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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/070,761	03/24/2011	Jerome B. Zeldis	12827-089-999	2735

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JONES DAY for Celgene Corporation
222 E. 41ST. STREET
NEW YORK, NY 10017

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
05/09/2012	PAPER

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

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	13/070,761	ZELDIS, JEROME B.	
	Examiner	Art Unit	
	JAGADISHWAR SAMALA	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)☐ 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) 38-47 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5a) Of the above claim(s) _____ is/are withdrawn from consideration.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) 38-47 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 *03/24/2011 and 02/08/2012*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

DETAILED ACTION

- Claims 38-47 are pending and presented for examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03/24/2011 and 02/08/2012 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pellegrino Musto et al., Haematologica vol. 87(8), pages 884-886, August 2002 in view of Muller et al (US 5,635,517).

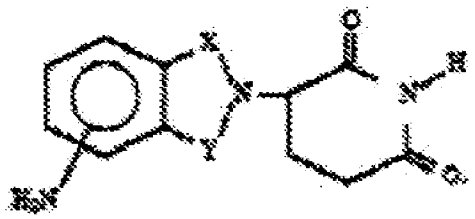
Claims are drawn to a method of treating a patient having transfusion dependent anemia due to low to intermediate-1-risk myelodysplastic syndrome comprising

administering to said patient about 5 to about 25 mg per day of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione.

Pellegrino discloses a method of treating transfusion-dependent patients with myelodysplastic syndrome (MDS) administering thalidomide (abstract). Pellegrino also discloses that the therapeutic role of thalidomide in MDS may significantly increase hemoglobin levels in about one third of treated patient. Additional disclosure includes that, studies confirmed that thalidomide at a relatively low doses, may be a very effective therapy for treating anemia in a selected group of transfusion-dependent, younger MDS patients with a recent diagnosis normal karyotype and no excess of marrow blasts (pages 884 and 885).

Pellegrino fails to teach thalidomide derivative comprising 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione.

Muller discloses a method of administering thalidomide analogs for reducing undesirable levels of TNFα in a mammal. The thalidomide analogs of the formula:



wherein one of X and Y is C=O and the other of X and Y is C=O or CH2, is 3-(4-amino- 1-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione would read on as recited in the instant claim (Col. 4 lines 20-34). The compound can be administered orally in the

form of tablets, capsules, and similar shaped, compressed pharmaceutical forms containing from 1 to 100 mg of drug per unit dosage (Col. 5 lines 62+). Additional disclosure includes that the inhibition of NFkB binding can regulate transcription of cytokine gene(s) and through this modulation and other mechanisms be useful in the inhibition of a multitude of disease states.

It would have been obvious to one of ordinary skill in the art at the time the invention was to incorporate 3-(4-maino-l-oxo-l,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione into Pellgegrino's composition. The person of ordinary skill in the art would have been motivated to make those modifications because Muller teaches that administration of an amino substituted oxoisoindolines and dioxoisoindolines compounds are particularly useful to reduce the levels of tumor necrosis factor a (TNFα) and/or increasing cAMP levies thus constitutes a valuable therapeutic strategy for the treatment of many inflammatory, infectious, immunological or malignant (cancer) diseases (Col. 1 lines 5-10 and Col. 3 lines 59+) and would have a reasonable expectation of success because Pellegrino teaches that thalidomide at a relatively low doses, may be a very effective therapy for treating anemia in a selected group of transfusion-dependent, younger MDS patients and overall response rate being 20% on an intention-to-treat analysis, 5 out of 7 (71.4%) patients with these characteristics responded to the treatment (page 885).

The method of administering the compound (dosage regimen or dosing intervals is clearly a result effective parameter that a person of ordinary skill in the art would

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