**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC,<br><br>Plaintiffs,<br><br>v.<br><br>WATSON LABORATORIES, INC.,<br><br>Defendant. | Civil Action No. 1:13-cv-01674 (RGA) |

**PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS COUNTS II AND IV OF THE COMPLAINT UNDER RULE 12(b)(1)**

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## I. INTRODUCTION AND SUMMARY

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc., RB Pharmaceuticals Limited, and MonoSol Rx, LLC (collectively, "Plaintiffs") respectfully submit this brief in opposition to Defendant Watson Laboratories, Inc.'s ("Watson") motion to dismiss the declaratory judgment counts of the complaint (counts II and IV) for lack of subject matter jurisdiction. (D.I. 12.) Plaintiffs request that Watson's motion to dismiss be denied because the controversy between the parties is real and immediate, and Plaintiffs' declaratory judgment counts are not obviated by the Hatch-Waxman Act.

There is a real and immediate controversy between Plaintiffs and Watson. Plaintiffs allege that Watson's generic Suboxone® will infringe the patents-in-suit, whereas Watson denies infringement and alleges that the patents-in-suit are invalid. In fact, Watson has filed its own declaratory judgment counterclaims against Plaintiffs and repeatedly stated that "[t]here is an actual and justiciable controversy between the parties" as to the infringement, validity, and enforceability of the patents-in-suit. (D.I. 14, Countercls. ¶¶ 10, 24, 28, 32, 36.)

Watson plans and intends to enter the market with its generic Suboxone® film product immediately following approval of its ANDA. Declaratory judgment jurisdiction exists under these facts and is consistent with the Federal Circuit's decision in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997), and with previous decisions in this District. *See, e.g.*, *Cephalon, Inc. v. Sandoz, Inc.*, No. 11-cv-00821-SLR, 2012 WL 682045 (D. Del. Mar. 1, 2012); *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338 (D. Del. 2009); and *In Re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409 (D. Del. 2010). In fact, in *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, 629 F. Supp. 2d 338

(D. Del. 2009), Watson has previously tried and failed to dismiss declaratory judgment counts based on arguments similar to those made here.

In addition, Watson's motion intimates that nothing is imminent, that its "decision to market its generic drug product" would be made in the "(future)." (D.I. 13, Br. at 1.) Yet, Watson is ready and able to enter the market with a generic version of Plaintiffs' Suboxone® sublingual film product immediately after the FDA approves its ANDA. Watson recently disclosed that it "believes it may be a 'first applicant' to file an ANDA for a generic version of Suboxone® Film and, should its ANDA be approved, may be entitled to 180 days of generic market exclusivity." Such generic exclusivity for a billion-dollar blockbuster drug like Suboxone® is extremely valuable to Watson. Moreover, Watson already markets a generic version of Plaintiffs' earlier Suboxone® tablet product, and the same sales and distribution used for the generic tablet can be used for the generic product at issue in this case. Being the first filer and having established marketing channels shows that the controversy is real and immediate, not remote or speculative as Watson argues.

Furthermore, the relief for a declaratory judgment of infringement under 35 U.S.C. § 271(a)-(c) is not preempted or displaced by the Hatch-Waxman Act (35 U.S.C. § 271(e)(2)). The contested counts (counts II and IV) prohibit all forms of infringement of the patents-in-suit, whether or not associated with the mere filing of Watson's ANDA.

## II. NATURE AND STAGE OF THE PROCEEDINGS

This is an action for infringement of U.S. Patents Nos. 8,475,832 ("the '832 patent") and 8,017,150 ("the '150 patent"). The complaint includes patent infringement counts under 35 U.S.C. § 271(e)(2) (counts I and III) and declaratory judgment of infringement counts under 35 U.S.C. § 271(a)-(c) (counts II and IV). On November 20, 2013, Watson moved to dismiss the

declaratory judgment of infringement counts (counts II and IV) under Rule 12(b)(1) of the Federal Rules of Civil Procedure for lack of subject-matter jurisdiction.

