IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd., Plaintiffs, v. Amneal Pharmaceuticals, LLC Defendant.	)	Civil Action No. 14-CV-2758 (PAC)

AMNEAL'S PROPOSED FINDINGS AND CONCLUSIONS OF LAW [REDACTED] RE:

AMNEAL'S NON-INFRINGEMENT OF THE '993 PATENT

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1. Plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. ("Plaintiffs") allege that Amneal Pharmaceuticals, LLC ("Amneal") infringes claims 1 and 22–25 of U.S. Patent No. 8,557,993 ("the '993 patent"), by the filing of Amneal's Abbreviated New Drug Application ("ANDA") No. 205961.

2. As an initial matter, Plaintiffs cannot meet their burden to prove infringement because they refused to produce their infringement expert Dr. James Kaduk for deposition by Amneal before trial. The Federal Rules of course explicitly provide that "[a] party may depose any person who has been identified as an expert whose opinions may be presented at trial." Fed. R. Civ. P. 26(b)(4)(A). The consequence of Plaintiffs' refusal of Amneal's deposition of Dr. Kaduk must be that his opinions cannot be presented at trial. Thus, Plaintiffs fail to prove infringement against Amneal without even reaching the merits of their claims.

3. Even if Dr. Kaduk is permitted to testify against Amneal at trial, for the reasons set forth below, Plaintiffs have failed to prove that Amneal's ANDA product will infringe any asserted claim, either literally or under the doctrine of equivalents. The opinions and evidence in Dr. Kaduk's expert reports (as to which Amneal was refused a deposition) are legally insufficient.

I. The '993 Patent and Asserted Claims

4. The '993 patent issued on October 15, 2013, from Application No. 13/664,498, which was filed on October 31, 2012. (DTX-1307, the '993 patent (MYLAN(Pitav) 009836–55).) The earliest date to which the '993 patent claims priority is February 12, 2003. (*Id.*)

A. The Asserted Claims

5. Claims 1 and 22–25 of the '993 patent are asserted against Amneal. These claims are directed to specific polymorphs of pitavastatin hemicalcium limited by either a characteristic

set of X-ray powder diffraction peaks (*i.e.*, corresponding 2θ values and relative intensities), or by the depiction of one or more particular diffractograms.[1]

6. Asserted claims 1 and 22–25 are reproduced below:

Claim 1:

> A crystalline polymorph A, B, C, D, E, F, or the amorphous form, of (3R,5S)-7-[2-cyclopropyl-4-(4-fluorophenye)quinolin-3-yl]-3,5-dihydroxy-6(E)-heptenoic acid hemicalcium salt wherein
>
> A) polymorph A exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in 2θ at 5.0 (s), 6.8 (s), 9.1 (s), 10.0 (w), 10.5 (m), 11.0 (m), 13.3 (vw), 13.7 (s), 14.0 (w), 14.7 (w), 15.9 (vw), 16.9 (w), 17.1 (vw), 18.4 (m), 19.1 (w), 20.8 (vs), 21.1 (m), 21.6 (m), 22.9 (m), 23.7 (m), 24.2 (s), 25.2 (w), 27.1 (m), 29.6 (vw), 30.2 (w), 34.0 (w);
>
> B) polymorph B exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in 2θ at 4.6 (w), 5.3 (vs), 6.2 (s), 7.7 (s), 9.2 (m), 9.6 (m), 10.3 (w), 11.3 (m), 11.7 (w), 12.6 (vw), 13.0 (w), 13.9 (m), 14.7 (vw), 14.9 (w), 15.6 (w), 16.3 (m), 17.0 (vw), 17.4 (vw), 18.0 (w), 18.7 (m), 19.3 (m), 20.0 (s), 20.5 (w), 20.8 (m), 21.2 (w, shoulder), 21.5 (m), 22.4 (m), 23.2 (s), 23.8 (m), 24.4 (vw), 25.2 (w, broad), 26.0 (w), 26.4 (vw), 27.0 (w), 27.9 (vw), 28.9 (w);
>
> C) polymorph C exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in 2θ at 4.1 (m), 5.6 (s), 7.8 (m), 8.3 (m), 10.3 (m), 11.6 (w), 17.5 (w), 17.9 (w),18.7 (m), 19.5 (s), 20.6 (m), 21.5 (vw), 21.9 (m), 23.1 (m), 24.0 (w), 24.8 (w);
>
> D) polymorph D exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in 2θ at 5.0 (m), 6.5 (m), 6.8 (s), 8.7 (m), 10.0 (m), 10.2 (m), 10.8 (m), 13.1 (w), 13.5 (m), 14.3 (s), 15.3 (vw), 16.1 (m), 16.8 (w), 18.2 (w), 18.5 (m), 19.0 (w), 19.9 (m), 20.5 (m), 21.0 (vs), 21.7 (s), 22.3 (w), 23.4 (m), 24.0 (m), 25.6 (w), 26.2 (m);
>
> E) polymorph E exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in 2θ at 4.4 (vw), 5.0 (s), 6.6 (s), 6.8 (s), 8.9 (s), 10.0 (m), 10.3 (s), 10.8 (m), 13.3 (s), 13.6 (m), 14.0 (s), 15.2 (vw), 15.9 (w),

