IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL -MYERS SQUIBB CO., and BRISTOL -MYERS SQUIBB PHARMACEUTICALS, Plaintiffs/Counterclaim-Defendants,	:	
v.	:	Civ. No. 09-651-LPS [redacted]
MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LTD., and MATRIX LABORATORIES LIMITED, and Defendants/Counterclaim-Plaintiffs,	:	PUBLIC VERSION
v.	:	
MERCK & CO., INC., and MERCK SHARP & DOHME CORP., Counterclaim-Defendants.	:	

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MEMORANDUM OPINION

Date: July 11, 2011
Wilmington, Delaware

Stark, U.S. District Judge:

This case arises under the Hatch Waxman Act. The issue presented is whether, under all of the circumstances, there is a controversy of sufficient immediacy and reality – and, therefore, declaratory judgment jurisdiction – between a patentee and a generic drug company with respect to infringement of two patents that are ***not*** being asserted by the patentee in this action. Because the patentee has provided the generic drug company a ***conditional*** covenant-not-so-sue, the Court finds the existence of a case or controversy and, therefore, jurisdiction.

BACKGROUND

I. The Hatch-Waxman Statutory Scheme

The Hatch-Waxman Act[1] ("Act") was enacted by Congress to regulate the Food and Drug Administration's (FDA) approval of new and generic drugs. *See* 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e). Congress' purpose in enacting the Act was to balance two competing public policy interests with respect to the pharmaceutical industry: "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., v. Biovail Corp.*, 276 F3d. 1368, 1371 (Fed. Cir. 2002).

The Act requires pioneering or brand name companies seeking to manufacture and sell new drugs first to get approval from the FDA by filing a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a) & (b). The NDA applicant must also identify all patents that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or

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[1]"Hatch-Waxman Act" is the name commonly used to refer to the "Drug Price Competition and Patent Term Restoration Act of 1984," Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA").

sale of the drug." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists these patents in a publication entitled "Approved Drug Products with Therapeutic Equivalent Evaluations" (commonly known as the "Orange Book"). *See* 21 U.S.C. § 355(j)(2)(A)(I).

For drug companies interested in developing generic versions of drugs covered by NDAs, the Act created an expedited approval process by allowing these companies to submit an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). An ANDA applicant must certify, as to each patent listed in the Orange Book as covering the listed drug, that: (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii). An applicant who makes a Paragraph IV certification is required to give notice to the NDA holder and the owner of the patent alleged to be invalid or not infringed, stating that an application has been filed with the FDA seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent. *See id.*; *see also Caraco Pharm. Labs. Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008); 21 U.S.C. § 355(j)(2)(B). The Act enables early resolution of patent disputes over ANDAs by providing that the mere act of filing a Paragraph IV ANDA constitutes an act of patent infringement. *See* 35 U.S.C. § 271(e)(2); *Caraco*, 527 F.3d at 1283; *Eli Lilly*, 496 U.S. at 678.

To prevent manipulation and unnecessary delay in the launch of generic drugs by subsequent ANDA filers, Congress amended the Act in 2003 to provide that the first ANDA filer's 180-day exclusivity period could be forfeited. *See* 21 U.S.C. § 355(j)(5)(D). These amendments were part of the MMA. The 2003 amendments also provided for a "civil action to

obtain patent certainty" ("CAPC"), designed to prevent NDA holders from "gaming" the Act by delaying the resolution of patent disputes with ANDA filers. *See* 21 U.S.C. § 355(j)(5)(C); *Caraco*, 527 F.3d at 1285; *USA, Inc. v. Novartis Pharms. Corps.*, 482 F.3d 1330, 1342-43 (Fed. Cir. 2007). With the CAPC provisions, if the NDA holder fails to sue a Paragraph IV ANDA filer within 45 days of receiving a Paragraph IV Notice Letter, the ANDA filer can sue the NDA holder to obtain a declaratory judgment that the Orange Book listed patents subject to Paragraph IV certifications are invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(C); *Caraco*, 527 F.3d at 1285.

