

UNITED STATES PATENT AND TRADEMARK OFFICE

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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'S SUR-REPLY**

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## I. INTRODUCTION

Sumitomo's Patent Owner Response carefully and meticulously sets forth how Slayback's arguments fundamentally failed to show that the '827 patent is not entitled to its priority date or that the patent claims are obvious. In its Reply, Slayback fails to address any of Sumitomo's arguments head on. Instead, Slayback:

- takes statements completely out of context;
- cherry picks data from the prior art in a failed attempt to support its obviousness position;
- inconsistently argues that Saji '372 is too broad to support priority, all the while relying on it for obviousness;
- illogically argues that Sumitomo waived certain positions by failing to respond to arguments that Slayback never made;
- outright fails to respond to both the facts and many of the arguments that Sumitomo made; and
- continues to ignore the complexity of atypical antipsychotics.

The reason for Slayback's approach is simple. As set forth below, it is clear to a person of skill in the art that the '827 patent is entitled to its priority date and that its claims are not obvious.

## II. THE '927 PROVISIONAL APPLICATION PROVIDES WRITTEN DESCRIPTION SUPPORT FOR THE MANIC DEPRESSIVE CLAIMS

Slayback fundamentally misunderstands and mischaracterizes the written description issue. Slayback repeatedly notes that the '927 provisional only mentions manic depressive psychosis in the background section and presents data only for schizophrenia.<sup>1</sup> In doing so, Slayback ignores evidence demonstrating how a POSA would interpret that disclosure. For example, at his deposition Dr. Stahl testified that a POSA would recognize that the claimed dosing regimen could treat manic depressive psychosis without weight gain on the basis of the schizophrenia data disclosed in the '927 provisional specification:

Q. Is there any mention in the '927 provisional application of no weight gain when treating manic depressive psychosis?

A. Yes.

Q. Where?

A. I don't know how many times we have to go through this, sir, because when you mentioned it first [sic] schizophrenia you are mentioning it for bipolar. People don't gain weight because they have schizophrenia. They gain weight because of some undetermined property of certain drugs. If you give the same drug that doesn't cause weight gain in A, it won't cause weight gain in B. There is nothing magic about schizophrenia that makes you gain weight on

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<sup>1</sup> Reply, 13-16.

antipsychotics as far as we know. Clearly you prefer to have certain things in certain places in certain explicit language certain ways, and maybe because it's not explicit you don't agree with me that these things are there, but I'm the POSA. I look at it. I see it.<sup>2</sup>

Dr. Stahl specifically explained how a person of ordinary skill would link the disclosure relating to schizophrenia with manic depressive psychosis because the conditions are *not* unrelated. Rather, both can include psychotic symptoms.<sup>3</sup> Psychotic symptoms, in turn, are the result of excess dopamine (“hyperdopaminergic”). Both conventional and atypical antipsychotics were known to treat schizophrenia and manic depressive psychosis by targeting the dopamine D<sub>2</sub> receptor.<sup>4</sup> Thus, a POSA, reading the '927 provisional application and '827 patent, would recognize that the claimed dosing regimen could treat psychoses generally, and schizophrenia and manic depressive psychosis specifically, without weight gain based on the data demonstrating successful treatment of schizophrenia without weight gain. As Dr. Stahl explained at his deposition:

Q. Is it your testimony that when the '827 patent says schizophrenia what it really means is schizophrenia or manic depressive psychosis?

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<sup>2</sup> Ex. 1054, 151:4-23.

<sup>3</sup> Ex. 2131, ¶¶ 37, 102; Ex. 2140.

<sup>4</sup> Ex. 2131, ¶ 102; Ex. 2140.

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