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1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF NEW YORK

3 KOWA PHARMACEUTICALS AMERICA, INC., et al.,

4 Plaintiffs,

5 v.

14 Civ. 2758 (PAC)  
14 Civ. 5575 (PAC)  
14 Civ. 7934 (PAC)  
15 Civ. 3935 (PAC)

6 AMNEAL PHARMAEUTICALS, LLC, et al.,

7 Defendants.

8  
9  
10 New York, N.Y.  
11 January 30, 2017  
12 9:30 a.m.

13 Before:

14 HON. PAUL A. CROTTY,

15 District Judge

16 APPEARANCES

17 MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO, P.C.  
18 Attorneys for Plaintiffs Kowa and Nissan

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20 DAVID G. CONLIN  
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Attorneys for Defendant Sawai

BY: MICHAEL DZWONCZKY AZY S. KOKABI

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APPEARANCES  
(Continued)

KELLEY DRYE & WARREN, LLP  
Attorneys for Defendant Lupin  
BY: DOUGLASS C. HOCHSTETLER  
CONSTANTINE KOUTSOUBAS

ALSO PRESENT:

ANDY CEPREGI, technician  
GEOFF ROBERTS, technician  
BRIAN SPARKS, technician

H1UsKOW1

1 (Trial resumed; in open court)

2 THE COURT: Good morning. Dr. Byrn is going to  
3 testify, is that right?

4 MR. CONLIN: Yes, your Honor.

5 THE COURT: With regard to Mr. Maddox's letter of  
6 January 26, the response of January 29; the letters of  
7 January 28 and the response of January 29 dealing with PTX 735,  
8 14B, and 74, the objection is sustained.

9 Call Dr. Byrn.

10 MR. MADDOX: Your Honor, just a quick question with  
11 respect to demonstratives for Dr. Byrn.

12 We have objected to several because they contain --  
13 you talked about those exhibits.

14 THE COURT: When we get to them, we will take them.

15 MR. MADDOX: Thank you.

16 THE COURT: Come on up, Dr. Byrn.

17 Dr. Byrn, you have been in the courtroom throughout  
18 the proceeding, haven't you?

19 THE WITNESS: Yes.

20 THE COURT: Let me remind you, you're still under  
21 oath. We are not going to swear you again.

22 THE WITNESS: OK.

23 STEPHEN R. BYRN, resumed.

24 THE COURT: Mr. Bauer.

25 MR. BAUER: Good morning, your Honor.

H1UsKOW1

Byrn - direct

1 DIRECT EXAMINATION

2 BY MR. BAUER:

3 Q. Good morning, Dr. Byrn.

4 A. Good morning.

5 MR. BAUER: Your Honor, we previously heard from  
6 Dr. Byrn in terms of his qualifications. I would like, with  
7 the court's permission, to just read in Mr. Byrn's  
8 qualifications as an expert to see if there is any objection.

9 THE COURT: Mr. Maddox, do you have any objection?

10 He's already been qualified as an expert. He's filed  
11 expert reports.

12 He's an expert, isn't he?

13 MR. MADDOX: Absolutely.

14 THE COURT: He is qualified as an excerpt. Prior  
15 qualification is good enough for this particular episode as  
16 well.

17 MR. BAUER: He's an expert in solid state chemistry,  
18 drug formulation, and manufacture of composition of  
19 pharmaceutical drug products.

20 THE COURT: OK.

21 BY MR. BAUER:

22 Q. Dr. Byrn, you have been here for the past two weeks and you  
23 have listened to all the testimony and seen the exhibits in the  
24 case?

25 A. Yes.

H1UsKOW1

Byrn - direct

1 Q. And have you rendered an opinion in this case concerning  
2 the validity of the '993 claims?

3 A. Yes.

4 Q. Based on evidence that you've seen in this case and the  
5 testimony that you've heard, has anything changed your opinion?

6 A. No. I still believe that the '993 patent is valid.

7 Q. For the court, could you please summarize the bases for the  
8 reasons that you believe that the claims of the '993 patent are  
9 valid?

10 A. Yes. I've got --

11 Q. And could you go to slide two, please.

12 A. So, first, form A, claims 1 and 22 to 25, are  
13 non-anticipated. That's still my opinion, and this is because  
14 there's insufficient information in the EP '406 and example  
15 three, and I'll describe that.

16 And second, that a person of skill could get -- and  
17 this is a key element -- could get different polymorphic forms  
18 of pitavastatin calcium following example three of the '406.  
19 That means that example three doesn't necessarily inevitably  
20 produce form A.

21 Q. And with respect to obviousness, Dr. Byrn?

22 A. And then for obviousness, form A of claims 1 and 22 to 25  
23 are not obvious.

24 In my opinion, the defendants' position is based on  
25 hindsight and that polymorphs are not at all predictable. And

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