Plaintiffs have also asserted the patents-in-suit in this District against other parties: *Reckitt Benckiser Pharmaceuticals Inc., et al. v. Par Pharmaceutical Inc., et al.*, No. 13-cv-01461-RGA (D. Del.); and *Reckitt Benckiser Pharmaceuticals Inc., et al. v. Alvogen Pine Brook, Inc., et al.*, No. 13-cv-02003-RGA (D. Del.).

The Federal Rule of Civil Procedure 16(b) conference in this case, as well as the related case against Par Pharmaceutical Inc. (No. 13-cv-01461-RGA), was held on December 13, 2013.

## III. STATEMENT OF FACTS

This action arises from Watson's[1] filing of Abbreviated New Drug Application ("ANDA") No. 20-4383 seeking FDA approval to engage in the commercial manufacture, use, and/or sale of a generic version of Suboxone® sublingual film before the expiration of Plaintiffs' U.S. Patents Nos. 8,475,832 ("the '832 patent") and 8,017,150 ("the '150 patent").

Suboxone® sublingual film incorporates a novel drug delivery system to treat opioid dependence and includes buprenorphine hydrochloride and naloxone hydrochloride as active ingredients. (D.I. 1, Compl. ¶ 23.) Suboxone® sublingual film is a highly successful product, which according to Watson itself, enjoys over a billion dollars in U.S. sales per year. (*See* Declaration of Houda Morad ("Morad Decl.") at ¶ 3, Ex. 1.)

On August 30, 2010, the FDA approved Plaintiffs' NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence. (D.I. 1, Compl. ¶ 23.) Plaintiffs have sold Suboxone® sublingual film since its

[1] Actavis, Inc., initially named as a defendant in this action, was dismissed by stipulation. (D.I. 10, Stipulation at 2.) Defendant Watson is a wholly-owned subsidiary of Actavis, Inc. (see D.I. 15, Rule 7.1 Disclosure Statement at 1.)

approval. (*See* Morad Decl. at ¶ 4, Ex. 2 at 23.) The '832 and '150 patents are listed in the Orange Book as covering Suboxone® sublingual film.[2] (D.I. 1, Compl. ¶ 24.)

On August 28, 2013, Plaintiffs received a letter from Watson stating that it: (1) filed ANDA No. 20-4383, including a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("PIV Certification") alleging that the '832 and '150 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA; and (2) submitted ANDA No. 20-4383 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of a generic buprenorphine hydrochloride and naloxone hydrochloride sublingual film before expiration of the patents-in-suit. (D.I. 1, Compl. ¶¶ 25-26.)

On October 8, 2013, Plaintiffs filed a Complaint in this action within 45 days of receiving Watson's Paragraph IV letter. (*Id.* at ¶ 27.) The complaint includes four counts. Counts I and III are based upon 35 U.S.C. § 271(e)(2) and arise from Watson's filing of an ANDA (*Id.* at ¶¶ 33, 45). The counts that Watson seeks to dismiss, counts II and IV, are based upon 35 U.S.C. § 271(a)-(c) and are premised upon Watson's stated intention to engage in the manufacture, offer for sale, sale, marketing, distribution, and/or importation of a generic Suboxone® sublingual film product immediately following approval of its ANDA No. 20-4383. (*Id.* at ¶¶ 28-47).

Further, Watson recently disclosed that it "believes it may be a 'first applicant' to file an ANDA for a generic version of Suboxone® Film and, should its ANDA be approved, may be entitled to 180 days of generic market exclusivity." (*See* Morad Decl. at ¶ 3, Ex. 1.) Watson is already on the market with a generic version of the Suboxone® tablet product. (*See* Morad Decl.

[2] Plaintiffs have also listed the newly-issued U.S. Patent No. 8,603,514 ("the '514 patent") in the Orange Book, but have not yet received Watson's Paragraph IV notice for the new patent.

at ¶ 5, Ex. 3.) Watson holds an approved ANDA for a generic version of Suboxone® tablet (ANDA No. 091422). (*See* Morad Decl. at ¶ 6, Ex. 4.)

