

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

PATENT OWNER'S RESPONSE

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EXHIBIT LIST

Exhibit No.	Exhibit Description
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 DrugsTM 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).

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