IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Jerome B. Zeldis	Confirmation No.:	9157
Serial No.:	10/411,649	Art Unit:	1614
Filed:	April 11, 2003	Examiner:	Kim, Vickie Y
For:	METHODS OF USING IMMUNOMODULATORY COMPOUNDS FOR THE TREATMENT AND MANAGEMENT OF MYELODYSPLASTIC SYNDROMES (as amended)	Attorney Dkt No.:	501872-999071 (Formerly 9516-072-999)

DECLARATION BY JEROME B. ZELDIS, M.D., Ph.D. UNDER 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Jerome B. Zeldis, M.D., Ph.D. declare that:

1. I earned an M.D. and a Ph.D. in Molecular Biophysics and Biochemistry at Yale University School of Medicine (New Haven, CT). After completion of these degrees, I completed an internship in Internal Medicine at U.C.L.A. Medical Center (Los Angeles, CA). I then completed a residency in Internal Medicine at U.C.L.A. Medical Center (Los Angeles, CA). I also held a Research Fellowship in Medicine at Harvard Medical School (Boston, MA) and at Massachusetts General Hospital (Boston, MA). In addition, I have held academic appointments at Harvard Medical School (Boston, MA), University of California (Davis, CA), and Cornell University Medical College (New York, NY). I am licensed to practice medicine in the States of California, New York, and New Jersey and in the Commonwealth of Massachusetts. I am presently a Vice President and the Chief Medical Officer of Celgene Corporation (Summit, NJ).

2. I am the named inventor of the pending application ("the '649 application"), and I am familiar with its disclosure and claims. A copy of the claims that I understand are currently pending is attached hereto as Exhibit A.

3. The '649 application discloses, in part, methods of treating a myelodysplastic syndrome, which comprise administering about 5 to about 50 mg per day of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione (REVLIMID®, formerly referred to as REVIMID™). I understand claims are being presented to this subject matter.

4. I understand that an Office Action issued on March 30, 2006 in connection with the '649 application rejecting the claims as being obvious over Publication No. WO 01/87307 A2 ("WO '307"), attached hereto as Exhibit B, which is an application that names me as one of the inventors. I understand that the Examiner stated that WO '307 discusses methods and compositions comprising thalidomide or analogs for the treatment of certain indications (*e.g.*, cancers and myelodysplastic syndrome) at pages 10-14. (Office Action, pages 5-6, attached hereto as Exhibit C).

5. I conceived of the treatment of MDS with REVIMID™ prior to July 19, 2001. This is evidenced by a clinical trial protocol identified within Celgene as "MDS-501-001" which is entitled "A PHASE II OPEN LABEL STUDY OF THE SAFETY AND EFFICACY OF CC-5013 (REVIMID™) TREATMENT FOR PATIENTS WITH MYELODYSPLASTIC SYNDROME." A redacted copy of the front page of this protocol description is attached hereto as Exhibit D.

6. Specifically, the protocol for treating MDS with the recited compound 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione was designed based upon my conception, and under my supervision and direction, prior to July 19, 2001. Patients were enrolled and treated with the compound under the protocol to the filing date of the present application. This is evidenced, in part, by the abstract attached hereto as Exhibit E, List *et al.*, "High Erythropoietic Remitting Activity of the Immunomodulatory Thalidomide Analog, CC-5013, In Patients with Myelodysplastic Syndrome (MDS)," *American Society of Hematology Abstract #353*, 2002, which reports the results obtained under the protocol MDS-501-001. This study is also disclosed in Section 5.3. "Clinical Studies In MDS Patients," on pages 34-35 of the specification.

7. Again based upon my conception, Dr. Alan F. List and Dr. Robert Knight conducted or coordinated the clinical study described in the protocol under my supervision or at my direction.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and

further that these statements were made with the knowledge that willful false statements and the like may be punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of any patent issuing from the '649 application.

Dated: June 22, 2006

Jerome B. Zeldis, M.D., Ph.D.