Finally, on November 20, 2013, the same day that it filed its motion to dismiss Plaintiffs' declaratory judgment counts, Watson also filed an Answer and Counterclaims and repeatedly stated therein that "[t]here is an actual and justiciable controversy between the parties" as to the infringement, validity, and enforceability of the patents-in-suit. (D.I. 14, Countercls. ¶¶ 10, 24, 28, 32, 36.)

## IV. ARGUMENT

### A. Legal Standards

Under the Declaratory Judgment Act, an actual controversy exists where the facts "show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citations omitted). Whether a declaratory judgment action presents an actual controversy must be determined based on "all the circumstances." *Id.* A justiciable dispute must be "definite and concrete, touching the legal relations of parties having adverse legal interests, . . . real and substantial, and admit of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Id.* at 127 (citations omitted).

A patentee may seek a declaration that a person will infringe a patent in the future. *See, e.g.*, *Glaxo*, 110 F.3d at 1570 (citing *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 763 (Fed. Cir. 1990)). Declaratory judgment jurisdiction exists where: "(1) the defendant [is] engaged in an activity directed toward an infringement charge or [is] making meaningful preparation for such activity; and (2) acts of the defendant [] indicate a refusal to change the course of its actions

in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming." *Cephalon, Inc. v. Sandoz, Inc.*, No. 11-cv-821-SLR, 2012 WL 682045, * 5 (D. Del. Mar. 1, 2012) (citing *Glaxo*, 110 F.3d at 1571) (hereinafter, "*Cephalon v. Sandoz*").

Watson's motion presents a factual challenge to the Complaint. Therefore, the Court is not confined to the allegations in the Complaint. Rather, the Court may consider evidence outside the pleadings to resolve factual issues bearing on the jurisdictional dispute. *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 345 (D. Del. 2009) (citing *Samsung Elecs. Co., Ltd. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645, 648 (D. Del. 2008)) (hereinafter, "*Cephalon v. Watson*").

B. Plaintiffs' Declaratory Judgment Counts Are neither Remote nor Speculative.

*1. The controversy is real and immediate.*

Watson contends that "[t]here is nothing 'real' or 'immediate'" about Plaintiffs' claims under § 271(a)-(c). (D.I. 13, Br. at 6.) Watson's conduct, however, clearly meets the standards for establishing declaratory judgment jurisdiction: (1) Watson is engaged in an activity directed toward an infringement charge and has already made meaningful preparation for such activity; and (2) Watson indicates a refusal to change the course of its actions in the face of Plaintiffs' patent infringement allegations. *See Cephalon v. Sandoz*, 2012 WL 682045, * 5 (citing *Glaxo*, 110 F.3d at 1571). Watson itself admits that an actual controversy exists in its own declaratory judgment counterclaims against Plaintiffs. (D.I. 14, Countercls. ¶¶ 10, 24, 28, 32, 36 ("There is an actual and justiciable controversy between the parties" as to the infringement, validity, and enforceability of the patents-in-suit.).)

The controversy is real and immediate. Watson's generic product has been manufactured, tested, and is pending approval from the FDA. Indeed, Watson submitted its ANDA and Paragraph IV certification for the specific purpose of obtaining FDA approval to

enter the market with a generic version of Plaintiffs' Suboxone® sublingual film product before the expiration of the patents-in-suit. In submitting its ANDA, Watson was required to fully develop a generic buprenorphine hydrochloride and naloxone hydrochloride sublingual film, establish bioequivalence between its product and Plaintiffs' Suboxone® sublingual film product, complete manufacturing control testing, and develop a proposed generic product label. See 21 C.F.R. § 314.94(a).

Further, Watson is already on the market with a generic version of the Suboxone® tablet product. Thus, Watson has established marketing capability to begin selling a generic version of Plaintiffs' Suboxone® sublingual film product immediately after FDA approval of its ANDA. It is unlikely, then, that Watson would change course, particularly given its highly beneficial status as "first applicant."