Congress granted federal jurisdiction over CAPCs "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1359 (Fed. Cir. 2008); *Caraco*, 527 F.3d at 1285. Therefore, federal courts have jurisdiction over declaratory judgment actions brought by Paragraph IV ANDA filers against NDA holders to the extent they present an Article III case or controversy. *See Novartis*, 482 F.3d at 1342; *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

In *MedImmune*, the Supreme Court overruled the Federal Circuit's "reasonable-apprehension-of-imminent-suit" test for evaluating jurisdiction over declaratory judgment actions. *See* 549 U.S. at 132 n.11; *see also Novartis*, 482 F.3d at 1342. The reasonable-apprehension-of-imminent-suit test was a two-part test that required: (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity. *See Caraco*, 527 F.3d at 1290-91; *Novartis*, 482 F.3d at 1339.

Defendants Mylan Pharmaceuticals Inc., Matrix Laboratories Ltd., and Matrix Laboratories Inc. (collectively "Mylan") have filed ANDA No. 91-471 seeking FDA approval to market generic efavirenz tablets that are bioequivalent to Sustiva®. (D.I. 56 at 2) [redacted] (D.I. 57 Ex. C) [redacted] (D.I. 64 at 16 n.4) On July 16, 2009, by a Notice Letter, Mylan notified BMS and Merck that the '071 and '964 patents – which are listed in the Orange Book but not asserted by BMS in this litigation (collectively "the Unasserted Patents") – were invalid, unenforceable, and/or will not be infringed by the sale of Mylan's ANDA product. (*See id.*) Mylan also included in its Notice Letter an Offer of Confidential Access to its ANDA application, along with a detailed recitation of the factual and legal basis of its Paragraph IV certifications with respect to the Unasserted Patents. *See id.*

In response to Mylan's Notice Letter, BMS filed the instant patent infringement action on August 31, 2009, alleging that the drug described in Mylan's ANDA will infringe BMS' U.S. Patent No. 6,673,372 B1 ("the '372 patent"). (D.I. 1) The '372 patent is not listed in the Orange Book with respect to Sustiva®. (D.I. 15 at 3) In its complaint, BMS sought a declaratory judgment that Mylan's ANDA would infringe the '372 patent. (D.I. 1 at 6-7) BMS did not, however, assert that Mylan's ANDA would infringe any of the five patents listed in the Orange Book for Sustiva®, including the Unasserted Patents (i.e., the '071 and '964 patents).

Mylan moved to dismiss BMS' complaint for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted. (D.I. 14, 15) The Court denied Mylan's

motion. (D.I. 31) Thereafter, Mylan answered BMS' complaint, asserting counterclaims seeking declaratory judgments of invalidity and non-infringement of the '372 patent (the First and Second Counterclaims) as well as declaratory judgments of non-infringement of the unasserted '071 and '964 patents (Third and Fourth Counterclaims). (D.I. 36) Later, Mylan filed an amended answer, adding Merck as a counterclaim defendant on the Third and Fourth Counterclaims, relating to the Unasserted Patents. (D.I. 47)

In lieu of responding to the amended Third and Fourth Counterclaims, BMS and Merck sent a letter to Mylan enclosing a proposed covenant-not-to-sue ("covenant") for infringement of the unasserted '071 and '964 patents. (D.I. 57 Ex. D) When Mylan failed to respond to the proposed covenant, BMS and Merck sent Mylan an executed version of the covenant. (D.I. 57 Ex. A, B) Subsequently, BMS and Merck filed their motion to dismiss Mylan's Third and Fourth Counterclaims for lack of subject matter jurisdiction. (D.I. 55)

The motion to dismiss was fully briefed as of July 30, 2010. The Court heard oral argument on June 8, 2011. (*See* Transcript (D.I. 111) ("Tr."))

LEGAL STANDARDS

Motion to Dismiss Pursuant to Rule 12(b)(1)

A claim, or counterclaim, may be dismissed for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). "The party asserting subject matter jurisdiction bears the burden of proving that it exists." *Church of the Universal Bhd. v. Farmington Twp. Supporters*, 296 Fed. Appx. 285, 288 (3d Cir. 2008); *see also Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005).

