Office Action Summary	Application No.	Applicant(s)	
	12/621,502	ZELDIS, JEROME B.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-17* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-17* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/5/2010 and 8/3/2011*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

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DETAILED ACTION

Formal Matters

Claims 1-17 are pending and under examination.

Priority

This application is a continuation application of U.S. non-provisional application 11/888,881, filed August 1, 2007, which claims the benefit of U.S. provisional application 60/835,752, filed August 3, 2006.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statements filed 3/5/2010 and 8/3/2011. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability

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and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.", (see MPEP § 2173).

Claims 1-2 and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 14 recite an active method step of administering to a human/patient having mantle cell lymphoma "from about 5 mg to about 50 mg" of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione. Dependent claims recite dose ranges or amounts of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered "per day".

Claims are given their broadest reasonable interpretation in light of the specification. However, limitations from the specification are not imported into the claims. In this case, while the specification and claims dependent from claim 1 recite doses and dose ranges of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione in terms of “per day”, claims 1 and 14 place no such limitation on the amounts of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered.

As such, claims 1-2 and 14-17 are indefinite because it is unclear whether the recited administering to a human/patient having mantle cell lymphoma "from about 5 mg to about 50 mg" of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione is intended to be limited to from about 5 mg to about 50 mg per day, or whether these amounts are total amounts of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione administered to the treated subject.

For example, in one possible interpretation of the claims, if a patient having mantle cell lymphoma is administered 5 mg 3-(4-amino-1-oxo-1,3-dihydro-

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isoindol-2-yl)-piperidine-2,6-dione every day for 20 consecutive days, i.e., a total amount of 100 mg, this treatment would not be encompassed by the claims because this would result in administration of 100 mg, which is outside the claimed range of "from about 5 mg to about 50 mg".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Zeldis** (US 2004/0029832 A1; Published Feb. 12, 2004) in view of **Damaj *et al.*** (Leukemia, 2003, vol. 17, pages 1914-1915), **Wilson *et al.*** (British Journal of Haematology, 2002, vol. 119, pages 128-130), and **Kaufmann *et al.*** (Blood, 2004, vol. 104, no. 8, pages 2269-2271).

Claimed Invention

The instant claims recite a method of treating mantle cell lymphoma comprising administration of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione (*i.e.*, Lenalinomid; Revlimid™; Revimid™) both alone and in combination with other active agents. Mantle cell lymphoma is disclosed in the instant specification as a type of non-Hodgkin's lymphoma (page 1, [0001]).

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Teachings of Zeldis

Zeldis teaches methods of treating, preventing, and/or managing cancer comprising administration of an immunomodulatory compound alone or in combination with a second active ingredient (Abstract).

The instantly claimed 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione (*i.e.*, Lenalinomid; Revlimid™; Revimid™) is disclosed as a preferred compound of the invention (page 2, [0016]; Fig. 1; page 3; [0034]; page 4, [0037].

With regard to cancers intended to be treated by the disclosed methods, Zeldis teaches that the term "cancer" includes, but is not limited to solid tumors and blood born tumors such as cancers of the lymph nodes and non-Hodgkin's lymphoma (page 9, [0107].

More specifically, Zeldis teaches that an immunomodulatory compound is administered alone or in combination with a second active ingredient such as vinblastine or fludarabine to patients with "various types of lymphoma", including, but not limited to, Hodgkin's lymphoma, non-Hodgkin's lymphoma, cutaneous T-Cell lymphoma, cutaneous B-Cell lymphoma, diffuse large B-Cell lymphoma or relapsed or refractory low grade follicular lymphoma (page 12, [0139]).

With regard to the doses and administration regimens recited in claims 3, 4, 5, 11, and 12, Zeldis teaches that the dose of Revimid™ may be administered in an amount of 5 to 25 mg per day, or alternatively from about 10 to about 50 mg every other day (page 10, [0113] or initially in an amount of 5 mg/day escalated every week to 10, 20, 25, 30, and 50 mg/day (page 10, [0114]). Cycling therapy, as recited in claims 11-12, is disclosed by Zeldis at page 14, [0173] wherein he describes administration of Revimid™ in amount of about 5, 10, or 25 mg/day,

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