**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, | ) | |
| Plaintiffs, | ) | |
| v. | ) | CA. No. 1:13-cv-01674 (RGA) |
| WATSON LABORATORIES, INC., | ) | |
| Defendant. | ) | |

**WATSON LABORATORIES, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS COUNTS II AND IV UNDER RULE 12(b)(1)**

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Dated: November 20, 2013

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## INTRODUCTION

The Court should dismiss Counts II and IV of the complaint for lack of subject matter jurisdiction. In this Hatch-Waxman case, alleged future infringement depends on two contingent future events: FDA approval of Watson's ANDA, and Watson's decision to market the ANDA product—a generic version of Suboxone®—before this case concludes. Nevertheless, with Counts II and IV, plaintiffs assert claims for ordinary patent infringement under 35 U.S.C. § 271(a)-(c), one claim for each of two patents, alleging that Watson "plan[s] and intend[s] to" manufacture, sell, or otherwise infringe the patents "immediately following approval of [the] ANDA." (D.I. 1, Compl. ¶¶ 33, 45.) These claims do not present any justiciable controversy, and they are contrary to the elaborate statutory scheme embodied in the Hatch-Waxman Act. They should be therefore dismissed.[1]

***First***, Counts II and IV allege a potential controversy that is far too remote and speculative to support federal jurisdiction. Watson's ANDA will not receive final approval until the conclusion (or lifting) of the Hatch-Waxman Act's 30-month stay.[2] Even then, Watson would then have to make the (future) decision to market its generic drug product "at risk." These speculative and highly contingent future harms fall well short of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). Accordingly, there is no live controversy. *See, e.g., Eisai Co. v. Mutual Pharm. Co.*, Civ. A. No. 06-3613, 2007 WL 4556958, at *18 (D.N.J. Dec. 20, 2007)

[1] Counts I and III of the Complaint allege that Watson infringed by filing its ANDA. *See* 35 U.S.C. § 271(e)(2). Watson does not seek to dismiss these claims.

[2] For purposes of this motion only, Watson accepts plaintiffs' allegations as true. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (requiring that the "facts alleged" demonstrate an actual controversy) (emphasis added). In particular, Watson accepts as true plaintiffs' allegations that they "commenced this action within 45 days of receiving [Watson's] Notification Letter," triggering the 30-month stay of FDA approval of Watson's ANDA. (D.I. 1, Compl. ¶ 27.)

(dismissing § 271(a) claim, explaining "only § 271(e)(2) allows Eisai to seek judicial resolution of its patent claims prior to ANDA approval"); *In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949, 2008 WL 5046424, at *12-13 (D. Del. Nov. 24, 2008) (same in substance); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 938 (N.D. Ill. 1995) (same in substance).

***Second***, Counts II and IV run counter to the Hatch-Waxman Act. These counts allege ordinary patent infringement—that Watson "plan[s] and intend[s] to" manufacture, use, or sell an infringing product in the future. But when Congress enacted the Hatch-Waxman Act, it created a new claim ***for the specific purpose*** of giving a patentee a claim for relief where none existed before: a patentee may sue for the "highly artificial" act of infringement for submitting an ANDA. 35 U.S.C. § 271(e)(2); *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Indeed, as the Supreme Court itself has recognized, subsection (e)(2) "[q]uite obviously" was created ***precisely to give the patentee a cause of action in this situation***. *Eli Lilly*, 496 U.S. at 678. Thanks to this new claim under (e)(2), a patentee may sue when a generic company submits an ANDA; only (e)(2) "allows [plaintiff] to seek judicial resolution of its patent claims prior to ANDA approval." *Eisai*, 2007 WL 4556958, at *18. If merely filing an ANDA gave rise to a claim under subsection (a), then subsection (e) would serve no purpose. Thus, permitting the 271(a)-(c) claims to proceed would be "inconsistent with Congressional intent." *Rosuvastatin*, 2008 WL 5046424, at *13.

