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.	C.A. No. 13-1461-RGA **Redacted Version DI 85**
RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. WATSON LABORATORIES, INC., Defendant.	C.A. No. 13-1674-RGA **Redacted Version DI 64**
RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. ALVOGEN PINE BROOK, INC., Defendant.	C.A. No. 13-CV-2003-RGA **Redacted Version DI 54**
RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC. and INTELGENX TECHNOLOGIES CORP., Defendants.	C.A. No. 14-422-RGA **Redacted Version DI 10**

JOINT STATUS REPORT

The parties submit this Joint Status Report in accordance with the Court's order during the April 7, 2014 discovery dispute conference, as modified by stipulation, regarding the status of each of the above cases.

Reckitt Benckiser Pharms., Inc. et al. v. Par Pharm., Inc., et al.,
C. A. Nos. 13-1461-RGA and 14-422-RGA

PLAINTIFFS' POSITION:

Plaintiffs' position is that all claims and counterclaims in Par case C.A. No. 13-1461 should be dismissed without prejudice based on a lack of subject matter jurisdiction arising from Par's service of Paragraph IV Notices that were premature and ineffective insofar as Par did not receive an acceptance for filing letter from FDA for its subject ANDA before [redacted] Therefore, none of Par's Paragraph IV Notices served before [redacted] were effective to trigger the ANDA litigation process or the running of a 30 month stay of FDA marketing for Par's proposed product. Plaintiffs have filed a motion to obtain such relief on that basis.

It is also Plaintiffs' position, as set forth in its Amended Complaint, that, as to the recent filed (C.A. No. 14-422) based on Par's March 25, 2014 Paragraph IV Notice, insofar as Par has received an FDA Acknowledgment Letter from the FDA with respect to the 8 mg/2 mg buprenorphine/naloxone dosage strength and has provided Plaintiffs with a Paragraph IV Notice directed to that dosage (namely, Par's March 2014 Notice Letter), Plaintiffs expect the present action to proceed, at the appropriate time, based on that Notice and that a 30-month stay of FDA approval as to that dosage strength will run from Plaintiffs' receipt of that Notice. Given that all of Par's pre-March 2014 Notice Letters were premature, Plaintiffs believe that the 30-month stay of FDA approval of Defendants' ANDA No. 20-5854 with respect to the 2mg/0.5 mg and 4mg/1

mg dosage strengths, which were the subject of an April 2014 Notice Letter from Par, will run, at the very earliest, from the date of that April Notice Letter.

With respect to the schedule in the new case, C.A. No. 14-422, Plaintiffs' position is that the schedule in that case should be consistent with what it would have been but for Par's having sent premature Notices that led Plaintiffs to sue Par last August.

Par's first Paragraph IV Notice was dated July 8, 2013, but its first effective Notice is dated March 25, 2014. That is an approximately 8.5 month span. The present trial date of August 31, 2015 (based on Par's ineffective Notice) is about 26 months from the date of Par's July 8, 2013 Notice. Applying those time periods in C.A. No. 14-422 yields a proposed trial date for that case in May 2016. Accordingly, Plaintiffs' position is that, subject to the Court's schedule, trial in C.A. No. 14-422 should be scheduled for May 2016 and that a discovery schedule similar to the structure of the one now in place in C.A. No. 13-1461 should be set for this action and that activity pursuant to that schedule will commence in about 8-9 months.

In response to Par's assertion that its July 2013 Notice Letter was not premature and that the recently filed Par case (C.A. No. 14-422) should be slotted into the schedule of the preexisting Watson case, Plaintiffs' briefly further respond as follows. Par's position that it is required to serve a Paragraph IV letter when it makes an amendment to an ANDA ***before that ANDA has been the subject of an acceptance for filing letter from the FDA*** has been consistently repudiated by the FDA and by the Courts, including, very recently, this Court in *Otsuka*—as detailed in Plaintiffs' pending Motion to Dismiss (D.I. 81) the earlier filed Par case, C.A. No. 14-422. Furthermore, the law has not "evolved," as Par would have it, since it served its premature July 2013 Notice Letter. *Otsuka* was not the first court decision to address this, Par's position was repudiated years ago in *SB Pharmaco* (as set forth in Plaintiffs' Motion to

Dismiss) and by the FDA. For all the reasons set forth in that Motion, Par's July 2013 Notice Letter was premature and ineffective to trigger the ANDA Litigation process.

