IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Jerome B. Zeldis	Continuation No.: 4802
Serial No.: 10/438,213	Group Art Unit: 1612
Filed: May 15, 2003	Examiner: Simmons, Chris E.
For: METHODS FOR TREATMENT OF MULTIPLE MYELOMA USING 3-(4-AMINO-1-OXO-1,3-DIHYDRO-ISOINDOL-2-YL)-PIPERIDINE-2,6-DIONE (AS AMENDED)	Attorney Docket No.: 9516-074-999 (CAM: 501872-999073)

RESPONSE AND STATEMENT OF INTERVIEW SUMMARY

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

Sir:

In response to Office Action dated August 3, 2010, and further to Examiner interview held on November 29, 2010 and to Interview Summary dated December 1, 2010, Applicant submits the following amendment and remarks for the consideration by the Examiner and entry into the record of the above-captioned application. Submitted herewith is Supplemental Information Disclosure Statement with fee, and Petition for extension of term from November 3, 2010 to and including January 3, 2011 with fee.

The listing of the claims begins on page 2 of this paper.

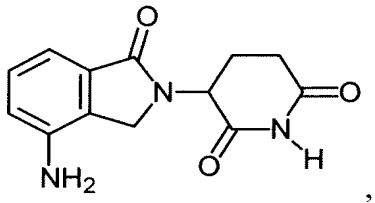
Remarks begin on page 4 of this paper.

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

Listing of the Claims:

Claims 1-23. (canceled)

24. (currently amended) A method of treating multiple myeloma, which comprises cyclically administering to a patient having multiple myeloma about 5 to about [[50]] 25 mg per day of a compound of the formula:



or a pharmaceutically acceptable salt thereof, for 21 consecutive days followed by seven consecutive days of rest from administration of said compound during a 28 day cycle, and ~~a therapeutically effective amount of dexamethasone~~ cyclically administering about 40 mg per day of dexamethasone during said 28 day cycle.

25. (canceled)

26. (previously presented) The method of claim 24, wherein the multiple myeloma is smoldering myeloma, indolent myeloma, chemotherapy responsive multiple myeloma, refractory myeloma, relapsed myeloma, or relapsed and refractory Dune-Salmon stage III multiple myeloma.

27-28. (canceled)

29. (previously presented) The method of claim 24, wherein the compound is a pharmaceutically acceptable salt.

30-56. (canceled)

57. (previously presented) The method of claim 24, wherein the multiple myeloma is relapsed, refractory or resistant to conventional therapy.

58. (previously presented) The method of claim 24, wherein the compound and dexamethasone are administered orally.

59. (previously presented) The method of claim 58, wherein the compound is administered in the form of a capsule or tablet.

60. (previously presented) The method of claim 24, wherein the compound is administered in an amount of from about 10 to about 25 mg per day.

61. (currently amended) The method of claim 24, wherein the compound is administered in an amount of about 5, 10, 20, or 25~~, 30, or 50~~ mg per day.

62. (canceled)

63. (previously presented) The method of claim 60, wherein the compound is administered in an amount of about 25 mg per day.

64-70. (canceled)

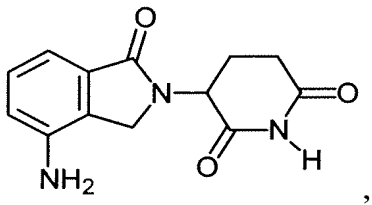
71. (previously presented) The method of claim 24, wherein the compound is administered in an amount of 5 mg per day.

72. (previously presented) The method of claim 60, wherein the compound is administered in an amount of 10 mg per day.

73. (previously presented) The method of claim 24, wherein the compound is administered in a capsule of 5 mg, 10 mg, 15 mg or 25 mg.

74. (canceled)

75. (previously presented) A method of treating multiple myeloma, which comprises administering, on a 28 day cycle, to a patient having multiple myeloma: (a) about 25 mg per day of a compound of the formula:



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or a pharmaceutically acceptable salt thereof, for 21 consecutive days followed by seven consecutive days of rest from administration of said compound, and; (b) about 40 mg per day of dexamethasone on days 1-4 every 28 days.

76-79. (canceled)

80. (previously presented) The method of claim 73, wherein the capsule comprises the compound, lactose anhydrous, microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

81. (canceled)

82. (new) The method of claim 24, wherein said dexamethasone is administered on days 1 to 4.

REMARKS

I. Applicant's Statement of the Substance of Interview and Response to the Examiner's Interview Summary of Record

A telephonic interview with Supervisory Patent Examiner Frederick Krass, Patent Examiner Chris E. Simmons, and attorneys for Applicant (Anthony M. Insogna and Yeah-Sil Moon), was held on November 29, 2010. Applicant appreciates the Examiner interview.

During the interview, the Examiners and attorneys for Applicant discussed the amendment to the claims and the pending rejections.

First, the Examiners and attorneys for Applicant discussed claim amendment proposal that was submitted to the PTO by a fax on November 22, 2010. Attorneys for Applicant pointed out that all the obviousness rejections should be withdrawn in view of previous arguments submitted on March 9, 2010, and in view of the further amendments submitted herewith.

In particular, attorneys for Applicant explained that Kyle *et al.* (*Semin. Oncol.*, 2001), Davies *et al.* (*Blood*, 2001) and Corral *et al.* (*Ann. Rheum. Dis.*, 1999), alone or in combination with other cited references, fail to suggest the claimed methods, which require the use of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione and dexamethasone for treating multiple myeloma in specific amounts and specific dosing regimens.

Further, attorneys for Applicant stressed that the obviousness rejections of record also can be overcome by unexpected results of the claimed invention. Attorneys for Applicant discussed articles previously submitted to evidence unexpected results of the claimed invention. *See e.g.* Gay, *Blood*, 2010: 115, 1343-1350, which was filed with March 9, 2010 response. In addition, attorneys for Applicant explained that the claimed method as amended relates to an FDA approved use of lenalidomide (product named Revlimid®) (Exhibit 1 filed with March 9, 2010 response). This method has resulted in one of the newest and most effective treatments available for multiple myeloma. Finally, attorneys for Applicant stated that the commercial success of this approved use supports non-obviousness of the claimed invention (Exhibits 3-4 filed with March 9, 2010 response).

In view of the foregoing, all the outstanding rejections over the cited references are moot and the case should proceed to allowance.

II. Conclusion

Entry of the above amendment and remarks, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

Date: December 7, 2010

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