



Slayback Pharma LLC. v. Sumitomo Dainippon Pharma Co.,  
Ltd.

IPR2020-01053

August 11, 2021 Oral Hearing  
Patent Owner's Presentation

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

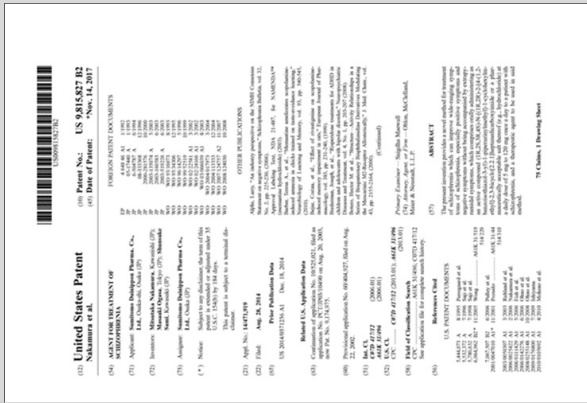
PDX-000

## Overview

- **Priority (Grounds 1 and 2)**
  - Grounds 1 and 2 apply only to claims 8-18, 25-28, 30-31, 33-39, 40-44, 46, 48-55, 56-60, 62, 64, 66, 67, 69, 71, 73, and 75.
  - These claims recite treating “manic depressive psychosis” or treating a patient with “an anti-psychotic.”
  - These claims are entitled to the August 22, 2002 provisional filing date
  - Because these claims are entitled to the Provisional Filing date, Grounds 1 and 2 fail as the art relied on is after that date.
- **Obviousness (Ground 3) – Claims 1-75 are patentable over *Saji*, US 5,532,372, a reference previously considered by the Patent Office**

# The Patented Invention

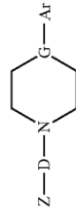
- 75 Claims (5 independent)
- Claims cover use of lurasidone as an antipsychotic
  - To treat schizophrenia or manic depressive psychosis
  - Administered: Once daily, oral administration of 20-120 mg
  - Without either clinically significant weight gain or weight gain



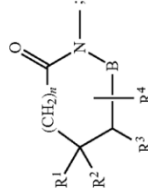
IPR2020-01053, Ex. 1001

# '827 Patent Specification Discloses Both Schizophrenia and Manic Depressive Psychoses

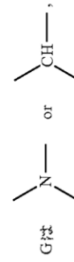
On the other hand, it has been known that the imide derivative of the following formula, which was found by the co-workers of the present inventors, may be useful as an antipsychotic (c.f., neuroleptic agent, anti-anxiety, etc.), especially as an agent for treatment of schizophrenia, senile insanity, manic depressive psychoses, and nervous breakdown (U.S. Pat. No. 5,532,372).



wherein Z is



D is a group of the formula:  $-(CH_2)_p-A-(CH_2)_q-$



etc., and  
Ar is an aromatic group, or an aromatic heterocyclic group,  
etc.

- Specification refers to both “manic depressive psychoses,” and schizophrenia
  - See IPR2020-01053 Ex. 1001 '827 Patent col. 2, ll. 5-10.
  - “Manic depressive psychoses” is understood by a person of skill to mean bipolar disorder
- See IPR2020-01053 Petition at 21.

# Weight Gain is a Known and Substantial Problem

## Weight Gain from Novel Antipsychotic Drugs: Need for Action

Alan L. Green, M.D.,<sup>1</sup> Jayendra K. Patel, M.D.,<sup>2</sup> Robert H. Cosman, M.D.,<sup>3</sup>  
David B. Clark, Ph.D.,<sup>4</sup> and George Balkestein, B.S.,<sup>1,2,3,4</sup>

**Introduction:** A rapid and increasing trend in the prevalence of obesity in the United States has been well documented. The prevalence of obesity in the United States has increased from 15% in 1975 to 35% in 2008. Obesity is a major risk factor for cardiovascular disease, type 2 diabetes, and other chronic diseases. The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue. The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue. The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue.

**Background:** The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue. The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue. The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue. The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue.

**Conclusion:** The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue. The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue. The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue. The prevalence of obesity in the United States is increasing rapidly, and this trend is expected to continue.

One untoward side effect of many antipsychotic drugs, especially the newer “novel” or “atypical” antipsychotics, is often-substantial weight gain [5–9]. Studies suggest that 40% to 80% of patients taking antipsychotic medication experience weight gain that exceeds ideal body weight by 20% or greater [10,11]. This noticeable and unwanted side effect may undermine compliance and thus predispose patients to relapse, in addition to increasing obesity-related comorbidities and health risks [5,11–13].

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POR at 12-13

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PDX-104

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