Filed on behalf of: Corcept Therapeutics, Inc.

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

PATENT OWNER'S EXHIBIT LIST

EX	Description
2001	August 2018 Update to the Office Patent Trial Practice Guide, 83 Fed. Reg. 39,989 (Aug. 13, 2018)
2002	Chart Comparing Arguments Made By Petitioner in PGR2019-00048 and in the District Court Litigation
2003	January 16, 2019 Email from U. Everett to Counsel
2004	*Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 18-cv-3632, D.I. 31 (D.N.J. Oct. 23, 2018)
2005	*Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 18-cv-3632, D.I. 73 (D.N.J. June 4, 2019)
2006	R. Pivonello et al., "The Treatment of Cushing's Disease," *Endocrine Rev.*, 36(4):385-486 (2015)
2007	D. Guelho & A. Grossman, "Emerging Drugs for Cushing's disease," *Exp. Op. on Emerging Drugs*, 20(3):463-78 (2015)
2008	M. Fleseriu & S. Petersenn, "New Avenues in the medical treatment of Cushing's disease: corticotroph tumor targeted therapy," *J. Neurooncol.*, 114:1-11 (2013)
2009	R.A. Feelders et al., "The burden of Cushing's disease: clinical and health-related quality of life aspects," *Eur. J. Endocrinol.*, 167:311-26 (2012)
2010	"Hyperglycemia in Diabetes," The Mayo Clinic (Nov. 3, 2018), https://www.mayoclinic.org/diseases-conditions/hyperglycemia/symptoms-causes/syc-20373631
2011	D. Cuevas-Ramos et al., "Update on medical treatment for Cushing's disease," *Clin. Diabetes & Endocrinol.*, 2:16 (2016)
2012	M. Fleseriu et al., "A New Therapeutic Approach in the Medical Treatment of Cushing's Syndrome: Glucocorticoid Receptor Blockade with Mifepristone," *Endocrine Practice*, 19(2):313-26 (2013)
2013	O. Heikinheimo et al., "The pharmacokinetics of mifepristone in humans reveal insights into differential mechanisms of antiprogestin action," *Contraception*, 68:421-26 (2003)
2014	U.S. Patent No. 8,921,348 ("Optimizing Mifepristone Levels in Plasma Serum of Patients Suffering from Mental Disorders Treatable with Glucocorticoid Receptor Antagonists")

2015	X. Bertagna et al., "Chapter 16: Cushing's Disease," in THE PITUITARY (Shlomo Melmed ed., 3rd ed. 2011)
2016	J.K. Oosterhuis et al., "Life-threatening *Pneumocystis jiroveci* pneumonia following treatment of severe Cushing's syndrome," *Netherlands J. Med.*, 65(6):215-17 (2007)
2017	Biaxin (clarithromycin) Full Prescribing Information (May 2016)
2018	Sporanox (itraconazole) Full Prescribing Information (April 2015)
2019	Nizoral (ketoconazole) Full Prescribing Information (2013)
2020	E. Charmandari et al., "Adrenal Insufficiency," *Lancet*, 383(9935):2152-67 (2014)
2021	A. Viera et al., "Potassium Disorders: Hypokalemia and Hyperkalemia," *American Family Physician*, 92(6):487-95 (2015)
2022	M. Basina et al., "Successful Long-Term Treatment of Cushing Disease with Mifepristone (RU486)," *Endocrine Practice*, 18(5):114-20 (2012)
2023	D. Greenblatt & J. Harmatz, "Ritonavir is the best alternative to ketoconazole as an index inhibitor of cytochrome P450-3A in drug-drug interaction studies," *Brit. J. Clin. Pharmacol.*, 80(3):342-50 (2015)
2024	Incivek (telaprevir) Full Prescribing Information (October 2013)
2025	VFEND (voriconazole) Full Prescribing Information (February 2015)
2026	Victrelis (boceprevir) Full Prescribing Information (January 2017)
2027	Tybost (cobicistat) Full Prescribing Information (June 2016)
2028	Vaprisol (conivaptan hydrochloride) Full Prescribing Information (October 2016)
2029	Crixivan (indinavir sulfate) Full Prescribing Information (September 2016)
2030	Kaletra (lopinavir and ritonavir) Full Prescribing Information (November 2016)
2031	Viracept (nelfinavir mesylate) Full Prescribing Information (September 2016)
2032	Technivie (ombitasvir, paritaprevir and ritonavir) Full Prescribing Information (February 2017)

