

571-272-7822

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS, LLC, PAR  
PHARMACEUTICAL, INC., AND WOCKHARDT BIO AG,  
Petitioner,

v.

JAZZ PHARMACEUTICALS, INC.,  
Patent Owner.

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IPR2015-00545 (Patent 8,589,182 B1)  
IPR2015-00546 (Patent 7,765,106 B2)  
IPR2015-00547 (Patent 7,765,107 B2)  
IPR2015-00548 (Patent 7,895,059 B2)  
IPR2015-00551 (Patent 8,547,988 B1)  
IPR2015-00554 (Patent 7,668,730 B2)

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Held: April 19, 2016

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BEFORE: JACQUELINE WRIGHT BONILLA, BRIAN P.  
MURPHY, and JON B. TORNQUIST, Administrative Patent  
Judges.

The above-entitled matter came on for hearing on Tuesday, April  
19, 2016, commencing at 9:02 a.m., at the U.S. Patent and  
Trademark Office, 600 Dulany Street, Alexandria, Virginia.

Case IPR2015-00545  
Patent 8,589,182 B1

APPEARANCES:

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1           MR. CERRITO: Good morning, Your Honors. Francis  
2 Cerrito from Quinn Emanuel on behalf of Jazz. With me today is  
3 Frank Calvosa, Eric Stops, Evangeline Shih and Gabe Brier. We  
4 also have a corporate representative from Jazz, Jana Gold, with  
5 us.

6           JUDGE MURPHY: Welcome everyone. And thanks  
7 for arriving a little bit early. We are a little bit earlier than usual,  
8 but we do appreciate it because we have longer arguments today.

9           So according to our hearing order, each side has  
10 90 minutes. Mr. Berman, are petitioners going to split the  
11 argument in any way or are you going to be presenting? How do  
12 you want to work that?

13          MR. BERMAN: I will be presenting all of it, Your  
14 Honor. And I'll be using 30 minutes for my initial presentation  
15 and 60 minutes for rebuttal.

16          JUDGE MURPHY: Okay. So we have you on the  
17 clock here, Mr. Berman. If you run over, that's fine. You'll just  
18 reduce your rebuttal time. Mr. Cerrito, you'll have 90 minutes, no  
19 rebuttal time.

20          I remind everyone that petitioners bear the ultimate  
21 burden of proof based on the preponderance of the evidence of  
22 their assertions upon patentability. I also remind the parties that  
23 this is a public hearing. We will have a transcript. We have a  
24 reporter up front. So please be mindful of that in terms of citing  
25 exhibits in the demonstratives. And if you are quoting from the

1 patent or other evidence, just take your time so we can get it all  
2 down and keep a clear record.

3 If there are no questions, Mr. Berman, please begin.

4 MR. BERMAN: Thank you, Your Honor. Good  
5 morning, Your Honors. Your Honors, here the patentees told the  
6 public about their restricted drug distribution system for Xyrem  
7 then tried to patent it a year and a half later, but you can't do that  
8 under U.S. law. The documents disclosed to the public,  
9 Exhibits 1003 through 1006, known collectively as the Advisory  
10 Committee Act or the ACA, render the six patents at issue here  
11 obvious.

12 Today I will be focusing on the following topics: The  
13 public availability of the ACA, claim construction and  
14 obviousness.

15 First the public availability issue. Jazz argues the  
16 petitioners have failed to prove the materials provided to the  
17 advisory committee, Exhibits 1003 through 1006, were publicly  
18 available prior to the critical date of December 17, 2001. Now, it  
19 is true that petitioners do not have eyewitness testimony that  
20 these briefing materials were posted on the FDA's website by the  
21 June 6, 2001, Xyrem advisory committee meeting. But it's well  
22 settled that that's not necessary. Here the totality of the evidence,  
23 which is the standard, easily shows that it's more likely than not  
24 that the briefing materials were posted in advance of the meeting.  
25 So let's go through this evidence.

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