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

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS

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STATUTES

Defendants Par Pharmaceutical, Inc. and IntelGenx Technologies Corp. (collectively, "Defendants") oppose Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc., RB Pharmaceuticals Limited and MonoSol Rx, LLC's (collectively, "Plaintiffs") motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) and Fed. R. Civ. P. 41(a)(2).

Plaintiffs' motion to dismiss should have no impact on this proceeding because Plaintiffs already have filed a second suit against Defendants asserting all of the claims asserted against Defendants in the present action. The second suit should be consolidated with the existing matter, and proceed on the same stipulated and Court-ordered schedule already entered in the present action. Dismissal would and should have no material effect on these proceedings.

Defendants present this submission, however, believing it is important to correct misimpressions that could be created by Plaintiffs' motion. Plaintiffs contend, *inter alia*, that Par: 1) sent its initial notices of Paragraph IV certifications prematurely, and contrary to law; and 2) sought to and gained some litigation advantage by doing so. Neither is the case. Par sent its initial notice of Paragraph IV certifications in accordance with a good faith understanding of controlling law at the time, and in accordance with its desire, and right, to seek the maximum benefit of existing law. Second, Par and IntelGenx have gained no litigation advantage because Plaintiffs' second-filed matter can proceed on the same schedule, and Defendants conceded that the 30-month stay was not triggered until the last-sent notice of Paragraph IV certification.

I. INTRODUCTION

Plaintiffs assert that Par's initial notices of Paragraph IV certifications were improper because Par sent each of those notices at the same time that it submitted to FDA amendments to Par's abbreviated new drug application ("ANDA") on buprenorphine and naloxone sublingual film product. Plaintiffs contend by submitting these notices prior to FDA notification that Par's ANDA was deemed acceptable for filing, Par intentionally tried to "prematurely" trigger the

Hatch-Waxman litigation process. Plaintiffs ignore the governing statute's express language, pursuant to which Par sent its notices of Paragraph IV certifications. The Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(B)(ii)(II), requires that notice be given to the NDA holder and the patent owner "at the time at which the applicant submits [an] amendment or supplement" to its ANDA. Plaintiffs filed this suit on August 20, 2013 after receiving Par's first Paragraph IV notice; and Plaintiffs admit they filed the lawsuit knowing that Par had not received FDA's notice of acceptance for filing (D.I. 82 at 5 n.2). The parties negotiated a coordinated schedule in this case, *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"). All of these cases are proceeding pursuant to that coordinated schedule: Plaintiffs have served infringement contentions; Defendants have served invalidity contentions; the parties have exchanged proposed claim terms for construction; and Plaintiffs have proposed serving supplemental infringement contentions.[1]

Since Par sent its initial notices of Paragraph IV certifications to Plaintiffs, Par has received notification from FDA that Par's ANDA was accepted for filing. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(I), Par then sent another notice of Paragraph IV certification to Plaintiffs. In response, Plaintiffs filed suit against Defendants in C.A. No. 14-422 on April 4, 2014, alleging infringement of the same patents at issue in the present action—by the same accused products at issue in the present action. Because C.A. No. 14-422 was filed, even if the present action is dismissed, Plaintiffs have already commenced a new action that asserts nearly identical issues as the present action, and it easily can progress on the same schedule. There is no dispute that the 30-month stay of approval was triggered only by Par's most recent notice of Paragraph IV

[1] Par will file a motion in C.A. No. 14-422 to consolidate that action with the present action, and with the Watson and Alvogen actions for discovery purposes.

certification; and Par has offered to execute a stipulation to that effect. This motion to dismiss, without prejudice, does nothing to resolve any dispute between the parties, and instead merely elevates form over substance.[2]

II. ARGUMENT

A. Par's Notice of Paragraph IV Certifications Required by the Clear and Unambiguous Language of the Statute

Par provided its initial notice of Paragraph IV certification with respect to its ANDA on buprenorphine and naloxone sublingual film product based on its good faith understanding of the law at the time. In sending notice, Par followed the express language of the Hatch-Waxman statute, which mandates that an ANDA applicant send notice of Paragraph IV certification under two circumstances:

> (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) (emphasis added). Thus, when Par submitted an amendment to its ANDA on July 8, 2013 that included a new Paragraph IV certification, Par complied with the clear and unambiguous language of the statute requiring that, at the same time, Par send notice to the NDA holder and the patent owner. Similarly, when Par again submitted amendments to its ANDA on February 3, 2014 and April 8, 2014 to add Paragraph IV certifications, Par again complied with the clear and unambiguous language of the statute. And when Par received

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[2] For the reasons discussed below, Par does not oppose Plaintiffs' motion to dismiss Par's counterclaims of no trade secret misappropriation and Par has not included a counterclaim for no trade secret misappropriation in C.A. 14-422.

notification from FDA that its ANDA was accepted for filing, Par again complied with the clear and unambiguous language of the statute, sending notice on March 25, 2014.

