

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  
PRELIMINARY 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 Preliminary Response 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 ten business days of the institution of trial in this matter on December 9, 2020. (Paper No. 7) 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 Preliminary 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.

Exhibits	Description	Objection
2001	López-Muñoz et al., “History of the discovery and clinical introduction of chlorpromazine,” <i>Annals of Clinical Psychiatry</i> . 17:113–35 (2005).	FRE 801-803, 402, 403, 1006
2002	ZYPREXA® (olanzapine) Label (2000).	FRE 801-803, 402, 403
2003	ABILIFY® (aripiprazole) Label (2002).	FRE 801-803, 402, 403
2004	LATUDA® (lurasidone) Label (2018).	FRE 801-803, 402, 403
2005	Laursen, “Excess Early Mortality in Schizophrenia,” <i>Annu. Rev. Clin. Psychol.</i> 10:425-48 (2014).	FRE 801-803, 402, 403
2006	Olfson et al., “Premature Mortality Among Adults with Schizophrenia in the United States,” <i>JAMA Psychiatry</i> 72(12) 1172-81(2015).	FRE 801-803, 402, 403
2007	Complaint filed 2/13/2018 in <i>Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. v. Emcure Pharmaceuticals Ltd.</i> , Case 2:18-cv-02065.	FRE 801-803, 402, 403

Exhibits	Description	Objection
2008	Complaint filed 2/23/2018 in <i>Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. v. Aurobindo Pharm Ltd. et al.</i> , Case 2:18-cv-02620.	FRE 801-803, 402, 403
2009	Complaint filed 8/31/2018 in <i>Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. v. Piramal Healthcare UK Limited</i> , Case 2:18-cv-13478.	FRE 801-803, 402, 403
2010	Complaint filed 9/12/2018 in <i>Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. v. Macleods Pharmaceuticals Ltd. and Macleods Pharma USA Inc.</i> , Case 2:18-cv-13833.	FRE 801-803, 402, 403
2011	Complaint filed 10/09/2018 in <i>Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. v. Alkem Laboratories Ltd.</i> , Case 2:18-cv-14787.	FRE 801-803, 402, 403
2012	Press Release: “Sumitomo Dainippon Pharma Announces Resolution of Disputes Under Consolidated Patent Infringement Lawsuit Regarding ANDAs for Latuda® in the U.S.,” November 27, 2018.	FRE 801-803, 402, 403
2013	Meltzer, “Treatment of Schizophrenia and Spectrum Disorders: Pharmacotherapy, Psychosocial Treatments, and Neurotransmitter Interactions,” <i>Biol. Psychiatry</i> 46:1321-1327 (1999).	FRE 801-803, 402, 403
2014	Stip, “Novel antipsychotics: issues and controversies. Typicality of atypical antipsychotics,” <i>J. Psychiatry Neurosci</i> 25(2):137-53 (2000).	FRE 801-803, 402, 403
2015	Tarazi and Stahl, “Iloperidone, Asenapine and Lurasidone: A Primer on their Current Status,” <i>Expert Opin. Pharmacother.</i> 13(13): 1911-22 (2012).	FRE 801-803, 402, 403

Exhibits	Description	Objection
2016	Diagnostic and Statistical Manual of Mental Disorders, 3 <sup>rd</sup> Edition, 1980 (Excerpt).	FRE 801-803, 402, 403
2017	Neel Burton, A Short History of Bipolar Disorder, Psychology Today, updated September 7, 2017.	FRE 801-803, 402, 403
2018	RESERVED	Exhibit Not Supplied
2019	Diagnostic and Statistical Manual of Mental Disorders, 4 <sup>th</sup> Edition, 2005, pp. 350-358.	FRE 801-803, 402, 403
2020	Newcomer, “Second-Generation (Atypical) Antipsychotics and Metabolic Effects: A Comprehensive Literature Review,” <i>CNS Drugs<sup>TM</sup> Supplement</i> , vol. 19, supplement 1, pp. 1-93 (2005).	FRE 801-803, 402, 403
2021	Allison et al., “Antipsychotic-Induced Weight Gain: A Comprehensive Research Synthesis,” <i>Am J Psychiatry</i> 156:1686-96 (1999).	FRE 801-803, 402, 403
2022	Green et al., “Weight Gain from Novel Antipsychotic Drugs: Need for Action,” <i>General Hospital Psychiatry</i> 22:224-35 (2000).	FRE 801-803, 402, 403
2023	Risperdal® Label	FRE 801-803, 402, 403
2024	Attachment 1 Ziprasidone (Ziprasidone HCl) NDA 20-825 Approval Letter and Labeling (2001).	FRE 801-803, 402, 403
2025	Geodon® Label (2017).	FRE 801-803, 402, 403
2026	Dawkins et al., “Antipsychotics: Past and Future, National Institute of Mental Health Division of Services and Intervention Research Workshop, July 14, 1998,” <i>Schizophrenia Bulletin</i> 25(2):395-405 (1999).	FRE 801-803, 402, 403
2027	Stahl, S., 2013. Stahl’s Essential Psychopharmacology. 4th ed. Cambridge University Press, Chapter 5.	FRE 801-803, 402, 403

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