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December 19, 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, et al. v. Watson Laboratories, Inc.*, C.A. No. 13-1674-RGA (Cons.) and *Reckitt Benckiser, et al. v. Par Pharmaceutical, Inc., et al.*, C.A. No. 14-422-RGA

We respectfully submit this response on behalf of Plaintiffs to Defendants Par Pharmaceutical, Inc. and IntelGenx Technologies Corp.'s (collectively, "Par") December 12, 2014 letter (D.I. 157) in the above-referenced litigation ("Par's 12.12.14 Letter"). At the December 3, 2014 Markman hearing in this action, Plaintiffs raised the point that the Court, in its Order consolidating the pretrial schedules of the Par case with that of the related Watson case, had invited Plaintiffs to request "a later trial and pretrial date for some or all of the issues in No. 14-422" (the Par case). (D.I. 66 at 2.) This issue arises because Par prematurely and improperly served its Paragraph IV notice on Plaintiffs about 8 months before it was allowed to do so under the Hatch Waxman statute, leading Plaintiffs to first sue Par much earlier than they would have if Par's Paragraph IV notice had been served at the proper time. At the Markman hearing, the Court recollected thinking that "there was an advantage of Par gained by the premature filing," and that "I didn't think it was fair to plaintiffs" (D.I. 147 at 130). The Court noted that, "I would say that based on what I remember, that I did intend to push the infringement trial for Par to some later date," and placed the "burden" on Par to show why the Court "shouldn't do that." (D.I. 147 at 133.) Par's 12.12.14 Letter fails to carry that burden.

Watson, and it appears thus far, Teva (the subject of a recently filed related action, 14-cv-1451-RGA), played by the rules and did not send Plaintiffs a Paragraph IV notice until it was permissible to do so. In contrast, Par did not comply with the rules and instead jumpstarted the Hatch-Waxman process. If Par had complied with the law, the trial in the Par case likely would have been set about 9 months after Watson's August 31, 2015 trial date. Par has already benefitted from "cutting in line" by having pretrial activities consolidated with those in the Watson case and seeks to further benefit, and unfairly prejudice Plaintiffs, by having what amounts to an expedited trial date many months earlier than it would have had if it had not sent a premature Paragraph IV notice. Nor has Par provided any compelling reason why its infringement trial should not be separated from Watson's trial and set at a date it would have had but for its premature actions.

As previously briefed on the motion to dismiss the original complaint against Par and to hold Par's premature Paragraph IV notice ineffective under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §314.95(b), an ANDA applicant cannot send a Paragraph IV notice to a NDA holder until the ANDA applicant receives an acknowledgement letter from the FDA that its ANDA is sufficiently complete to permit a substantive review. Here, Par, as it has done in at least some previous cases, sent Plaintiffs a Paragraph IV notice in July 2013 ***without*** having received such an acceptance of filing letter, thus prematurely and improperly initiating the Hatch-Waxman litigation process. Par did not receive such an acceptance of filing letter until March 2014, and, consequently, it was not until March 2014 that Par sent Plaintiffs an effective Paragraph IV notice, which led to the filing of the complaint in the current Par case in April 2014. (*See* D.I. 82 at 1-7 and D.I. 91 at 2-7 in No. 13-1461-RGA.) Par's March 31, 2014 interrogatory response to Plaintiffs confirmed that Par did not receive the required FDA acceptance of filing letter until March 14, 2014. (D.I. 82 at 6.)

As implicitly recognized in this Court's Order granting Plaintiffs' motion to dismiss (D.I. 92), in the Court's similar Order in *Otsuka Pharma Co. Ltd. V. Par Pharm., Inc.*, No. 13-1979 (D. I. 24) (D.Del. March 10, 2014), as well as by at least one previous court and by the FDA (*see e.g.*, D.I. 91 at 3-4), Congress struck a fine balance in enacting Hatch-Waxman's statutory scheme and it would be contrary to the legislative history and the policies animating the Act to allow ANDA filers to "jump" the queue and the timings established by the statute, including by gaining an undue advantage from triggering the process based on a premature Paragraph IV notice. For all these reasons, Par's protestations in its 12.12.14 Letter that it acted in "good faith" are beside the point. There is no need for the Court to find that Par was a "bad actor" and Plaintiffs position is not a request to "punish" Par. Rather, Par simply is not entitled to benefit from having kick started this action many months earlier than it was allowed to under Hatch-Waxman. This is not about punishing Par; it is about not allowing Par to reap a further undue strategic advantage while unfairly prejudicing Plaintiffs.[1]

