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

Kowa Company, Ltd. et al., Plaintiffs, v. Aurobindo Pharma Limited et al., Defendants.	Civil Action No. 14-CV-2497 (PAC)
Kowa Company, Ltd. et al., Plaintiffs, v. Amneal Pharmaceuticals LLC, Defendant.	Civil Action No. 14-CV-2758 (PAC)
Kowa Company, Ltd. et al., Plaintiffs, v. Mylan Inc. et al., Defendants.	Civil Action No. 14-CV-2647 (PAC)
Kowa Company, Ltd. et al., Plaintiffs, v. Orient Pharma Co., Ltd., Defendant.	Civil Action No. 14-CV-2759 (PAC)

Kowa Company, Ltd. et al., Plaintiffs, v. Zydus Pharmaceuticals (USA) Inc. et al., Defendants.	Civil Action No. 14-CV-2760 (PAC)
Kowa Company, Ltd. et al., Plaintiffs, v. Sawai USA, Inc. et al., Defendants.	Civil Action No. 14-CV-5575 (PAC)

PLAINTIFFS' RESPONSIVE CLAIM CONSTRUCTION BRIEF

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Pursuant to the Civil Case Management Plan and Scheduling Order entered by the Court on October 17, 2014, Plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc. ("Kowa") and Nissan Chemical Industries, Ltd. ("Nissan") (collectively "Plaintiffs") hereby submit their Responsive Claim Construction Brief.

I. SUMMARY

In their Opening Brief, Defendants assert that "the parties have key disagreements regarding claim scope that may impact noninfringement and/or invalidity, rendering it necessary to construe the respective terms." Defendants' Joint Opening Claim Construction Brief ("D.Br.") at 2. Plaintiffs respectfully disagree. As pointed out in Plaintiffs' Opening Brief, "there is not much in dispute." Plaintiffs' Opening Claim Construction Brief ("P.Br.") at 1.

The parties' opening briefs reflect that, for the most part, the parties actually agree on the meaning of the claim language at issue. For example, the parties agree that claim 1 of the '336 Patent encompasses optical isomers. *See* P.Br. at 13; D.Br. at 15-16. Similarly, for the '477 Patent, both parties agree that pH should be measured as described in the specification. *See* P.Br. at 19; D.Br. at 21-22. The dispute between the parties with respect to claim construction thus results from a disagreement over how to express what the claims say. All of this, however, stems from Defendants' efforts to construe claim language that does not need to be construed in the first place.

It has been and remains Plaintiffs' position that the claim language at issue does not need to be construed. Nonetheless, in an effort to compromise with Defendants and avoid burdening the Court, Plaintiffs proposed alternative claim constructions to try to resolve these issues. In their Opening Brief, Defendants ascribe these alternative constructions to a purported intent to change the meaning of the claims. In point of fact, nothing in Plaintiffs' proposed alternative

constructions suggests that they have the meaning Defendants ascribe to them. For instance, contrary to Defendants' suggestion, there is nothing in Plaintiffs' alternative construction for the '336 Patent that would exclude optical isomers from the scope of claim 1. *See* D.Br. at 19. Similarly, nothing in Plaintiffs' alternative construction would read the 6.8 to 7.8 pH range out of claim 1 of the '477 Patent. *See* D.Br. at 20-21. Likewise, nothing in Plaintiffs' alternative construction would require one to derive the referenced pH from just the active pharmaceutical ingredient ("API") rather than from the "pharmaceutical composition" (which would include the API plus inert ingredients ("excipients")). *See* D.Br. at 22-23.[1] In any event, much of Defendants' Opening Brief is devoted to tilting at windmills, attacking these unsupported interpretations of Plaintiffs' proposed alternative constructions.

As discussed in Plaintiffs' Opening Brief, the claims that Defendants have asked the Court to construe do not warrant construction, because construction is not necessary to adjudicate any disputed issues with respect to validity or infringement. *Jang v. Boston Scientific Corp.*, 532 F. 3d 1330, 1337 (Fed. Cir. 2008) (warning against providing advisory opinions by construing claim terms that do not impact the ultimate issue of infringement). In the event that the Court construes the claims, however, Plaintiffs respectfully request that the Court reject Defendants' proposed claim constructions. Defendants' proposed construction for the language at issue in the '336 Patent requires the Court to redefine the term "compound" as a "genus," which is improper because there is nothing in the claim language, the specification, or the prosecution history that supports Defendants' re-definition. *Cf. Endo Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, 11-717, 2013 LEXIS 111004 (D. Del. Aug. 7, 2013) (rejecting a

[1] Had Defendants not declined to substantively confer on the parties' proposed constructions, the foregoing could have been clear at the outset.

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