IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP. Defendants.	)	Civ. No. 13-1461-RGA

REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS

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The Plaintiffs' original complaint against Par was premised on Par's premature Paragraph IV Notice letter served in July 2013. Plaintiffs recently filed complaint (C.A. No.: 14-cv-422) is premised on Par's March 2014 Notice letter, the first such Notice from Par that was not premature. As set forth in Plaintiffs' opening brief and as further discussed below, the present case should be dismissed in its entirety without prejudice and a new case schedule should be put into place based on the properly served March 2014 Paragraph IV Notice and the resulting complaint.

Par acknowledges that the 30-month stay of FDA marketing approval of Par's ANDA provided under the Hatch-Waxman Act was not triggered until Par served its March 2014 Paragraph IV Notice. However, Par argues that Plaintiffs' recently filed action against Par (C.A. No.: 14-cv-422) should be consolidated with this action and be placed on the same case schedule—a schedule to which only Watson is entitled. Par should not be allowed to gain a strategic benefit that unfairly prejudices Plaintiffs by sharing the Watson case schedule leading to a trial in August 2015. Rather, the parties should discuss a new schedule that results in a trial date around May 2016—the schedule Par would have had but for its having prematurely triggered the ANDA litigation process.

Par's pre-March 2014 Notice letters were clearly premature and ineffective to trigger the Hatch Waxman litigation process, and all claims and counterclaims in the present action should be dismissed without prejudice the new action.[1] The law has not "evolved," as Par argues. This Court's recent decision in *Otsuka* was not the first court decision to address this—Par's position was repudiated in *SB Pharmco* and its position has been contradicted by the FDA.

[1]Par states that it no longer has "a good faith belief that a justiciable case or controversy existed regarding whether Par had misappropriated Monosol's trade secrets." As a result, Par's counterclaims of no trade secret misappropriation should be dismissed without prejudice.

ARGUMENT

I. PAR SHOULD NOT BE REWARDED, AND PLAINTIFFS SHOULD NOT BE PREJUDICED, BY PAR'S HAVING PREMATURELY TRIGGERED THE ANDA LITGATION PROCESS

Par now agrees that the 30-month stay did not begin to run until Plaintiffs' receipt of Par's March 2014 Paragraph IV Notice letter. But, using its having prematurely triggered the litigation process as a *fait accompli*, Par seeks to be rewarded for improperly jumpstarting the Hatch Waxman process by maintaining the litigation schedule of the original action. To the contrary, the original schedule should only apply to Watson.

As set forth in Plaintiffs' section of the recent joint status report (D.I. 85), the earlier Par case should be dismissed without prejudice and the newly-filed Par action should be decoupled from the Watson pretrial and trial schedule. Trial in the new Par case should be set where it would have been had Par complied with the law—namely, about nine months after the Watson trial date of August 31, 2015.

This result is supported by the policy considerations behind the Hatch Waxman Act, as well as fairness to Plaintiffs who should not be prejudiced by Par's attempt to bootstrap itself into a compressed case schedule that it does not deserve. The legislative history of the Hatch-Waxman Act reveals policy considerations articulated by both Congress and the FDA regarding the importance of timing of Paragraph IV Notices. "Congress did not intend that applicants be permitted to circumvent this notice requirement [proposed 21 C.F.R. § 314.95(b)] by filing sham ANDA's or ANDA's which are substantially incomplete." *SB Pharmco Puerto Rico, Inc. v. Mutual Pharm. Co.*, 552 F. Supp. 2d 500, 507 (E.D. Pa. 2008) (citing 59 Fed. Reg. 50,338, 50,349 (Oct. 3, 1994) (quoting H. R. Rep. No. 98-857, at 24 (1984))) (internal quotations omitted). The FDA expressed similar concerns:

> To permit an ANDA applicant to provide notice [to the patentee] before FDA has determined whether the ANDA is sufficiently complete would be contrary to the legislative history because it would only encourage ANDA applicants to file incomplete or 'sham' ANDA's and to supplement them later to secure a place in the review queue in an attempt to secure the first ANDA approval.

SB Pharmco, 552 F. Supp. 2d at 508. Permitting Par to rely on its premature July 2013 Notice letter as a *fait accompli* basis for remaining (putting the new Par case) in the preexisting Watson case schedule is directly contrary to the legislative history and only serves to encourage ANDA filers to file sham or incomplete ANDAs.