Motions brought under Rule 12(b)(1) may present either a facial or factual challenge to

the Court's subject matter jurisdiction. When a facial challenge to subject matter jurisdiction is raised, the Court must accept all factual allegations pled in the counterclaim as true and draw all reasonable inferences in favor of the counterclaim plaintiff. In this situation, the Court's inquiry under Rule 12(b)(1) is limited to the allegations in the counterclaim, the documents referenced in or attached to the counterclaim, and matters in the public record. *See Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). The Court may also consider exhibits to a motion to dismiss without converting the motion to a summary judgment motion, if the claims or counterclaims are based on the documents and the documents are undisputedly authentic. *See Pension Benefit Guaranty Corp. v. White Consolidated Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

In reviewing a factual challenge to the Court's subject matter jurisdiction, the Court is not confined to the allegations of the complaint – or in this case the counterclaim – and the presumption of truthfulness does not attach to the allegations in the counterclaim. *See Mortensen v. First Fed. Sav. and Loan*, 549 F.2d 884, 891 (3d Cir. 1977). Instead, the Court may consider evidence outside the pleadings, including affidavits, depositions, and testimony, to resolve any factual issues bearing on jurisdiction. *See Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997).

DISCUSSION

At the hearing, the parties agreed there is only a single issue the Court needs to decide in connection with the motion: whether the covenant-not-to-sue provided by BMS and Merck to Mylan is sufficiently broad and definite to eliminate the Court's jurisdiction over Mylan's

counterclaims for declaratory judgment of non-infringement of the Unasserted Patents.[2] The Court agrees with Mylan that, given the conditional nature of the covenant, there remains a case or controversy between the parties. Thus, the covenant is not sufficiently broad and definite to eliminate the Court's jurisdiction.

Mylan brings its counterclaims pursuant to the Declaratory Judgment Act, which provides in relevant part: "In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). In *MedImmune*, the Supreme Court articulated the burden Mylan bears, as the party asserting jurisdiction, to show that this Court has jurisdiction over its declaratory judgment counterclaims. Specifically, Mylan must, "under all the circumstances show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127. Mylan must further show that the dispute relating to the Unasserted Patents is "definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Id.*

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[2]Mylan previously opposed the motion on three additional grounds: (1) the covenant did not protect Mylan from causes of action other than patent infringement; (2) the covenant did not protect Mylan from parties other than BMS (and Merck) that might have had rights to enforce the Unasserted Patents; and (3) a case or controversy exists due to Mylan's interest in obtaining market entry – with exclusivity, if possible – as early as possible. (D.I. 64 at 9, 16) Mylan has now withdrawn these contentions. (Tr. at 13)

A covenant-not-to-sue may divest a court of declaratory judgment jurisdiction. For instance, in *Super Sack Manufacturing Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059-60 (Fed. Cir. 1995), the Federal Circuit held that an unconditional promise not to sue "for infringement as to any claim of the patent-in-suit based upon products currently manufactured and sold . . . was sufficient to divest the court of jurisdiction over . . . counterclaims for non-infringement." *See also Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1345-48 (Fed. Cir. 2007) (holding that covenant-not-to-sue divested district court of subject matter jurisdiction); *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999) ("[A] covenant not to sue for any infringing acts involving products 'made, sold, or used' on or before the filing date is sufficient to divest a trial court of jurisdiction over a declaratory judgment action."). However, "whether a covenant not to sue will divest the trial court of jurisdiction depends on what is covered by the covenant." *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1297 (Fed. Cir. 2009) (finding case or controversy remained because covenant did not cover future sales).

BMS contends that its covenant "has removed any cause for concern" that Mylan could be held liable for infringement of the Unasserted Patents with respect to ANDA No. 91-471. (D.I. 56 at 6) As a result, BMS argues that the controversy over the Unasserted Patents is moot and the Court lacks subject matter jurisdiction over Mylan's declaratory judgment counterclaims for non-infringement. *Id.* In response, Mylan argues that BMS' covenant is conditional; specifically, BMS' agreement to refrain from suing Mylan is conditioned on the accuracy of Mylan's Notice Letter describing its ANDA product. (D.I. 64 at 10) Hence, in Mylan's view, the covenant leaves open the possibility that BMS may, at any time, file a lawsuit against Mylan

to enforce the Unasserted Patents, evading the covenant based on what BMS would contend are challenges to the accuracy of the Notice Letter. (*See id.*)

The relevant part of the BMS' covenant reads:

