IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC.,

Plaintiff,

v.

ACTAVIS PLC, ACTAVIS, INC., WATSON LABORATORIES, INC., and ACTAVIS PHARMA, INC. (F/K/A WATSON PHARMA, INC.),

Defendants.

CIVIL ACTION NO. 2:14-cv-638

HIGHLY CONFIDENTIAL
Filed Under Seal

ALLERGAN, INC.'S MOTION FOR SUMMARY JUDGMENT ON COUNT I, AND MOTION TO DISMISS COUNTS II, III, IV, AND V

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I. INTRODUCTION

This is a second case that Allergan should not have been forced to bring. The Watson Defendants want to obtain FDA approval to sell a generic version of Allergan's patented drug RESTASIS®. Watson sent Allergan a letter alleging that the FDA "has received" Watson's Abbreviated New Drug Application and that the application "contains the required bioequivalence data and/or bioequivalence waiver." If that were true, then Watson's application would trigger claims for patent infringement under 35 U.S.C. § 271(e)(2), and its notice letter would trigger a 45-day window in which Allergan would have to file suit to obtain a statutory 30-month stay on final FDA approval of Defendants' product. Allergan thus had to rely on Defendants' letter and file this suit—otherwise it risked missing these statutory deadlines.

But, as it turns out, Watson's statements were not true. There was an inkling of inconsistency after Defendants issued a press release stating that the FDA "refused to receive" the application. But Watson has ignored Allergan's efforts to clarify the issue, forcing Allergan to file this suit before the 45-day window closed. Watson's document production has now revealed that the statements in its pre-suit notice were false: [redacted]

In light of these facts, Watson's notice to Allergan was premature as a matter of law, and its actions have not yet triggered the infringement provision of § 271(e)(2). The applicable statute, legislative history, and FDA regulations address this precise situation and state that Watson should not have sent its notice. The three courts to have addressed this situation—including one prior case involving Watson—reached the same conclusion. This Court should thus rule that Watson's paragraph IV notice was premature and has no legal effect, and dismiss this infringement case without prejudice for lack of subject matter jurisdiction.

II. LEGAL FRAMEWORK FOR THE HATCH-WAXMAN ACT

A. The Hatch-Waxman Act Is a Compromise Between the Interests of Innovator and Generic Drug Companies

The Hatch-Waxman Act creates a specific process through which innovator and generic drug companies can resolve patent infringement disputes—a process that was carefully calibrated "to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1326 (Fed. Cir. 2001).

An innovator company obtains FDA approval to sell a new drug by submitting a New Drug Application (NDA) that contains extensive clinical data showing the drug is safe and effective in humans. *See* 21 U.S.C. § 355(a). These clinical trials typically cost tens of millions of dollars on top of the extensive research and development costs incurred by the innovator company. (D.I. 1, at ¶ 49.) For these reasons, it is estimated that the median cost to bring a single innovator drug to market is over $350 million, with that figure going up to nearly $5.5 billion per drug for innovator companies that get more drugs approved. (*Id.*; *see also* Matthew Herper, "The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change," www.forbes.com (last accessed on June 16, 2014).)

If the innovator has obtained patent protection on its new drug, as is typical, it must inform the FDA of all existing patents that cover the drug (or a method of using it). The FDA then lists those patents in a publication it calls the Orange Book. *See* 21 U.S.C. § 355(b)(1) and (c)(2).

A generic company that wants to market a copycat version of the drug may try to submit an Abbreviated New Drug Application (ANDA). *See* 21 U.S.C. § 355(j). Under the auspices of

what is known as the Hatch-Waxman "safe harbor," the generic company is free to develop its copycat product—including conducting any necessary lab work—without liability for patent infringement, despite the innovator's patents listed in the Orange Book. *See* 35 U.S.C. § 271(e)(1). When the generic company is finished developing its copy, the generic company is then permitted to rely on the innovator's clinical data—and thus avoid having to conduct its own costly human clinical trials. *Id*.

These twin rights—the "safe harbor" from patent infringement and the ability to rely on the innovator's clinical trials—are enormously valuable. Because there is great potential to abuse them, the FDA has established strict requirements for what a generic company must include in its ANDA. If the generic company fails to include these materials, the FDA will not invest its resources to review the ANDA, and, in theory, a lawsuit like this should never have to be filed.

