

1           IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
2                   BEFORE THE PATENT TRIAL AND APPEAL BOARD

3  
4    AMNEAL PHARMACEUTICALS, LLC,            )  
      and AMNEAL PHARMACEUTICALS OF        ) IPR2018-00608  
5    NEW YORK, LLC,                            ) Patent No.  
  ) 9,161,926  
6    Petitioners,    )  
  )  
7    vs.                                        )  
  )  
8    ALMIRALL, LLC,                            )  
  )  
9    Patent Owner. )  
  )  

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14           DEPOSITION OF ALEXANDER M. KLIBANOV, PH.D.  
15                   San Diego, California  
16                   Wednesday, March 13, 2019

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24    Stenographically reported by:  
      Tricia Rosate, RDR, RMR, CRR, CCRR  
      CSR No. 10891  
25    Job No. 156070

Wednesday, March 13, 2019  
8:58 a.m.

DEPOSITION OF ALEXANDER M. KLIBANOV, PH.D.,  
taken at Regus, 350 Tenth Avenue, Suite 1000, San Diego,  
California, commencing at 8:58 a.m. and concluding at  
1:20 p.m., Wednesday, March 13, 2019, before  
Tricia Rosate, RDR, RMR, CRR, CCRR, CSR 10891,  
a Certified Shorthand Reporter.

**A P P E A R A N C E S:**

For the Petitioners:  
STERNE, KESSLER, GOLDSTEIN & FOX  
1100 New York Avenue  
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BY: DENNIES VARUGHESE, Pharm.D.  
ADAM LaROCK, ESQ.

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BY: ELIZABETH HAGAN, PH.D.

I N D E X		
WITNESS: Alexander M. Klibanov, Ph.D.		
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E X H I B I T S		
EXHIBIT	DESCRIPTION	PAGE
Exhibit 1001	United States Patent No. 9,161,926	42
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SAN DIEGO, CALIFORNIA; WEDNESDAY, MARCH 13, 2019  
8:58 A.M. - 1:20 P.M.

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ALEXANDER M. KLIBANOV, PH.D.,  
having been first duly sworn, testified as follows:

EXAMINATION

BY MR. VARUGHESE:

Q. Good morning, Dr. Klibanov.

A. Good morning, Mr. Varughese.

Q. Can you state your name for the record, your full name.

A. Alexander M. Klibanov, K-l-i-b-a-n-o-v.

Q. And have you testified before in deposition?

A. Yes.

Q. About how many times?

A. Quite a few times.

Q. Would you say more than ten?

A. Over what period of time?

Q. Your career.

A. Yes.

Q. More than 20?

A. Yes.

Q. More than 30?

A. I'm not sure.

Q. Fair to say between 20 and 30, roughly?

1 A. May be fair. I don't know how accurate it is.

2 Q. Of those cases, how many were patent cases?

3 A. All.

4 Q. How many times have you testified at trial,  
5 would you say?

6 A. Over what period of time?

7 Q. Your career.

8 A. I would say maybe between a dozen and two dozen  
9 times.

10 Q. Okay. So you're generally familiar with the  
11 process of a deposition. I'll ask you questions. You'll  
12 let me finish asking the questions. You'll answer the  
13 questions. If you don't understand the questions, you'll  
14 ask me for clarification?

15 A. Well, I -- what you just said sort of seems  
16 inherently unfair because you said that I'll let you  
17 finish your question, but you didn't say that you'll let  
18 me finish my answer.

19 Q. I didn't say I wouldn't let you finish the  
20 answer, either.

21 A. But if you found it necessary to say that I'll  
22 let you finish your answer -- your question, then it  
23 seems reasonable for you to say that you'll let me finish  
24 my answer.

25 Q. I think that sounds reasonable. So it looks

1 A. I'll be flattered.

2 Q. Okay. Please proceed.

3 A. So, as I said, it's basically one error, which  
4 unfortunately was repeated several times, and the error  
5 itself is that it says "comprising"; whereas, in fact, it  
6 should have said "consisting of."

