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December 12, 2014

VIA CM/ECF & HAND DELIVERY
The Honorable Richard G. Andrews
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

Re: ***Reckitt Benckiser Pharms., Inc. et al. v. Par Pharm. Inc., et al.,***
C.A. No. 13-1674-RGA (Consolidated)

Dear Judge Andrews:

We, along with Latham & Watkins, represent Defendants Par Pharmaceutical, Inc. and IntelGenx Technologies Corp. (together, "Par") in the above litigation. Par requests that Par's case (14-422) remain consolidated in its entirety with Plaintiffs' case against Defendant Watson Laboratories, Inc. ("Watson"), and proceed to trial on the current trial date because consolidation for both infringement and invalidity would maintain fairness and judicial economy.

Par's actions in sending its first Notice Letter to Plaintiffs were done based on a good faith belief that it was required to do so under statute. Additionally, Par has not gained any unfair advantage, nor have Plaintiffs or Watson been prejudiced by Par's consolidation. ANDA cases filed on similar schedules as Watson's case and the second Par case are routinely consolidated and tried together, and accordingly doing so here would not cause prejudice to any party.

I. Factual Background

On July 9, 2013, Par sent Plaintiffs a Notice Letter containing a certification that the '832 patent and the '150 patent were invalid and not infringed by Par's proposed buprenorphine and naloxone sublingual film ANDA product. Par served its Notice Letter at the same time it amended its ANDA to include a paragraph IV certification, even though Par had not yet received notice from FDA of acceptance for filing of its previously-submitted ANDA. Par sent its first Notice Letter at that time under the good faith belief that it was required by the statute. *See* D.I. 89 in 13-1461 ("*Par I*"), at 3-6.[1]

On August 20, 2013, Plaintiffs filed a complaint against Par alleging that Par's proposed ANDA Product infringed the patents-in-suit. D.I. 1 in 13-1461. Plaintiffs filed a complaint

[1] This Court's decision in *Otsuka Pharmaceutical Co. Ltd. v. Par Pharmaceutical Inc.*, D.I. 24 in 13-1979 (D. Del. Mar. 10, 2014) was issued eight months after Par sent its first notice of Paragraph IV certification. At the time Par served its first notice letter, Par understood that failure to send notice upon amendment would disqualify an ANDA applicant from first-filer status. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 888 (D.C. Cir. 2004). *See* D.I. 89 in 13-1461, at 5-6.

against Watson on October 8, 2013, and against Alvogen on December 6, 2013, alleging infringement of the same patents.

Plaintiffs have stated that at the time they filed suit, they were fully aware that Par had not yet received notification from FDA that Par's ANDA had been accepted for filing,[2] yet they commenced suit "in order to protect their rights." D.I. 82 in 13-1461 at 5 n.2. Plaintiffs affirmatively negotiated a joint scheduling and case management order, which included limitations on discovery and claim construction that presumed both Watson and *Par I* would proceed on the same schedule. *See* Ex. 1. Plaintiffs' proposal also contemplated that their newly-filed case against Alvogen (13-2003) should be subject to that schedule, even though that case was filed on December 6, 2013—nearly four months after *Par I* and just days before Plaintiffs provided their proposal. *Id.* Ultimately, the same schedule was entered in all three cases. D.I. 33 in 13-1461.

In March 2014, Par received notice from FDA that its ANDA was acceptable for filing, and Par sent Plaintiffs a second Notice Letter. Plaintiffs filed a second complaint against Par on April 4, 2014 (D.I. 1 in 14-422), and moved to dismiss *Par I*. The Court granted Plaintiffs' motion to dismiss on May 27, 2014, but consolidated the 14-422 case with the Watson 13-1674 case for pretrial purposes until further notice. D.I. 66 at 2. The Court ordered that the cases proceed along the same schedule for the time being, noting that it would entertain a request from Plaintiffs at a later date. *Id.* Specifically, the Court noted that it would entertain a request to sever the issue of infringement for Case No. 14-422, or "we might try all issues at the same time, and I would issue the 13-1674 opinion separately and before the No. 14-422 opinion." *Id.* at 2, n.1.

II. Principles of Equity and Judicial Economy Warrant Trying These Cases Together

A. Par Sent Its Initial Notice Letter in Good Faith[3]

Par sent its first Notice Letter to Plaintiffs in good faith. Par believed that the express language of the Hatch-Waxman statute required it to send a Notice Letter with its ANDA amendment. 21 U.S.C. § 355(j)(2)(B)(ii). Par also understood that failure to send notice upon amendment had been held to disqualify an ANDA applicant from first-filer status. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 888 (D.C. Cir. 2004). Par has since reached agreement with the Agency on how to proceed for future products, and therefore Par does not expect that this circumstance will be repeated again.

Thus, Par's actions in sending its first Notice Letter were not premised on bad faith. Indeed, Par's counsel informed Plaintiffs' counsel that Par had not received acceptance for filing, and gave Plaintiffs' counsel a waiver to represent the opposing party. Plaintiffs' actions in

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[2] Before Plaintiffs filed suit, Reckitt's counsel Daniel Ladow asked Par's in-house counsel David Silverstein for a waiver to represent Reckitt in the present matter. Mr. Silverstein granted the waiver and informed Mr. Ladow that Par had not received an acceptance-for-filing letter for its ANDA from FDA. *See* D.I. 82 in 13-1461 at 5 n.2.

