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Application of: Jerome B. Zeldis	Group Art Unit: 1629
Application No.: 12/621,502	Confirmation No.: 2588
Filed: November 19, 2009	Examiner: Anderson, James D.
For: METHODS USING 3-(4-AMINO-1-OXO-1,3-DIHYDRO-ISOINDOL-2-YL)-PIPERIDINE-2,6-DIONE FOR TREATMENT OF MANTLE CELL LYMPHOMAS	Attorney Docket No.: 9516-904-999 (CAM: 501872-999904)

RESPONSE UNDER 37 CFR § 1.116

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

Sir:

In response to the final Office Action mailed September 19, 2013, Applicant submits the following amendments and remarks for consideration by the Examiner and entry into the record of the above-captioned application. Applicant also submits herewith (i) a Certification and Request for Consideration Under The After Final Consideration Pilot Program 2.0; (ii) a Declaration under 37 C.F.R. § 1.132 with Exhibits A and B; and (iii) and a supplemental Information Disclosure Statement.

Amendment to the Claims are shown in a listing of the claims that begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

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AMENDMENTS TO THE CLAIMS

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

Listing of Claims:

1. (Currently Amended) A method of treating mantle cell lymphoma in a human, which comprises (a) administering to a human having mantle cell lymphoma from about 5 mg to about 25 mg per day of 3-(4-amino-l-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione or a pharmaceutically acceptable salt or hydrate thereof for ~~a period of time~~ 21 days followed by ~~a period of~~ seven days rest in a 28 day cycle; and (b) repeating step (a), wherein the mantle cell lymphoma is relapsed, refractory, or relapsed and refractory to conventional therapy.

2. (Canceled)

3. (Currently Amended) The method of claim 1 ~~2~~, wherein the amount of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is about 5, 10 , 15, 20 or 25 mg per day.

4. (Previously Presented). The method of claim 3, wherein the amount of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is about 10, 15, 20, or 25 mg per day.

5. (Previously Presented). The method of claim 4, wherein the amount of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is about 25 mg per day.

6. (Previously Presented) The method of claim 3, wherein 3-(4-amino-oxo-l ,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is enantiomerically pure.

7. (Previously Presented) The method of claim 6, wherein 3-(4-amino-oxo-l ,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is S enantiomer.

8. (Previously Presented) The method of claim 6, wherein 3-(4-amino-oxo-l ,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is R enantiomer.

9. (Previously Presented) The method of claim 3, wherein 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione is administered orally.

10. (Previously Presented) The method of claim 9, wherein 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione is administered in the form of a capsule or tablet.

11. (Canceled)

12. (Canceled)

13. (Currently Amended) The method of claim 1 ~~12~~, further comprising administration of rituximab in an amount of 375 mg/m^2 by intravenous infusion weekly.

14. (Currently Amended) A method of treating mantle cell lymphoma, which comprises (a) administering to a patient having mantle cell lymphoma from about 5 mg to about 25 mg per day of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione or a pharmaceutically acceptable salt or hydrate thereof for ~~a period of time~~ 21 days followed by ~~a period of~~ seven days rest in a 28 day cycle; (b) repeating step (a); (c) administering to the patient a therapeutically effective amount of a second active agent selected from a hematopoietic growth factor, a cytokine, an anticancer agent, an antibiotic, a cox-2 inhibitor, a corticosteroid, rituximab, or a combination thereof for a period of time followed by a period of rest; and (d) repeating step (c), wherein the mantle cell lymphoma is relapsed, refractory, or relapsed and refractory to conventional therapy.

15. (Previously Presented) The method of claim 14, wherein the second active agent is rituximab.

16. (Previously Presented) The method of claim 14, wherein the second active agent is dexamethasone.

17. (Previously Presented) The method of claim 14, wherein the second active agent is prednisone.

18. (Currently Amended) The method of claim 1 or 14, wherein the amount of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is about 5 mg to about 25 mg per day ~~for 21 days followed by seven days rest in a 28 day cycle~~.

19. (Currently Amended) The method of claim 18, wherein the amount of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is about 5 mg per day ~~for 21 days followed by seven days rest in a 28 day cycle~~.

20. (Currently Amended) The method of claim 18, wherein the amount of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is about 10 mg per day ~~for 21 days followed by seven days rest in a 28 day cycle~~.

21. (Currently Amended) The method of claim 18, wherein the amount of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is about 15 mg per day ~~for 21 days followed by seven days rest in a 28 day cycle~~.

22. (Currently Amended) The method of claim 18, wherein the amount of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is about 20 mg per day ~~for 21 days followed by seven days rest in a 28 day cycle~~.

23. (Currently Amended) The method of claim 18, wherein the amount of 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered is about 25 mg per day ~~for 21 days followed by seven days rest in a 28 day cycle~~.

24. (Previously Presented) The method of claim 14, wherein 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione is administered orally.

25. (Previously Presented) The method of claim 24, wherein 3-(4-amino-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione is administered in the form of a capsule or tablet.

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