

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS INTERNATIONAL GMBH,
Petitioner,

v.

CORCEPT THERAPEUTICS, INC.
Patent Owner.

Case PGR2019-00048
U.S. Pat. No. 10,195,214 B2

PETITIONER'S EXHIBIT LIST

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<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)

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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 Antiprogestone 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 Glucocorticod 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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1023	Greenblatt, D., “ <i>In Vitro</i> Prediction of Clinical Drug Interactions With CYP3A Substrates: We Are Not There Yet,” <i>Clin. Pharm. Ther.</i> 95(2): 133-135 (2014)
1024	Greenblatt, D.J., <i>et al.</i> , “Mechanism of cytochrome P450-3A inhibition by ketoconazole,” <i>J. Pharm. Pharmacol.</i> 63: 214–221 (2011)
1025	Greenblatt, D.J. and von Moltke, L.L., “Clinical Studies of Drug-Drug Interactions: Design and Interpretation,” in <i>Enzyme- and Transporter-Based Drug-Drug Interactions: Progress and Future Challenges</i> . Pang, K.S. <i>et al.</i> , ed., pp. 625-649, New York, Springer (2010)
1026	Greenblatt, D.J., <i>et al.</i> , “The CYP3 Family” in <i>Cytochromes P450: Role in the Metabolism and Toxicity of Drugs and other Xenobiotics</i> . Ionnides, C., ed., pp. 354-383, Royal Society of Chemistry: (2008)
1027	Ohno, Y., <i>et al.</i> , “General Framework for the Quantitative Prediction of CYP3A4-Mediated Oral Drug Interactions Based on the AUC Increase by Coadministration of Standard Drugs,” <i>Clin. Pharmacokinet.</i> 46(8): 681-696 (2007)
1028	Archive History of NCT00936741 History of Changes for Study: NCT00936741 An Extension Study of CORLUX in the Treatment of Endogenous Cushing's Syndrome (July 9, 2009) on ClinicalTrials.gov
1029	Fleseriu, M., <i>et al.</i> , “Mifepristone, a Glucocorticoid Receptor Antagonist, Produces Clinical and Metabolic Benefits in Patients with Cushing’s Syndrome,” <i>J. Clin. Endocrinol. Metab.</i> 97(6):2039–2049 (2012)
1030	Morgan, F.H. and Laufgraben, M.J., “Mifepristone for Management of Cushing’s Syndrome,” <i>Pharmacotherapy</i> 33(3):319-329 (2013)
1031	Schteingart, D.E., “Drugs in the medical treatment of Cushing's syndrome,” <i>Expert Opin. Emerging Drugs</i> 14(4):661-671 (2009)

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1032	Dang, C.N. and Trainor, P., “Pharmacological Management of Cushing’s Syndrome: An Update,” <i>Arq. Bras. Endocrinol. Metab.</i> 51(8):1339-1348 (2007)
1033	Zhang, L., <i>et al.</i> , “Predicting Drug–Drug Interactions: An FDA Perspective,” <i>The AAPS Journal</i> 11(2): 300-306 (2009)
1034	Nguyen, D. and Minze, S., “Effects of Ketoconazole on the Pharmacokinetics of Mifepristone, a Competitive Glucocorticoid Receptor Antagonist, in Healthy Men,” <i>Adv. Ther.</i> 34:2371–2385 (2017)
1035	File History of U.S. Patent No. 10,195,214 B2
1036	Korlym Label Revised: 05/2017 (2017)
1037	Kaesar, B., <i>et al.</i> , “Drug-Drug Interaction Study of Ketoconazole and Ritonavir-Boosted Saquinavir,” <i>Antimicrobial Agents and Chemotherapy</i> 53(2): 609–614 (2009)
1038	Truong, H.L., <i>et al.</i> , “Budget impact of pasireotide for the treatment of Cushing’s disease, a rare endocrine disorder associated with considerable comorbidities,” <i>J. Med. Economics</i> 17(4): 299-295 (2014)
1039	Belanoff, J. and Gross, C., “Optimizing Mifepristone Levels for Cushing's Patients,” U.S. Patent No. 9,943,526 B2 (filed April 20, 2016; issued April 17, 2018)
1040	“A Guide to Drug Safety Terms,” FDA Consumer Health Information / U. S. Food and Drug Administration, (2012) downloaded from www.tinyurl.com/y6oao2sj
1041	“Guidance for Industry Drug Interaction Studies — Study Design, Data Analysis, and Implications for Dosing and Labeling,” U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER) (2006)
1042	File History for U.S. Patent No. 9,943,526 B2

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