B. The FDA Must "Receive" an ANDA with Sufficient Bioequivalence Information Before a Generic Company May Begin the Hatch-Waxman Litigation Process

In order to be reviewed by the FDA for potential approval, a generic company's ANDA must include the "information to show that the new drug is bioequivalent." 21 U.S.C. § 355(j)(2)(A)(iv). Bioequivalence means, generally, that the drug will act the same in the body as the innovator's drug. So, generic acetaminophen should, in theory, be bioequivalent to the famous Tylenol. But if the ANDA product is not bioequivalent, then the innovator's clinical data says nothing about the ANDA product's safety and efficacy, and the ANDA applicant will be unable to obtain approval merely by relying on the innovator's data. *Id*.

The ANDA also must include one of several certifications for any Orange Book patents that cover the innovator's drug. 21 U.S.C. § 355(j)(2)(A)(vii). If the ANDA applicant wishes to

obtain approval before the innovator company's Orange Book listed patents expire, then the generic company must submit a "paragraph IV" certification that the patents are allegedly not infringed by the ANDA applicant's proposed generic product or are invalid. *Id*.

When the generic tries to submit an ANDA, the FDA conducts an initial review to determine whether the ANDA "may be received." 21 C.F.R. § 314.101(b). The FDA's initial review includes assessing whether the ANDA is missing the statutorily required data needed to determine if the generic is actually "bioequivalent." 21 C.F.R. § 314.101(d)(3); 21 U.S.C. § 355(j)(2)(A)(iv). After completing this initial review, the FDA either tells the generic it will "receive" the ANDA for filing or tells generic that it considers the ANDA "not to have been received," and, if so, explains why. 21 C.F.R. § 314.101(b)(3).

The timing of the receipt of the ANDA is an important economic consideration for generics—the first generic company to submit a substantially complete ANDA is potentially eligible for a lucrative six months of market exclusivity if it meets certain conditions. 21 U.S.C. § 355(j)(5)(B)(iv); *see* Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective*, 25 Biotech. L. Rep. 525, 525–6 (2006) ("In general, most generic companies estimate that 60% to 80% of their potential profit for any one product is made during this exclusivity period."); Martin A. Voet, *The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management* 61 (2005) (arguing that this exclusivity period often provides the majority of total profits for generic manufacturers). This is known as "generic exclusivity" or "180-day exclusivity," and, along with the "safe harbor" and the ability to rely on the innovator's data, is enormously valuable to any generic drug company.

If—and only if—the FDA formally receives the ANDA for substantive review, then the generic must notify the innovator of any paragraph IV patent certification within 20 days and

explain the factual and legal basis of its claim that the patent is not infringed or invalid. 21 U.S.C. § 355(j)(2)(B). The FDA's regulations explicitly require that the ANDA be "received" by the FDA before an ANDA applicant may send its "paragraph IV notice":

> (b) Sending the notice. The [ANDA] 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) (emphasis added). The FDA's regulations also require that the "paragraph IV notice" include a "statement that FDA has received an abbreviated new drug application submitted by the applicant containing any required bioavailability or bioequivalence data or information." 21 C.F.R. § 314.95(c)(1); *see also* 21 U.S.C. § 355(j)(2)(B)(iv)(I).

After the innovator receives a proper paragraph IV notice from the ANDA filer, it can evaluate whether its patents cover the product described in the ANDA. The statute permits an innovator that determines its patents cover the ANDA product to file suit to protect its rights. In particular, the statute makes it an "act of infringement" for the generic to submit an ANDA for a patented drug if the ANDA complies with the requirements of 21 U.S.C. § 355(j):

> (2) It shall be an act of infringement to submit—
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [which is 21 U.S.C. § 355(j)] or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent.

35 U.S.C. § 271(e)(2); *see AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1376–77 (Fed. Cir. 2012).

The statute imposes specific timing requirements on the innovator's § 271(e)(2) claim to balance the protection of patent rights with efficient generic drug approval. If the innovator company files suit within 45 days of receiving the paragraph IV notice, the suit triggers an

automatic 30-month stay, during which the FDA is not permitted to approve the ANDA product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Like the rights given to generic companies, this 30-month stay has great value to the innovator companies. As Congress recognized when it enacted the stay provisions, the stay gives the innovator the necessary time to litigate its patent rights without the generic company being able to launch its product. This is a necessary protection because a generic drug product destroys the market for the innovator product by dramatically undercutting the innovator's prices. *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009). The generic company can do this, of course, because it has almost no research and development costs, no clinical trial costs, and no marketing costs to recoup in order to make a profit. The innovator company has already done all that for the generic, and, consequently, the generic company, if it succeeds in making it to market, can simply cut the price and still make large profits.