Accordingly, Counts II and IV should be dismissed for lack of subject-matter jurisdiction. Alternatively, should this Court find jurisdiction, it should decline to exercise that jurisdiction in order to focus its resources on the ANDA counts and to preserve Congress's judgment, reflected in the Hatch-Waxman Act, that ANDA cases be litigated under Section 271(e)(2).

## NATURE AND STAGE OF THE PROCEEDINGS

This is a patent litigation arising under the Hatch-Waxman Act. On October 8, 2013, plaintiffs sued Defendants Watson Laboratories, Inc. and Actavis, Inc. alleging that defendants infringed U.S. Patent Nos. 8,475,832 ("the '832 patent") and 8,017,150 ("the '150 patent") by filing ANDA No. 204383 with the FDA. (D.I. 1.) The ANDA's subject matter is generic Suboxone®, Buprenorphine and Naloxone Sublingual Film for Sublingual Administration, used to treat opioid dependence. On November 7, 2013, the parties filed a stipulation dismissing Actavis without prejudice, leaving Watson as the only defendant. (D.I. 10, 11.)

Now, Watson moves to dismiss Counts II and IV of the Complaint under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

## SUMMARY OF THE ARGUMENT

(1) In any action for a declaratory judgment, the plaintiff has the burden to show that the facts alleged, under all the circumstances, 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*, 549 U.S. at 127. Here, the purported "controversy" supporting the claims under Section 271(a)-(c) is too remote. "The alleged future infringement depends on two contingent future events: FDA approval of [Watson's] ANDA, and [Watson's] decision to market a generic version of [Suboxone®] pursuant to that ANDA." *Eisai*, 2007 WL 4556958, at *18. "Because a generic-drug manufacturer has not yet placed the drug into the market when it files an ANDA application, a patent-holder cannot make a claim for patent infringement under § 271(a)." *Novo Nordisk, Inc. v. Mylan Pharms., Inc.*, No. 09-2445, 2010 WL 1372437, at *9 (D.N.J. Mar. 31, 2010). Therefore, Counts II and IV should be dismissed for lack of subject-matter jurisdiction.

(2) The Hatch-Waxman Act created a new, artificial act of infringement: filing an ANDA. *See* 35 U.S.C. § 271(e)(2). Congress intended for this subsection to ***create*** a remedy where none existed before: in a case arising out of an ANDA filing where the proposed drug has not been approved. *See Rosuvastatin*, 2008 WL 5046424, at *12-13 (dismissing claim for declaratory judgment under Section 271(a)). Allowing a § 271(a) claim to proceed would be inconsistent with this Congressional intent.

(3) "[E]ven if a case or controversy exists, the trial court has significant discretion in determining whether or not to exercise declaratory judgment jurisdiction." *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3.d 1322, 1328 n.3 (Fed. Cir. 2012). Here, the declaratory judgment claims of Counts II and IV are unnecessary. In the end, plaintiffs seek the same thing in Counts I and III: a ruling that Watson may not sell its proposed drug. Accordingly, even if this Court finds jurisdiction over Counts II and IV, it should decline to exercise that jurisdiction.

## BACKGROUND AND STATEMENT OF FACTS

### A. The ANDA Process

Under the Hatch-Waxman Act, a company seeking approval to market a generic pharmaceutical product may file an ANDA with the FDA, identifying a branded drug as the "reference drug" to expedite approval. *See generally Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 440-41 (D.N.J. 2006) (explaining Hatch-Waxman proceedings). The ANDA contains information describing the proposed generic drug product. If the branded drug is associated with any patents on the FDA's "Orange Book," then the ANDA must contain a certification as to those patents; a "Paragraph IV" certification states that the listed patent is invalid, unenforceable, and/or will not be infringed by the proposed ANDA product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA applicant submitting a Paragraph IV certification must give notice of such certification to the patentee.