Now Par seeks to be rewarded for having ignored these prior repudiations of its position by the FDA and the Courts and asks the Court to treat its having wrongfully triggered the filing of the earlier Par action as a *fait accompli*. But the simple fact is that Par was not entitled to trigger the ANDA litigation process prematurely—close to 9 months prematurely as it turns out. Par's having flouted the governing rules and procedures should not be the basis of its reaping a strategic advantage by being on the same procedural track as Watson, which followed the rules, and by obtaining a trial date, at which Par intends to attack the validity and exclusivity of Plaintiffs' patents, that is about 9 months earlier than the trial date Par would have received had it played by the rules and not prematurely triggered the filing of the lawsuit in C.A. No. 14-422. Allowing Par to slot into the Watson schedule thus not only unduly and unjustifiably prejudices Plaintiffs but would only serve to further embolden Par to continue to attempt to game the system by filing premature Paragraph IV Notices so that it can trigger the premature filing of ANDA litigation.

Par's references to the discovery conference transcript and Plaintiffs' comments about not having the cases out of "snyc" are taken entirely out of context. The context there was one where the cases where assumed to be proceeding in parallel. Now as set forth in Plaintiffs' respective Motions to Dismiss (the Alvogen case and the earlier-filed Par case), believe that the Alvogen case should be dismissed altogether and the Par case should be on a decidedly different track, as it would have been if Par had not pulled the trigger prematurely, many months early. Additionally, contrary to Par, the prejudice to Plaintiffs is clear: Plaintiffs will be deprived of the benefits that they are afforded under the Hatch Waxman statute, namely, not to have to

commencement litigation against an ANDA filer until the appropriate time under the statute and not have an ANDA filer be allowed to prematurely trigger the litigation process and have a normal, not accelerated, pretrial and trial schedule in a strategic attempt to prematurely pressure the brand company and subject the brand's asserted patents prematurely to attack by a second filer. Finally, as to the issue of judicial economy, that consideration should not be allowed to bootstrap Par into a position to which it is not entitled, and remains to be seen in any event given that the Watson trial isn't scheduled until August 2015 and the Par trial should be in May 2016—there are numerous scenarios in which either judicial economy may not be affected or in which any such concerns would be substantially mitigated.

For all these reasons, the newly filed Par case should be decoupled from the Watson case schedule and Par should be placed on a trial schedule similar to that it would have received had it refrained from triggering premature litigation by serving its premature July 2013 Notice Letter. Accordingly, trial in the new Par case, C.A. No. 14-422, should be scheduled for May 2016 and that a discovery schedule similar to the structure of the one now in place in C.A. No. 13-1461 should be set for this action with activity pursuant to that schedule to commence in about 8-9 months.

DEFENDANTS' POSITION:

Par and IntelGenx believe that no change to this Court's December 30, 2013 scheduling order (D.I. 33) is required or sensible. That scheduling order coordinates discovery, contentions, claim construction and other pre-trial deadlines for this matter and the two related matters, *Reckitt Benckiser Pharm., Inc. et al. v. Watson Labs., Inc.*, C.A. No. 13-1674-RGA (the "Watson action") and *Reckitt Benckiser Pharm., Inc. et al. v. Alvogen Pine Brook, Inc.*, C.A. No. 13-cv-2003-RGA (the "Alvogen action"). Under that scheduling order, discovery is underway,

infringement and invalidity contentions have been served, claim construction is about to commence (claim terms for construction are due to be exchanged May 2, 2014), and all defendants actively are participating in the litigation under that scheduling order. Par and IntelGenx believe that Plaintiffs' request to delay this litigation is inconsistent with the statutory mandate that the parties "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

Par and IntelGenx believe the most sensible outcome is that C.A. No. 14-422 should be consolidated with the instant action, and maintained on the current schedule, in parallel with the Watson action and the Alvogen action. The issues in C.A. No. 14-422 involve the same patents and the same products as C.A. No. 13-1461.

Plaintiffs filed the new action against Par and IntelGenx, C.A. No. 14-422, on April 4, 2014. That action was filed in response to a Notice Letter Par sent to Plaintiffs on March 25, 2014, after Par received an FDA Acknowledgment Letter. Par subsequently amended its ANDA to add the 2mg/05.mg and 4 mg/1 mg dosage strengths, as well as to add Paragraph IV Certifications for the three suit patents with regard to the 2mg/05.mg and 4 mg/1 mg dosage strengths. At the same time, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(II), Par sent another Notice Letter to Plaintiffs on April 8, 2014. After receiving that letter, Plaintiffs served an Amended Complaint in C.A. No. 14-422, which added allegations pertaining to the new strengths. (C.A. No. 14-422, D.I. 9.)

The timing of Par's earlier Paragraph IV letters, and the new dosage strengths that are the subject of Par's April 8, 2014 Notice Letter, provide no basis to delay the schedule or to require Par to litigate and try this matter on a schedule that is different from, and materially longer than, the schedule in place for these three related actions.