For these reasons, the generic company has an incentive to send its paragraph IV notice as soon as it can, so it can start the clock on the 30-month stay. The problem here, however, is that Defendants sent their paragraph IV notice too early, to try to start running out the 30-month stay even though the composition of its ANDA product is still a moving target, and indeed, when it is unclear whether the FDA will even accept Defendants' ANDA for filing. The FDA views the practice of sending premature paragraph IV notices as an improper gaming of the system by generics who might hope to gain six months of market exclusivity by filing a sham or incomplete ANDA. The FDA's regulations, relying on the intent of Congress, prohibit that practice.

III. STATEMENT OF UNDISPUTED MATERIAL FACTS

The innovator drug at issue here is RESTASIS®—the first and only product to treat dry eye by increasing tear production. Dry eye afflicts millions of Americans, and, if left untreated,

can lead to pain, ulcers, scars on the cornea, and vision loss. The FDA approved Allergan's New Drug Application for RESTASIS® in December 2002.

[redacted]

In the interim, five of Allergan's U.S. patents that cover RESTASIS® and methods of using RESTASIS® have issued in 2014, and the FDA listed them in the Orange Book. (*See* D.I. 1, at ¶¶ 5–6, 42–61 (Complaint); D.I. 1-2 (Ex. 1 to Complaint, U.S. Patent No. 8,633,162, issued

Jan. 21, 2014); D.I. 1-3 (Ex. 2 to Complaint, U.S. Patent No. 8,642,556, issued Feb. 4, 2014); D.I. 1-4 (Ex. 3 to Complaint, U.S. Patent No. 8,648,048, issued Feb. 11, 2014); and D.I. 1-5 (Ex. 4 to Complaint, U.S. Patent No. 8,685,930, issued Apr. 1, 2014).) Rather than waiting for the FDA to "receive" its ANDA, Watson ignored the statutory mandate and sent to Allergan two identical paragraph IV notice letters regarding the '111 patent, which Allergan received on January 21, and a third paragraph IV notice letter regarding the '162, '556, '048, and '930 patents, which Allergan received on April 8. (*See* D.I. 1, at ¶¶ 5–6; D.I. 1-6 (Ex. 5 to Complaint, Paragraph IV notification letter from Watson dated Apr. 7, 2014).) Watson's letters falsely stated that the FDA "has received" its ANDA and that the ANDA "contains the required bioequivalence data and/or bioequivalence waiver." (*Id.*, at 1.) [redacted] And Watson's parent acknowledged these statements were false in a January 22 press release, which stated that the "FDA notified Actavis' subsidiary [Watson] that it had refused to receive the ANDA for filing" and that Actavis "remains in discussions with the FDA concerning the filing status of its application." (D.I. 1-7 (Ex. 6 to Complaint, Jan. 22, 2014 Actavis Press Release).)

Confused by the inconsistency between Watson's January paragraph IV notice letters and its parent's press release, Allergan sent Watson a letter on February 7 explaining that the paragraph IV notice was premature and asking Watson to withdraw the notice and thereby avoid the cost of this suit. (D.I. 1-8 (Ex. 7 to Complaint, Feb. 7, 2014 Letter from Allergan to Watson).) Allergan also contacted the FDA to check whether it had formally "received" Watson's ANDA. (*See* D.I. 1-9 (Ex. 8 to Complaint, Mar. 4, 2014 Letter from FDA to Allergan's counsel).) The FDA responded on March 4 and explained that its website includes

"the date on which the first ***substantially complete*** ANDA was submitted to the agency" for a drug and that it is "currently up-to-date" for RESTASIS®. (*Id.*) The FDA's website did not list any ANDA for RESTASIS® on that date (and still does not). (D.I. 1-10 (Ex. 9 to Complaint, FDA website printout, dated May 22, 2014, and list of Paragraph IV Patent Certifications, last updated May 19, 2014); Ex. C (FDA website printout, dated June 17, 2014, and list of Paragraph IV Patent Certifications, last updated June 10, 2014).) The upshot is that the FDA was telling Allergan the same thing it had told Watson—that it was refusing to receive the ANDA.