To enable the patentee to contest the Paragraph IV certification, the Act creates a new "technical" act of infringement: submitting the ANDA. *See* 35 U.S.C. § 271(e). As the Supreme Court has noted, the purpose of this creation "is to enable the judicial adjudication upon which the ANDA . . . schemes depend." *Eli Lilly*, 496 U.S. at 678. Moreover, if the patentee sues within 45 days of receiving notice, ANDA approval is stayed until either thirty months have passed or the litigation has concluded, whichever occurs first. 21 U.S.C. § 355(j)(5)(B)(iii).

**B. Watson's ANDA**

Under this scheme, Watson filed ANDA No. 204383, seeking FDA approval to market a generic version of Suboxone® sublingual film. (D.I. 1, Compl. ¶ 1.) Watson subsequently notified plaintiffs of the filing of ANDA No. 204383, and further that the ANDA contained a "Paragraph IV certification" stating that Watson's proposed ANDA product did not infringe any valid claim of U.S. Patent Nos. 8,475,832 or 8,017,150. (*Id.* ¶¶ 25, 26.) Plaintiffs then brought this action. (*Id.* ¶ 27.)

**C. Plaintiffs' Claims**

The complaint asserted four claims, two directed to each patent. Counts I and III invoked the highly artificial act of infringement created by the Hatch-Waxman Act, alleging that Watson infringed the patent by filing its ANDA. (*Id.* ¶¶ 30, 42.) Counts II and IV, however, asserted ordinary patent infringement claims under 35 U.S.C. § 271(a)-(c). These claims allege, "[o]n information and belief," that Watson "intend[s] to" infringe by manufacture or otherwise "immediately following approval of [the] ANDA." (*See, e.g.*, *id.* ¶ 33.)

**LEGAL STANDARD**

In any action for a declaratory judgment, the plaintiff has the burden to show that the facts alleged, under all the circumstances, 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*, 549 U.S. at 127.

## ARGUMENT

Counts II and IV should be dismissed. These counts are based entirely on speculation about what Watson "plan[s] and intend[s] to" do sometime in the indefinite future. (*See* D.I. 1, Compl. ¶¶ 33, 35, 36, 37, 45.) They do not allege "a substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127. Accordingly, these two counts must be dismissed for lack of subject-matter jurisdiction. *See* Fed. R. Civ. P. 12(b)(1).

### A. Any Purported Controversy Is Too Remote And Speculative To Support Jurisdiction.

There is nothing "real" or "immediate" about the highly contingent and long-distant events that would have to occur for a patent infringement claim to arise under Section 271(a)-(c). Watson's proposed product has not been marketed; it has not even been approved. Both events are necessary to support the Counts II and IV, but final approval is not expected for ***two and a half years***, and post-approval commercial marketing of Watson's product before resolution of the issues of patent infringement and invalidity is, now, nothing more than pure conjecture.

"Declaratory judgment jurisdiction may not be predicated on pure speculation." *Rosuvastatin*, 2008 WL 5046424, at *13 n.12. Here, it is. Plaintiffs have alleged that they sued Watson within 45 days of receiving Watson's notification of the ANDA submission and its Paragraph IV certification. (D.I. 1, Compl. ¶ 27.) If true—as this Court must presume for the purposes of this motion—then final FDA approval of Watson's ANDA is on hold until thirty months have passed. 21 U.S.C. § 355(j)(5)(B)(iii). (The only way FDA approval could come earlier is if this litigation is concluded. In that event, there would no longer be a controversy.)

Thus, "a controversy will only materialize if the FDA approves the accused drug and if [Watson] decides to market the drug." *Abbott Labs.*, 934 F. Supp. at 939. And consequently, Counts II and IV do not raise a justiciable controversy that is "of sufficient immediacy and reality" to warrant a declaratory judgment. *MedImmune*, 549 U.S. at 127. That is, "[a]t least until the ANDA is approved . . . the controversy is not sufficiently immediate." *Eisai*, 2007 WL 4556958, at *18 (dismissing declaratory judgment claim prior to FDA approval); *see also Abbott Labs.*, 934 F. Supp. at 938-39 (same).

