U.S. PATENT DOCUMENTS

5,945,452	A	8/1999	Cooke et al.
6,011,040	A	1/2000	Muller et al.
6,022,879	A	2/2000	Crow et al.
6,046,010	A	4/2000	Andersson
6,103,230	A	8/2000	Billiar et al.
6,117,872	A	9/2000	Maxwell et al.
6,153,615	A	11/2000	Gross
6,162,806	A	12/2000	Arai et al.
6,162,914	A	12/2000	Toderi et al.
6,177,280	B1	1/2001	Yan et al.
6,180,597	B1	1/2001	Liao
6,200,758	B1	3/2001	Richardson
6,245,776	B1	6/2001	Skwierczynski et al.
6,251,953	B1	6/2001	Baranowitz
6,274,581	B1	8/2001	Gross
6,288,067	B1	9/2001	Okamura et al.
6,288,535	B1	9/2001	Chass
6,319,905	B1	11/2001	Mandel et al.
6,346,519	B1	2/2002	Petrus
6,410,535	B1	6/2002	Kashiwagi et al.
6,417,205	B1	7/2002	Cooke et al.
6,423,751	B1	7/2002	Liao
6,428,990	B1	8/2002	Mukerji et al.
6,441,038	B1	8/2002	Loder et al.
6,486,168	B1	11/2002	Skwierczynski et al.
6,500,857	B1	12/2002	Perricone
6,537,992	B2	3/2003	Parker
6,544,994	B2	4/2003	Rabelink et al.
6,562,969	B1	5/2003	Robertus et al.
6,576,105	B1	6/2003	Ma
6,617,359	B2	9/2003	Wohlfart et al.
6,649,345	B2	11/2003	Richardson
6,656,925	B2	12/2003	Petrus
6,660,831	B2	12/2003	Fallon
6,689,385	B2	2/2004	Richardson et al.
6,693,094	B2	2/2004	Pearson et al.
6,696,480	B2	2/2004	Liao
6,706,728	B2	3/2004	Hedenstrom et al.
6,749,875	B2	6/2004	Selleck
6,784,178	B2	8/2004	Gross et al.
6,995,158	B2	2/2006	Rabelink et al.
7,566,462	B2 *	7/2009	Jungles et al. 424/464
2002/0037284	A1	3/2002	Fallon
2002/0052374	A1	5/2002	Rabelink et al.
2002/0058674	A1	5/2002	Hedenstrom et al.
2002/0061862	A1	5/2002	Billiar et al.
2002/0076782	A1	6/2002	Rosazza et al.
2002/0082261	A1	6/2002	Kashiwagi et al.
2002/0106645	A1	8/2002	Richardson
2002/0119952	A1	8/2002	Petrus
2002/0155445	A1	10/2002	Jarvik
2002/0187958	A1	12/2002	Horrobin et al.
2003/0004125	A1	1/2003	Hirst et al.
2003/0032616	A1	2/2003	Moskowitz et al.
2003/0045543	A1	3/2003	Hedenstrom et al.
2003/0077335	A1	4/2003	Richardson et al.
2003/0078231	A1	4/2003	Wilburn
2003/0124524	A1	7/2003	Kornman et al.
2003/0212135	A1	11/2003	Gross et al.
2003/0216400	A1	11/2003	Rabelink et al.
2003/0232835	A1	12/2003	Ishihara et al.
2004/0002129	A1	1/2004	Hennies et al.
2004/0014167	A1	1/2004	Yabuta et al.
2004/0034030	A1	2/2004	Richardson et al.
2004/0058896	A1	3/2004	Dietrich et al.
2004/0077859	A1	4/2004	Waer et al.
2004/0115182	A1	6/2004	Fallon
2004/0162269	A1	8/2004	Petrus
2005/0137141	A1	6/2005	Hilfinger
2005/0239807	A1	10/2005	Stamler et al.
2006/0035900	A1	2/2006	Moser et al.
2006/0040946	A1	2/2006	Oppenheimer et al.
2006/0194808	A1	8/2006	Richardson et al.
2006/0211701	A1	9/2006	Muntau-Heger et al.
2007/0167353	A1	7/2007	Hilfinger et al.
2007/0270581	A1	11/2007	Jungles et al.
2008/0075666	A1	3/2008	Dudley et al.
2008/0090832	A1	4/2008	Oppenheimer et al.
2008/0146577	A1	6/2008	Matalon et al.
2008/0207624	A1	8/2008	Sugita et al.
2008/0213239	A1	9/2008	Morris