[1] As of the parties' pre-trial filing exchanges, Plaintiffs' only alleged basis for infringement of any '993 patent claim against Amneal was as to the claimed crystalline polymorph "A." Plaintiffs thus dropped any allegation that the API in Amneal's ANDA product alternatively meet the claimed polymorph "E" limitations, or that Amneal infringes any of the previously-asserted claims (32 and 33) directed only to form E.

16.4 (w), 16.9 (vw), 17.8 (vw), 18.3 (m), 18.9 (w), 20.2 (vs), 20.4 (m), 20.7 (m), 20.9 (m), 21.1 (vs), 21.6 (m), 21.7 (m), 22.3 (m), 23.5 (m), 23.8 (m), 24.1 (w), 24.7 (vw), 25.4 (vw), 26.6 (m), 30.2 (w), 34.0 (vw); and

F) polymorph F exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in 2θ at 5.1 (m), 5.6 (w), 7.0 (s), 8.8 (m), 9.6 (s), 10.2 (w), 10.9 (m), 11.3 (w), 11.9 (m), 12.5 (m), 13.0 (s), 13.7 (m), 14.4 (s), 14.7 (m), 15.3 (vw), 15.5 (w), 16.8 (m), 17.6 (w), 18.3 (m), 19.3 (m), 19.7 (m), 20.6 (m), 21.2 (vs), 21.8 (s), 22.8 (s), 23.1 (w), 23.8 (w, shoulder), 24.1 (s), 24.8 (s), 25.7 (m), 26.2 (vw), 26.6 (m), 26.9 (w), 28.4 (w), 29.5 (w), 29.8 (vw), 30.9 (m);

wherein, for each of said polymorphs, (vs) stands for very strong intensity; (s) stands for strong intensity; (m) stands for medium intensity; (w) stands for weak intensity; (vw) stands for very weak intensity.

Claim 22:

A pharmaceutical composition comprising an effective amount of the crystalline polymorph or amorphous form according to claim 1, and a pharmaceutically acceptable carrier.

Claim 23:

A crystalline polymorph A, B, C, D, E, F, or the amorphous form, of (3 R,5 S)-7-[2-cyclopropyl-4-(4-fluorophenyl)quinolin-3 -yl]-3,5-dihydroxy-6(E)-heptenoic acid hemicalcium salt of claim 1, wherein polymorph A has an X-ray powder diffraction pattern substantially as depicted in FIG. 1, polymorph B has an X-ray powder diffraction pattern substantially as depicted in FIG. 2, polymorph C has an X-ray powder diffraction pattern substantially as depicted in FIGS. 3A and 3B, polymorph D has an X-ray powder diffraction pattern substantially as depicted in FIG. 4, polymorph E has an X-ray powder diffraction pattern substantially as depicted in FIG. 5, polymorph F has an X-ray powder diffraction pattern substantially as depicted in FIG. 6, and the amorphous form has an X-ray powder diffraction pattern substantially as depicted in FIGS. 7A and 7B.

Claim 24:

A crystalline polymorph A of (3R,5S)-7[2-cyclopropyl-4-(4-fluorophenyl) quinolin-3-yl]-3,5-dihydroxy-6(E)-heptenoic acid hemicalcium salt, which exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in 2θ at 5.0 (s), 6.8 (s), 9.1 (s), 10.0 (w), 10.5 (m), 11.0 (m), 13.3 (vw), 13.7 (s), 14.0 (w), 14.7 (w), 15.9 (vw), 16.9 (w), 17.1 (vw), 18.4 (m), 19.1 (w), 20.8 (vs), 21.1 (m), 21.6 (m), 22.9 (m), 23.7 (m), 24.2 (s), 25.2 (w), 27.1 (m), 29.6 (vw), 30.2 (w), and 34.0 (w), wherein (vs) stands for very strong intensity, (s) stands for strong intensity, (m) stands for medium

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