

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICAL LLC and AMNEAL  
PHARMACEUTICALS OF NEW YORK, LLC,  
Petitioner,

v.

ALLERGAN, INC.,  
Patent Owner.

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Appeal IPR2018-00608  
Patent 9,161,926 B2

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Record of Oral Hearing  
Held June 5, 2019

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Before GRACE KARAFFA OBERMANN, SHERIDAN K. SNEDDEN,  
and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

IPR2018-00608  
Patent 9,161,926 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

DENNIES VARUGHESE, ESQUIRE  
ADAM LAROCK, ESQUIRE  
Sterne Kessler Goldstein & Fox  
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ON BEHALF OF THE PATENT OWNER:

JAMES TRAINOR, ESQUIRE  
ELIZABETH HAGAN, ESQUIRE  
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New York, NY 10010-6035

The above-entitled matter came on for hearing on Monday, June 5, 2019, commencing at 9:59 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

1 PROCEEDINGS

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6 JUDGE SNEDDEN: Please be seated. Good morning. This is the  
7 final hearing in IPR 2018-00608. I'm Judge Snedden. I have with me Judge  
8 Paulraj and Judge Obermann with me on the panel today. I'll begin by  
9 stating that we have received Petition Owner's objections to Patent Owner's  
10 demonstratives, and we understand that Patent Owner untimely served their  
11 demonstratives on May 27th, Memorial Day, and not May 24th, the Friday  
12 before Memorial Day; and we have considered that issue and determined  
13 that under the circumstances it would be not in the interest of justice to not  
14 allow Patent Owner access to its slides today. Although Petitioner objects,  
15 they raise no persuasive reasons that outweigh the interest of justice in  
16 providing Patent Owner the ability to refer to their demonstratives today.

17 Okay, with that let's move on to appearances starting with Petitioner.  
18 Please stand; introduce yourself; and who you have with you today.

19 MR. VARUGHESE: Good morning, Your Honors. If it pleases the  
20 Board, my name is Dennies Varughese from the law firm of Sterne Kessler  
21 Goldstein & Fox. Joining me today is my colleague, Adam LaRock, also  
22 from the Sterne Kessler law firm on behalf of Petitioner, Amneal.

23 JUDGE SNEDDEN: Can you pronounce your name one more time?

24 MR. VARUGHESE: Dennies Varughese.

25 JUDGE SNEDDEN: Thank you, Mr. Varughese.

26 MR. VARUGHESE: Thank you.

1 MR. TRAINOR: Good morning, Your Honors. James Trainor of the  
2 law firm of Fenwick & West here on behalf of the Patent Owner, Almirall.  
3 With me today is my colleague Elizabeth Hagan also from Fenwick & West.

4 JUDGE SNEDDEN: Per our order granting this oral hearing, each  
5 party will have 60 minutes of total time to present its arguments. Petitioner  
6 will open the hearing by presenting its case regarding the challenged claims  
7 for which we institute a trial; and Patent Owner will then respond to  
8 Petitioner's argument. Each side may reserve time for rebuttal. Patent  
9 Owner is limited to five minutes of rebuttal time.

10 Okay, Mr. Varughese, you may begin when you're ready. Are you reserving  
11 any time for rebuttal?

12 MR. VARUGHESE: Yes, Your Honor, I'd like to reserve 20 minutes  
13 for rebuttal.

14 JUDGE SNEDDEN: You may begin when you're ready.

15 MR. VARUGHESE: Good morning, Your Honors. Once again, if it  
16 pleases the Board, my name is Dennies Varughese from Sterne Kessler  
17 Goldstein & Fox here on behalf of Petitioners, Amneal Pharmaceuticals  
18 LLC and Amneal Pharmaceuticals of New York, LLC.

19 Your Honors, we brought with us printed copies of the  
20 demonstratives. If it pleases the Board, we're happy to hand them out to  
21 you.

22 JUDGE SNEDDEN: I'll take one; thank you.

23 MR. VARUGHESE: If it pleases the Board, so that we have a clear  
24 record, I'm going to call out each slide number before we flip to it, unless the  
25 Board has some type of rejection to that -- slide 2. Your Honors, the parties  
26 have submitted an extensive record comprising briefing, and exhibits, and

1 declaration of experts that we believe demonstrate, overwhelmingly, the  
2 obviousness of the challenged claims -- claims 1 to 6 in the '926 Patent.

3 It's certainly not my intention to rehash every single one of those  
4 points, but, rather, what I intended to do today is to provide the Board with  
5 an overview of the key points that demonstrate obviousness.

6 In terms of an overview of my presentation, we're going to start with a  
7 quick overview of the claims themselves; and then we're going to begin by  
8 talking about Almirall's claim construction argument. As I'm going to  
9 discuss in just a few minutes, we think this argument is really a red herring,  
10 there's no dispute. Amneal does not dispute what dapsone means; and we'll  
11 talk about that. And then we're going to dive right into the two separate and  
12 independent grounds that Amneal put forward to demonstrate that claims 1  
13 to 6 are obvious.

14 Ground one is that the claims are obvious over the Garrett reference in  
15 view of Nadu-Fourcade; and ground two is that those same claims are  
16 obvious over, again, the Garrett reference in view of Bonacucina. After an  
17 overview of the grounds themselves and the strong *prima facie* case that  
18 Amneal's put forward, I'd like to spend some time addressing what we  
19 believe to be a number of ineffective, unpersuasive, and legally and factually  
20 flawed arguments that Almirall has advanced in trying to save its claims  
21 from obviousness.

22 And a quick point, I think, it's noteworthy right now -- as this Board  
23 and counsel for parties is well aware, there's an oft-quoted passage from  
24 federal circuit jurisprudence that says that oftentimes objective indicia or  
25 evidence of secondary considerations, so-called real-world evidence is often  
26 the most cogent or probative evidence of non-obviousness. I think it's

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