	4.440/DTO			Complete if Known		
Substitute for	1449/PTO			Application Number	12/966,261	
	RMATION			Filing Date	December 13, 2010	
STA	STATEMENT BY APPLICANT			First Named Inventor	Williams et al.	
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	(use as many sheets as necessary)			Examiner Name	Kai Rajan	
Sheet	1	of	6	Attorney Docket Number	CELG-0642	

U. S. PUBLICATION AND PATENT DOCUMENTS							
Examiner Initials	Cite No.	Document Number Number – Kind Code (if known)	Publication or Grant Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document			
	1	2005/0090425	04-28-2005	Reardan et al.			
	2	2005/0216309	09-29-2005	Reardan et al.			
	3	2005/0222874	10-06-2005	Reardan et al.			
	4	2006/0129433	06-15-2006	Koneru			
	5	5,299,121	03-20-1994	Brill et al.			
	6	5,594,637	01-14-1997	Eisenberg et al.			
	7	5,619,991	04-15-1997	Sloane			
	8	5,660,176	08-26-1997	lliff			
	9	5,758,095	05-26-1998	Albaum et al.			
	10	5,832,449	11-03-1998	Cunningham			
	11	5,845,255	12-01-1998	Mayaud			
	12	5,974,203	10-26-1999	Tadokoro et al.			
	13	6,014,631	01-11-2000	Teagarden et al.			
	14	6,045,501	04-04-2000	Elsayed et al.			
	15	6,055,507	04-25-2000	Cunningham			
	16	6,063,026	05-16-2000	Schauss et al.			
	17	6,128,620	10-03-2000	Pissanos et al.			
	18	6,131,090	10-10-2000	Basso Jr., et al.			
	19	6,202,923	03-20-2001	Bayer et al.			
	20	6,315,720	11-13-2001	Williams et al.			
	21	6,561,976	05-13-2003	Elsayed et al.			
	22	6,561,977	05-13-2003	Williams et al.			
	23	6,755,784	06-29-2004	Williams et al.			
	24	6,767,326	07-27-2004	Elsayed et al.			

Examiner	/John Pauls/ (06/29/2012)	Date	
Signature	/JUDITITY duts/ (UU/23/2012)	Considered	06/29/2012

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.P./



	1.1.10/DTO			Complete if Known		
Substitute for 1	1449/PTO			Application Number	12/966,261	
INFORMATION DISCLOSURE				Filing Date	December 13, 2010	
STAT	STATEMENT BY APPLICANT			First Named Inventor	Williams et al.	
				Art Unit	3769	
	(use as many sheets as necessary)			Examiner Name	Kai Rajan	
Sheet	2	of	6	Attorney Docket Number	CELG-0642	

U. S. PUBLICATION AND PATENT DOCUMENTS						
Examiner	Cite	Document Number	Publication or			
Initials	No.	Number – Kind Code (if known)	Grant Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		
	25	6,869,399	03-22-2005	Williams et al.		
	26	6,908,432	06-21-2005	Elsayed et al.		
	27	7,141,018	11-28-2006	Williams et al.		
	28	7,959,566	06-14-2011	Williams et al.		

	FOREIGN PATENT DOCUMENTS								
Examiner Initials	Cite No.	Foreign Patent Document Country Code- Number -Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Т				
	29	CA 2352619	01-06-2003	Rajewski, Robert					
	30	WO 00/51053	08-31-2000	Gemini Research Ltd.					
	31	WO 02/35440	05-02-2002	Celgene Corp.					
	32	WO 98/13783	04-02-1998	Azron Inc.					
	33	WO 98/58338	12-23-1998	Promedicus Systems Inc.					
	34	WO 99/10829	03-04-1999	Lernout & Hauspie Speechprod					

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.	Include name of the author, title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), Volume-issue Number(s), publisher, city and/or country where published.	Т				
	35	"About the CNR", https://www.clozarilcare.com/care/newUsrRegPersonal.jsp, 1 page					
	36	"Complaint", In the United States District Court District of New Jersey, Case No.: 2:07-cv-00286-PGS-RJH, Filed January 18, 2007, 16 pages					
	37	"Defendant Barr Laboratories Inc.'s Answer, Counterclaims and Demand for Jury Trial", In the United States District Court District of New Jersey, Case No.: 2:07-cv-00286-PGS-RJH, filed March 01, 2007, 67 pages					
	38	"Guide to the Clozaril Patient Monitoring Service", A Reference Manual for the Clozaril Patient Monitoring Service, First Edition, November 1997, 45 pages					

