation between dose, plasma concentration and toxicity in a phase I trial using high dose intermittent administration of an alkylating agent, diacetyldianhydrogalactitol (DADAG), in Cancer Chemotherapy and Pharmacology, 1986, Vol 16, pp 264-268. pg 264, abstract; pg 264, Col 1, para 1	5-67;70;71;75-159;163-164;166-169;171;174;176-197
Y	US 2002/0037328 A1 (BROWN) 28 March 2002 (28.03.2002) para [0013]-[0018];[0021];[0023]	68-77;170-175
Y	US 2008/0176923 A1 (SALAMA) 24 July 2008 (24.07.2008) para [0007];[0017];[0018];[0020];[0021];[0023];[0024];[0026];[0028];[0030];[0053]	26-29;48-53;78-81;90-109;136-160;165;173;175
Y	US 2006/0018842 A1 (BLUMENTHAL et al) 26 January 2006 (26.01.2006) para [0017];[0024]	185 86-89
Y	MOK et al. A double-blind placebo-controlled randomized study of Chinese herbal medicine as complementary therapy for reduction of chemotherapy-induced toxicity in Annals of Oncology, 2007, Vol 18, pp 768-774. pg 768, abstract; pg 769, Col 1; pg 769, Col 2, para 5; pg 774, Col 2	82-89

☒ Further documents are listed in the continuation of Box C.

* 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

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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

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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.
Y	KHANDARE et al. Polymer/drug conjugates: Progress in polymeric prodrugs in Progress Polymery Science, 2006, Vol 31, pp 359-397. pg 359, abstract; pg 361, Col 1, para 1, Table 2;pg 362, Col 1, para 2 to Col 2, para 2;pg 364, Col 1, para 2; pg 365, Figure 3; pg 366, Figure 4; pg 374, Col 1, para 1-2	114-131;188-195