



3E

7-9-04

1614

0260

EXPRESS MAIL NO. EV475140930US

**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.

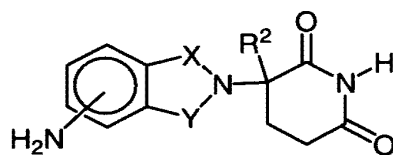
**Remarks** begin on page 4 of this paper.

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of the Claims:**

Claims 1-38. (canceled without prejudice)

39. (new) A method of treating a myelodysplastic syndrome, which comprises administering to a patient in need thereof a therapeutically effective amount of a compound of formula (I):

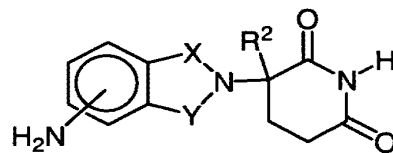


(I)

or a pharmaceutically acceptable salt, solvate or stereoisomer thereof, wherein one of X and Y is C=O, the other of X and Y is C=O or CH<sub>2</sub>, and R<sup>2</sup> is hydrogen or lower alkyl.

40. (new) The method of claim 39, wherein R<sup>2</sup> is hydrogen.

41. (new) The method of claim 39, wherein the compound has formula (I):



(I)

wherein one of X and Y is C=O, the other of X and Y is C=O or CH<sub>2</sub>, and R<sup>2</sup> is hydrogen or lower alkyl.

42. (new) The method of claim 39, wherein the compound is a pharmaceutically acceptable salt.

43. (new) The method of claim 39, wherein the compound is a pharmaceutically acceptable solvate.

44. (new) The method of claim 39, wherein the compound is a pharmaceutically acceptable stereoisomer.

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- $\alpha$  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 41<sup>st</sup> 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



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/411,649	04/11/2003	Jerome B. Zeldis	501872-999071	9157
20583	7590	03/09/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.