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(54) Title: D-ENANTIOMER OF DFMO AND METHODS OF USE THEREOF FOR TREATING CANCER

(57) Abstract: The present invention concerns a method for preventing and/or treating cancer in a patient comprising administering an effective amount of substantially purified D enantiomer of difluoromethylornithine (D-DFMO) or an analog of D-DFMO to the patient. D-DFMO or an analog thereof is administered at a dose of about 0.05 to about 20.0 gm/M²/day. D-DFMO or an analog thereof may be administered more than once for the treatment and/or prevention of cancer. Methods of administration as well as compositions and formulations of substantially purified D-DFMO and analogs of D-DFMO are described.

INTERNATIONAL SEARCH REPORT

ational Application No

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A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K31/195 A61P35/00

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, CHEM ABS Data, BIOSIS, EMBASE, MEDLINE, SCISEARCH

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 14188 A (ILEX ONCOLOGY INC ; LOVE RICHARD (US); MANGOLD GINA (US); WEIS ALEX) 9 April 1998 (1998-04-09) page 5, line 1-23 page 8, line 3-12, 27-32 page 12, line 5-14, 26-30 page 17, line 24-33 page 18, line 1-6 examples 5, 9, 10, 14 claims 1-3, 10, 11 ---	1-38
X	WO 98 19667 A (ILEX ONCOLOGY INC ; MCGINITY JAMES (US); WEIS ALEXANDER (US)) 14 May 1998 (1998-05-14) page 3, line 17 - page 4, line 11 page 11, line 7-17 page 30, line 5-16 claims 1, 8-11 ---	1-24, 28-35
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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

E earlier document 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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Name and mailing address of the ISA

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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	WO 98 25603 A (ILEX ONCOLOGY INC ;SHAKED ZE EV (US); WEIS ALEXANDER (US)) 18 June 1998 (1998-06-18) page 7, line 18-32 page 8, line 14-11 page 9, line 32 -page 10, line 5 figure 4B page 11, line 30 -page 12, line 33 page 17, line 19-26 page 23, line 21-33 page 39, line 5-7 page 43, line 1,2 claims 1-3,8-10	1-19, 28-30
X	WO 99 49859 A (MEYSKENS FRANK L JR ;GERNER EUGENE W (US); UNIV ARIZONA (US); UNIV) 7 October 1999 (1999-10-07) page 5, line 3 -page 6, line 6 page 12, line 1-15 claims 1,4-12,14-20	1-19
P,X	WO 00 69434 A (ILEX ONCOLOGY INC ;LOVE RICHARD (US)) 23 November 2000 (2000-11-23) page 4, line 29 -page 5, line 9 page 6, line 25-30 page 8, line 19 -page 11, line 27 page 19, line 1-6,22-27 page 20, line 18-20 claims 1,4-8,12-21	1-19
X	LOPRINZI, CHARLES L. (1) ET AL: "A prospective clinical trial of difluoromethylornithine (DFMO) in patients with resected superficial bladder cancer." JOURNAL OF CELLULAR BIOCHEMISTRY SUPPLEMENT, (1992) VOL. 0, NO. 16 PART I PP. 153-155. , XP001041875 abstract page 154, left-hand column, line 25-29	1-19

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1-38 relate to an undefined number of possible compounds (analogs of DFMO).

The term analogue is vague and unclear and leaves in doubt as to the meaning of the technical features to which it refers.

The use of this term in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT. The lack of clarity is such as to render a meaningful complete search impossible. Furthermore the experimental data reported in the description refer only to DFMO and the activity of the alleged analogs has not been evaluated.

There also is no unequivocal generally accepted meaning of the term "substantially enriched".

Consequently, the search has been restricted to D-DFMO.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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