> In reliance upon Mylan and Matrix's representation that the only efavirenz material contained in the drug products covered by ANDA 91-471 is [redacted] set out in the attached Exhibit 1, Merck, MSD, BMS, and BMS Pharma each hereby covenant not to sue or otherwise hold Mylan and Matrix liable for infringement under any claims of United States Patent Nos. 6,639,071 and 6,939,964 (collectively, the "patents-at-issue") with respect to:
>
> > (a) Matrix's filing of ANDA No. 91-471 seeking approval for efavirenz drug products wherein the only efavirenz material contained in the drug products covered by ANDA 91-471 is [redacted] as represented and characterized in the attached Exhibit 1; or
> >
> > (b) the manufacture, use, distribution, sale, offer for sale, or importation by, for, or to Mylan or Matrix of the products described in, and the subject of, ANDA No. 91-471 for efavirenz drug products wherein the the [sic] only efavirenz material contained in the drug products is [redacted] as represented and characterized in the attached Exhibit 1.

(D.I. 64 Ex. A at 1)

In its briefing, BMS confirmed (in a somewhat circuitous manner) that it intended the covenant to be conditional, and that it was reserving to itself the right to sue Mylan for infringement of the Unasserted Patents if BMS concluded, at any point, that Mylan's Notice Letter inaccurately described Mylan's ANDA product. For instance, in its reply brief, BMS wrote: "the covenant is unequivocal, unconditional, and comprehensive, and fully protects

Defendants from an infringement action – ***provided Defendants' representation of their ANDA product provided in their notice letter accurately describes the ANDA product.***" (D.I. 67 at 2) (emphasis added) BMS further wrote that it was not unreasonable for a patent holder, such as itself, to provide a covenant not to sue but nonetheless "reserve the right to bring an infringement suit should it discover that the representations found in the notice letter were inaccurate." (D.I. 67 at 3) At oral argument, BMS again acknowledged that its covenant is conditional, and that it is reserving a right to sue Mylan, even if Mylan never changes the product it has proposed in its ANDA. (Tr. at 6-7)[3]

By conditioning the covenant on BMS' own view of the accuracy of Mylan's representations, and by reserving to itself the right to sue Mylan for infringement of the Unasserted Patents based on Mylan's ANDA as it presently exists, BMS has failed to provide Mylan with the certainty to which it is entitled. Despite the covenant, BMS is free, at any time, to assert that Mylan's ANDA product infringes the '071 and/or '964 patents, and BMS may attempt to evade the covenant by contending that BMS believes the representations Mylan made in the Notice Letter were somehow inaccurate. This is a sufficiently real possibility as to present a substantial controversy. Mylan wishes to eliminate any uncertainty as to whether its presently-proposed ANDA product infringes the Unasserted Patents. Mylan is entitled to such resolution, so it can know whether the '071 and/or '964 patents are obstacles to its desire to market its generic product. Mylan is further entitled to know that BMS is not holding these patents in

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[3]It is undisputed that the covenant does not protect Mylan from suit by BMS for infringement of the '071 and '964 patents if Mylan modifies its proposed generic product from its currently-proposed form. Mylan does not argue that this fact is a deficiency in the covenant. The potential of such future modifications is too speculative to constitute a present case or controversy. *See Super Sack*, 57 F.3d at 1060.

reserve as a potential basis for suing Mylan at a time when Mylan is much closer to launching its product.

The Court acknowledges, as has been noted by BMS, that Mylan is obligated to be truthful in its representations in its ANDA and its Notice Letter, and that the representations in the Notice Letter here are consistent with those made by Mylan in its ANDA. The Court, like BMS, sees no reason to doubt the factual accuracy of the Notice Letter representations. (Tr. at 20-21) Notwithstanding these circumstances, however, BMS and Merck have steadfastly refused to provide an unconditional covenant not to sue regarding Mylan's ANDA product as it is presently-proposed. If BMS and Merck wish to reserve their right to sue for infringement of the Unasserted Patents despite a professed belief that the product as represented does not infringe, then Mylan is free to pursue its right to obtain a judicial determination as to whether its product does infringe the Unasserted Patents.