Plaintiffs argue that Par's actions are inconsistent with the statute—but that argument cites only the first provision of the statute, claims it is "unambiguous," and ignores express language in the second clause that requires notice be sent at the same time an amendment or supplement to an ANDA is filed with FDA. While the first clause of the statute includes the requirement that the ANDA "has been filed" before notice is given, that requirement is entirely absent from the second clause. FDA's regulations implementing this second provision of the statute (which Plaintiffs also ignore) likewise do not include the requirement that the ANDA "has been filed" with respect to Paragraph IV certifications in an amendment or supplement to an ANDA:

> If an abbreviated application is amended to include the certification described in 314.94(a)(12)(i)(A)(4), 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.

21 C.F.R. § 314.95(d) (emphasis added). "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (citation omitted). *See also Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (recognizing the Court's "duty to refrain from reading a phrase into the statute when Congress has left it out").

Plaintiffs argue that *SB Pharmco Puerto Rico, Inc. v. Mutual Pharm. Co.*, 552 F. Supp. 2d 500, 507 (E.D. Pa. 2008) and FDA's policy statements supersede Congress' statutory directive. Par, however, believes that the *SB Pharmco* court improperly gave deference to FDA's statutory interpretation that read into the second clause of the statute the requirement that

an ANDA "has been filed." If the statute is clear and unambiguous, no deference is owed to FDA's statutory interpretation. "[T]he Court must consider first whether the language of the statute is clear. If it is, consideration of administrative interpretation contrary to such language is inappropriate; the agency cannot by its interpretation, override congressional will as memorialized in the statutory language." *Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1526 (D.D.C. 1989).

Defendants acknowledge that their statutory interpretation differs from FDA's, and with the *SB Pharmco* court. But that does not make Par's position wrong as a matter of law, particularly where *SB Pharmco* has not been followed or cited with approval, and where neither that decision nor the FDA's statutory interpretation has been addressed by any higher court.[3] Defendants have offered to stipulate with Plaintiffs that neither Par's original July 8, 2013 notice or its February 3, 2014 notice triggered the 30-month stay. Plaintiffs rejected that proposal, and filed this motion instead.

When Par initially sent notice to Plaintiffs of Par's Paragraph IV certification, Par did not know whether any generic applicant had achieved the status of being a "first applicant" and thus the opportunity to be eligible to receive 180 days of marketing exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv).[4] The D.C. Circuit has held that an ANDA applicant that failed to provide notice to the NDA holder and the patent holder at the same time that the ANDA applicant filed an amendment to its ANDA, in compliance with 21 U.S.C. § 355(j)(2)(B)(ii), caused the ANDA applicant to lose its status as a first applicant. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877,

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[3] This Court's decision in *Otsuka Pharmaceutical Co. Ltd. v. Par Pharmaceutical Inc.*, C.A. No. 13-1979 (D. Del. Mar. 10, 2014) was issued eight months after Par sent its first notice of Paragraph IV certification.

[4] Par has since learned that it is not the "first applicant" for this product, at least with respect to the strength included in Par's original ANDA.

888 (D.C. Cir. 2004). Thus, based on *Purepac* and the state of the law at the time, Par sought to protect its maximum rights by following the express language of 21 U.S.C. § 355(j)(2)(B)(ii).

Par's conduct was reasonable and consistent with the express language of the statute and the state of the law as it existed at the time. Plaintiffs' assertions that Par's actions were instead a result of an "incentive[] to prematurely submit incomplete ANDA filings" are baseless. (D.I. 82 at 4.) First, the earliest ANDA filer is granted 180 days of marketing exclusivity ***only if that ANDA is complete***. Thus, contrary to Plaintiffs' assertions to the contrary, there is no incentive for a generic filer to prematurely file an incomplete application. Indeed, in this case, FDA found that Par's ANDA was complete, and there is therefore no basis for any claim that Par prematurely filed an incomplete ANDA. Second, Plaintiffs' claim that "[p]rematurely filing, or prematurely notifying the NDA holder or patent owner, allows the ANDA filer the potential to market its generic drug much earlier than ordinarily allowed" is equally without merit. (*Id.*) The FDA has interpreted the thirty-month stay to run from the notice sent after an ANDA is accepted—and Defendants have offered to stipulate to that effect. Thus, Defendants have not "reap[ed] any strategic advantage" as Plaintiffs assert. (*Id.*) Finally, Plaintiffs' claim that improper notification causes the NDA holder or patent holder to expend resources in a suit that may ultimately be unnecessary is moot in light of the fact that Par has, in fact, received acceptance for filing. Thus, Plaintiffs' assertions that Par is attempting to reap an unwarranted strategic benefit are just wrong as a matter of fact and law.