7 In one instance, which I will specifically  
8 denote, it's actually "comprise," which actually should  
9 have been "consists of."

10 And this clerical error is made in the following  
11 places in my declaration. First there's page 9 -- and  
12 so, as I state them, I will also correct them in the copy  
13 of the declaration that I have in front of me.

14 So the first one is page 9, paragraph 14, third  
15 bullet point on that page, second line. So instead of  
16 "comprising," it should be "consisting of."

17 The second is page 61, paragraph 137, third  
18 bullet point, second line. Again, same clerical error,  
19 "consisting of" should be instead of "comprising."

20 Next one is -- next page is page 79 --

21 Q. Hang on. Before you move on --

22 Thank you. Go ahead.

23 A. The next one is then page 79, title of the  
24 subsection there. It's subsection 3, the second line.  
25 Again, instead of "comprising," it should have been

1 like you and I are both two reasonable guys here today,  
2 huh?

3 A. I can only speak for myself.

4 Q. Okay.

5 MR. VARUGHESE: Can I get a copy of the  
6 declaration?

7 Q. Dr. Klibanov, I'm going to mark -- or I'm going  
8 to hand you what's been marked as Almirall Exhibit 2003.

9 A. Thank you.

10 (Exhibit 2003 was referenced.)

11 BY MR. VARUGHESE:

12 Q. Do you recognize this document?

13 A. It seems to be a copy of my IPR declaration  
14 minus the exhibits and attachments. And so, before you  
15 continue, let me just say that there is a clerical error  
16 that I found in my declaration in preparation for my  
17 deposition, a clerical error that unfortunately is  
18 repeated several times, for which I apologize, and I'd  
19 like to correct this clerical error for the record before  
20 we proceed with the deposition.

21 Q. Sure. Please.

22 Before you start, Dr. Klibanov, I just want to  
23 note for the record that you took out a piece of paper  
24 that looks like you have some notes on it. I'm going to  
25 ask that that be marked at this deposition.

1 "consisting of."

2 Next one on the same page, page 79,  
3 paragraph 170, both in the first and the third lines.  
4 Instead of "comprising," it should be "consisting of."

5 Next one is page 80, paragraph 171. In the  
6 first line, it says "comprise," which should be "consists  
7 of" -- "consist of."

8 And in the third line, instead of "comprising,"  
9 it should be "consisting of."

10 Next one is page 82, paragraph 176. It's the  
11 sixth line. Again, instead of "comprising," it should be  
12 "consisting of."

13 The next line is -- and that's the last page  
14 where this clerical error has been made. It's page 91.  
15 First of all, the title of subsection 3, instead of  
16 "comprising," "consisting of."

17 Also paragraph 195, the third line, instead of  
18 "comprising," "consisting of."

19 And, finally, paragraph 196, third line, instead  
20 of "comprising," again, "consisting of."

21 So that's all. And I apologize for this  
22 clerical error, and I am pleased to hand over to you the  
23 notes that I made for myself.

24 MR. LaROCK: That will be AMN1051.

25 (Exhibit AMN1051 was marked for identification.)

1 BY MR. VARUGHESE:

2 Q. Thank you for that, Dr. Klibanov.

3 Is there any other errors that you wish to  
4 correct in your declaration?

5 A. Well, first of all, I don't view those as  
6 errors. I think it's one clerical error that  
7 unfortunately was repeated several times.

8 And, second of all, the answer to your question  
9 is no.

10 Q. When did you -- strike that.

11 I'm going to refer to it as an error. Do you  
12 want me to call it something else? Is it an error?

13 A. I would like to call it a clerical error.

14 Q. Okay. When did you become aware of this  
15 clerical error?

16 A. When I started preparing for this deposition the  
17 other day.

18 Q. Do you remember which day?

19 A. I believe it was -- so today is Wednesday, so  
20 that was Monday.

21 Q. Was it brought to your attention by an attorney  
22 or anyone else?

23 A. No. I discovered it myself, and then yesterday,  
24 when I was preparing for this deposition with Dr. Hagan  
25 here, I mentioned it to her.

