

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 UPDATED EXHIBIT LIST

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). |

| | |
|------|---|
| 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 _{2C} receptor and antipsychotic induced weight gain – mechanisms and genetics,” <i>J. Psychopharmacology</i> 20(4) Supplement 15-18 (2006). |
| 2040 | Certified Translation of Horisawa et al., Japanese Journal of Neuropsychopharmacology 19(6) 1999. |
| 2041 | Mentalhelp.net “Schizophrenia Symptoms, Patterns and Statistics and Patterns”, downloaded from the internet at https://www.mentalhelp.net/schizophrenia/statistics/ on September 10, 2020. |
| 2042 | Ritchie et al. “Mental Health,” downloaded from the internet at https://ourworldindata.org/mental-health on September 10, 2020. |

| | |
|------|--|
| 2043 | FDA Atypical Antipsychotic Drugs Information, downloaded from the internet at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/atypical-antipsychotic-drugs-information on September 10, 2020. |
| 2044 | Franklin, “Lurasidone for the treatment of bipolar depression: an evidence-based review,” <i>Neuropsychiatric Disease and Treatment</i> , 2015:11 2143–2152 (2015). |
| 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). |
| 2046 | Kane et al. “Clozapine for the Treatment-Resistant Schizophrenia.” <i>Arch Gen Psychiatry</i> , Vol. 45, September 1988, pp. 789-796. |
| 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). |
| 2048 | Symbyax® Label. |
| 2049 | Seroquel® Label. |
| 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). |
| 2051 | Thase, “Quetiapine monotherapy for bipolar depression,” <i>Neuropsychiatric Disease and Treatment</i> 4(1) 21-31, pp. 11-21 (2008). |
| 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). |
| 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). |
| 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). |

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.