

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

SLAYBACK PHARMA LLC,

Petitioner

v.

SUMITOMO DAINIPPON PHARMA CO., LTD,

Patent Owner

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Case No. IPR2020-01053

Patent No. 9,815,827

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**PETITIONER'S OBJECTIONS TO PATENT OWNER'S EXHIBITS  
TO PATENT OWNER'S RESPONSE**

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Slayback Pharma LLC (“Petitioner”) objects to the admissibility of the following exhibits filed by Patent Owner Sumitomo Dainippon Pharma Co., Ltd. (“Patent Owner”) in the Patent Owner’s Response (Paper No. 15) in the above-captioned inter partes review.

Petitioner’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within five business days of the filing of Patent Owner’s Response (Paper No. 15) in this matter on March 11, 2021.

Petitioner’s objections provide notice to Patent Owner that Petitioner may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

In this paper, a reference to “FRE” means the Federal Rules of Evidence and a reference to “CFR” means the Code of Federal Regulations.

Petitioner’s objections to Patent Owner’s exhibits under FRE 801-803 (hearsay) apply to the extent Patent Owner seeks to rely on such exhibits for the truth of any matters stated in such exhibits.

Petitioner objects to all of Patent Owner’s exhibits under FRE 901-902 (authenticity) to the extent that Patent Owner fails to provide a sponsoring witness who can attest to the authenticity of such documents, including translations of

foreign publications, or to demonstrate that such exhibits are self authenticating under the FRE.

Exhibit descriptions provided in this table are taken from Patent Owner’s Response Exhibit List and are used for identification purposes only. Petitioner’s use of Patent Owner’s descriptions does not indicate that Petitioner agrees with Patent Owner’s descriptions or any other characterizations of such exhibits.

Exhibit No.	Description	Objection
2043	FDA Atypical Antipsychotic Drugs Information, downloaded from the internet at <a href="https://www.fda.gov/drugs/postmarket-drug-safetyinformation-patients-and-providers/atypical-antipsychotic-drugs">https://www.fda.gov/drugs/postmarket-drug-safetyinformation-patients-and-providers/atypical-antipsychotic-drugs</a> information on September 10, 2020.	FRE 801-803, 402, 403
2044	Franklin, “Lurasidone for the treatment of bipolar depression: an evidence-based review,” <i>Neuropsychiatric Disease and Treatment</i> , 2015:11 2143–2152 (2015).	FRE 801-803, 402, 403
2045	Shayegan et al., “Atypical Antipsychotics: Matching Receptor Profile to Individual Patient’s Clinical Profile,” <i>CNS Spectrums</i> 9(10)(suppl 11):6-14 (October, 2004).	FRE 801-803, 402, 403
2046	Kane et al. “Clozapine for the Treatment-Resistant Schizophrenia.” <i>Arch Gen Psychiatry</i> , Vol. 45, September 1988, pp. 789-796.	FRE 801-803, 402, 403
2047	Nashed et al., “Olanzapine-Induced Weight Gain in Patients with Bipolar I Disorder: A Meta-Analysis,” <i>Prim. Care Companion CNS Disord.</i> 13(6) (2011).	FRE 801-803, 402, 403
2048	Symbyax® Label.	FRE 801-803, 402, 403

Exhibit No.	Description	Objection
2049	Seroquel® Label.	FRE 801-803, 402, 403
2050	Lieberman et al., “Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia,” <i>New Eng. J. Med.</i> 353(12) 1209-1223 (September 22, 2005).	FRE 801-803, 402, 403
2051	Thase, “Quetiapine monotherapy for bipolar depression,” <i>Neuropsychiatric Disease and Treatment</i> 4(1) 21-31, pp. 11-21 (2008).	FRE 801-803, 402, 403
2052	Hoyberg et al., “Risperidone versus perphenazine in the treatment of chronic schizophrenic patients with acute exacerbations,” <i>Acta Psychiatr. Scand</i> 88:395-402 (1993).	FRE 801-803, 402, 403
2053	Lombardo et al., “Two 6-Week, randomized, Double-Blind, Placebo- Controlled Studies of Ziprasidone in Outpatients with Bipolar I Depression,” <i>J Clin Psychopharmacol.</i> 32(4) pp. 470-478 (2012).	FRE 801-803, 402, 403
2054	Sachs et al., “Efficacy and Safety of Adjunctive Oral Ziprasidone for Acute Treatment of Depression in Patients With Bipolar I Disorder: A Randomized, Double-Blind, Placebo-Controlled Trial,” <i>J Clin Psychiatry</i> 72(10):1413-1422 (2011).	FRE 801-803, 402, 403
2055	Pacher et al., “Cardiovascular Side Effects of New Antidepressants and Antipsychotics: New Drugs, Old Concerns?” <i>Curr Pharm Des.</i> 10(20):2463-2475, 6 (2004).	FRE 801-803, 402, 403
2056	Stimmel et al., “Ziprasidone: An Atypical Antipsychotic Drug for the Treatment of Schizophrenia,” <i>Clinical Therapeutics</i> 24(1): 21-37 (2002).	FRE 801-803, 402, 403
2057	Fala, “Latuda (Lurasidone HCL) Receives 2 New Indications for Use in Bipolar Depression as Monotherapy and as Adjunctive Therapy with Lithium or Valproate,” <i>American Health &amp; Drug Benefits</i> , Vol. 7, pp. 123-126 (2014).	FRE 801-803, 402, 403

Exhibit No.	Description	Objection
2058	<b>CONFIDENTIAL</b> D1050231 Clinical Study Report, October 23, 2009.	FRE 801-803, 402, 403
2059	<b>CONFIDENTIAL</b> D1050233 Clinical Study Report, May 3, 2011.	FRE 801-803, 402, 403
2060	<b>CONFIDENTIAL</b> D1050249 Clinical Study Report, October 5, 2009.	FRE 801-803, 402, 403
2061	Meltzer et al., “Lurasidone in the Treatment of Schizophrenia: A Randomized, Double-Blind, Placebo- and Olanzapine-Controlled Study,” <i>Am J Psychiatry</i> 168:957-967 (2011).	FRE 801-803, 402, 403
2062	RESERVED	Exhibit Not Supplied
2063	RESERVED	Exhibit Not Supplied
2064	Correll et al., “Effects of Olanzapine Combined With Samidorphan on Weight Gain in Schizophrenia: A 24-Week Phase 3 Study”, <i>Am. J. Psych.</i> , vol. 177, No. 12, 1168-78 (Dec. 2020).	FRE 801-803, 402, 403
2065	RESERVED	Exhibit Not Supplied
2066	Reiffen et al., “Generic Drug Industry Dynamics,” <i>The Review of Economics and Statistics</i> , Vol. 87, No. 1, pp. 37-49 (2005).	FRE 801-803, 402, 403
2067	DiMasi et al. “The price of innovation: new estimates of drug development costs,” <i>Journal of Health Economics</i> , Vol. 22, 151-185 (2003).	FRE 801-803, 402, 403

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