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October 10, 2014

VIA ECF AND U.S. MAIL

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 Ltd., et al., and related cases*
C.A. No. 14-cv-2497, -2758, -2647, -2760, -2759, -5575 (S.D.N.Y.) (PAC)
Letter Brief on Contention Interrogatories

Dear Judge Crotty:

We represent plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. ("Plaintiffs") in the above-referenced matter. Pursuant to this Court's Order from the October 6, 2014 Conference, we respectfully submit this letter brief on Defendants' request to deviate from Local Rule 33.3(c) regarding contention interrogatories relating to preliminary infringement and invalidity contentions.

Hatch-Waxman litigation differs drastically from a typical patent litigation. Ordinary infringement plaintiffs have the advantage of being able to investigate infringing products, which are on the market and available prior to suit. This is not the case in Hatch-Waxman cases. Hatch-Waxman plaintiffs have little information about the infringing generic drug product because it is not yet available prior to FDA approval. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *In re Fenofibrate Patent Litig.*, 910 F. Supp. 2d at 714. ANDA filings are confidential, and generic defendants are not required to provide patent holders with any ANDA information beyond the paltry information contained in a Paragraph IV notice, "most commonly the only knowledge that the pioneer company has of the ANDA." Hon. D. Folsom, E.D. Tex.

Gen. Order 11-3, at 21-22 (Mar. 15, 2011) (implementing Hatch-Waxman local patent rules). ANDAs are typically extremely complicated, and voluminous.

Because Hatch-Waxman actions are based on artificial acts of infringement by hypothetical products described in defendants' ANDAs, the ANDAs themselves are essential to any infringement analysis. *Medicines Co. v. Mylan Inc.*, 11-CV-1285, 2013 WL 6633085, at *20 (N.D. Ill. Dec. 16, 2013) ("infringement analysis under § 271(e)(2)(A) is necessarily a 'hypothetical inquiry . . . properly grounded in the ANDA application and the extensive materials typically submitted in its support'."); *see also Ferring B.V. v. Watson Labs., Inc.-Florida*, 2014-1416, 2014 WL 4116461, at *7; *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). Thus typical patent rules, such as Local Patent Rule 6, do not apply reasonably to Hatch-Waxman cases. Patent Rule 6 calls for Plaintiffs to produce asserted claims and infringement contentions within 45 days of the Scheduling Conference. In this case, there is nothing to ensure that any of the Defendants will even produce their ANDAs within that period, much less that Plaintiffs would have any significant time for analysis of any ANDAs produced. Hatch-Waxman Plaintiffs should not be required to produce infringement contentions at least until after all defendants have produced their complete ANDAs and Plaintiffs have had reasonable time to analyze them.

Recognizing this difficulty, Federal District Courts including the District of New Jersey, Eastern District of Texas, and Northern District of Ohio have adopted special local patent rules specific to Hatch-Waxman litigation, which require very early disclosure of the defendants' ANDAs and further require the disclosure of defendants' invalidity and noninfringement contentions to be made before plaintiffs' infringement contentions. *See* D.N.J. L. Pat. R. 3.6;

E.D. Tex. P. R. 3-8; N. D. Ohio L. P. R. 3.9.

Since Local Patent Rule 6 does not reasonably apply to this Hatch-Waxman litigation, and this Court has no special Hatch-Waxman rules, Plaintiffs contend that Local Rule 33.3(c) should apply to these contentions, as it does to other contention interrogatories.

In an effort to compromise the issue, plaintiff proposed a date of March 30, 2015, which should be a reasonable time after the six defendants produce their ANDAs, for Plaintiffs to provide asserted claims and preliminary infringement contentions, and a date of April 30, 2015 for Defendants to provide their preliminary invalidity contentions. Defendants have rejected that compromise, and proposed that Plaintiffs should provide their asserted claims and infringement contentions within 30 days of each defendant's production of its ANDA, or in any event by February 2, 2015. It is patently unreasonable for Defendants to unnecessarily require Plaintiff to analyze six ANDAs within thirty days.[1]

Since the local patent rules do not apply well in ANDA cases, the contentions of both sides should be treated as general contentions under Local Rule 33.3(c). Alternatively, this Court should allow Plaintiffs' sufficient time to analyze the ANDAs of the six defendants prior to serving infringement contentions.

Thank you for your consideration.

Respectfully submitted,

David G. Conlin

cc: Counsel of record (via ECF)

[1] The only reason identified by Defendants in support of their effort to force an artificially rushed deadline upon Plaintiffs is a purported concern about Markman deadlines. Plaintiffs suggested that the reasonable approach to address that concern would be to adjust the Markman deadlines correspondingly, which would not affect any other deadlines.