Multiple courts in this district have dismissed similar claims in similar cases. In *Rosuvastatin*, the court emphasized the 30-month stay, which would not expire until 19 months after the decision. 2008 WL 5046424, at *12. Accordingly, "there [was] simply no sufficient immediacy to the controversy." *Id.* And in another case, the court emphasized that that the patentee "could not predict when, or if, the FDA would approve the [accused] product." *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, C.A. No. 05-590, 2006 WL 2375035, at *3 (D. Del. Aug. 16, 2006). Further, the accused infringer had not engaged in any sales or marketing activity. *Id.* Accordingly, there was no imminent controversy. Just so here. Neither FDA approval nor marketing of Watson's accused generic drug product is imminent, so these claims fail.

**B. Counts II and IV Should Be Dismissed As Contrary To The Hatch-Waxman Scheme.**

Additionally, Counts II and IV should be dismissed as inconsistent with Congressional intent in enacting the Hatch-Waxman Act. "Congress evidently believed that a patentee in [plaintiffs'] position did not have a cause of action under § 271(a)—indeed, the lack of such an action was a motivating factor in creating the § 271(e)(2) action." *Rosuvastatin*, 2008 WL 5046424, at *13. That is, § 271(e)(2) "provided patentees with a defined act of infringement sufficient to ***create case or controversy jurisdiction*** . . .when . . . the ANDA applicant was not

making, using, or selling the patented product." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (emphasis added); *see also Eli Lilly*, 496 U.S. at 678 (noting that "the purpose of [§ 271(e)(2)] is to ***enable*** the judicial adjudication upon which the ANDA . . . schemes depend" by creating the "highly artificial" act of patent infringement—filing an ANDA) (emphasis added); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1366 (Fed. Cir. 2003) (reiterating that § 271(e)(2) "***creates case-or-controversy jurisdiction***" before the product goes to market) (emphasis added).

But the "elaborate and specific framework" of the Hatch-Waxman Act leaves no room for claims based on Section 271(a)-(c). *See Rosuvastatin*, 2008 WL 5046424, at *12. As Judge Stark has explained, "[n]othing in the Hatch-Waxman Act appears to contemplate that a patentee, at the same time it pursues the § 271(e) action created for it by the Act, would also pursue an ordinary § 271(a) patent infringement action on the same patent and based on all the same facts." *Id.* "In short, section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003). Counts II and IV, which are ***not*** based on section 271(e)(2), should be dismissed.

### C. In Its Discretion, The Court Should Decline To Exercise Jurisdiction If It Exists.

The Court should decline to exercise declaratory judgment jurisdiction even if a sufficient case or controversy exists. "[T]he trial court has significant discretion in determining whether or not to exercise declaratory judgment jurisdiction." *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3.d 1322, 1328 n.3 (Fed. Cir. 2012). Here, as described above and as noted by Judge Stark, the declaratory judgment claims based on ordinary infringement are inconsistent with the Hatch-Waxman Act. *See Rosuvastatin*, 2008 WL 5046424, at *13. Should it conclude that

jurisdiction exists, the Court should nevertheless decline to exercise it. *See Abbott Labs.*, 934 F. Supp. at 938-39 (declining to exercise jurisdiction over § 271(a) claim when it would "undermine" Congress's policy in enacting Hatch-Waxman and because a controversy would materialize only after FDA approval and generic marketing).

Further, it would be a waste of time and resources to allow Counts II and IV to remain in this litigation. "There 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]." *Rosuvastatin,* 2008 WL 5046424, at *13. When the ANDA claims are fully litigated, "all will know whether or not Defendants' intended entry into the market" will infringe a valid patent. *Id.* In their present form, Counts II and IV add nothing to this case. This Court should focus its resources on the ANDA counts.

**CONCLUSION**

For the foregoing reasons, Counts II and IV should be dismissed.

Dated: November 20, 2013

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