*2. The weight of the authority supports declaratory judgment jurisdiction in the context of concurrent claims under § 271(e)(2) and § 271(a)-(c).*

Watson argues that "[m]ultiple courts in this district have dismissed similar claims [as in Plaintiffs counts II and IV] in similar cases." (D.I. 13, Brief at 7.) Watson is wrong.

In the context of a Hatch-Waxman case and claims under § 271(e)(2), multiple courts have found that declaratory judgment jurisdiction exists when an ANDA applicant declares its intent to manufacture, market, and sell potentially infringing products ***following*** ANDA approval by the FDA and before expiration of the patent-in-suit. *See, e.g., Cephalon v. Watson*, 629 F. Supp. 2d at 351 ("The court concludes, under the totality of the circumstances, that such a controversy exists. Defendants have filed the ANDA and have declared their intent to manufacture, market, and sell potentially infringing products in the event that the FDA approves the ANDA."); *In Re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d at 419 (denying motion to dismiss declaratory judgment and stating "[i]n the

context of a §271(e)(2) infringement action, where the court is engaged in a forward-looking analysis of what defendants will do upon ANDA approval, defendants' declared intent is sufficient to make the controversy real and immediate"); *Cephalon v. Sandoz*, 2012 WL 682045, * 5 (D. Del. Mar. 1, 2012) (finding that declaratory relief was available when defendant was "systematically attempting to meet the applicable regulatory requirements while preparing to manufacture its product") (citing *Glaxo*, 110 F.3d at 1571); *Bayer Healthcare, LLC v. Norbrook Labs.*, Ltd., Nos. 08-C-953; 09-C-108, 2009 WL 6337911, *13-14 (E.D. Wis. Sept. 24, 2009).

Similarly, in this case, Plaintiffs allege that Watson plans and intends to engage in the manufacture, offer for sale, sale, marketing, distribution, and/or importation of a generic Suboxone® film product immediately following approval of its ANDA No. 20-4383 (D.I. 1, Compl. ¶¶ 33, 45). Further, as discussed above, Watson was required to develop a generic sublingual film product, establish bioequivalence between its product and Plaintiffs' Suboxone® film product, complete manufacturing control testing, and develop a proposed generic product label. *See* 21 C.F.R. § 314.94(a). Thus, Watson is ready to enter the market with a generic version of Plaintiffs' Suboxone® sublingual film product immediately after FDA approval of its ANDA.

Further evidence demonstrates that Plaintiffs' allegations are neither remote nor speculative. Watson recently disclosed that it "believes it may be a 'first applicant' to file an ANDA for a generic version of Suboxone® Film and, should its ANDA be approved, may be entitled to 180 days of generic market exclusivity." (*See* Morad Decl. at ¶ 3, Ex. 1.) Such generic exclusivity for a billion-dollar blockbuster drug like Suboxone® is extremely valuable and Watson cannot credibly argue that this case does not present a real controversy. *See Bayer*, 2009 WL 6337911, *4 (citing 21 U.S.C. §§ 355(j)(5)(B)(iv)) ("[A] generic manufacturer benefits

from being the first to file an ANDA with a Paragraph IV certification. As an incentive for generic manufacturers to challenge a patented drug, the Hatch-Waxman Act . . . provide[s] a 180-day exclusivity period to the generic manufacturer who files the first Paragraph IV certification."). Furthermore, Watson is already on the market with a generic version of the Suboxone® tablet product. Thus, the potential for Watson to launch a generic version of Suboxone® sublingual film following ANDA approval is real and this case presents an actual controversy for this Court to decide, as Watson itself appears to acknowledge by way of its own declaratory judgment counterclaims.

The cases Watson relies upon are factually distinguishable. For example, the *In re Rosuvastatin* decision dismissed the plaintiffs' declaratory judgment counts under § 271(a) because they were "based on all the same facts" as the § 271(e)(2) counts, namely, that the defendants had merely submitted an ANDA. *In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949, 2008 WL 5046424, *12 (D. Del. Nov. 24, 2008). In the case at bar, however, facts beyond the mere filing of the ANDA support the declaratory judgment counts, including (1) Watson's self-proclaimed status as the potential "'first applicant' to file an ANDA for a generic version of Suboxone® Film" and (2) Watson's current presence on the market with a generic version of the Suboxone® tablet product.

