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Alkermes Pharma Ireland Ltd.
and Alkermes, Inc.
Petitioners,

v.

Otsuka Pharmaceutical Co., Ltd.
Patent Owner

Patent No. 9,125,939 B2
Issued: September 8, 2015
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Inventors: Tetsuro Kikuchi, Taro Iwamoto, Tsuyoshi Hirose

Title: CARBOSTYRIL DERIVATIVES AND MOOD STABILIZERS FOR
TREATING MOOD DISORDERS

Inter Partes Review No. IPR2017-00287

**PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 9,125,939**

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Ex. 1002	Declaration of Allen Frances, M.D. in Support of the Petition for Inter Partes Review of U.S. Patent No. 9,125,939
Ex. 1003	Allen Frances, M.D., <i>Curriculum Vitae</i>
Ex. 1004	Declaration of Jessie Au, Pharm.D., Ph.D. in Support of the Petition for Inter Partes Review of U.S. Patent No. 9,125,939
Ex. 1005	Jessie Au, Pharm.D., Ph.D., <i>Curriculum Vitae</i>
Ex. 1006	Tohen et al., <i>Efficacy of olanzapine in combination with valproate or lithium in the treatment of mania in patients partially nonresponsive to valproate or lithium monotherapy</i> , ARCH. GEN. PSYCHIATRY, v. 59(1): 62-69 (2002) “Tohen”
Ex. 1007	Keck PE Jr et al., <i>Aripiprazole versus placebo in acute mania</i> , Abstracts of the 2002 Annual Meeting of the American Psychiatric Association; Philadelphia, PA. USA (2002) (New Research Abstract 314 (NR314)). “Keck”
Ex. 1008	Citrome et al., <i>Pharmacokinetics and safety of aripiprazole and concomitant mood stabilizers</i> , Abstracts of the 2002 Annual Meeting of the American Psychiatric Association; Philadelphia, PA. USA (2002) (New Research Abstract 317 (NR317)). “Citrome”
Ex. 1009	<i>American Psychiatric Association, Practice guideline for the treatment of patients with bipolar disorder (Revision)</i> , AM. J. PSYCHIATRY, 159:4, April 2002 Supplement. “APA Practice Guidelines 2002”
Ex. 1010	Kowatch R.A. et al., <i>The use of mood stabilizers and atypical antipsychotics in children and adolescents with bipolar disorders</i> , CNS SPECTRUMS, 8(4): 273-280 (2003). “Kowatch”
Ex. 1011	Vieta, Eduard, et al., <i>Olanzapine as long-term adjunctive therapy in treatment-resistant bipolar disorder</i> , J. CLIN. PSYCHOPHARMACOL., v.21(5): 469-473 (2001). “Vieta”
Ex. 1012	Ketter, TA. et al., <i>Rapid efficacy of olanzapine augmentation in nonpsychotic bipolar mixed states</i> [letter], J. CLIN. PSYCHIATRY,

	59:83-85. (1998) “Ketter”
Ex. 1013	McElroy SL, et al., <i>Olanzapine in treatment-resistant bipolar disorder</i> , J. AFFECT DISORD. 49:119-122. (1998) “McElroy”
Ex. 1014	Sachs, G.S. et al., <i>Quetiapine versus placebo as adjunct to mood stabilizer for the treatment of acute mania</i> , BIPOLAR DISORDER 4 suppl. I. 133. (2002) “Sachs I”
Ex. 1015	Yatham, Lakshmi N. et al., <i>The role of novel antipsychotics in bipolar disorder</i> , J. CLIN. PSYCHIATRY 63: 10-14 (2002) “Yatham”
Ex. 1016	Petrie, J.L. et al., <i>Aripiprazole, a new atypical antipsychotic: phase II clinical trial results</i> . EUR. NEUROPSYCHOPHARM 7 (Suppl 2):S227 (1997) “Petrie”
Ex. 1017	Goodwin, G.M., <i>Typical and atypical antipsychotics in the treatment of mania</i> , EUR. NEUROPSYCHOPHARM 11 (Suppl 3): S132 (2001) “Goodwin”
Ex. 1018	Chang, Kiki D. and Ketter, Terence A., <i>Mood stabilizer augmentation with olanzapine in acutely manic children</i> , J. CHILD AND ADOLESCENT PSYCHOPHARMACOLOGY, v:10(1): 45-49 (2000) “Chang”
Ex. 1019	Del Bello M.P. et al., <i>A double-blind, randomized, placebo-controlled study of quetiapine as adjunctive treatment for adolescent mania</i> , J. AM. ACAD. CHILD ADOLESC. PSYCHIATRY, 41: 1216-1223. (2002) “Del Bello”
Ex. 1020	Tohen M. et al., <i>Efficacy of olanzapine in acute bipolar mania: a double-blind, placebo-controlled study</i> , ARCH. GEN. PSYCHIATRY 57(9): 841-849 (2000) “Tohen II”
Ex. 1021	Haddad P. et al., <i>Adjunctive use of olanzapine in the treatment of mania</i> , INT. J. PSYCHIATRY IN CLIN PRACTICE, v3: 213-215 (1999) “Haddad”
Ex. 1022	Excerpts from the Diagnostic and Statistical Manual of Mental Disorder-IV “DSM-IV”

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