Examiner		Date	0.010.010.010
Signature	/John Pauls/ (06/29/2012)	Considered	06/29/2012



0 1 111 1 1	4.4.4.0./DT-0			Complete if Known		
Substitute for	1449/PTO			Application Number	12/966,261	
INFORMATION DISCLOSURE				Filing Date	December 13, 2010	
STA	STATEMENT BY APPLICANT			First Named Inventor	Williams et al.	
				Art Unit	3769	
	(use as many sheets as necessary)			Examiner Name	Kai Rajan	
Sheet	3	of	(ass as many should be necessary)		CELG-0642	

	NON PATENT LITERATURE DOCUMENTS				
39	"Managing a Product under Attack: A Firsthand report on Colzaril", Medical Marketing & Media, September 20, 1991, 26(10), 8 pages				
40	"Thalomid Information from Drugs.com", June 22, 2006, accessed February 01, 2008, http://www.drugs.com/thalomid.html				
41	Bakken et al., "Local Monitoring Center for Clozapine Therapy: Quality Assurance of Drug Treatment in a Group of Psychiatric Patients", Tidsskr Nor Laegeforen nr., 1998, 118, 1076-1078				
42	Bastani et al., "Development of the Clozaril Patient Management System", Psychopharmacology, 1998, 99, S122-S125				
43	Bates et al., "Effect of Computerized Physician order Entry and a Intervention on Prevention of Serious Medication Errors", The Journal of the American Medical Association, October 21, 1998, 280(15), 1289-1316				
44	Behm, No Title, Am. Pharmacy 13 th APhA Annual Meeting Highlights, 1990, NS30(6), page 7				
45	Bender, "FDA approves reduced clozapine monitoring; increased patient access versus increased risk," Psychiatric Times, 1998, Vol. XV, Issue 5, page 13				
46	Black et al., "A centralized system for monitoring clozapine use in British Columbia," Psychiatric Services, 1996, 47(1), 81-83				
47	Bruera et al., "The uses of psychotropics in symptom management in advanced cancer," Psycho-Oncology., 1998, 7, 346-358				
48	Celgene Corporation, "Thalomid (thalidomide): Balancing the Benefits and the Risks", System for Thalidomide Education and Prescribing Safety, November 1998, 52 pages				
49	Celgene Corporation, "Thalomid (thalidomide): Clinical Information and Prescribing Guidelines", Reference Guide, September 1998, 26 pages				
50	Center for Drug Evaluation and Research Food and Drug Administration, "Forty-Seventh Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee", September 04-05, 1997, 447 pages				
51	Clark et al., "Thalidomide Capsules, A review of the first 18 months of spontaneous postmarketing adverse event surveillance, including off-label presrcribing," Drug Safety., 2001, 24(2), 87-117				

/John Pauls/ (06/29/2012)	20/2012) Date	
Signature /John Pauls/ (06/29/2012) Considered	29/2012)	



	1.1.10/DTO			Complete if Known		
Substitute for 1	1449/PTO			Application Number	12/966,261	
_	RMATION		_	Filing Date	December 13, 2010	
STA	STATEMENT BY APPLICANT			First Named Inventor	Williams et al.	
				Art Unit	3769	
	(use as many sheets as necessary)			Examiner Name	Kai Rajan	
Sheet	4	of	6	Attorney Docket Number	CELG-0642	

