

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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.

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-1-oxo-1,3-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-1,3-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-1,3-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-1,3-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-1,3-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-1,3-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-1,3-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-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione is administered orally.

10. (Previously Presented) The method of claim 9, wherein 3-(4-amino-oxo-1,3-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 142, further comprising administration of rituximab in an amount of 375 mg/m² 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-1,3-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-1,3-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-1,3-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-1,3-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-1,3-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-1,3-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-1,3-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-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione is administered orally.

25. (Previously Presented) The method of claim 24, wherein 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione is administered in the form of a capsule or tablet.

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.