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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/411,649	04/11/2003	Jerome B. Zeldis	501872-999071	9157

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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/411,649	ZELDIS, JEROME B.	
	Examiner	Art Unit	
	Vickie Kim	1618	

-- 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 _____.

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

3)☐ 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

4)☒ Claim(s) *39-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-80* is/are rejected.

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

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

Application Papers

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

10)☐ 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).

11)☐ 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

12)☐ 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-1449 or PTO/SB/08)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 8/19/05 . Upon entering the amendment, New claims 55-80 are added.

2. The claims 34-80 are pending and presented for the examination.

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on July 14, 2004; April 27, 2005 and August 19, 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Response to Arguments

1. Applicant's arguments with respect to claims 39-54 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. 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.

1. Claims 39-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raza et al(Aug. 2001, Blood) in view of Zeldis et al(WO 01/87307 A2), or Hariri et al(US2003/0235909-provisional application 60/372,348, filed 4/2002).

The claims are drawn to a method of treating a myelodysplastic syndrome(e.g. chronic myelomocytic anemias) using a therapeutically effective amount of a compound of formula (i) as recited in claim 39.

Raza et al teaches a treatment of myelodysplastic syndromes (hereinafter, MDS) such as refractory anemias, chronic myelomonocytic leukemia using a therapeutically effective amount of thalidomide, see abstract and page 959 last two paragraphs.

Applicant's claims differ because they require amino substituted thalidomide analogs as shown in instant claims.

However, it would have been obvious to one of ordinary skill in the art at that time of the invention was made to substitute thalidomide (Raza's) with amino-thalidomide analoges(e.g. Actimid ™ or Revimid™) because secondary references(above) remedy the deficiency found in Raza's teaching.

Firstly, Zeldis(WO'307 hereinafter) teaches a treatment of cancers(e.g. hematopoietic cancer including myelogeneous leukemia such as chronic myelomonocytic leukemia), wherein the treatment comprising administering a composition containing thalidomide or it's analogues especially amino analogues, see page 4;page 14, lines 5-25; page 15, lines 10-15. Zeldis et al (WO'307 hereinafter)

further teaches pure diastereomers(optically pure or pure enantiomer), see page 11, lines 10-30.

WO'307 particularly states that the patented invention is based on the ability of thalidomide to treat cancer(see page 11, line 38), and amino thalidomides are preferred thalidomide used in the said treatment(at page 14, lines 24-25).

Secondly, Hariri et al(US'909, (60/372348)) teach use of immunomodulatory compound such as thalidomide or amino-substituted isoindolines(e.g. Actimid ™ or Revimid™) in the treatment for various diseases via regulating abnormal differentiation expansion or of hematopoietic cells (see provisional application 60/372348 at pages 14, 37 and 42). US'348(prov. Appl) also teaches that the compound used in the patent include racemic, stereomerically enriched and pure and pharmaceutically acceptable salts, solvates , hydrates, stereoisomers and prodrugs, see page 32, lines 29-30.

US'909 also teaches use of additional active agent such as cytokines, G-CSF to induce stimulate the proliferation or propagation of embryonic stem cells, see page 40.

It is noted that Actimid™ or Revimid™ is potent immunomodulatory thalidomide analogs which is same compound required by the instant claims 47 or 48, respectively.

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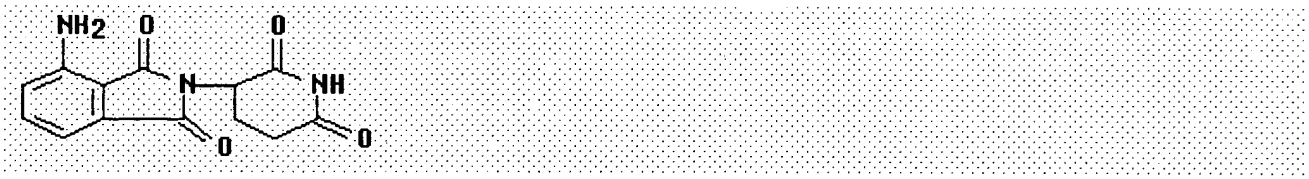

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