

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. 6,315,720 to Williams *et al.*

Issue Date: November 13, 2001

Title: Methods For Delivering A Drug To A Patient While Avoiding The
Occurrence Of An Adverse Side Effect Known Or Suspected
Of Being Caused By The Drug

Inter Partes Review No. Unassigned

**Petition For *Inter Partes* Review Of U.S. Patent No. 6,315,720
Under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123**

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Exhibits

Exhibit 1001 - U.S. Patent No. 6,315,720

Exhibit 1002 - Powell et al., Guideline for the clinical use and dispensing of thalidomide, Postgrad. Med. J. 70:901 (1994)

Exhibit 1003, Office Action, U.S. Patent Application Serial No. 09/694,217, January 18, 2001, Paper 2

Exhibit 1004 Amendment, U.S. Patent Application Serial No. 09/694,217, March 23, 2001

Exhibit 1005 Amendment, U.S. Patent Application Serial No. 09/694,217, June 25, 2001

Exhibit 1006 - Dishman et al., Pharmacists' role in clozapine therapy at a Veterans Affairs medical center, Am. J. Hosp. Pharm 51: 899 (1994)

Exhibit 1007 - Bastani et al., Development of the Clozaril Patient Management System, Psychopharmacology 99:S122 (1989)

Exhibit 1008(a) and (b) - The 47th Meeting of the Dermatologic and Ophthalmic Advisory Board (September 4-5, 1997, (the "FDA Meeting"))

Exhibit 1009 - CDC Meeting, Centers for Disease Control, Preventing Birth Defects, March 26, 1997

Exhibit 1010 - Mitchell et al., A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin, New England J. Med. 333(2):101 (1995)

Exhibit 1011 - Honigfeld, Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis, Psychiatric Services 47:52 (1996)

Exhibit 1012 - Declaration Matthew W. Davis M.D. RhP.

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