Meanwhile, the days continued to pass after Watson's paragraph IV notices, and Watson had still not responded to Allergan's pre-suit letter asking it to withdraw the notices as premature. This put Allergan in a difficult situation—Allergan received an alleged paragraph IV notice on January 21 that should have no legal effect. But the stakes are so high that Allergan could not risk the chance that the 45-day clock to file suit and obtain the 30-month stay had started to run. So Allergan filed the first suit on March 6, seeking a declaratory judgment that Watson's paragraph IV notice regarding the '111 patent was premature, and in the alternative, Allergan asserted a protective claim for infringement of the '111 patent under § 271(e)(2). (C.A. No. 2:14-cv-188-JRG.)

Events since the first complaint have underscored that all of Watson's alleged paragraph IV notice letters were premature. Watson sent another paragraph IV notice letter to Allergan regarding the '162, '556, '048, and '930 patents—four new Allergan patents on RESTASIS® that issued after the '111 patent and were recently added the Orange Book. (D.I. 1-6 (Ex. 5 to Complaint, Paragraph IV notification letter from Watson dated Apr. 7, 2014).) [redacted]

[redacted]

Given this development, Allergan again asked Watson to withdraw its premature paragraph IV notices, this time citing case law in which another district court had held that such a notice was premature. (Ex. E (Apr. 11, 2014 Letter from Allergan to Watson).) Watson refused, citing no authority for its position. (Ex. F (Apr. 14, 2014 Letter from Watson to Allergan).) Seeing as Watson was continuing to deny that its paragraph IV notices were premature, Allergan was forced to file this action seeking a declaratory judgment that Watson's paragraph IV notice regarding the '162, '556, '048, and '930 patents was premature and does not start the 45-day clock for filing an infringement suit. (D.I. 1, at ¶¶ 93–99.) In the alternative, Allergan also asserted protective claims for infringement of the '162, '556, '048, and '930 patents under § 271(e)(2). (*Id.*, at ¶¶ 100–127.) Even as of the filing of this motion, the FDA's website contains no indication that it has formally received any ANDA related to RESTASIS®. (Ex. C.)

IV. SUMMARY JUDGMENT STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Unless a different time is set by local rule or the court orders otherwise, a party may file a motion for summary judgment at any time until 30 days after the close of all discovery." Fed. R. Civ. P. 56(b). Neither the local rules nor a prior order in this case sets a "different time," making Allergan's motion for summary judgment ripe for resolution.

V. STATEMENT OF THE ISSUES

1. Whether the Court should grant Allergan summary judgment on Count I and issue a declaratory judgment that Watson's paragraph IV notice is premature and has no legal effect.

2. If so, whether the Court should then dismiss Count II, III, IV, and V of Allergan's complaint—the protective § 271(e)(2) infringement claims that Allergan pleaded in the alternative—for lack of subject matter jurisdiction.

VI. ARGUMENT

The five counts in Allergan's complaint can be resolved based on a single, undisputed fact: the FDA has refused to receive Watson's ANDA. (Ex. A.) As a result, Watson's paragraph IV notice was premature as a matter of law and could not trigger the 45-day window for filing § 271(e)(2) claims or the 30-month stay. The Court should thus enter a declaratory judgment to that effect and then dismiss Allergan's patent infringement claims without prejudice, as there is no case or controversy under § 271(e)(2) unless and until Watson submits a complete ANDA.

A. The Court Should Issue a Declaratory Judgment that Watson's Paragraph IV Letter Was Premature Because the FDA Has Not "Received" the ANDA

There should be no question that Watson's paragraph IV notice is premature. The applicable regulations and legislative history anticipated this precise situation and both indicate that Watson should not yet have given notice. The Court should thus grant summary judgment and issue a declaratory judgment to that effect.