1 A. Well, there are nine bullet points. In some of  
2 those places, it was actually more than once.

3 Q. So more than nine. Yes?

4 A. I mean, I just said that there are nine places  
5 where -- nine pages where this clerical error is made  
6 and, in some of them, more than once.

7 Q. So more than nine instances, that clerical error  
8 appears in your declaration; correct?

9 A. Correct.

10 Q. Let's turn to page 13 of your declaration.

11 A. Just a second. I'm looking at the bottom of the  
12 page, and there are two sets of numbers. There is one  
13 number that was actually my number that I put there, and  
14 then there's another one that says, for example, "7 of  
15 108." So when you refer to page number, what number do  
16 you refer to?

17 Q. Fair enough. Thanks for that. I'm going to be  
18 referring to what you called your number, which, for the  
19 record, will be the number on top.

20 So there are two numbers. The bottom number is  
21 what we're going to call the Bates number, and the top  
22 number is what we're going to refer to as your number.  
23 So I'll be referring to your number unless I say  
24 otherwise.

25 A. So, actually, they are both at the bottom of the

1 Q. And who wrote these errors in the first -- these  
2 clerical errors in the first place? Was that you, or was  
3 it somebody else?

4 A. I'm not sure I understand the question.

5 Q. What part don't you understand?

6 A. You said, "Who wrote these errors?" And it just  
7 doesn't make sense to me.

8 Q. Someone wrote the declaration; right?

9 A. I wrote my declaration. Yes.

10 Q. So you typed up every word of this declaration?

11 A. No. I typed many words of this declaration.  
12 Some others, I dictated or explained what I want stated.

13 Q. Okay. Did anyone else type or dictate any part  
14 of this declaration?

15 A. I presume that a secretary in the law firm did  
16 some typing because, as I said, I only typed portions of  
17 this declaration. But whoever typed whatever portion,  
18 it's my responsibility, and that's why I sincerely  
19 apologize for that.

20 Q. And so these nine clerical errors, did you type  
21 or dictate those errors, or did somebody else?

22 A. There's no nine clerical errors. There is one  
23 clerical error that was repeated several times. And I  
24 don't remember the exact nitty-gritty of that.

25 Q. Repeated nine times; correct?

1 page, but one is higher than the other; right?

2 Q. Correct.

3 A. Okay.

4 Q. Yeah.

5 A. So page 9?

6 Q. Page 13.

7 A. Oh, 13. I'm sorry.

8 Q. No problem.

9 So, specifically, I want to draw your attention  
10 to the remainder of paragraph 27 in your declaration.

11 You see the very first line. There's a phrase  
12 there. It says "wherein the composition does not  
13 comprise adapalene"? Do you see that?

14 A. Yes.

15 Q. So is this the last part of claim 1 of the '926  
16 patent?

17 A. Yes, that is the end of claim 1 of the '926  
18 patent.

19 Q. And would you agree if I were to say that that's  
20 the last limitation of claim 1 of the '926 patent?

21 A. So where the last limitation starts with the  
22 word "wherein"?

23 Q. Correct.

24 A. I mean, again, I'm not an attorney or a legal  
25 expert, but it seems reasonable to me.

1 Q. Okay. That last limitation -- and I'm going to  
2 repeat it for the record -- "wherein the composition does  
3 not comprise adapalene," what does that limitation mean  
4 to you?

5 A. That the claim composition doesn't comprise  
6 adapalene.

7 Q. So would that be adapalene and dapsone in a  
8 single formulation, that the claimed composition does not  
9 have both of those actives in a single formulation?