[3] Par has already briefed this issue before the Court. D.I. 88, 89 in 13-1461.

proceeding to file the 13-1461 case against Par and negotiating a joint schedule, underscore Par's good faith belief that it was mandated by statute to send its first Notice Letter to Plaintiffs. Therefore any punitive relief Plaintiffs seek is wholly unwarranted.

B. A Consolidated Trial Does Not Prejudice Watson

Par believes that Watson would not be prejudiced by a consolidated trial. First, at the *Markman* hearing, Watson's counsel indicated that Watson would prefer to keep the invalidity case together. D.I. 147 at 133:5-8. Watson and Par are coordinating on issues of invalidity, and therefore Par also believes that at the very least issues of invalidity should be consolidated for trial.

Par and Watson have also been coordinating on discovery issues to date, drafting joint discovery requests and jointly taking depositions. Watson and Par together drafted claim construction briefing and argument at the *Markman* hearing, which also may present common issues with respect to their non-infringement defenses.

Moreover, staggering trials would preclude Watson and Par from sharing experts, such as invalidity experts and potentially experts on infringement issues. For example, certain issues in the invalidity case may also have direct bearing on infringement. Par's Proposed ANDA Product contains a single polyethylene oxide that was known in the prior art. Plaintiffs' infringement contentions have asserted that this single polyethylene oxide satisfies both polyethylene oxide limitations of one of the asserted patents. To the extent Plaintiffs' experts maintain that position, admissions and assertions made in the context of the infringement case may have direct bearing on Defendants' obviousness case. Similarly, Plaintiffs' manner of asserting the claims against Par may demonstrate the indefiniteness of certain claims or terms.

Proceeding on the current consolidated schedule through trial does not affect any 180-day exclusivity period, to which Watson will be entitled regardless of the timing of the decision in the consolidated case before the Court. Therefore, Par believes that a consolidated trial on both the issues of invalidity and infringement would not prejudice Watson.

C. A Consolidated Trial Does Not Prejudice Plaintiffs

Similarly, Plaintiffs are not prejudiced by a consolidated trial. Plaintiffs seek to delay the infringement case against Par seven or eight months after the Watson trial. However, Plaintiffs have provided no basis to do so.

First, Plaintiffs made no objection to trying their claims with Alvogen on the same schedule, even though Plaintiffs filed suit against Alvogen nearly four months after they filed suit against Par and two months after they filed suit against Watson. ANDA cases filed on similar schedules as the Watson case and the second Par case, are frequently consolidated even though they were filed at different times and do not present identical issues. Such cases are routinely consolidated for pre-trial and trial on issues of invalidity and infringement.[4]

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[4] *See, e.g., GlaxoSmithKline LLC v. Anchen Pharms., Inc.*, C.A. No. 11-046-RGA, D.I. 24 (Ex. 2) (joint scheduling order for cases filed in a nine month time period); *Somaxon Pharms., Inc. v. Actavis Elizabeth LLC*, C.A. No. 10-1100-SLR/MPT, D.I. 55 (Ex. 3) (consolidating cases against parties filed in a six month time period); *Viiv Healthcare UK Ltd. v. Lupin Ltd.*,

Second, Plaintiffs have benefitted from the current consolidated schedule, and will continue to benefit. Plaintiffs do not have to present their witnesses for depositions twice, and have responded to joint discovery requests. Indeed, Par produced its ANDA to Plaintiffs in *Par I*. Thus, Plaintiffs had even more time to evaluate their infringement positions against Par.

Furthermore, both the Watson and Par cases are identically situated with respect to the current case schedule. Both cases have a fact discovery cut-off of January 16, 2015. Par has provided discovery to Plaintiffs according to the current schedule. Continuing on the same schedule through trial minimizes the risk of conflicting results at trial, and ensures consistent application of facts and law in both infringement cases against Watson and Par.

Because consolidation of all issues for trial best promotes judicial economy and efficiency, Par respectfully requests that the Court decline to defer Par's infringement trial in the 14-422 case. We are available to discuss at the Court's convenience.

Respectfully,

/s/ Steven J. Fineman

Steven J. Fineman (#4025)

cc: All counsel of record (via CM/ECF)

C.A. No. 11-576-RGA, D.I. 23, 139 (consolidating cases for discovery and trial) (Exs. 4-5); *Otsuka Pharm. Co., Ltd. v. Hetero USA Inc.*, C.A. No. 14-789-RGA, D.I. 25 (ordering joint scheduling order, including trial date) (Ex. 6); *Unimed Pharms., LLC v. Perrigo Co.*, C.A. No. 13-236, D.I. 15 (Ex. 7) (consolidating cases for all purposes); *see also Cima Labs., Inc. v. Actavis Group* HF, No. 07-893, 2007 WL 1672229, at *8 (D.N.J. June 7, 2007); *Smithkline Beecham Corp. v. Geneva Pharm., Inc.*, No. 99-cv-2926, 2001 WL 1249694, at *5-6 (E.D. Pa. Sept. 26, 2001).