

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT AND TRIAL APPEAL BOARD

INITIATIVE FOR RESPONSIBILITY IN DRUG PRICING, LLC

Petitioner

v.

CELGENE CORPORATION

Patent Owner

U.S. Patent No. 6,045,501 to Elsayed *et al.*

Issue Date: August 28, 1998

Title: Methods For Delivering A Drug To A Patient While Preventing The
Exposure Of A Foetus Or Other Contraindicated Individual To The Drug

Inter Partes Review No. Unassigned

**Petition For *Inter Partes* Review Of U.S. Patent No. 6,045,501
Under 35 Usc §§ 311-319 And 37 Cfr §42.100 *Et Seq.***

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EXHIBITS

- Exhibit 1001 - U.S. Patent No. 6,045,501
- Exhibit 1002 - Office Action, U.S. Patent Application Serial No. 09/143,569, Paper 5, 10/07/99
- Exhibit 1003 - U.S. Patent Application Serial No. 09/143,569, Amendment '569 Application, page 3, November 10, 1999
- Exhibit 1004 - Dishman et al., Pharmacists' role in clozapine therapy at a Veterans Affairs medical center, Am. J. Hosp. Pharm 51: 899 (1994)
- Exhibit 1005 - Bastani et al., Development of the Clozaril Patient Management System, Psychopharmacology 99:S122 (1989)
- Exhibit 1006 – Powell et al., Guideline for the clinical use and dispensing of thalidomide, Postgrad. Med. J. 70:901 (1994)
- Exhibit 1007 – Declaration Matthew W. Davis M.D. RhP.
- Exhibit 1008 – Mitchell et al., A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin, New England J. Med. 333(2):101 (1995)
- Exhibit 1009 – Honigfeld, Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis, Psychiatric Services 47:52 (1996)
- Exhibit 1010 - The 47th Meeting of the Dermatologic and Ophthalmic Advisory Board (September 4-5, 1997, (the "FDA Meeting")
- Exhibit 1011 - CDC Meeting, Centers for Disease Control, Preventing Birth Defects, March 26, 1997

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