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BY ECF & EMAIL

Hon. Paul A. Crotty
United States District Judge
United States Courthouse
500 Pearl Street, Room 735
New York, NY 10007

Re: *Kowa Company, Ltd. et al. v Aurobindo Pharma Limited et al.*, and related cases, 14-cv-2497-PAC, 14-cv-2647-PAC, 14-cv-2758, 14-cv-2759, 14-cv-2760-PAC, and 14-cv-5575-PAC.

Dear Judge Crotty,

Our firm, with Rakoczy Molino Mazzochi Siwik LLP, represents the Mylan Defendants in this matter. We submit the within letter brief on behalf of all Defendants in the related matters. This brief addresses the question of whether the Court must apply the Local Patent Rules, which require early disclosure of infringement/invalidity contentions, to this matter.¹

Argument: The Local Patent Rules Require An Early Exchange of Infringement and Invalidity Contentions.

Effective April 8, 2013, the United States District Courts for the Southern and Eastern Districts of New York adopted Local Patent Rules that “apply to patent infringement, validity and unenforceability actions and proceedings.” L. Pat. R. 1. The Local Civil Rules also apply to patent actions and proceedings, “except to the extent they are inconsistent with [the] Local Patent Rules.” *Id.* Defendants submit that Local Patent Rule 1 confirms that the Local Patent Rules take precedence over the Local Civil Rules if there is a perceived conflict between the two.

¹ For the convenience of the Court, Defendants sought to include a placeholder in the case schedule submitted today identifying those topics on which the Court had ordered letter briefing. Plaintiffs refused to include this. Thus, the non-inclusion of the issue in the proposed schedule should not be construed as a waiver by Defendants on the issue.

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Local Patent Rules 6 and 7, in contrast to Local Civil Rule 33.3(c), require early disclosure of the parties' contentions regarding patent infringement and invalidity. Specifically, under Local Patent Rule 6, a party claiming patent infringement must serve a set of infringement contentions within 45 days after the initial scheduling conference "which identifies for each opposing party, each claim of each patent-in-suit that is allegedly infringed and each product or process of each opposing party of which the party claiming infringement is aware that allegedly infringes each identified claim." L. Pat. R. 6. Under Local Patent Rule 7, the opposing party must serve invalidity contentions within 45 days after service of such infringement contentions that "identify each item of prior art that the party contends allegedly anticipates or renders obvious each asserted claim, and any other grounds of invalidity, including any under 35 U.S.C. § 101 or § 112, or unenforceability of any of the asserted claims." L. Pat. R. 7. The parties have an ongoing duty to supplement their infringement and invalidity contentions pursuant to Fed. R. Civ. P. 26(e). L. Pat. R. 9.

This District has applied the schedule contemplated in the Local Patent Rules in other Hatch-Waxman litigation. *See, e.g., Purdue Pharma L.P. v. Amneal Pharm. LLC*, 13-cv-03188-SHS, Order (S.D.N.Y. Sept. 20, 2013). Here, Plaintiffs received Notice Letters from each individual Defendant at least 45 days before filing the respective Complaints. Each individual Defendant's Notice Letter identified non-infringement positions and included an Offer of Confidential Access that gave the Plaintiffs an opportunity to review each individual Defendant's ANDA for the purpose of determining whether an infringement action was appropriate. Plaintiffs further had an obligation to satisfy Rule 11 prior to filing an infringement claim. We presume that Plaintiffs believe they had a good faith basis to bring suit; therefore, they cannot now complain that they will not have enough time to determine whether the Defendants'

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respective ANDA products infringe the patents-in-suit before serving their infringement contentions.

Contrary to Plaintiffs' suggestion during the Rule 16 Conference, there is nothing about a Hatch-Waxman case that warrants a departure from the Local Rules. Rather, the expedited nature of a Hatch-Waxman case strongly favors a prompt and early disclosure of infringement and invalidity contentions so as to allow the parties to streamline discovery and focus on issues that are genuinely disputed. In accordance with these Local Patent Rules, Defendants' proposed Civil Case Management Plan and Scheduling Order, submitted on October 3, 2014, specified that "Plaintiffs must serve Disclosure of Asserted Claims and Preliminary Infringement Contentions" by December 5, 2014 (60 days after the October 6, 2014 initial scheduling conference), and that "Defendants must serve Preliminary Invalidity Contentions" by January 16, 2014 (42 days after service of Plaintiffs' Preliminary Infringement Contentions).

Plaintiffs proposed simply that the parties should "[c]onform to local rules regarding contention interrogatories (L.R. 33.3(c))." Local Civil Rule 33.3(c), however, is clearly inconsistent with the early contention disclosure requirements of Local Patent Rules 6 and 7 and is, therefore, to that extent, inapplicable here. *See* L. Pat. R. 1.

* * *

Accordingly, Defendants respectfully request that this Court order the following:

The Local Patent Rules will apply to this case. Further, Plaintiffs shall serve their Local Patent Rule 6 Disclosure of Asserted Claims and Preliminary Infringement Contentions on or before December 5, 2014, and Defendants shall serve their Local Patent Rule 7 Preliminary Invalidity Contentions on or before January 16, 2015.

Respectfully submitted,

/s Jakob B. Halpern

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cc: All counsel of record (by ECF & email)