

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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IPR 2020-01053  
Patent 9,815,827 B2

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Record of Oral Hearing  
Held: August 11, 2021

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Before SUSAN L. C. MITCHELL, ZHENYU YANG, and  
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

IPR 2020-01053  
Patent 9,815,827 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

LOUIS H. WEINSTEIN, ESQUIRE  
Windels, Marx, Lane & Mittendorf, LLP  
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ON BEHALF OF PATENT OWNER:

CHAD SHEAR, ESQUIRE  
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The above-entitled matter came on for hearing on Wednesday, August 11, 2021, commencing at 1:00 p.m., EDT, at the U.S. Patent and Trademark Office, by video/by telephone, before Walter Murphy, Notary Public.

P R O C E E D I N G S

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1 JUDGE YANG: Good afternoon. This is a hearing for IPR 2020-  
2 01053. The challenged patent is 9,815,827. I am Judge Yang. Judges  
3 Mitchell and Sawert are also on the panel. Now counsel, please introduce  
4 yourselves. Let's start with Petitioner.

5 MR. WEINSTEIN: I am Louis Weinstein, Your Honor, from the law  
6 firm of Windels, Marx, Lane & Mittendorf. I represent Petitioner Slayback  
7 Pharma, LLC.

8 JUDGE YANG: Welcome. Patent Owner.

9 MR. SHEAR: Good afternoon everyone. My name is Chad Shear.  
10 I'm an attorney with Fish & Richardson and I represent Sumitomo  
11 Dainippon Pharma, SDP for short, the Patent Owner.

12 JUDGE YANG: Thank you and welcome everyone. Before we start  
13 the oral argument we will quickly go through a couple of housekeeping  
14 items. For today's hearing each party has 60 minutes to present its  
15 arguments starting with Petitioner, followed by Patent Owner. Both parties  
16 may, if you desire, reserve time for rebuttal. During your argument please  
17 clearly identify the record so the transcript is clear and so we can follow you  
18 because we are conducting this hearing remotely, we cannot see what you  
19 put on but we have the record including your demonstratives so if you  
20 identify what you are referring to clearly we'll be able to follow you.

21 For today's hearing, if you have any objection please do not interrupt  
22 the other side. Instead, if you could just hold it until the other side has  
23 finished the argument, that would be great. A very important point, please  
24 mute yourself and only unmute when you are talking. You also should have

1 contact number for the Board if you encounter any technical difficulties,  
2 please let us know ASAP. Lastly, after we're finished the oral argument the  
3 parties please stay on the line even though the panel will sign off, please stay  
4 on the line to help the court reporter with any spellings or any clarification,  
5 that sort of thing. Are there any questions? Okay. I take that silence as no.  
6 So then now Petitioner, would you like to reserve any time for rebuttal?

7 MR. WEINSTEIN: Yes, Your Honor. Petitioner would like to please  
8 reserve up to half its time for rebuttal.

9 JUDGE YANG: All right. That means you have 30 minutes now. I  
10 will keep time here on my phone. If you could try to keep time that would  
11 be great. All right. You may begin whenever you're ready.

12 MR. WEINSTEIN: If it please the Board, as the papers show -- well,  
13 let me introduce myself for the record. I'm Louis Weinstein from the law  
14 firm Windels, Marx, Lane & Mittendorf. I represent Petitioner Slayback  
15 Pharma, LLC.

16 As the papers show Petitioner asserts three grounds. Grounds 1 and 2  
17 are directed to the manic depressive claims and hinge on written description  
18 in the '927 provisional. Ground 3 is that all claims are obvious. Petitioner  
19 would like to start with several points on grounds 1 and 2 and then move on  
20 to ground 3.

21 For its first point, Petitioner would like to direct the Board to page 4  
22 of Petitioner's demonstrative exhibits, that's Exhibit 1057 and that's page 4.  
23 This page summarizes the elements of claim 8. Claim 8 is illustrative of the  
24 manic depressive claims. But even for claim 8 Patent Owner never went  
25 through the process of showing how the '927 provisional described the  
26 method with all these limitations. In fact, if Patent Owner had tried it would

1 have been very messy. This is because, if you look at Lurasidone and its salt  
2 is never mentioned in the context of manic depressive psychosis. Nowhere  
3 in the '927 provisional is Lurasidone mentioned in that context. Also 20 to  
4 120 milligrams per day is never explicitly recited as arranged in the '927  
5 provisional and the phrase "no clinically significant weight gain" is not  
6 explicitly recited. So it would have been very messy if they had tried to go  
7 element by element for illustrative claim 8 and perhaps that's why they did  
8 not do it.

9 Now Petitioner pointed out that Patent Owner, you know, had failed  
10 to do this and Patent Owner's response is at the bottom of page 3. That  
11 would be Petitioner demonstrative exhibit page 3 and if you look at the  
12 bottom, Patent Owner said in its surreply,

13 "It goes without saying that 'the claimed Lurasidone dosing regimen'  
14 means 'the claimed method with all limitations.'"

15 Your Honors, Petitioner submits that saying it goes without saying is  
16 not good enough. It was Patent Owner's burden to show written description  
17 of a method with all the limitations of the manic depressive claims and  
18 Patent Owner did not.

19 Petitioner would now like to go on to its next point and would like to  
20 say that the only mention of manic depressive psychosis in the '927  
21 provisional is a single passing reference in a complex field. Patent Owner  
22 admits that the field of anti-psychotic drugs is complex.

23 If we could please turn to page 6 of Petitioner's demonstrative  
24 exhibits. This comes right out of the '927 provisional and it shows the single  
25 reference to manic depressive psychosis in the entirety of the '927  
26 provisional and Petitioner notes that this one mention is in the background

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