

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Jerome B. Zeldis

Group Art Unit: *To be assigned*

Serial No.: *To be assigned* (Continuation of  
Serial No. 12/777,765)

Confirmation No.: *To be assigned*

Examiner: *To be assigned*

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Attorney Docket No.: 12827-089-999  
(CAM 226269-999089)

For: METHODS OF TREATING  
MYELODYSPLASTIC SYNDROMES  
USING LENALIDOMIDE (as amended)

**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 Title** begin on page 2 of this paper.

**Amendments to the Specification** begin on page 3 of this paper.

**Amendments to the Claims** are reflected in the listing of the claims that begins on page 4 of this paper.

**Remarks** begin on page 6 of this paper.

**Amendment to the Title:**

Please amend the title of the application as follows:

METHODS OF TREATING MYELOYDYSPLASTIC SYNDROMES WITH A  
COMBINATION THERAPY USING LENALIDOMIDE AND AZACITIDINE

**Amendments to the Specification:**

Please replace the first paragraph after the title on Page 1 with the following amended paragraph:

This application is a continuation application of U.S. Patent Application No. 12/777,765, filed May 11, 2010, presently pending, which is a continuation-in-part of U.S. Patent Application No. 11/985,032, filed November 12, 2007, which is continuation of U.S. Patent Application No. 11/654,550 filed January 16, 2007, now issued U.S. Patent No. 7,393,863, which is divisional of U.S. Patent Application No. 10/411,649 filed April 11, 2003, now issued U.S. Patent No. 7,189,740, which claims the benefit of U.S. Provisional Patent Application No. 60/418,468 filed on October 15, 2002, the contents of each of which are incorporated by reference herein in their entireties.

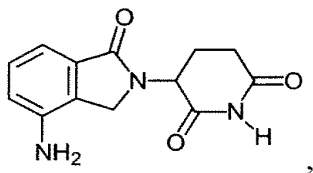
**Amendment to the Claims:**

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

**Listing of the Claims:**

Claims 1-37. (canceled)

38. (New) A method of treating a patient having transfusion dependent anemia due to low to intermediate -1- risk myelodysplastic syndrome, which comprises administering to said patient about 5 to about 25 mg per day of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione having the formula:



or a pharmaceutically acceptable salt, solvate or stereoisomer thereof.

39. (New) The method of claim 38, wherein the compound is administered in the amount of 5 mg per day.

40. (New) The method of claim 38, wherein the compound is administered in the amount of 10 mg per day.

41. (New) The method of claim 38, wherein the compound is administered in the amount of 15 mg per day.

42. (New) The method of claim 38, wherein the compound is administered in the amount of 25 mg per day.

43. (New) The method of claim 39, wherein the compound is administered orally in an amount of 5 mg as a capsule per day.

44. (New) The method of claim 40, wherein the compound is administered orally in an amount of 10 mg as a capsule per day.

45. (New) The method of claim 41, wherein the compound is administered orally in an amount of 15 mg as a capsule per day.

46. (New) The method of claim 42, wherein the compound is administered orally in an amount of 25 mg as a capsule per day.

47. (New) The method of claim 43, 44, 45 or 46, wherein the compound 3-(4-amino-1-oxo-1,3-dihydro-isindol-2-yl)-piperidine-2,6-dione is as a free base.

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