



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/801,262	03/13/2013	Jerome B. Zeldis	12827-392-999	4855
84802	7590	04/29/2014	EXAMINER	
JONES DAY for Celgene Corporation 222 E. 41ST. STREET NEW YORK, NY 10017			SAMALA, JAGADISHWAR RAO	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			04/29/2014	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.

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

- Claims 1-37 are pending and presented for examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03/13/2013 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 following is a quotation of pre-AIA 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.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1618

consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ionescu et al (US 6,887,855) in view of Muller et al (US 5,635,517), Zeldis et al (WO-01/87307) and Raza et al (Blood, Vol 98(4), 958-965, 2001).

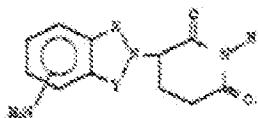
Claims are drawn to a method of treating a myelodysplastic syndrome (MDS) comprising, administering to a patient having a myelodysplastic syndrome a therapeutically effective amount of 5-azacytidine, and a therapeutically effective amount of 3-(4-maino-1-oxo-1,3-dihydro- isoindol-2-yl)-piperidine-2,6-dione or a pharmaceutically acceptable salt thereof, wherein the MDS is refractory anemia or chronic myelomonocytic leukemia and administration further comprises at least one additional active agent.

Ionescu discloses a pharmaceutical composition comprising the 5-azacytidine and pharmaceutically acceptable excipient or carrier used in the treatment of myelodysplastic syndromes (MDS), (Col. 1 lines 5-10). The pharmaceutical formulations are preferably prepared in a unit dosage form containing from about 5 mg to about 200 mg to produce the desired therapeutic effect (Col. 9 lines 40+). Additional disclosure includes that the formulations are used for parenteral or oral administration.

Ionescu fails to incorporate 3-(4-maino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione and at least one additional active agent.

Art Unit: 1618

Muller discloses a method of administering thalidomide analogs for reducing undesirable levels of TNF α 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-maino- 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, alone or in combination with other therapeutic agents including antibiotics, to a mammal in need of treatment (Col. 4 lines 37-40). Additional disclosure includes that decreasing TNF α levels and/or increasing cAMP levels thus constitutes a valuable therapeutic strategy for the treatment of malignant (cancer) diseases.

Zeldis teaches a treatment of primary and/or metastatic cancers (e.g. hematopoietic cancer including myelogeneous leukemia such as chronic myelomonocytic leukemia), wherein the treatment comprising administering a composition containing thalidomide or its analogues especially amino analogues (page 8, lines 5-25; page 15, line 10- 15). Zeldis also teaches pure diastereomers (optically pure or pure enantiomer, Page 11, line 10-30). Zeldis further teaches pharmaceutical compositions comprising thalidomide, or a derivative and at least one other anti-cancer drug such as irinotecan hydrochloride, vinblastine sulfate and like (page 12, line 14-17 and page 17). Zeldis particularly states that the patented invention is based on the ability of thalidomide to treat cancer (Page 11, line 38), and amino thalidomides are

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.