

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC

PETITIONER

V.

CELGENE CORPORATION

PATENT OWNER

CASE NO.: IPR2015-01096

PATENT NO. 6,315,720

FILED: OCTOBER 23, 2000

ISSUED: NOVEMBER 13, 2001

INVENTORS: BRUCE A. WILLIAMS, JOSEPH K. KAMINSKI

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

**PETITIONER'S CURRENT EXHIBIT LIST OF AUGUST 13, 2015
PURSUANT TO 37 C.F.R. § 42.63(e)**

PETITIONER'S CURRENT EXHIBIT LIST
(August 13, 2015)

Exhibit No.	Exhibit Description	Date Filed
1001	U.S. Patent No. 6,315,720 to Bruce A. Williams and Joseph K. Kaminski, filed on Oct. 23, 2003, and issued on Nov. 13, 2001 (the “720 patent”)	04/23/15
1002	U.S. Patent No. 6,315,720 Prosecution History (“720 prosecution history”)	04/23/15
1003	U.S. Patent No. 6,045,501 to Marc Elsayed and Bruce Williams, filed on Aug. 28, 1998, and issued on Apr. 4, 2000 (“Elsayed”)	04/23/15
1004	U.S. Patent No. 6,063,026 to Mark A. Schauss and Patricia Kane, filed on Mar. 22, 1996, and issued on May 16, 2000 (“Schauss”)	04/23/15
1005	U.S. Patent No. 6,202,923 to Joseph H. Boyer <i>et al.</i> , filed on Aug. 23, 1999, and issued on Mar. 20, 2001 (“Boyer”)	04/23/15
1006	“THALOMID™ (thalidomide) Capsules Revised Package Insert” (Jul. 15, 1998) (“Thalomid PF”)	04/23/15
1007	“Guideline for the clinical use and dispensing of thalidomide,” R.J. Powell and J.M.M Gardner-Medwin, Postgrad Med. J. (1994) 79, 901–904 (“Powell”)	04/23/15
1008	“Pharmacists’ role in clozapine therapy at a Veterans Affairs medical center,” Benjamin R. Dishman <i>et al.</i> , Am. J. Hosp. Pharm. (Apr. 1, 1994) 51, 899–901 (“Dishman”)	04/23/15
1009	U.S. Patent No. 5,832,449 to David W. Cunningham, filed on Nov. 13, 1995, and issued on Nov. 3, 1998 (“Cunningham”)	04/23/15
1010	U.S. Patent No. 6,055,507 to David W. Cunningham, filed on Aug. 20, 1998, and issued on Apr. 25, 2000 (“Cunningham Divisional”)	04/23/15
1011	“A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin,” Allen A. Mitchell <i>et al.</i> , New Eng. J. Med. (Jul. 13, 1995) 333:2, 101–06 (“Mitchell”)	04/23/15
1012	“S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide,” Jerome B. Zeldis <i>et al.</i> , Clinical Therapeutics (1999) 21:2, 319–30 (“Zeldis”)	04/23/15

1013	Transcript of the FDA's "Forty-Seventh Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee," Sept. 4, 1997 (" <i>FDA Meeting Part 1</i> ")	04/23/15
1014	Transcript of the FDA's "Forty-Seventh Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee," Sept. 5, 1997 (" <i>FDA Meeting Part 2</i> ")	04/23/15
1015	"CDC Meeting: 03/26/1997 Minutes and Agenda Regarding Thalidomide" (" <i>CDC Meeting</i> ")	04/23/15
1016	"Assessing the Effectiveness of a Computerized Pharmacy System," Reed M. Gardner <i>et al.</i> , Decision Support Systems in Critical Care, 1994, M.M. Schabot <i>et al.</i> , eds. (" <i>Gardner</i> ")	04/23/15
1017	"Review of computer applications in institutional pharmacy—1975–1981," Ken W. Burleson, Am. J. Hosp. Pharm. (1982) 39:53–70 (" <i>Burleson</i> ")	04/23/15
1018	"Challenges of thalidomide distribution in a hospital setting," Daniel P. Keravich and Charles E. Daniels, Am. J. Health-Syst. Pharm. (Sept. 1, 1999) 56:1721–75 (" <i>Keravich</i> ")	04/23/15
1019	"The Assessment of Refill Compliance Using Pharmacy Records: Methods, Validity, and Applications," John F. Steiner and Allan V. Prochazka, J. Clin. Epidemiol. (1997) 50:1, 105–16 (" <i>Steiner</i> ")	04/23/15
1020	"Therapeutic Antibiotic Monitoring: Surveillance Using a Computerized Expert System," Stanley L. Pestotnik <i>et al.</i> , Am. J. Med. (Jan. 1990) 88:43–48 (" <i>Pestotnik</i> ")	04/23/15
1021	Declaration of Jeffrey Fudin, R.Ph., B.S., Pharm.D., DAAPM, FCCP, FASHP (" <i>Fudin Decl.</i> ")	04/23/15
1022	Curriculum Vitae for Jeffrey Fudin, R.Ph., B.S., Pharm.D., DAAPM, FCCP, FASHP (" <i>Fudin CV</i> ")	04/23/15
1023	"Joint Claim Construction and Prehearing Statement," <i>Celgene Corp. v. Natco Pharma Ltd.</i> , NJD-2-10-cv-05197, Jul. 18, 2011 (" <i>Celgene Claim Construction Brief</i> ")	04/23/15
1024	"Interactive Voice Response Systems in Clinical Research and Treatment," James C. Mundt, Psychiatric Services (May 1997) 48:5, 611–12, 623 (" <i>Mundt</i> ")	04/23/15
1025	"Center for Drug Evaluation and Research Approval Package for: Application Number NDA 20-785 Approval Letter(s)," Sept. 19, 1997, and Jul. 16, 1998	04/23/15