First, Par's earlier Paragraph IV letters were not "premature." Par's July 8, 2013 Notice Letter was not premature. Par believed in good faith that such letters were required by statute and FDA regulations interpreting that statute—they were sent at the same time Par amended its ANDA to include a new Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(ii)(II) ("[I]f [a Paragraph IV Certification] is in an amendment or supplement to the application, [the Notice Letter shall be sent] at the time at which the applicant submits the amendment of supplement[.]"); 21 C.F.R. § 314.95(d) ("If an abbreviated application is amended to include [a Paragraph IV certification], the applicant shall send the notice required by paragraph (a) of this section at the same time that the amendment to the abbreviated application is submitted to FDA."). Thus, Par was acting under a good-faith belief that this certification was required by law. Plaintiffs effectively seek to sanction Par based on the court's decision in *Otsuka*—which was issued more than eight months after Par's notice letter was served. Although the law has evolved since Par served its original notice letter, the schedule should not be adjusted as a punitive measure for Par's good faith attempt to comply with the law. Moreover, Par has offered to stipulate with Plaintiffs that Par's original July 8, 2013 Notice Letter did not trigger the 30-month stay.

Par's April 8, 2014 Notice Letter was not "premature" and was sufficient to trigger the 30-month stay with regard to the new dosage strengths. Par sent the April 8, 2014 Notice Letter at the same time it amended its ANDA (*see* 21 U.S.C. § 355(j)(2)(B)(ii)(II)) and Par expects that under applicable statutes and FDA regulations, that it will not receive a new and separate FDA Acknowledgement Letter as to the 2mg/0.5 mg and 4 mg/1 mg dosage strengths. Accordingly, Par believes that the timing of these Notice Letters does not justify delaying the current schedule.

Second, Plaintiffs provide no support for their claim that they will suffer prejudice if the cases are allowed to proceed on the current schedule. Plaintiffs' assertion that the case should be tried nine months later is arbitrary and without support. Even if Plaintiffs had sued Par at a later date, that would not prevent the Court from consolidating that case with the earlier-filed *Watson* case. Courts in Hatch-Waxman cases frequently consolidate cases that were filed at different times so long as the cases present common issues and consolidation would promote judicial efficiency. *See, e.g., Cima Labs. Inc. v. Actagis Group* HF, No. 07-893, 2007 WL 1672229, at *5-8 (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). Indeed, Plaintiffs' proposal would necessitate separate *Markman* hearings and trials on the same patents, even though the parties have already prepared to begin claim construction next week.

Plaintiffs' prejudice claims contradict their earlier statements in this case. For example, when Par sought a protective order against the production of its ANDA before MonoSol identified its trade secrets, Plaintiffs complained they were prejudiced because the delayed production "interfere[d] with MonoSol's ability to coordinate its case presentation in the Par, Watson, and Alvogen cases." (D.I. 50, at 3.) Similarly, at the hearing regarding that dispute, Plaintiffs cited the overlap among the three cases and indicated that Plaintiffs would "rather not have things get out of sync." (Ex. A, at 22:13-23:5.) Par struggles to square Plaintiffs' prior assertions that multiple schedules would prejudice Plaintiffs with Plaintiffs' current request to "decouple" the Par litigation from the consolidated matters that are underway.

Finally, the new dosage strengths that are the subject of Par's most recent letter should not delay the schedule. Plaintiffs can amend their infringement contentions to address the new strengths, and Defendants can (if necessary) amend their invalidity contentions. Thus, because

C.A. No. 14-422 presents common issues with C.A. No. 13-1461, the Watson action, and the Alvogen action, consolidation of the schedules in those actions would promote judicial efficiency.

***Reckitt Benckiser Pharms., Inc. et al. v. Watson Labs., Inc.,* C. A. No. 13-1674-RGA**

PLAINTIFFS' POSITION:

Plaintiffs' position is that the schedule in the Watson case will remain in place.

DEFENDANT'S POSITION:

Defendant's position is that the schedule in the Watson case will remain in place.

***Reckitt Benckiser Pharms., Inc. et al. v. Alvogen Pine Brook, Inc.,* C. A. No 13-cv-2003-RGA**

PLAINTIFFS' POSITION:

Plaintiffs' position is that all claims and counterclaims in the Alvogen case should be dismissed without prejudice based on a lack of subject matter jurisdiction arising from Alvogen's service of Paragraph IV Notices that were premature and ineffective insofar as Alvogen has, to date, not received an acceptance for filing letter from FDA for Alvogen's subject ANDA, and therefore neither the ANDA litigation process nor the running of a 30 month stay of FDA marketing for Alvogen's proposed product has been triggered. Plaintiffs are seeking such relief on those grounds in their pending Motion to Dismiss all claims and counterclaims in the Alvogen action without prejudice.

DEFENDANT'S POSITION:

Alvogen is currently considering the Motion to Dismiss filed by Plaintiffs on April 18, 2014 as well as a proposed stipulation of dismissal provided by Plaintiffs.

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