

571-272-7822

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

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)

Held: April 19, 2016

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

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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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