

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC, AMNEAL  
PHARMACEUTICALS OF NEW YORK, LLC, and MYLAN  
PHARMACEUTICALS INC.,  
Petitioners

v.

ALMIRALL, LLC,  
Patent Owner.

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Case IPR 2019-00207  
Patent 9,517,219 B2

RECORD OF ORAL HEARING  
Oral Hearing Held: February 7, 2020

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Before SUSAN L. C. MITCHELL, CHRISTOPHER G. PAULRAJ,  
and RYAN H. FLAX, *Administrative Patent Judges*.

Case IPR 2019-00207  
Patent 9,517,219 B2

APPEARANCES:

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The above-entitled matter came on for hearing on Friday, February 7, 2020, commencing at 1:00 p.m. at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia

P-R-O-C-E-E-D-I-N-G-S

1:01 p.m.

JUDGE FLAX: Okay. Good afternoon, everybody.

MR. VARUGHESE: Good afternoon, Your Honor.

JUDGE FLAX: I'm Judge Flax and we are here with Judge Mitchell and Judge Paulraj.

We are here today for IPR 2019-00207, and to that has been joined IPR 2019-01095.

If you all are not here for those, you are in the wrong room.

I know that we've got a lot of issues to deal with today, the first of which, I know that someone intends to show some confidential information, or discuss confidential information during the hearing. Is that still accurate?

MR. VARUGHESE: Good afternoon, Your Honor. Dennis Varughese for Petitioner Amneal. The confidential information, I think, implicated a deposition transcript of Inventor Warner that we received a few weeks ago.

We included some flagged demonstratives in our demonstrative kit, but we are happy to rest on our supplemental briefing and not delve into any of that at this public hearing, if that resolves the issue.

JUDGE FLAX: Well, I won't tell you what to do, of course, that would probably be the easiest way to do it. We wouldn't have to decide who stays in the room and who doesn't stay in the room. So --

MR. VARUGHESE: We're happy to do that.

JUDGE FLAX: -- if that is how you want to do it, that is fine. All right, then, if everyone is ready we can begin.

1           So, we'll start with Petitioner's case. Each side is going to  
2 have an hour to make their arguments. But when you get up and  
3 introduce yourself you can let me know if you want to reserve some  
4 time for rebuttal afterwards.

5           So, that being said, if Petitioner's case wants to proceed --  
6 when you are ready.

7           MR. VARUGHESE: Good afternoon, Your Honors. If it  
8 pleases the Board, my name is, once again, Dennies Varughese, from  
9 the law firm of Sterne, Kessler, Goldstein and Fox and we represent  
10 Petitioner.

11           Joining me today is Adam LaRock and Tyler Liu, also of  
12 Sterne Kessler. And the client representative, Mr. Bryan Sonmese, is  
13 here from Amneal.

14           MR. MALIK: Your Honor, also, I'm Jitendra Malik. I'm  
15 counsel for Amneal.

16           JUDGE FLAX: And sir, do you want to reserve any time for  
17 rebuttal?

18           MR. VARUGHESE: Yes. I would like to reserve 15 minutes  
19 for rebuttal, Your Honor.

20           JUDGE FLAX: Okay.

21           MR. VARUGHESE: Slide 2.

22           Your Honors, both sides have submitted a voluminous record  
23 for the Board to consider and it's certainly not my intention to go over  
24 every single point of our case. But in terms of a quick overview, I'd  
25 like to discuss the three references that form the basis of both of the  
26 grounds: the Garrett Reference, Nadau-Fourcade, and Bonacucina,  
27 and discuss where each and every limitation of the claims is disclosed  
28 in those references and then spend a few minutes addressing some of

1 the arguments that Almirall has put forward here in trying to rebut  
2 what we believe is a strong prima facie case and then conclude by  
3 discussing the relevant objective indicia and how they don't apply here  
4 to save the patent from the prima facie case.

5 Slide 4.

6 Your Honor --

7 JUDGE FLAX: Could I ask you a quick question before you -  
8 - we get into it?

9 MR. VARUGHESE: Yes.

10 JUDGE FLAX: Are the definitions between the parties of the  
11 person of ordinary skill in the art the same, or are they not the same,  
12 and are they being argued today?

13 MR. VARUGHESE: To my knowledge, Your Honor, I don't  
14 think we have disputed the level of skill or whether, to the extent there  
15 is any minor differences, whether they impact case, that's our  
16 approach. I was not intending to argue that today.

17 JUDGE FLAX: Okay.

18 MR. VARUGHESE: So, on Slide 4, the '219 Patent contains  
19 eight claims -- two independent claims that are nearly identical.

20 So, this is Claim 1, and I don't think there is a dispute. The  
21 Parties have been operating as if all claims rise and fall together.  
22 There has been no special arguments put forward for any of the  
23 claims.

24 Claim 1 recites a method of treating a dermatological  
25 condition consisting of acne and rosacea. Using a formulation that  
26 contains about seven and a half percent of dapson, about 30 to 40  
27 percent of a solvent known as DGME --

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