

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT AND TRIAL APPEAL BOARD

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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

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*Inter Partes* Review No. Unassigned

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**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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