

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.
Petitioner,

v.

CORCEPT THERAPEUTICS, INC.
Patent Owner.

Case No: PGR2019-00048
U.S. Patent No. 10,195,214

Title: CONCOMITANT ADMINISTRATION OF GLUCOCORTICOID
RECEPTOR MODULATORS AND CYP3A INHIBITORS

Petition for Post-Grant Review
Under 35 U.S.C. §§ 321-328 and 37 C.F.R. § 42.200 *et seq.*

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 B. 2009: Corcept initiates a clinical trial to obtain FDA approval to market mifepristone for the treatment of Cushing’s syndrome. 9

 C. 2012: The FDA approves Korlym to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing’s syndrome patients who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery, but imposes a post-marketing requirement that Corcept conduct a drug-drug interaction study with mifepristone and ketoconazole..... 10

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LIST OF EXHIBITS

<i>Teva</i> <i>Exhibit #</i>	<i>Description</i>
1001	Belanoff, J.K., "Concomitant Administration Of Glucocorticoid Receptor Modulators And CYP3A Inhibitors," U.S. Patent No. 10,195,214 B2 (filed June 19, 2017; issued February 5, 2019)
1002	Declaration of David J. Greenblatt, M.D.
1003	Curriculum Vitae for David J. Greenblatt, M.D.
1004	Korlym Label (2012)
1005	Lee <i>et al.</i> , Office of Clinical Pharmacology Review NDA 20687 (Addendum, Korlym TM , Mifepristone) (2012)
1006	FDA Approval Letter for Korlym (mifepristone) tablets, NDA 20217, dated February 17, 2012
1007	Tsunoda, S.M., <i>et al.</i> , "Differentiation of intestinal and hepatic cytochrome P450 3A activity with use of midazolam as an in vivo probe: Effect of ketoconazole," <i>Clin. Pharmacol. Ther.</i> 66(5): 461-471 (1999)
1008	Ullmann, A., <i>et al.</i> , "Method For Treating Cushing's Syndrome," U.S. Patent Application Publication No. 2010/0261693 A1 (filed October 13, 2008; published October 14, 2010)
1009	Sartor, O. and Cutler, G.B., "Mifepristone: Treatment of Cushing's Syndrome," <i>Clinical Obstetrics and Gynecology</i> 39(2): 506-510 (1996)
1010	Pozza, C., <i>et al.</i> , "Management Strategies for Aggressive Cushing's Syndrome: From Macroadenomas to Ectopics," <i>J. Oncol.</i> 109: 1-9 (2012)
1011	Castinetti, F., "Medical Treatment of Cushing's Syndrome: Glucocorticoid Receptor Antagonists and Mifepristone," <i>Neuroendocrinology</i> 92(suppl. 1): 125-130 (2010)
1012	Nieman, L.K., "Successful Treatment of Cushing's Syndrome with the Glucocorticoid Antagonist RU 486*," <i>J. Clin. Endocrinol. Metab.</i> 61(3): 536-540 (1985)

<i>Teva</i> <i>Exhibit #</i>	<i>Description</i>
1013	Brogden, R.N., <i>et al.</i> , "Mifepristone A Review of its Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Potential," <i>Drugs</i> 45(3): 384-409 (1993)
1014	Molitch. M.E., "Current approaches to the pharmacological management of Cushing's disease," <i>Mol. Cell. Endocrinol.</i> 408: 185–189 (2015)
1015	Sitruk-Ware, R. and Spitz, I.M., "Pharmacological properties of mifepristone: toxicology and safety in animal and human studies," <i>Contraception</i> 68: 409–420 (2003)
1016	Heikinheimo, O., "Pharmacokinetics of The Antiprogesterone RU 486 in Women During Multiple Dose Administration," <i>J. Steriod. Biochem.</i> 32(1A): 21-25 (1989)
1017	Heikinheimo, O., <i>et al.</i> , "The pharmacokinetics of mifepristone in humans reveal insights into differential mechanisms of antiprogestin action," <i>Contraception</i> 68: 421–426 (2003)
1018	Blasey, C.M., <i>et al.</i> , "Efficacy and Safety of Mifepristone for the Treatment of Psychotic Depression," <i>J. Clin. Psychopharmacol.</i> 31:436-440 (2011)
1019	Belanoff, J.K., "Optimizing Mifepristone Levels in Plasma Serum of Patients Suffering from Mental Disorders Treatable with Glucocorticoid Receptor Antagonists," U.S. Patent No. 8,921,348 B2 (filed October 29, 2013; issued December 30, 2014)
1020	Belanoff, J.K., "Optimizing Mifepristone Levels in Plasma Serum of Patients Suffering from Mental Disorders Treatable with Glucocorticoid Receptor Antagonists," U.S. Patent No. 8,598,149 B2 (filed August 27, 2008; issued December 3, 2013)
1021	Castinetti, F., <i>et al.</i> , "Merits and pitfalls of mifepristone in Cushing's syndrome," <i>Eur. J. Endocrinol.</i> 160: 1003–1010 (2009)
1022	Jang, G.R., <i>et al.</i> , "Identification of CYP3A4 as the Principal Enzyme Catalyzing Mifepristone (RU 486) Oxidation in Human Liver Microsomes," <i>Biochem. Pharmacol.</i> 52: 753-761 (1996)

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