FOREIGN PATENT DOCUMENTS

EP	079 574		5/1983
EP	0108890		5/1984
EP	191 335		8/1986
EP	0209689		1/1987
EP	0318926		11/1988
EP	0349204		6/1989
EP	0488078		6/1992
EP	0722731		7/1996
EP	0 906 913	A1	4/1999
EP	0908182		4/1999
EP	0983765		3/2000
EP	1314782		5/2003
EP	1964566		12/2005
EP	1757293		2/2007
JP	59-021685		2/1984
JP	05009065		5/1984
JP	60204786		10/1985
JP	63063613		3/1988
JP	63 267781	A	11/1988
JP	4-082888		3/1992
JP	9-157270		6/1997
WO	WO 95/13075		5/1995
WO	WO 95/28377		10/1995
WO	WO 97/44029		11/1997
WO	WO 98/08516		3/1998
WO	WO 99/43325		9/1999
WO	WO 99/47153		9/1999
WO	WO 00/03746		1/2000
WO	WO 00/37653		6/2000
WO	WO 00/56403		9/2000
WO	WO 01/56551		8/2001
WO	WO 02/17898		3/2002
WO	WO 03/072096		9/2003
WO	WO 03/077837		9/2003
WO	WO 03/080063		10/2003
WO	WO 03/084388		10/2003
WO	WO 2004/002404		1/2004
WO	WO 2004/016764		2/2004
WO	WO 2004/017955		3/2004
WO	WO 2004/041169		5/2004
WO	WO 2004/044602		5/2004
WO	WO 2004/058268		7/2004
WO	WO 2005 049000		6/2005
WO	WO 2005 049614		6/2005
WO	WO 2005 065018		7/2005
WO	WO 2005/107759		11/2005
WO	WO 2006/063215		6/2006
WO	WO 2006/112495		10/2006
WO	WO 2006/118322		11/2006
WO	WO 2007/007291		1/2007
WO	WO 2007/067570		6/2007

OTHER PUBLICATIONS

Sugimoto et al., *Bull. Chem. Soc. Japan*, 52(1):181-183 (1979).

Visontini et al., *Helv. Chim. Acta.*, 52:1225 (1969).

Whiteley et al., *Anal. Biochem.*, 137(2):394-6 (1984).

FDA Center for Drug Evaluation and Research (CDER) Draft Guidance for Industry ANDAs: Pharmaceutical Solid Polymorphism Chemistry, Manufacturing, and Controls Information; Dec. 2004.

"Tetrahydrobiopterin tablets" by Schircks Laboratories, Aug. 15, 2003.

"Data Sheet—Tetrahydrobiopterin" by Schircks Laboratories, Sep. 16, 2003.

"Summary of product characteristics-Tetrahydrobiopterin 10 mg/50 mg Tablets" by Schircks Laboratories, Jan. 7, 2004.

"Certificate of Analysis" by Schircks Laboratories, Mar. 11, 2005.

"Tetrahydrobiopterin tablets" by Schircks Laboratories, Jan. 8, 2008.

"Statement for the Record" from the file history of U.S. Appl. No. 10/990,316, Feb. 25, 2008.

"Summary of product characteristics-Tetrahydrobiopterin tablets" by Schircks Laboratories, Mar. 31, 2008.

Office Action mailed Aug. 6, 2008, U.S. Appl. No. 12/106,621.