UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC

Petitioner

v.

SUMITOMO DAINIPPON PHARMA CO., LTD

Patent Owner

Case No. IPR2020-01053
U.S. Patent 9,815,827

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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Cases

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LISTING OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 9,815,827, *Agent for Treatment of Schizophrenia* (filed Aug. 28, 2014) (issued Nov. 14, 2017) (the "'827 Patent")
1002	Expert Declaration of Dr. Thomas R. Kosten, M.D. ("Kosten")
1003	U.S. Patent Application 14/471,919 (filed Aug. 28, 2014) ("the '827 Patent Application")
1004	U.S. Patent Application 10/525,021 (filed Aug. 20, 2003) ("Priority Application")
1005	U.S. Application 60/404,927 (filed Aug. 22, 2002) ("Provisional Application" or "the '927 Provisional") with translation from Japanese to English)
1006	Preliminary Amendment in the '827 Patent Application (October 5, 2015) ("Second Preliminary Amendment")
1007	Information published in *American Journal of Psychiatry,* Vol. 170, No. 8, August 2013, regarding approval of "Latuda® (lurasidone HCl) tablets" for "treatment of major depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate in adults" ("Latuda® Information") (Stamped "AUG 06 2013")
1008	*Neuropsychopharmacology*, Vol. 38 (2012), pp. S314–S446, including, Loebel, Antony, et al. "Lurasidone Monotherapy for the Treatment of Bipolar Depression: Results of the 6-Week, Double-blind, Placebo-controlled PREVAIL-2 Study," *Neuropsychopharmacology*, Vol 38 (2012), W183, pp. S422–423 ("Loebel")
1009	U.S. Patent No. 5,532,372, *Imide Derivatives, and Their Production and Use* (filed Aug. 30, 1993) (issued Jul. 2, 1996) ("Saji Patent")
1010	Preliminary Amendment in Priority Application (Feb. 18,

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