

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Jerome B. Zeldis

Group Art Unit: 1618

Application No.: 13/801,262

Confirmation No.: 4855

Filed: March 13, 2013

Examiner: SAMALA, Jagadishwar Rao

For: METHODS OF TREATING  
MYELODYSPLASTIC SYNDROMES  
USING LENALIDOMIDE

Attorney Docket No.: 12827-392-999

**RESPONSE**

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

In response to the non-final Office Action mailed April 29, 2014, Applicant respectfully submits the following claim amendments and remarks for consideration by the Examiner and entry into the record of the above-identified application. Also submitted herewith is a Petition for Extension of Time for three months from July 29, 2014 to and including October 29, 2014.

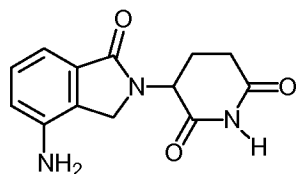
**Amendments to the Claims** are reflected in a **listing of the claims** that begins on page 2 of this paper.

**Remarks** begin on page 8 of this paper.

**Listing of the Claims:**

1-37. (canceled)

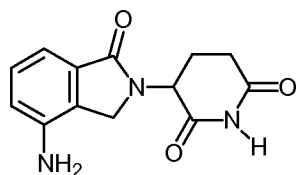
38. (new) A method of treating myelodysplastic syndrome, which comprises administering to a patient in need thereof about 1 mg to about 50 mg per day of a compound having the formula:



or a pharmaceutically acceptable salt, solvate or stereoisomer thereof.

39. (new) The method of claim 38, 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.

40. (new) The method of claim 38, wherein the compound is



and is not a pharmaceutically acceptable salt, solvate or stereoisomer.

41. (new) The method of claim 38, wherein the compound is a pharmaceutically acceptable salt.

42. (new) The method of claim 38, wherein the compound is a pharmaceutically acceptable solvate.

43. (new) The method of claim 38, wherein the compound is a pharmaceutically acceptable stereoisomer.

44. (new) The method of claim 38, wherein the patient is not previously treated for a myelodysplastic syndrome.

45. (new) The method of claim 38, wherein the patient has been previously treated for a myelodysplastic syndrome.

46. (new) The method of claim 38, which further comprises administering a therapeutically effective amount of a second active agent.

47. (new) The method of claim 46, wherein the second active agent is dexamethasone.

48. (new) The method of claim 46, wherein the second active agent is azacitidine.

49. (new) The method of claim 38, wherein the compound 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.

50. (new) The method of claim 38, wherein the compound is administered cyclically.

51. (new) The method of claim 38, wherein compound is administered for 21 consecutive days followed by seven consecutive days of rest in a 28 day cycle.

52. (new) The method of claim 38, which comprises cyclically administering the compound until disease progression or unacceptable toxicity.

53. (new) The method of claim 38, wherein the compound is administered in an amount of about 2.5 mg per day.

54. (new) The method of claim 38, wherein the compound is administered in an amount of about 5 mg per day.

55. (new) The method of claim 38, wherein the compound is administered in an amount of about 10 mg per day.

56. (new) The method of claim 38, wherein the compound is administered in an amount of about 15 mg per day.

57. (new) The method of claim 38, wherein the compound is administered in an amount of about 20 mg per day.

58. (new) The method of claim 38, wherein the compound is administered in an amount of about 25 mg per day.

59. (new) The method of claim 38, wherein the compound is administered in an amount from about 5 mg per day to about 25 mg per day for 21 consecutive days followed by seven consecutive days of rest in a 28 day cycle.

60. (new) The method of claim 38, wherein the compound is administered in an amount of about 10 mg per day or about 15 mg per day for 21 consecutive days followed by seven consecutive days of rest in a 28 day cycle.

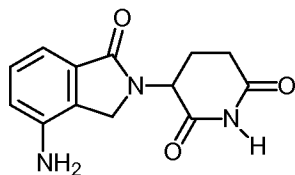
61. (new) The method of claim 38, wherein the compound is administered orally.

62. (new) The method of claim 61, wherein the compound is administered in the form of a capsule or tablet.

63. (new) The method of claim 62, wherein the compound is administered in a capsule in an amount from about 1 mg to about 50 mg.

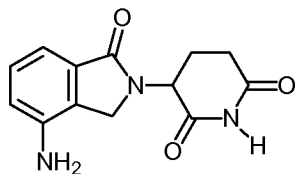
64. (new) The method of claim 62, wherein the compound is administered in a capsule in an amount of about 2.5 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg or about 25 mg.

65. (new) A method of treating transfusion dependent anemia due to low to intermediate-1-risk myelodysplastic syndrome, which comprises administering to a patient in need thereof about 1 mg to about 50 mg per day of a compound having the formula:



or a pharmaceutically acceptable salt, solvate or stereoisomer thereof.

66. (new) The method of claim 65, wherein the compound is



and is not a pharmaceutically acceptable salt, solvate or stereoisomer.

67. (new) The method of claim 65, wherein the compound is a pharmaceutically acceptable salt.

68. (new) The method of claim 65, wherein the compound is a pharmaceutically acceptable solvate.

69. (new) The method of claim 65, wherein the compound is a pharmaceutically acceptable stereoisomer.

70. (new) The method of claim 65, wherein the patient is not previously treated for a myelodysplastic syndrome.

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