UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALVOGEN PINE BROOK LLC

Petitioner,

v.

CELGENE CORP.

Patent Owner

Case No. UNASSIGNED Patent 7,968,569

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-15 OF U.S. PATENT NO. 7,968,569



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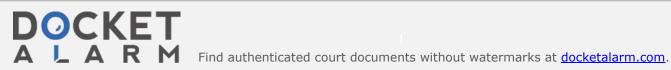
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LIST OF EXHIBITS

| Exhibit | Document |
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| No. | |
| Ex. 1001 | U.S. Patent No. 7,968,569 ("the '569 patent") |
| Ex. 1002 | Prosecution History excerpts for U.S. Patent No. 7,968,569 |
| Ex. 1003 | Expert Declaration of Dr. Guido Tricot |
| Ex. 1004 | Sampaio et al., "Thalidomide selectively inhibits tumor necrosis |
| | factor alpha production by stimulated human monocytes," J. Exp. |
| | Med., 173(3): 699-703 (1991). ("Sampaio") |
| Ex. 1005 | Tramontana et al., "Thalidomide Treatment Reduces Tumor Necrosis |
| | Factor α Production and Enhances Weight Gain in Patients with |
| | Pulmonary Tuberculosis," <i>Molecular Medicine</i> , 1:384-397 (1995). |
| | ("Tramontana") |
| Ex. 1006 | Singhal et al., "Antitumor Activity of Thalidomide in Refractory |
| | Multiple Myeloma," N. Engl. J. Med., 341:1565-1571 (1999) |
| | ("Singhal") |
| Ex. 1007 | Durie & Stepan, "Efficacy of Low Dose Thalidomide in Multiple |
| | Myeloma," Electronic Journal of Oncology, 1:1-8 (2000). ("Durie") |
| Ex. 1008 | Muller et al., "Amino-substituted Thalidomide Analogues: Potent |
| | Inhibitors of TNF-α Productions," <i>Bioorganic & Medicinal</i> |
| | Chemistry Letters, 9:1625-1630 (1999). ("Muller") |
| Ex. 1009 | Corral et al., "Differential Cytokine Modulation and T Cell |
| | Activation by Two Distinct Classes of Thalidomide Analogues That |
| | are Potent Inhibitors of TNF-α," <i>J. Immunol.</i> , 163: 380-386 (1999). |
| 7 1010 | ("Corral I") |
| Ex. 1010 | Corral & Kaplan, "Immunomodulation by thalidomide and |
| | thalidomide analogues," Ann. Rheum. Dis., 58: I107-I113 (1999). |
| E 1011 | ("Corral II") |
| Ex. 1011 | Rajkumar & Kyle, "Thalidomide in the Treatment of Plasma Cell |
| | Malignancies," J. of Clinical Oncology, 19(16):3593-3595 (Aug. |
| E 1012 | 2001). ("Rajkumar 2001") |
| Ex. 1012 | Celgene Corp., "Positive Interim Results Presented at the VIIIth |
| | International Myeloma Workshop on Celgene Corporation's Lead |
| | IMiD(TM) (REVIMID(TM)); Lead Investigators from Dana-Farber |
| | Cancer Institute and the Arkansas Cancer Research Center Reported |
| | on REVIMID's Activity and Safety Profile," May 8, 2001. ("May |
| Ev. 1012 | Press Release") Colore Comparation Asserted Additional Potent |
| Ex. 1013 | Celgene Corp., "Celgene Corporation Awarded Additional Patent |



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