Further, in the other cases cited by Watson, including *Eisai Co. v. Mutual Pharm. Co.*, No. 06- 3613, 2007 WL 4556958 ( D.N.J. Dec. 20, 2007); *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 05-590, 2006 WL 2375035 (D. Del. Aug. 16, 2006); and *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925 (N.D. Ill. 1995), there was no concurrent jurisdiction under § 271(e)(2). *See, e.g., Cephalon v. Sandoz*, 2012 WL 682045, *5 (distinguishing *Eisai* and disagreeing with "the sweeping conclusion that the absence of a Paragraph IV certification

limits, as a matter of law, the court's subject matter jurisdiction under both 35 U.S.C. § 271(e)(2) and 28 U.S.C. § 2201."); *Bayer,* 2009 WL 6337911, *14 ("[I]n *Eisai*, 2007 WL 4556958 at * 9, the court determined that there was no § 271(e)(2) claim. Therefore, the decision in *Eisai* to decline a declaratory judgment claim is distinguishable from the circumstances of this instant action.").

Finally, the *Novo Nordisk* case cited by Watson is inapposite and taken out of context. The court properly stated that "a patent-holder cannot make a claim for patent infringement under § 271(a)" because in that case, those claims were not made in the context of declaratory judgment jurisdiction. *Novo Nordisk, Inc. v. Mylan Pharms., Inc.*, No. 09-cv-2445, 2010 WL 1372437, *9, *13 (D.N.J. Mar. 31, 2010) ("Novo Nordisk does not appear to request declaratory relief under § 2201. . . . Consequently, this Court must presume that Novo Nordisk is not seeking relief under the Declaratory Judgment Act."). Further, in the *Novo Nordisk* case, there was also no jurisdiction under § 271(e)(2) because Defendant Mylan filed a "section viii statement"[3] with its ANDA. *Id.* at *13.

In short, the weight of the authority supports declaratory judgment jurisdiction in this case, including *Cephalon v. Watson*, 629 F. Supp. 2d 338 (D. Del. 2009), where Watson itself lost a motion to dismiss based upon the very same arguments presented here.

C. The 30-Month Stay Does Not Negate Declaratory Judgment Jurisdiction.

A controversy that is sufficiently real and immediate to confer declaratory judgment jurisdiction may exist several years prior to the launch of a generic product. *See, e.g., Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 402-03 (S.D.N.Y. 2004) (holding that Watson's actions of developing a generic drug and applying for FDA approval

[3] A "section viii statement" is a statement by the ANDA applicant asserting that the "patent is inapplicable to the indication for which the drug product will be marketed." *Novo Nordisk*, 2010 WL 1372437, *2 (citations omitted).

created a sufficiently immediate controversy, even where Watson claimed it could not market the generic product until several years thereafter, in 2011); *Glaxo Group, Ltd. v. Apotex*, Inc., 130 F. Supp. 2d 1006, 1008-09 (N.D. Ill. 2001) (finding declaratory judgment proper where Apotex intended to sell the accused generic product upon approval of its ANDA, even when FDA approval was two years away).

Watson has declared its intent to enter the market with a generic version of Plaintiffs' Suboxone® film product immediately after FDA approval of its ANDA. This intent is further exhibited by Watson's highly beneficial status as "first applicant." These facts, alone, demonstrate that there is a real and immediate controversy between the parties.

D. Plaintiffs' Declaratory Judgment Counts Are Not Contrary to the Hatch-Waxman Scheme.

*1. Relief under the declaratory judgment counts is not duplicative.*

Watson contends that "it would be a waste of time and resources to allow Counts II and IV to remain in this litigation." (D.I. 13, Br. at 13.) Watson, however, points to no specific added burden on the Court or the parties given the concurrent jurisdiction under § 271(e)(2).

