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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: 03/30/2006

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 *28 December 2005*.

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4a) Of the above claim(s) _____ is/are withdrawn from consideration.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) Paper No(s)/Mail Date. 3/23/06.

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 12/28/06.Upon entering the amendment, the claims 39-80 are pending and presented for the examination.

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on 2/23/06. 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 39-80 have been considered but are not persuasive.

Raza et al ((Blood,2001)

Applicant argues that Raza et al, alone or in combination with Zeldis et al(WO'307), fails to teach specific amino substituted thalidomides in the treatment MDS because the study result is questionable and also applicant believes that Raza's teaching is only limited to thalidomide and no motivation for modification or substitution with amino-substituted thalidomide as claimed. Although, This examiner stated, in previous office action, the motivational statement to combine or suggestion for the substitution with and obviousness due to reasonable expectation of success, applicant alleges that the references alone or in combination, fails to suggest each and every

claim element, much less provide a reasonable expectation of success(see remaks at page 8).

Applicant's argument is not persuasive for the reasons as follows.

Firstly, Raza clearly teaches a treatment of MDS using thalidomide (see abstract and page 959) OR its analogues such as aminothalidomides (e.g. actimid™ or revlimid™) when it is taken in view of WO'307. In applicant's remarks at page 8, last paragraph, applicant acknowledges the effectiveness of thalidomide in the treatment of syndrome of MDS by referring "Raza et al states that this thalidomide study is encouraging some MDS. Applicant also particularly emphasized that Raza et al's study is cloncluded that low-risk MDS patients need more studies".

At the time of the invention was made, Raza et al clearly teaches that **Thalidomide was considered a potentially useful drug for MDS patients**." , see introduction, col.2, 1st paragraph at page 958. Although the mechanism of action was not clearly understood, and thalidomide's as immune-modulatory agent with anticytokine and antiangiogenic effects, the advantages from thalidomide therapy against MDS is clearly shown during study, and Raza et al concluded that **thalidomide , as a single agent, is effective in improving cytopenias of some MDS patients**, see abstract, last paragraph at page 958.

Furthermore, both Raza et al and applicant conclude that suppressing excessive apoptosis mediated by cytokines(e.g. TNF-alpha or IL-1beta or IL-6) is responsible for improving MD, see Raza et al(at page 958, introduction(col.1)) and instant specification at page 11, lines 27-33.

a. Applicant should also be reminded that the feature included in arguments(i.e. different patient population or group such as high risk or low risk MDS patient) is not required by the instant claims. However, the claims must be given their broadest reasonable interpretation. Therefore, the interpretation of claims (i.e. treating MDS in any patient group or population) should be made based on the full definition of the term "a patient in need thereof".

b. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As evidenced by applicant's own admission (see instant specification at pages 11-12), applicant's invention is relates to a treatment of MDS syndromes using immunomodulatory agent having inhibitory activities against TNF-alpha, LPS induced IL1beta, IL12 and partially IL6 production(e.g. thalidomide or its analogues such as aminothalidomides). As suggested in WO'307, amine or amide substituted thalidomide (see page 10) and It's therapeutic effectiveness against MDS syndrome(see example 5.3 at page 32), thalidomide (Raza et al) should be functionally equivalent to aminesubstituted thalidomide as claimed or envisaged when Raza et al's teaching is learned

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