The FDA's regulations are crystal clear—the ANDA applicant is to send the paragraph IV notice "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). Nothing suggests that an earlier notice is allowed. And, indeed, the notice must state that the FDA "has received" the ANDA and that the ANDA contains "any required bioavailability or bioequivalence data or information." 21 C.F.R. § 314.95(c)(1). The generic cannot truthfully make those statements unless the FDA has actually "received" the ANDA. So, unless that

regulation is directing ANDA applicants to make statements that are untrue (as Watson did in its notice), it necessarily contemplates that the generic must wait until the FDA formally receives the ANDA before sending notice.

The FDA's interpretation of its regulations confirms that Watson's notice is premature. When the FDA responded to comments about its regulations, it reiterated that ANDA applicants are not allowed to send a paragraph IV notice before the FDA determines the ANDA is substantially complete and formally "receives" it:

> As written, § 314.95(b) is consistent with the legislative history because it requires the ANDA applicant to provide notice ***once FDA has determined that the ANDA is substantially complete*** to permit a substantive review. ***To permit an ANDA applicant to provide notice 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.

59 Fed. Reg. 50338, 50350 (Oct. 3, 1994) (emphasis added).

The FDA's understanding of the legislative history was dead on. Congress wanted the generic to give notice simultaneously with the "submission" of the ANDA but recognized that when the ANDA is missing key information (like bioequivalence data), then there is not really any submission at all and it is thus too early to send a paragraph IV notice:

> This notice must be given simultaneously with the submission of an ANDA. The Committee ***does not intend that applicants be permitted to circumvent this notice requirement by filing sham ANDA's or ANDA's which are substantially incomplete.***
>
> While the Committee does not intend that failure to include a minor piece of information in an ANDA vitiates the effective date of the notice required under paragraph (2)(B), ***an ANDA must include the results of any required bioavailability or bioequivalence tests.*** Failure to include the results of such tests when required ***will void the effectiveness of any notice*** under paragraph (2)(B). ***Notice must then be given again when an ANDA with any required bioavailability or bioequivalence data is submitted to the FDA.***

H. Rep. No. 98-857 pt. 1, 24 (1984) (emphasis added).

What is more, every district court that has addressed this issue—including one that resolved a prior case involving Watson—has found that a generic may not send a paragraph IV notice before the FDA formally "receives" the ANDA. For example, in *SB Pharmco Puerto Rico, Inc. v. Mutual Pharm. Co., Inc.*, 552 F. Supp. 2d 500 (E.D. Pa. 2008), the patentee had to file a suit to protect its rights after the generic sent a paragraph IV notice before the FDA had formally "received" its ANDA. *Id*. at 503-05. The generic argued its notice was permissible because it submitted the notice with an amendment to the still unreceived ANDA. *Id*. at 509-12. The court rejected that argument, explaining that a paragraph IV notice is premature until the FDA actually accepts the generic's ANDA for filing, regardless of whether the defendant submits any additional amendments later:

> When we consider Defendants' argument in the context of the statute as a whole, the sequential ANDA submission framework, which distinguishes between ANDAs physically and officially received, the FDA's reasoning for this framework, including the concern that submitted ANDAs might be incomplete and could create unnecessary work for the FDA or trigger unnecessary litigation, the sequential timing provisions for sending notice of Paragraph IV certification, and Congress's interest in preventing the filing of "sham" ANDAs, it is clear that Defendants' reading of 21 U.S.C. § 355(j)(2)(B)(ii)(II) leads to a result that undermines the entire statutory framework. ***If an ANDA applicant could send a Paragraph IV notice when amending an ANDA that has not yet been accepted as received, the applicant could accelerate the timing provisions and litigation process well beyond the framework that Congress intended.***

Id. at 510. The court thus granted judgment on the pleadings on the patentee's claim for a declaratory judgment that the paragraph IV notice was premature. *Id*.

The two other cases addressing this issue, both by Judge Andrews of the District of Delaware, have reached the same result. In the first, *Merck & Cie v. Watson Pharms., Inc.*, Watson tried the same tactic it has tried here—it sent the innovator a paragraph IV notice before the FDA accepted its ANDA for filing. (Ex. G (Sept. 25, 2012 Order, C.A. No. 12-161-RGA).) That forced the innovator to file a protective patent infringement claim, only to then move to