In addition, Watson also contends that "[t]here is no relief Plaintiffs could be awarded by prevailing on counts II and IV that they would not also be able to obtain if they prevail on counts I and III." (D.I. 13, Br. at 9.) Watson's suggestion that the relief under Plaintiffs' declaratory judgment counts is duplicative of relief under 35 U.S.C. § 271(e) is wrong. 35 U.S.C. § 271(e)(2), provides in relevant part that:

> It shall be an act of infringement to submit—
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act 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,
>
> . . .
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a

> drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Thus, § 271(e)(2) relates to acts of infringement associated with Watson's ANDA. In addition, § 271(e)(4) provides that "[t]he remedies prescribed by subparagraphs (A), (B), (C), and (D) are ***the only remedies*** which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285." 35 U.S.C. § 271(e)(4) (emphasis added).

On the other hand, the relief under the declaratory judgment counts for infringement under 35 U.S.C. § 271(a)-(c) is broader than under counts I and III (infringement under 35 U.S.C. § 271(e)(2)), and would prohibit all forms of infringement of the patents-in-suit, whether or not associated with Watson's ANDA. *See, e.g., Teva Pharm. Indus. Ltd. v. AstraZeneca Pharms. LP*, No. 08–4786, 2009 WL 2616816, *2 (E.D. Pa. 2009) ("[O]nly limited remedies are available to patent holders in [] suits [under] 35 U.S.C. § 271(e)."). *See also id.* at *6 ("[T]he elements of infringement differ between [] cases [under 35 U.S.C. § 271( a) and § 271( e)], as do the available remedies.").

In light of the uncertainty of the relief available under § 271(e) and the real and immediate controversy between the parties, Plaintiffs should be allowed to proceed with their declaratory judgment counts.

*2.* *Plaintiffs' declaratory judgment counts do not conflict with the Hatch-Waxman Act.*

Plaintiffs' declaratory judgment counts are not contrary to the Hatch-Waxman Act. The exercise of jurisdiction under the Declaratory Judgment Act is appropriate "whether or not further relief is or could be sought." 28 U.S.C. § 2201; *Lang*, 895 F.2d at 764 ("[T]he fact that the patent owner, unlike the accused infringer, will have an express statutory remedy for

infringement at a later time is irrelevant."). Because such declaratory judgment counts are necessary in order to fully resolve the controversy between the parties, they are often included in ANDA complaints and litigated without subject matter jurisdiction challenge. (*See, e.g.*, D.I. 1, Compl. in *Brigham and Women's Hosp., Inc. v. Teva Pharms. USA Inc.*, No. 08-cv--464 (D. Del. Jul. 25, 2008).)

As explained in *Cephalon v. Sandoz*, "the Hatch-Waxman Act [does not] preclude a patent holder from establishing jurisdiction under 28 U.S.C. § 2201(a)." 2012 WL 682045, *5 (denying motion to dismiss in the context of concurrent claims under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § (a)-(c)). *See also Takeda*, 329 F. Supp. 2d at 403 ("At its heart, Watson's argument is that allowing a declaratory judgment action on a Section 271(b) claim undermines the structure of the Hatch-Waxman Act. . . . The short answer is that the Hatch-Waxman Act did not revise or replace Section 271(b)."); *Cephalon v. Watson*, 629 F. Supp. 2d at 351 (denying motion to dismiss in the context of concurrent claims under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § (b)-(c)); *id.* ("In the context of a § 271(e)(2) infringement action, where the court is engaged in a forward-looking analysis of what defendants will do upon ANDA approval, defendants' declared intent is sufficient to make the controversy real and immediate."); *In Re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d at 419 (same).

Where, as here, the jurisdictional requirements are met, the assertion of infringement counts under § 271(e)(2) does not prevent concurrent declaratory relief.

## V. CONCLUSION

For all the foregoing reasons, Watson's motion to dismiss counts II and IV of the complaint should be denied.

Date: December 13, 2013

Respectfully submitted,

By: */s/ Mary W. Bourke*

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**CERTIFICATE OF SERVICE**

I hereby certify that on December 13, 2013, 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 December 13, 2013, upon the following individuals via electronic mail:

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