B. Par's Receipt of Acceptance for Filing and Plaintiffs' Complaint in Response Render Plaintiffs' Motion to Dismiss Irrelevant

Plaintiffs' motion to dismiss should have no practical effect on this litigation. Plaintiffs filed a new action against Defendants, C.A. No. 14-422, on April 4, 2014. The new action was filed in response to Plaintiffs' receipt of a notice of Paragraph IV certification sent by Par on

March 25, 2014, subsequent to FDA's notification to Par that its ANDA was accepted for filing. The new action involves the same ANDA, the same products and the same patents as the current action. Because C.A. 14-422 is currently pending, dismissal of the present action without prejudice places form over substance. With the exception of Par's counterclaim regarding alleged trade secret misappropriation, discussed below, the identical claims and defenses are subsumed with the new action. In view of the two actions being materially identical, Par will move for consolidation of C.A. No. 14-422 with the current action, and with the Watson and Alvogen actions for discovery purposes. However, even without consolidation, dismissal of the current action serves no useful purpose because C.A. No. 14-422 already is pending.

Plaintiffs' effort to delay the schedule for Par's matter is unwarranted. Plaintiffs have arbitrarily asserted that the schedule in the second litigation should be postponed by 8.5 months—the difference between Plaintiffs' receipt of Par's initial notice of Paragraph IV certification and its notice sent after acceptance for filing. (D.I. 85 at 3.) But there is no prescribed timeline for discovery in an ANDA case that requires that the schedule be delayed—indeed, courts frequently consolidate cases with earlier-filed actions. *See, e.g.*, *Cima Labs., Inc. v. Actavis Grp. 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). Because C.A. No. 14-422 presents identical issues to this one, and similar issues to the Watson and Alvogen cases, it can and should proceed under the existing Court-ordered schedule. Nothing about the newly-filed complaint materially alters the infringement or invalidity contentions or otherwise effects the discovery that has already commenced.

Plaintiffs' request to delay the schedule is particularly troubling because before Plaintiffs filed the complaint at issue in this motion, "Par's counsel informed Plaintiffs' counsel that Par

had not received an acceptance of filing letter for its ANDA from FDA." (D.I. 82 at 5 n.2.) That is, Plaintiffs' motion complains of a fact it has known of since before it filed this complaint on August 20, 2013, and since then Plaintiffs not only filed the complaint but participated in scheduling negotiations, proceeded in court hearings regarding that schedule, and acted pursuant to the schedule with no mention of prejudice from the allegedly early notice letter. (D.I. 85 at 9.) Indeed, it was Plaintiffs who advocated that their claims against Par proceed along the same schedule as the Watson and Alvogen actions. If Plaintiffs believed the Par cases should have been tried on a separate schedule after acceptance for filing was received, it should have sought to stay the case or raised the issue at the outset. Instead, admittedly with full knowledge that Par had not received an acceptance for filing before the suit was commenced, Plaintiffs waited until Par had coordinated with co-defendants and engaged in discovery before belatedly seeking to set the suit back 8.5 months. Any alleged "prejudice" that results from the discovery or activity that has taken place in this case is a problem of Plaintiffs' own making; and in fact Par could suffer prejudice if the schedule is continued because Plaintiffs will have benefitted from possessing Par's ANDA, invalidity contentions, and claim construction terms, and an additional 8.5 months to prepare their case. Defendants respectfully submit that any ruling on Plaintiffs' motion to dismiss should have no effect on the schedule, which should apply to C.A. No. 14-422.

C. Par's Counterclaims Regarding Trade Secrets Were Made in Good Faith

At the time that Par filed its Declaratory Judgment counterclaim alleging that it has not misappropriated any valid trade secrets belonging to MonoSol, Par had a good faith basis for that counterclaim. Prior to filing suit, MonoSol requested access to Par's confidential ANDA for consideration of trade secret misappropriation claims where the Hatch-Waxman Act provided for access solely for consideration of claims of patent infringement. *See* 21 U.S.C. § 355(j)(5)(C)(i)(III) (providing for an offer of confidential access "for the purpose of

determining whether [a patent infringement action] should be brought"). MonoSol had demonstrated its willingness to protect its intellectual property by filing the present patent infringement suit. Par feared that if it did not seek to obtain certainty with regard to MonoSol's trade secret claims, MonoSol could delay asserting those claims until the patent litigation between the parties was well advanced or even until Par obtained approval of its ANDA product. Such delay could create severe prejudice to Par. Thus, at the time it filed its answer and counterclaims, Par had a good faith belief that a justiciable case or controversy existed regarding whether Par had misappropriated MonoSol's trade secrets.

Since Par's initial filing of its trade secret counterclaims, MonoSol has had an extended opportunity to review Par's ANDA, receiving a complete copy of Par's ANDA on January 31, 2014. MonoSol has since made a corporate representation—in response to an interrogatory—that it has not identified information in Par's ANDA that evidences misappropriation of a MonoSol trade secret. (*See* D.I. 71-1 at Ex. 3 (Plaintiffs' Response and Objections to Defendant Par Pharmaceutical, Inc.'s Interrogatory No. 2)). In light of the interrogatory response, Par does not oppose dismissal of Par's counterclaim regarding trade secrets.[5]

III. CONCLUSION

For the reasons stated above, Defendants respectfully request that the Court deny Plaintiffs' Motion to Dismiss as to the claims of patent infringement.

[5] In its Answer to Plaintiffs' complaint in C.A. 14-422, Par will not re-allege its counterclaim of no trade secret misappropriation.

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