10 A. I'm sorry. I don't understand the question.

11 Q. What part don't you understand?

12 A. The question makes no sense to me.

13 Q. Well, help me help you understand. So tell me  
14 what doesn't -- what you don't understand about it.

15 A. If I don't understand something, I don't know  
16 what it means. So, I mean, I can't help you because I  
17 don't know what it is that you want to ask me. It  
18 specifically says "wherein the composition does not  
19 comprise adapalene." So it means that the claim  
20 composition does not comprise adapalene. I think it's  
21 crystal clear.

22 Q. So, Dr. Klibanov, I just want to be very up  
23 front with you. We have a limited amount of time for  
24 this deposition. I'm going to be asking you quite a bit  
25 of complicated questions. If you're going to simply say

1 you don't know to a bunch of them and we're going to use  
2 up all our time, we're going to ask the board to bring  
3 you back for a second deposition or we may call the board  
4 today.

5 So it's up to you. I'm not here to play any  
6 word games with you. I'm going to use plain English. If  
7 there's a part of my question you don't understand,  
8 please let me know what part of that you don't  
9 understand. Is that okay?

10 A. Okay. Let me say, first of all, you don't need  
11 to threaten me.

12 Second of all, I'm not afraid of your threats.  
13 We'll spend whatever time we have here. My objective --  
14 since I, in contrast to you, am under oath here, my  
15 objective is to give the best -- the most precise answers  
16 I can, and we will spend whatever time we need, whether  
17 it's today or subsequently.

18 If I don't understand the question and the  
19 question doesn't make sense to me, I don't know how to  
20 explain to you what it is about the question that I don't  
21 understand. As I already said, it doesn't make sense to  
22 me. And I'm not playing word games with me [as said].  
23 I'm sure you will not be playing word games with me.

24 Q. So, Dr. Klibanov, I wasn't making threats. I  
25 was putting you on notice, and it appears that you

1 understand my notice; that, if you do waste our time  
2 here, we will bring you back here again for a second  
3 deposition, and we will let the board decide whether you  
4 are being reasonable or not.

5 A. Okay. And I resent the statement that I'm  
6 wasting anybody's time. I think you are actually wasting  
7 time now by arguing about things that are not worth  
8 arguing about.

9 Q. So let's go back to my question.

10 The word "composition," do you have an  
11 understand whether that's talking about a single  
12 formulation or not?

13 A. It refers to what was in line 1 of claim 1,  
14 where it says "A topical pharmaceutical composition  
15 comprising:" and then it says, again, the limitation that  
16 we're discussing now "wherein the composition."

17 So that's that same composition that mentioned  
18 in the first line of the claim.

19 Q. So I'm going to ask my question again.

20 Does the word "composition" in claim 1, to you,  
21 mean a single formulation?

22 MS. HAGAN: Objection. Asked and answered.

23 THE WITNESS: I mean, to me, the word  
24 "composition" in this claim, and typically in general, is  
25 synonymous with the word "formulation." So we're talking

1 about this particular -- composition of this particular  
2 formulation.

3 BY MR. VARUGHESE:

4 Q. Okay. So let's say there's a formulation that  
5 has dapsone as the only active ingredient. Would that  
6 meet that limitation, in your opinion?

7 MS. HAGAN: Objection. Vague.

8 THE WITNESS: So it contains dapsone as the sole  
9 active pharmaceutical ingredient, and it also contains  
10 the excipients that are listed in claim 1, but it does  
11 not contain adapalene.

12 Is that the question?

13 BY MR. VARUGHESE:

14 Q. No.

15 My question was: Let's say we have a  
16 pharmaceutical formulation that has dapsone as the only  
17 active ingredient. Would that meet that limitation?

18 A. But it can also contain excipients; correct?

19 Q. Sure.

20 A. Well, as I just said, if it contains dapsone as  
21 the only active ingredient and it also contains the  
22 excipients that are listed, then it will meet this  
23 limitation because it clearly will not comprise  
24 adapalene.

25 Q. So let's say we have a formulation that has

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