

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SLAYBACK PHARMA LLC,  
Petitioner,

v.

SUMITOMO DAINIPPON PHARMA CO., LTD.,  
Patent Owner.

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Case IPR2020-01053  
U.S. Patent 9,815,827

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**PATENT OWNER SUMITOMO DAINIPPON PHARMA CO., LTD.'S  
PRELIMINARY RESPONSE**

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**EXHIBIT LIST**

<b>Exhibit No.</b>	<b>Exhibit Description</b>
2001	López-Muñoz et al., “History of the discovery and clinical introduction of chlorpromazine,” <i>Annals of Clinical Psychiatry</i> . 17:113–35 (2005).
2002	ZYPREXA® (olanzapine) Label (2000).
2003	ABILIFY® (aripiprazole) Label (2002).
2004	LATUDA® (lurasidone) Label (2018).
2005	Laursen, “Excess Early Mortality in Schizophrenia,” <i>Annu. Rev. Clin. Psychol.</i> 10:425-48 (2014).
2006	Olfson et al., “Premature Mortality Among Adults with Schizophrenia in the United States,” <i>JAMA Psychiatry</i> 72(12) 1172-81(2015).
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.
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.
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.
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.
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.
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.

2013	Meltzer, "Treatment of Schizophrenia and Spectrum Disorders: Pharmacotherapy, Psychosocial Treatments, and Neurotransmitter Interactions," <i>Biol. Psychiatry</i> 46:1321-1327 (1999).
2014	Stip, "Novel antipsychotics: issues and controversies. Typicality of atypical antipsychotics," <i>J. Psychiatry Neurosci</i> 25(2):137-53 (2000).
2015	Tarazi and Stahl, "Iloperidone, Asenapine and Lurasidone: A Primer on their Current Status," <i>Expert Opin. Pharmacother.</i> 13(13): 1911-22 (2012).
2016	Diagnostic and Statistical Manual of Mental Disorders, 3rd Edition, 1980 (Excerpt).
2017	Neel Burton, A Short History of Bipolar Disorder, Psychology Today, updated September 7, 2017.
2018	RESERVED
2019	Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, 2005, pp. 350-358.
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).
2021	Allison et al., "Antipsychotic-Induced Weight Gain: A Comprehensive Research Synthesis," <i>Am J Psychiatry</i> 156:1686-96 (1999).
2022	Green et al., "Weight Gain from Novel Antipsychotic Drugs: Need for Action," <i>General Hospital Psychiatry</i> 22:224-35 (2000).
2023	Risperdal® Label
2024	Attachment 1 Ziprasidone (Ziprasidone HCl) NDA 20-825 Approval Letter and Labeling (2001).
2025	Geodon® Label (2017).
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).
2027	Stahl, S., 2013. Stahl’s Essential Psychopharmacology. 4th ed. Cambridge University Press, Chapter 5.
2028	Casey et al., “The Pharmacology of Weight Gain with Antipsychotics,” <i>J Clin. Psychiatry</i> 62[suppl 7]:4-10 (2001).
2029	Reynolds, “Weight Gain, Antipsychotic Drug Treatment and Pharmacogenomics,” <i>Pharmacogenomics</i> 3(5):567-70 (2002).
2030	Loebel and Citrome, “Lurasidone: a novel antipsychotic agent for the treatment of schizophrenia and bipolar depression,” <i>BJPsych Bulletin</i> 39:237-41 (2015).
2031	Notice of allowance mailed 8/13/15 (U.S. 9,174,975).
2032	Wong et al., U.S. Patent No. 6,964,962.
2033	Pozuelo, U.S. Patent Pub. No. 2001/0047010.
2034	Seroquel XR (quetiapine fumarate) Extended-Release Tablets Label 2009.
2035	Wirshing et al., “Novel Antipsychotics: Comparison of Weight Gain Liabilities,” <i>J Clin Psychiatry</i> 60:358-63 (1999).
2036	Jones et al., “Weight Change and Antipsychotic Treatment in Patients with Schizophrenia,” <i>J Clin Psychiatry</i> 62[suppl 2]:41-44 (2001).
2037	Loebel et al., “Efficacy and safety of lurasidone 80 mg/day and 160 mg/day in the treatment of schizophrenia: A randomized, doubleblind, placebo- and active-controlled trial,” <i>Schizophrenia Research</i> 145:101-109 (2013).
2038	Daniel et al., “Ziprasidone 80 mg/day and 160 mg/day in the Acute Exacerbation of Schizophrenia and Schizoaffective Disorder: A 6-Week Placebo-Controlled Trial,” <i>Neuropsychopharmacology</i> 20(5):491-505 (1999).
2039	Reynolds et al., “The 5-HT <sub>2C</sub> receptor and antipsychotic induced weight gain – mechanisms and genetics,” <i>J. Psychopharmacology</i> 20(4) Supplement 15-18 (2006).

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