In reaching this conclusion, the Court is mindful that a mechanism exists for BMS to readily determine, to a certainty, whether the product described by Mylan in its Notice Letter to BMS accurately reflects the product Mylan proposed in its ANDA. Mylan has offered to produce its ANDA product to BMS for testing. (Tr. at 14, 16-17) BMS has explained that, with Mylan's product in hand, BMS can confirm that the representations in the Notice Letter are accurate. (Tr. at 8, 12, 21-25) Once BMS reaches its conclusion, it is likely that one of the following will happen: (i) the parties will resolve their dispute over the Unasserted Patents, perhaps by BMS providing Mylan an unconditional covenant not to sue; or (ii) the parties will actively litigate whether Mylan's presently-proposed ANDA product infringes the Unasserted Patents, resulting

in a judgment on the merits resolving the dispute.[4]

In any event, Mylan asserted its counterclaims relating to the Unasserted Patents in order to obtain certainty that, provided Mylan does not modify its ANDA, BMS and Merck will not be able to assert the Unasserted Patents as a basis to prevent Mylan from bringing its ANDA product to the market. While BMS' covenant goes a long way toward providing Mylan with that certainty, it does not go quite far enough. A judicial finding of non-infringement (or infringement) of the Unasserted Patents would provide the certainty to which Mylan is entitled as a result of this litigation.

Accordingly, the Court concludes that there is a case or controversy between the parties with respect to Mylan's Third and Fourth Counterclaims. This Court has subject matter jurisdiction. Thus, the motion to dismiss will be denied.

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[4]The Court recognizes that the willingness BMS expressed at the oral argument to undertake such a test was predicated on a ruling that, in the meantime, its motion to dismiss would remain pending and discovery would not be available from Merck. For the reasons expressed in this Memorandum Opinion, the Court is denying the motion to dismiss and permitting discovery to proceed against Merck. Therefore, while the Court is not at this time ordering BMS to undertake the test it represented it believed could be done in a fairly expeditious manner, the Court remains hopeful that the parties will be able to resolve their remaining disputes regarding the Unasserted Patents.

CONCLUSION

For the foregoing reasons, the Court denies BMS' Motion to Dismiss.[5] An appropriate Order follows.

[5]At the conclusion of the oral argument on the motion to dismiss, the Court heard from the parties on a discovery dispute. (Tr. at 24-35) Mylan requests that the Court compel Merck to respond substantively to discovery requests (requests for production of documents and interrogatories). (D.I. 97) Merck has objected to providing discovery during the pendency of its motion to dismiss. (D.I. 98) Given that the Court has now decided to deny the motion to dismiss, Merck's objections are moot, and Merck must provide the requested discovery. (Tr. at 31) (Merck's counsel stating: "[W]e have agreed, should the motion to dismiss be denied, we will produce fully in discovery . . . .") In addition, the Court rejects Merck's contention that it has been, until now, merely an "alleged party" (Tr. at 29), based on Merck's belief that it had filed a meritorious motion to dismiss. Merck is a party, and has been at all times since Mylan sued Merck as a counterclaim defendant. A party cannot unilaterally absolve itself of its obligation to participate in discovery. Should a party believe it has a basis to refrain from participating in discovery, it should seek a protective order or a stay of discovery. *See, e.g.*, *Willemijn Houdstermaatschaapij BV v. Apollo Computer, Inc.*, 707 F. Supp. 1429, 1441 (D. Del. 1989) ("[U]nless and until it is granted a stay, defendant should be required to conduct discovery as if no motion had been filed at all."); *Standard Chlorine v. Sinibaldi*, 821 F. Supp. 232, 261 (D. Del. 1992) (stating parties' assumption "that their filing of a motion for protective order permitted them to disregard [opposing party's] discovery requests . . . is incorrect"); *see also generally* D.I. 83 ¶ 3.f (setting out procedures for bringing discovery-related disputes, including disputes over protective orders, to Court's attention).

IN THE UNITED STATES DISTRICT COURT
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v.	:	Civ. No. 09-651-LPS
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v.	:	
MERCK & CO., INC., and MERCK SHARP & DOHME CORP., Counterclaim-Defendants.	:	

ORDER

At Wilmington this **11th** day of **July, 2011**, for the reasons set forth in the Memorandum Opinion filed this same date,

IT IS HEREBY ORDERED THAT:

1. The motion to dismiss (D.I. 55) is DENIED.

2. Mylan's request to compel discovery from Merck (D.I. 97) is GRANTED.

Honorable Leonard P. Stark
United States District Judge