dismiss it without prejudice for lack of subject matter jurisdiction upon learning the FDA had not actually received the ANDA. (*Id*.) Judge Andrews ruled that "a Paragraph IV Notice letter that has been sent absent a received ANDA is of no legal effect under 21 U.S.C. § 355(j)(B)(iii) and 21 C.F.R. § 314.95(b), and does not invoke the 45-day window for a patent holder to file suit, nor does it commence the 30-month stay before the ANDA can be approved." (*Id*.) He thus dismissed the protective patent infringement claim for lack of subject matter jurisdiction. (*Id*.) In the second case, *Otsuka Pharm. Co., Ltd. v. Par Pharm., Inc.*, Judge Andrews faced the same situation once again, and granted the patent holder's Rule 12(c) motion on its claim for a declaratory judgment that the paragraph IV notice was premature, without legal effect, and did not start the clocks for either the 45-day window to file suit or the 30-month stay. (Ex. H (Mar. 10, 2014 Order, C.A. No. 13-1979 (RGA)).) He then also dismissed the patent holder's patent infringement complaint without prejudice for lack of subject matter jurisdiction. (*Id*.)

This weight of authority demonstrates that Watson's paragraph IV notice here was premature as matter of law. There can be no genuine dispute that the FDA has refused to receive Watson's ANDA. Therefore, as in *SB Pharmco*, *Merck*, and *Otsuka*, the Court should determine that Watson was not permitted to send Allergan a paragraph IV notice. [redacted] 21 U.S.C. § 355(j)(2)(A)(iv). That is the very type of deficiency that the legislative history says will "void the effectiveness" of any paragraph IV notice the generic tries to send. *See* H. Rep. No. 98-857, pt. 1, 24 (1984). [redacted] The Court should thus grant

summary judgment in Allergan's favor on Count I and enter a declaratory judgment that Watson's paragraph IV notice has no legal effect. Fed. R. Civ. P. 56(a).

B. The Court Should Dismiss the Patent Infringement Claims Because There Is No Case or Controversy until the FDA "Receives" Watson's ANDA

If it decides that Watson's paragraph IV notice was premature, the Court should dismiss the § 271(e)(2) infringement claims without prejudice for similar reasons. Section 271(e)(2) makes it an act of infringement to "submit" an ANDA that complies with the applicable provisions of 21 U.S.C. § 355(j). [redacted] Therefore, Watson has failed to "submit" an ANDA within the meaning of § 271(e)(2) and there is no actual case or controversy on those claims, requiring the Court to dismiss them without prejudice. *See* Fed. R. Civ. P. 12(h)(3) ("If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.").

The three decisions discussed above—*SB Pharmco*, *Otsuka*, and *Merck*—all dismissed the infringement claim without prejudice. For example, in *SB Pharmco* the court explained that there was no subject matter jurisdiction because the defendant does not "submit" an ANDA within the meaning of § 271(e)(2) until the FDA formally receives it for filing:

> Considering the statutory framework and legislative history that we have addressed above, ***the term "submit" in § 271(e)(2) clearly means that an ANDA has been received, not merely delivered***. It would be illogical for the statutory provisions and federal regulations to carefully construct a safeguard against incomplete ANDAs, only to allow those same potentially insufficient applications to constitute the act of infringement that triggers litigation. . . .

> In this case, at the time that Plaintiffs filed their Complaint, Defendants' actions had not satisfied the statutorily-defined act of infringement that an ANDA be submitted to the FDA because ANDA 90-132 had not yet been received. ***Therefore, the subject matter jurisdiction afforded by 35 U.S.C. § 271(e)(2) was not available when this case was filed.***

552 F. Supp. 2d at 512. This analysis makes sense—the FDA cannot approve the ANDA if it has not even "received" it for review, and, with no possibility of FDA approval of the generic, there is no imminent injury to the plaintiff and thus no subject matter jurisdiction. *Id*. Judge Andrews reached the same result in both *Otsuka* and *Merck*. (Exs. G & H.) This Court should thus follow the same course and dismiss Allergan's alternative patent infringement claims without prejudice.

VII. CONCLUSION

For the reasons above, the Court should grant summary judgment in Allergan's favor on Count I and enter a declaratory judgment that Watson's paragraph IV notice was premature, without legal effect, and does not start the 45-day window to file suit or the 30-month stay. Based on that conclusion, the Court should then dismiss Allergan's alternative patent infringement claims under § 271(e)(2) without prejudice for lack of subject matter jurisdiction.

Dated: June 17, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email on this the 17th day of June, 2014.

/s/ Susan M. Coletti