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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#6

Application of: Jerome B. Zeldis

Group Art Unit: 1614

Serial No.: 10/411,649

Examiner: To be assigned

Filed: April 11, 2003

Attorney Docket No.: 501872-999071

(Formerly 9516-072-999)

For: METHODS OF USING AND
COMPOSITIONS COMPRISING
IMMUNOMODULATORY
COMPOUNDS FOR THE TREATMENT
AND MANAGEMENT OF
MYELODYSLPASTIC SYNDROMES

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Prior to examination on the merits, please enter the following amendments and remarks into the file of the above-captioned application.

Amendments to the Claims are reflected in the listing of the claims that begins on page 2 of this paper.

Remarks begin on page 4 of this paper.

45. (new) The method of claim 44, wherein the stereoisomer is an enantiomerically pure R isomer.

46. (new) The method of claim 44, wherein the stereoisomer is an enantiomerically pure S isomer.

47. (new) The method of claim 39, wherein the compound is 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione.

48. (new) The method of claim 39, wherein the compound is 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione.

49. (new) The method of claim 39, which further comprises administering a therapeutically or prophylactically effective amount of a second active agent.

50. (new) The method of claim 49, wherein the second active agent is capable of improving blood cell production.

51. (new) The method of claim 49, wherein the second active agent is a cytokine, hematopoietic growth factor, an anti-cancer agent, an antibiotic, a proteasome inhibitor, or an immunosuppressive agent.

52. (new) The method of claim 51, wherein the second active agent is etanercept, imatinib, anti-TNF- α antibodies, infliximab, G-CSF, GM-CSF, EPO, topotecan, pentoxifylline, ciprofloxacin, irinotecan, vinblastine, dexamethasone, IL2, IL8, IL18, Ara-C, vinorelbine, isotretinoin, 13-cis-retinoic acid, arsenic trioxide or a pharmacologically active mutant or derivative thereof.

53. (new) The method of claim 39, wherein the myelodysplastic syndrome is refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, or chronic myelomonocytic leukemia.

54. (new) The method of claim 39, wherein the compound or a pharmaceutically acceptable salt, solvate or stereoisomer thereof is administered before, during or after transplanting umbilical cord blood, placental blood, peripheral blood stem cell, hematopoietic stem cell preparation or bone marrow in the patient.

REMARKS

New claims 39-54 appear in the application for the Examiner's consideration. Claims 1-38 have been canceled without prejudice to Applicant's right to pursue them in one or more continuations, divisionals or continuations-in-part. The new claims are supported by canceled claims 1-38 and the originally filed specification. No new matter has been added.

No fee is believed due for this Preliminary Amendment. However, if a fee is due, please charge such fee to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date July 7, 2004



Yeahsil Moon (Reg. No. 52,042)
Jones Day
222 East 41st Street
New York, New York 10017

For: Anthony M. Insogna (Reg. No. 35,203)
Jones Day
12750 High Bluff Drive, Suite 300
San Diego, CA 92130



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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

KIM, VICKIE Y

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