Furthermore, as the Court noted at the Markman hearing, as to "having two infringement trials, there is not that much … duplication from my point of view." (D.I. 147 at 130.) As Plaintiffs' counsel stated at the hearing (D.I. 147 at 128), in this action, Defendants Watson and Par's proposed ANDA products contain the same active ingredients but differ significantly in various respects, including the presence, amounts, and ratios of certain excipients. Therefore, the respective infringement cases are likely to be different in various respects, requiring separate proofs and separate testimony, including expert testimony. Accordingly, there is no compelling reason based on judicial economy to consolidate Par's infringement trial, rather than set it at what would be the appropriate time, such as May 2016. Furthermore, the efficiencies now obtained from consolidated pre-trial activities and claim construction will not be lost if Par

[1] While Par's "good faith" is irrelevant to the present point, Plaintiff Reckitt's counsel, Mr. Ladow, would like to add a clarification to footnote 2 in Par's 12.12.14 letter. When Mr. Ladow spoke with Par's representative before suit was filed, Mr. Ladow's view, as he expressed at the time, was that no waiver was needed from Par because he was not then representing Par and had never represented them in regard to the subject matter of this action; the discussion about a waiver concerned an unrelated action.

receives a later, more appropriate, trial date. Nor will separate infringement trials preclude Watson and Par from sharing experts—the experts can easily appear at each trial. And, while separate trials may be less convenient for Par, the issue would not have arisen if they hadn't prematurely triggered the process to begin with. Lastly, the alleged risk of conflicting results is minimal as both trials will be before this Court.

In footnote 4 of its 12.12.14 Letter, Par cites various cases in support of its assertion that ANDA cases "are routinely consolidated for pre-trial and trial on issues of invalidity and infringement." (Ltr. at 3.) First, not all ANDA cases are consolidated and, given the schedule in the Watson case and the timing of Par's Paragraph IV notice, it appears unlikely that Par's case would have been consolidated with Watson's had Par not triggered the process prematurely. Second, this Court has already consolidated the Par and Watson cases for pretrial purposes, and, to Plaintiffs' knowledge, no party is arguing that these cases should not be consolidated for the remainder of the pretrial proceedings, or for the trial on invalidity.[2]

Third, the cases Par cites are inapposite to the present issue. Both *Cima Labs* and *Smithkline Beecham* deal only with pre-trial consolidation and thus do not address the issue before the Court. In *Somaxon* and *Viiv*, the parties stipulated to consolidated trials, subject to the Court's approval. In *Unimed*, this Court consolidated the actions for all purposes, but specifically bifurcated some issues. Finally, to Plaintiffs' knowledge, none of the cases cited by Par involve the issue here, where an ANDA filer sent its initial Paragraph IV notice letter months before its ANDA was accepted by the FDA, thus prematurely triggering litigation.

The simple fact is that if Par had followed the rules under the Hatch-Waxman statute, Par would not be allowed to reach a potential determination of its case until many months later than under the presently consolidated schedule. The only reason Par, which has a proposed, non-FDA approved, not yet marketed product, is currently able to litigate any issues of infringement or validity of Plaintiffs' patents is because of the procedures provided by the Hatch-Waxman regime, which represents a careful, negotiated balance between the interests of brand-name pharmaceutical innovators and the interests of would-be generic competitors. That balance includes the timing of potential judicial determinations of the issues of validity and infringement. There is no justification for allowing Par to leapfrog the Hatch-Waxman sequence to schedule a non-entitled, premature trial date, particularly, in the present situation, in regard to infringement, or to otherwise gain any potential and undue strategic advantage by having improperly "cut the line" on the way to the courthouse.

Respectfully submitted,

Mary W. Bourke

cc: Counsel of Record

[2] Plaintiffs reserve the right to address whether there should be separate invalidity trials after expert discovery.