	(“ <i>FDA Thalomid Approval Letters</i> ”)	
1026	Orange Book Drug Product Listing Corresponding to the ‘501 Patent, as published by the U.S. Food and Drug Administration on August 4, 2015	08/13/15
1027	Orange Book Drug Product Listing Corresponding to U.S. Patent No. 6,315,720, as published by the U.S. Food and Drug Administration on August 4, 2015	08/13/15
1028	Pricing Information for Revlamid® (lenalidomide) capsules from “Information for Vermont Prescribers of Prescription Drugs,” from Medi-Span and Celgene Corporation (July 1, 2015)	08/13/15
1029	Pricing Information for Thalomid® (thalidomide) capsules from “Information for Vermont Prescribers of Prescription Drugs,” from Medi-Span and Celgene Corporation (July 1, 2015)	08/13/15
1030	Pricing Information for Pomalyst® (pomalidomide) capsules from “Information for Vermont Prescribers of Prescription Drugs,” from Medi-Span and Celgene Corporation (July 1, 2015)	08/13/15
1031	<i>Celgene Corp. v. Barr Laboratories, Inc. et al.</i> , Complaint, filed January 18, 2007, U.S. Dist. Ct. New Jersey, Case No.: 2:33-av-00001	08/13/15
1032	<i>Celgene Corp. v. Natco Pharma Ltd.</i> , U.S. Dist. Ct. New Jersey, Complaint, Case No: 2:10-cv-05197-SDW-SCM	08/13/15
1033	<i>Celgene Corp. v. Lannett Holdings Inc., et al.</i> , Complaint, U.S. Dist. Ct. New Jersey, Case No. 2:15-cv-00697-SDW-SCM	08/13/15
1034	<i>Celgene v. Barr</i> , Stipulated Dismissal, dated and filed May 21, 2010, in U.S. Dist. Ct. New Jersey Case No. 2:07-cv-00286-SDW-MCA	08/13/15
1035	<i>International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund v. Celgene Corp.</i> , Class Action Antitrust Complaint, filed November 7, 2014, U.S. Dist. Ct. New Jersey, 2:14-cv-06997-KSH-CLW	08/13/15
1036	Celgene Letter Motion dated September 3, 2014, to Bifurcate and Stay Expert discovery re: REMS Patents, in <i>Celgene Corp. v Natco Pharma Ltd.</i> , U.S. Dist. Ct. New Jersey, Case No: 2:10-cv-05197-SDW-SCM	08/13/15
1037	October 24, 2014, Court Order granting Celgene Motion to	08/13/15

	Bifurcate and Stay Expert discovery re: REMS Patents, in <i>Celgene Corp. v Natco Pharma Ltd.</i> , U.S. Dist. Ct. New Jersey, Case No: 2:10-cv-05197-SDW-SCM	
1038	Orange Book Patents Corresponding to Celgene’s Thalomid® (thalidomide) capsules, as published by the U.S. Food and Drug Administration on August 6, 2015	08/13/15
1039	Orange Book Patents Corresponding to Celgene’s Revlamid® (lenalidomide) capsules, as published by the U.S. Food and Drug Administration on August 6, 2015	08/13/15
1040	Orange Book Patents Corresponding to Celgene’s Pomalyst® (pomalidomide) capsules, as published by the U.S. Food and Drug Administration on August 6, 2015	08/13/15
1041	To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy—A Report by the Federal Trade Commission October 2003	08/13/15
1042	“Evergreening: A Deceptive Device in Patent Rights,” Gaurav Dwivedi <i>et al.</i> , <i>Tech. in Society</i> (2010) 32:324-330	08/13/15
1043	“Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions,” FTC Staff Study January 2010	08/13/15
1044	May 28, 2015 Statement of the Federal Trade Commission on <i>FTC v. Cephalon, Inc.</i>	08/13/15
1045	“The Impact of Exempting the Pharmaceutical Industry from Patent Reviews,” Dean Baker, Center for Economic and Policy Research (July 2015)	08/13/15
1046	Declaration of Juan (Julie) Wu, Ph.D., M.S. (“ <i>Wu Decl.</i> ”)	08/13/15
1047	<i>Review of Recent Judicial Decisions on Patent Law: Hearing Before the Subcomm. on Intellectual Property, Competition, and the Internet of the H. Comm. on the Judiciary, 112th Cong. 29 (2011)</i>	08/13/15
1048	<i>America Invents Act: Hearing Before the Subcomm. on Intellectual Property, Competition, and the Internet of the H. Comm. on the Judiciary, 112th Cong. 52 (2011)</i>	08/13/15
1049	LexisNexis SHEPARD’S® Report on <i>Neumann v. Vidal</i> , 710 F.2d 856 (D.C. Cir. 1983)	08/13/15
1050	Curriculum Vitae of Juan (Julie) Wu, Ph.D., M.S.	08/13/15
1051	Diether et al, “It’s SHO Time! Short-Sale Price Tests and Market Quality,” <i>J. Fin.</i> , 64: 37-73 (2009)	08/13/15
1052	Timeline Summarizing Legislation and Regulation on Short Selling	08/13/15

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