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| 13/801,262 | 03/13/2013 | Jerome B. Zeldis | 12827-392-999 | 4855 |

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| EXAMINER | |
|---|---|
| SAMALA, JAGADISHWAR RAO | |
| ART UNIT | PAPER NUMBER |
| 1618 | |
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| 04/29/2014 | PAPER |

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

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. 13/801,262 | Applicant(s) ZELDIS, JEROME B. | |
|---|---|---|---|
| | Examiner JAGADISHWAR SAMALA | Art Unit 1618 | AIA (First Inventor to File) Status No |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims***

5)☒ Claim(s) 1-37 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) 1-37 is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

**Application Papers**

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

The present application is being examined under the pre-AIA first to invent provisions.

## DETAILED ACTION

- Claims 1-37 are pending and presented for examination.

### Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03/13/2013 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

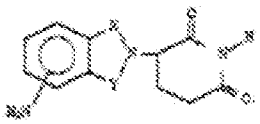
Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ionescu et al (US 6,887,855) in view of Muller et al (US 5,635,517), Zeldis et al (WO-01/87307) and Raza et al (Blood, Vol 98(4), 958-965, 2001).

Claims are drawn to a method of treating a myelodysplastic syndrome (MDS) comprising, administering to a patient having a myelodysplastic syndrome a therapeutically effective amount of 5-azacytidine, and a therapeutically effective amount of 3-(4-maino-l-oxo-l,3-dihydro- isoindol-2-yl)-piperidine-2,6-dione or a pharmaceutically acceptable salt thereof, wherein the MDS is refractory anemia or chronic myelomonocytic leukemia and administration further comprises at least one additional active agent.

Ionescu discloses a pharmaceutical composition comprising the 5-azacytidine and pharmaceutically acceptable excipient or carrier used in the treatment of myelodysplastic syndromes (MDS), (Col. 1 lines 5-10). The pharmaceutical formulations are preferably prepared in a unit dosage form containing from about 5 mg to about 200 mg to produce the desired therapeutic effect (Col. 9 lines 40+). Additional disclosure includes that the formulations are used for parenteral or oral administration.

Ionescu fails to incorporate 3-(4-maino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione and at least one additional active agent.

Muller discloses a method of administering thalidomide analogs for reducing undesirable levels of TNFα in a mammal. The thalidomide analogs of the formula:



wherein one of X and Y is C=O and the other of X and Y is C=O or $CH_2$, is 3-(4-maino- 1-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione would read on as recited in the instant claim (Col. 4 lines 20-34). The compound can be administered orally, alone or in combination with other therapeutic agents including antibiotics, to a mammal in need of treatment (Col. 4 lines 37-40). Additional disclosure includes that decreasing TNFα levels and/or increasing cAMP levels thus constitutes a valuable therapeutic strategy for the treatment of malignant (cancer) diseases.

Zeldis teaches a treatment of primary and/or metastatic cancers (e.g. hematopoietic cancer including myelogeneous leukemia such as chronic myelomonocytic leukemia), wherein the treatment comprising administering a composition containing thalidomide or its analogues especially amino analogues (page 8, lines 5-25; page 15, line 10- 15). Zeldis also teaches pure diastereomers (optically pure or pure enantiomer, Page 11, line 10-30). Zeldis further teaches pharmaceutical compositions comprising thalidomide, or a derivative and at least one other anti-cancer drug such as irinotecan hydrochloride, vinblastine sulfate and like (page 12, line 14-17 and page 17). Zeldis particularly states that the patented invention is based on the ability of thalidomide to treat cancer (Page 11, line 38), and amino thalidomides are

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