2033	Invirase (saquinavir mesylate) Full Prescribing Information (September 2016)
2034	D. Cuevas-Ramos & M. Fleseriu, "Treatment of Cushing's disease: a mechanistic update," *J. Endocrinol.*, 223(2):R19-39 (2014)
2035	T. Carroll & J.W. Findling, "The Use of Mifepristone in the Treatment of Cushing's Syndrome," *Drugs of Today*, 48(8):509-18 (2012)
2036	E. Dunnigan et al., "Mifepristone (RU-486) in the treatment of Refractory Cushing's Disease," *Endocrine Rev., Suppl. 1*, 31(3):S1201 (2010)
2037	Nefazodone Hydrochloride Tablets Full Prescribing Information (May 2014)
2038	Noxafil (posaconazole) Full Prescribing Information (September 2016)
2039	Norvir (ritonavir) Full Prescribing Information (December 2016)
2040	Excerpts of Physician's Desk Reference (58th ed. 2004)
2041	"The Hazards of Seldane," N.Y. TIMES (January 17, 1997)
2042	European Medicines Agency, "European Medicines Agency recommends suspension of marketing authorisations for oral ketoconazole," July 26, 2013
2043	M. Tran & J. Grillo, "Translation of Drug Interaction Knowledge to Actionable Labeling," *Clin. Pharmacol. & Therapeutics*, 105(6):1292-95 (2019)
2044	M. Fleseriu et al., "Changes in Plasma ACTH Levels and Corticotroph Tumor Size in Patients With Cushing's Disease During Long-term Treatment With the Glucocorticoid Receptor Antagonist Mifepristone," *J. Clin. Endocrinol. Metab.*, 99(10):3718-27 (2014)
2045	"Treatment for Aspergillosis," Centers for Disease Control and Prevention (Jan. 2, 2019), https://www.cdc.gov/fungal/diseases/aspergillosis/treatment.html
2046	"Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers," U.S. Food and Drug Administration (Nov. 14, 2017), https://www.fda.gov/drugs/drug-interactions-labeling/drug-development-and-drug-interactions-table-substrates-inhibitors-and-inducers
2047	September 6, 2019 Email from D. Sterling to Counsel
2048	Declaration of Nicholas A. LoCastro

2049	D.J. Greenblatt & L. Von Moltke, "Clinical studies of drug-drug interactions: design and interpretation," Chapter 24 in ENZYME- AND TRANSPORTER-BASED DRUG-DRUG INTERACTIONS: PROGRESS AND FUTURE CHALLENGES (2010)
2050	N.N. Sarkar, "Mifepristone: bioavailability, pharmacokinetics and use-effectiveness," *Eur. J. Obstetrics & Gynecol & Reproductive Biol.*, 101(2):113-20 (2002)
2051	D.J. Greenblatt, "Drug-Drug Noninteractions," *Cardiovascular Therapeutics*, 27:226-29 (2009)
2052	H.K. Greenblatt & D.J. Greenblatt, "Liver Injury Associated with Ketoconazole: Review of the Published Evidence," *J. Clin. Pharmacol.*, 54(12):1321-29 (2014)
2053	L. Von Moltke et al., "In Vitro Approaches to Predicting Drug Interactions in Vivo," *Biochem. Pharmacol.*, 55:113-22 (1998)
2054	D.J. Greenblatt et al., "Kinetic and dynamic interaction study of zolpidem with ketoconazole, itraconazole, and fluconazole," *Clin. Pharmacol. & Therapeutics*, 64:661-71 (1998)
2055	D. Roman, Cross Discipline Team Leader Review, NDA 202107 (2012)
2056	Declaration of F. Peter Guengerich, Ph.D.
2057	Declaration of Ty Carroll, M.D.
2058	Declaration of Laurence Katznelson, M.D.
2059	Deposition Transcript of Dr. Greenblatt
2060	O. Heikinheimo et al., "Antiprogesterone RU 486 – A Drug for Non-Surgical Abortion," *Annals of Medicine*, 22:75-84 (1990)
2061	Y. Shi et al., "Pharmacokinetic study of RU 486 and its metabolites after oral administration of single doses to pregnant and non-pregnant women," *Contraception*, 48:133-149 (1993)
2062	Y. Huang et al., "Pharmacokinetics and Dose Proportionality of Ketoconazole in Normal Volunteers," *Antimicrobial Agents & Chemotherapy*, 30(2):206-10 (1986)
2063	"FDA advises against using oral ketoconazole in drug interaction studies due to serious potential side effects," Oct. 18, 2013. Internet Archive,

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