NON PATENT LITERATURE DOCUMENTS				
52	Dimopoulis et al. "Adverse effects of Thalidomide administration in patients with neoplastic diseases," Am. J. Med., October 1, 2004, 117, 508-515			
53	Dunning, "Hoechst Arava Pregnancy Registry Recommended to Track Teratogenicity", The Pink Sheet, August 17, 1998, 60(033), 3 pages			
54	Dunning, "Thalidomide Protocols and Patient Materials designed by FDA for Studies without Commercial Sponsors", The Pink Sheet, November 18, 1996, 58(047), page T&G-4			
55	Fax to Ian Hilley of GenPharm Inc. to John Jackson of Celgene Corp., October 14, 2004, re: Isotretinoin Pregnancy Risk Management Program, 26 pages			
56	Freeman et al., "Will routine therapeutic drug monitoring have a place in clozapine therapy?," Clinical Pharmacokinetics, 1997, 32(2), 93-100			
57	Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths related to Agranulocytosis", Psychiatric Services, January 1996, 47(1), 52-56			
58	Honigfeld, "Reducing clozapine-related morbidity and mortality: 5 years of experience with the clozaril national registry," J. Clin. Psychiatry, 1998, 59(Suppl. 3), 3-7			
59	Janet Woodcock, "Supervisory Review of NDA 20-785", Center for Drug Evaluation and Research, July 07, 1998, 12 pages			
60	Kumar "Clozaril monitoring systems, registry data and analyses," Presentation, Novartis, 2002, 44 pages			
61	Lieberman et al., "A report of clozapine – induced agranulocytosis in the United States (Incidence and risk factors)," Drug Safety, Proceedings of a symposium held in London, 1991, Hoffbrand, A.V, et al. (Eds.), 1-2			
62	Love et al., "Computerized relational database for monitoring clozapine therapy," Am. J. Hosp. Pharm., 1993, 1657-1662			
63	Martin, "APhA says plan continues to interfere with pharmacists' practice prerogatives," Am. Pharmacy, 1991, NS31(5), 30-31			
64	McCullough, "Roche Announces FDA Approval of Enhanced Pregnancy Prevention Program for Accutane", Current News Releases, October 31, 2001, 1 page			
65	Mitchell et al., "A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin", New England Journal of Medicine, July 13, 1995, 333(2), 101-106			
66	Mordue, "Rational approach to clozaril distribution," Am. Pharmacy, 1990, NS30(6), page 7			

Examiner	/John Pauls/ (06/29/2012)	Date	00/00/0040
Signature	TOOTH T WAIGH (OUTEOTE)	Considered	06/29/2012



Substitute for 1449/PTO		Complete if Known			
		Application Number	12/966,261		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			_	Filing Date	December 13, 2010
			ANT	First Named Inventor	Williams et al.
				Art Unit	3769
				Examiner Name	Kai Rajan
Sheet	5	of	6	Attorney Docket Number	CELG-0642

NON PATENT LITERATURE DOCUMENTS				
67	National Institutes of Health et al, "Thalidomide: Potential Benefits and Risks", Open Public Scientific Workshop, NIH Testimony, http://www.fda.gov/oashi/patrep/nih99.html , September 09, 1997			
68	National Institutes of Health et al, "Thalidomide: Potential Benefits and Risks", Open Public Scientific Workshop, NIH Testimony, http://www.fda.gov/oashi/patrep/nih910.html , September 10, 1997			
69	National Institutes of Health et al., "Thalidomide: Potential Benefits and Risks:", Open Public Scientific Workshop, Program and Abstracts, September 09-10, 1997			
70	Notification Letter dated December 05, 2006 from Sterne Kessler to Celgene Corporation Re: Notification Pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act			
71	Notification Letter dated December 15, 2006 from Sterne Kessler to Celgene Corporation Re: Supplemental Notification Pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act			
72	Notification Letter dated December 19, 2006 from Sterne Kessler to Celgene Corporation Re: Supplemental Notification Pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act			
73	Notification Letter dated October 04, 2007 from Barr Laboratories to Cegene Corporation Re: Supplemental Notification Pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act			
74	Oyesanmi et al., "Hematologic side effects of psychotropics," Psychosomatics, 1999, 40, 414-421			
75	Pastuszak et al, "Use of the Retinoid Pregnancy Prevention Program in Canada: Patterns of Contraception Use in Women treated with Isotretinoin and Etretinate", Reproductive Toxicology, 1994, 8(1), 63-68			
76	Patt et al., "Durable Clinical response of refractory hepatocellular to orally administered thalidomide," Am. J. Clin. Oncol. (CCT., 2000, 23(3), 319-321			
77	Peck et al., "FDA's position on the clozaril patient management system," Hospital & Community Psychiatry, 1990, 41(8), 876-877			
78	Richardson et al., "Thalidomide: Emerging role in cancer medicine," Annu. Rev. Med., 2002, 53, 629-657			

Examiner	/John Pauls/ (06/29/2012)	Date	06/29/2012
Signature	(OSINIT ASION (OSINIONNO)	Considered	OO/LU/LU IL



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