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| 13/070,761   | 03/24/2011  | Jerome B. Zeldis     | 12827-089-999           | 2735             |
| 84802  | 7590        | 05/09/2012           | EXAMINER                |                  |
| JONES DAY for Celgene Corporation<br>222 E. 41ST. STREET<br>NEW YORK, NY 10017 |             |                      | SAMALA, JAGADISHWAR RAO |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
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**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.



### 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

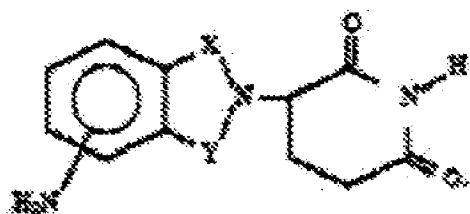
Art Unit: 1618

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 TNF $\alpha$  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 CH<sub>2</sub>, is 3-(4-amino-1-oxo-1,3-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

Art Unit: 1618

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 (TNF $\alpha$ ) 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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