Par should not be allowed to use its vastly premature Paragraph IV Notice letters to secure an expedited case schedule. Par argues that the Court should simply overlook the undue prejudice to Plaintiffs that would result. There are no compelling reasons based on judicial economy to unduly prejudice Plaintiffs and reward Par's prematurity. Par's approximate trial date would be far enough into the future that considerations of judicial economy cannot be confidently predicted.[2]

Accordingly, in addition to dismissing all claims and counterclaims in the present Par action without prejudice, the Court should not allow Par to benefit and should not allow Plaintiffs to be unfairly prejudiced by permitting the newly filed Par case to be slotted into the Watson pretrial and trial schedule. Instead, Par should be placed on a trial schedule similar to that it would have received based on the commencement of the newly filed action against Par, which was based on Plaintiffs' receipt of Par's March 2014 Notice letter.

[2]Par can also elect to conserve judicial resources by staying its case pending the outcome of the Watson case.

II. PAR'S DEFENSE OF ITS SERVICE OF PREMATURE NOTICE LETTERS HAS NO SUPPORT IN, AND IS CONTRARY TO, THE STATUTE, THE FDA'S POSITION AND THE CASE LAW

The statutory guidance on when an ANDA filer may properly send a Paragraph IV notice to an NDA holder is abundantly clear.

> Timing of notice. An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph –
>
> (I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or
>
> (II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

21 U.S.C. § 355(j)(2)(B)(ii). The corresponding federal regulation construing is equally unambiguous: "The applicant shall send the notice required by paragraph (a) of this section when it receives from FDA an acknowledgment letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b).

The crux of Par's argument is that the amendment provision, § 355(j)(2)(B)(ii)(II), requires that an ANDA filer send a Paragraph IV notice to the patent owner and NDA holder, regardless of whether the original ANDA has been acknowledged as received in sufficiently complete form by the FDA to permit a substantive review. As explained in Plaintiffs' moving brief, this is a previously rejected and misguided interpretation of the language.In *SB Pharmco*, the court noted that reading the entire provision in its entirety, "it seems clear that subparagraph (II) refers to an amendment to an ANDA for which the FDA has already acknowledged receipt." *Id*. at 509 n.4. The court interpreted 21 U.S.C. § 355(j)(2)(B)(ii)(II) to mean that notice be sent simultaneously with the amendment or supplement "only if the amendment is submitted for an

ANDA that has already been accepted for filing." *Id*. at 510. Subparagraph II very clearly addresses an "*amendment or supplement*" to a previously accepted ANDA application. Here, Par admittedly did not send notice that its ANDA was accepted by filing by the FDA until March 25, 2014. Thus, there could have been no "amendment or supplement" as contemplated by § 355(j)(2)(B)(ii)(II) until after the ANDA application was accepted for filing, and certainly not before Par's Paragraph IV Notice letter that was sent on July 8, 2013.

Similarly, Par's reliance on *Purepac Pharm. Co. v. Thompson,* 354 F.3d 877, 888 (D.C.C. 2004) for the proposition that an ANDA applicant must provide notice to the NDA holder and patent owner when an amendment or supplement is filed or risk losing first-filer rights is misplaced because *Purepac* is factually inapposite. *Purepac* involved two ANDAs that had already been received for review when the applicants submitted new Paragraph IV certifications and sent notices under the amendment provision. Purepac does not address notice pursuant to § 355(j)(2)(B)(ii)(II) where the underlying ANDA has not yet been accepted for review.

Moreover, *Purepac* also addressed legal issues not relevant to the current motion. In *Purepac*, the FDA concluded that a generic company was entitled to first-filer status despite its delay in providing notice of the amendment to its ANDA, rejecting the contention that the statute requires notice of the amendment simultaneous with its filing, lest the new Paragraph IV certification be rendered invalid. *Purepac*, 354 F.3d at 888. The court held that the penalty for an applicant that fails to provide notice at the same time that it files an amendment to an already-accepted ANDA is that the certification simply becomes effective when the applicant does provide proper notice. *Id*. Both the district court and appellate court upheld this decision.

Par is unable to cite to a single court opinion or agency decision to support its interpretation of § 355(j)(2)(B)(ii). Furthermore, Par has failed to address this Court's recent Order of dismissal in the *Otsuka* case. Instead, Par relies on an entirely unsupported interpretation of the amendment provision that has been rejected by the FDA, the *SB Pharmco* court, and this Court.

The point here is simply that Par's basis for serving its premature July 2013 Paragraph IV Notice position not in compliance with and is contradicted by the statute, has been fully rejected by the FDA and the applicable case law, and is contrary to the policies that animate the relevant provisions of the Hatch Waxman statute. Par's position, as this Court itself previously held in *Otsuka*, is clearly wrong and any Paragraph IV Notice letters that Par served on Plaintiffs before March 2014 were premature and ineffective to trigger the Hatch Waxman litigation process. Therefore, this action should be dismissed without prejudice in its entirety.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court dismiss the claims in this case, without prejudice, in their entirety and that the Court reject Par's request to have the case schedule in the present case apply to the recently filed action against Par.

Dated: May 14, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on May 14, 2014, upon the following individuals via electronic mail:

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