

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC
Petitioner,

v.

CORCEPT THERAPEUTICS, INC.
Patent Owner.

Case IPR2018-01494
Patent No. 8,921,348 B2

**NEPTUNE GENERICS, LLC'S MOTION TO SUBMIT
LABELED EXHIBITS AND CORRECT EXHIBIT 1008**

I. RELIEF REQUESTED

Petitioner Neptune Generics, LLC hereby requests entry of attached labeled Exhibits 1001-1034 to replace Exhibits 1001-1034 filed with the original Petition for *Inter Partes* Review filed in this case on August 2, 2018. The Board may, in its own judgment, after correction, expunge the Exhibits filed with the original Petition.

II. STATEMENT OF FACTS AND REASONS FOR THIS MOTION

Petitioner electronically filed the original Petition in this case on August 2, 2018, along with Exhibits 1001-1034. The original Exhibits were inadvertently improperly labeled in accordance with 37 C.F.R. § 42.63(d). In addition, the electronically-filed version of Exhibit 1008 was inadvertently misfiled – it was, in fact, a duplicate of Exhibit 1007, and not Exhibit 1008.

On August 23, 2018, the Board issued Paper No. 3 in this case, according the Petition the filing date of August 2, 2018, but also stating that “the Petitioner must label each exhibit and correctly file Exhibit 1008. After correction, each exhibit filed August 2, 2018, will be expunged.” Paper No. 3 at 2. “Petitioner must correct the defect(s) within FIVE BUSINESS DAYS from this notice. Failure to correct the defect(s) may result in an order to show cause as to why the Board should institute the trial.” *Id.*

Accordingly, Petitioner now timely files this motion along with the correct and properly labeled Exhibits 1001-1034 in response to the Board’s direction. The Table of Exhibits from the original Petition is reproduced below. Petitioner respectfully requests that the Board grant this motion and enter attached Exhibits 1001-1034 into the record.

Date: August 28, 2018

Respectfully Submitted,

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**Table of Exhibits for Petition for *Inter Partes* Review Of
U.S. Patent No. 8,921,348**

Exhibit	
1001	U.S. Patent 8,921,348 to Belanoff
1002	U.S. Application 14/065792 File History
1003	U.S. Application 12/199114 File History
1004	Declaration of Mikko A. Oskari Heikinheimo, M.D., Ph.D.
1005	Curriculum Vitae of Dr. Heikinheimo
1006	<i>Possible Use of Glucocorticoid Receptor Antagonists in the Treatment of Major Depression: Preliminary Results Using RU 486 – Murphy et al. (1993) J. Psychiatr Neurosci, Vol. 18, No. 5, 209-213.</i>
1007	<i>An Open Label Trial of C-1073 (Mifepristone) for Psychotic Major Depression by Belanoff et al., Biol. Psychiatry (2002) 52:386-392 .</i>
1008	<i>Pharmacological properties of mifepristone: toxicology and safety in animal and human studies by Sitruk-Ware et al., (2003) Contraception 68, 409–420</i>
1009	<i>Rapid Reversal of Acute Psychosis in the Cushing Syndrome with the Cortisol-Receptor Antagonist Mifepristone (RU 486) by van der Lely et al., Annals of Internal Medicine. (1991) 114:143-144.</i>
1010	U.S. Patent 6,964,953 B2 to Belanoff entitled “ <i>Methods for treating stress disorder using glucocorticoid receptor specific antagonists</i> ” issued November 15, 2005
1011	<i>Clinical Pharmacokinetics of Mifepristone, Heikinheimo, Clin. Pharmacokinet. 1997 July, 33 (I): 7-17 (Ex. 1011)</i>
1012	<i>“Plasma concentrations and receptor binding of RU 486 and its metabolites in humans,” Heikinheimo, et al. J. Steroid Biochem Vol. 26: 279-284, 1987</i>
1013	<i>Pharmacokinetics of the Antiprogesterone RU 486 in Women During Multiple Dose Administration, Heikinheimo, et al. J. Steroid Biochem. Vol. 32, No. 1A, pp. 21-25, 1989.</i>
1014	<i>Pharmacokinetics of Mifepristone After Low Oral Doses, Kekkonen, et al. Contraception 1996; 54:229-234.</i>
1015	<i>A Study of the Effect of Mifepristone (Antiprogesterone) Followed by Prostaglandin on Uterine Activity and Fetal Heart Rate in Patients Having a Termination of Pregnancy, Pulkkinen, et al. Arch Gynecol Obstet (1989) 244:75-</i>

1016	<i>Pharmacokinetic study of RU 486 and its metabolites after oral administration of single doses to pregnant and non-pregnant women, Shi, et al. Contraception August 1993:48, 133-149</i>
1017	<i>Mifepristone (RU-486) treatment for depression and psychosis: a review of the therapeutic implications, Gallagher et al, Neuropsychiatric Disease and Treatment 2006:2(1) 33–42</i>
1018	“Express Scripts – Specialty Drug Update”
1019	<i>Differential kinetics of serum and cervical insulin-like growth factor-binding protein-1 during mifepristone± misoprostol-induced medical termination of early pregnancy, Honkanen et al., Molecular Human Reproduction Vol. 10, No. 1 pp. 65-70, 2004.</i>
1020	<i>Pharmacokinetic Properties of the Antiglucocorticoid and Antiprogestone Steroid RU 486 in Man,” Kawai et al, Pharmacol, And Experimental Therapeutics 241:401-406 (1987).</i>
1021	US 6,150,349 to Schatzberg and Belanoff
1022	National Center for Biotechnology Information. PubChem Compound Summary for CID 55245; available at http://pubchem.ncbi.nlm.nih.gov/compound/55245#section=Top
1023	<i>Successful Long-Term Treatment of Refractory Cushing’s Disease with High-Dose Mifepristone (RU 486), Chu, Belanoff et al. The Journal of Clinical Endocrinology & Metabolism 86(8):3568–3573 (2001)</i>
1024	US 2004/0029848 to Belanoff “ <i>Methods for Treating Delirium Glucocorticoid Receptor-Specific Antagonists</i> ” published February 12, 2004
1025	“ <i>Rapid Reversal of Psychotic Depression Using Mifepristone,</i> ” Belanoff et al., (2001) Journal of Clinical Psychopharmacology Vol. 21, No. 5, 516-521
1026	US 6,362,173 to Schatzberg and Belanoff
1027	US 8,450,379 to Belanoff (published 2004-07-08 as US 2004/013270)
1028	US 7,361,646 to Belanoff (published 2004-08-26 as US 2004/0167110)
1029	DeBattista C, Belanoff J., “The use of mifepristone in the treatment of neuropsychiatric disorders.” Trends Endocrinol Metab. Apr;17(3):117-21. Epub 2006 Mar 10.
1030	DeBattista, Belanoff et al., “Mifepristone versus Placebo in the Treatment of Psychosis in Patients with Psychotic Major Depression” Biol Psychiatry. Dec 15;60(12):1343-9. Epub 2006 Aug 4.
1031	Annual Report of Corcept Therapeutics Incorporated for the fiscal year ending December 31, 2016, Form 10-K available at

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