IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CARACO PHARMACEUTICAL LABORATORIES, LTD., Plaintiff, vs. FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD. and H. LUNDBECK A/S, Defendants.	Civil Action No. 4:07-CV-10737

DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION

Defendants Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd. and H. Lundbeck A/S move this Court to dismiss Plaintiff's complaint pursuant to Fed. R. Civ. P. Rule 12(b)(1).

Pursuant to Local Rule 7.1(a)(2), Defendants conferred with Plaintiff's counsel and requested but did not obtain concurrence in the relief sought by this motion.

The grounds for this motion are set forth in the accompanying **DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION**.

Dated: March 13, 2007

Respectfully submitted,

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INTRODUCTION

Pursuant to Fed. R. Civ. P. Rule 12(b)(1), Defendants Forest Laboratories, Inc. ("Forest"), Forest Laboratories Holdings, Ltd. ("Forest Holdings"), and H. Lundbeck A/S ("Lundbeck") (collectively, "Defendants") submit this memorandum of law in support of Defendants' Motion To Dismiss Plaintiff's Complaint For Lack Of Subject Matter Jurisdiction.

Caraco's complaint seeking a judicial declaration that its generic escitalopram products will not infringe Defendant's U.S. Patent No. 6,916,941 (the "'941 patent") should be dismissed for lack of subject matter jurisdiction. A federal court cannot exercise subject matter jurisdiction over this action unless it presents a "case" or "controversy" as required by Article III of the United States Constitution. In declaratory judgment actions regarding patent validity or infringement, a case or controversy is only present if there has been "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." *See, e.g., Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1332 (Fed. Cir. 2005), *reh'g en banc denied*, 405 F.3d 990 (Fed. Cir. 2005).

Here, Defendants have taken no action that could lead Caraco to anticipate that Defendants would sue for infringement of the '941 patent. In accordance with the requirements of the Hatch-Waxman Act, Defendant Forest, the manufacturer of LEXAPRO® brand escitalopram oxalate tablet products, submitted information about the '941 patent to the United States Food and Drug Administration ("FDA") for publication in the FDA's Orange Book, which lists patents relating to approved drug products. The '941 patent includes claims which would cover drug products containing large escitalopram particles, but its claims do not necessarily include all potential generic escitalopram products. Caraco later sought FDA approval to market

its own generic escitalopram products before the expiration of Defendants' listed patents and submitted a "Paragraph IV certification" asserting that the '941 patent was invalid and/or not infringed by its proposed generic products. In a notice letter informing Forest of its certification, Caraco represented that its proposed generic products would not infringe because they contained escitalopram particles nearly one-twentieth of the size recited in the claims of the '941 patent. Based on that representation, Defendants have not asserted the '941 patent against Caraco. Moreover, Defendants have not even communicated with Caraco regarding the '941 patent.

There is no subject matter jurisdiction over this declaratory judgment action because Caraco cannot be under a reasonable apprehension of suit based on Defendants' actions. A patentee's submission of patent information to the FDA for listing in the Orange Book does not create reasonable apprehension of suit. *See, e.g., id.* at 1333; *Torpharm, Inc. v. Pfizer, Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756, at *9 (D. Del. June 8, 2004), *vacated as moot*, 125 F. App'x 987 (Fed. Cir. 2005); *Dr. Reddy's Labs., Ltd. v. Pfizer, Inc.*, No. 03-CV-736 (JAP), 2003 WL 21638254, at *5 (D.N.J. July 8, 2003).[1] The fact that the patentee has been involved in litigation with the declaratory judgment plaintiff regarding a different patent does not change this result. *See, e.g., Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd.*, 325 F. Supp. 2d 502, 507 (D.N.J. 2004); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, No. Civ. 05-2881 JLL, 2005 WL 3619389, at *1, 4 (D.N.J. Dec. 12, 2005). Furthermore, Caraco cannot be under a reasonable apprehension of suit when Defendants have never even communicated with them regarding the '941 patent. *See, e.g., West Interactive Corp. v. First Data Res., Inc.*, 972 F.2d 1295, 1296-98 (Fed. Cir. 1992); *Torpharm*, 2004 WL 1465756, at *11; *Mutual Pharm. Co. v. Pfizer Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004).

[1] Copies of all unpublished cases cited herein are attached at Exhibit A.

Requiring Caraco to demonstrate a reasonable apprehension of suit before this court may exercise subject matter jurisdiction over this action promotes the policy goals of the Hatch-Waxman Act, the statutory scheme governing the balance between innovator and generic drug manufacturers. Under the Hatch-Waxman Act, the first generic manufacturer to file a Paragraph IV certification against an Orange Book listed patent is awarded 180 days of market exclusivity during which it may sell its generic products without competition from other generic manufacturers. This exclusivity is an incentive for generic manufacturers to risk the expensive litigation that often results from such challenges. Caraco was not willing to accept these risks and chose not to be the first filer against any of Defendants' listed patents. Instead, Ivax Pharmaceuticals, Inc. ("Ivax") was the first filer against the '941 patent. Knowing that, under the Hatch-Waxman Act, a court decision finding the '941 patent not infringed would trigger Ivax's 180-day exclusivity period, Caraco has filed this declaratory judgment action in an attempt to extinguish the 180 days of exclusivity that was properly awarded to Ivax. However, with no reasonable apprehension of suit, plaintiff lacks the basis for attacking Ivax's exclusivity period through this declaratory judgment action.

Because Caraco cannot be under a reasonable apprehension of being sued for infringement of the '941 patent, Caraco's complaint does not present a Constitutional case or controversy and should be dismissed for lack of subject matter jurisdiction.

FACTUAL BACKGROUND

A pharmaceutical manufacturer seeking to market a new drug in the United States must first receive FDA approval of a New Drug Application ("NDA") demonstrating, *inter alia*, that

the drug is safe and effective. *See* 21 U.S.C. § 355(a), (b). Under the Hatch-Waxman Act,[2] an NDA applicant is required to inform the FDA of the patent number and expiration date of any patent that claims the drug described in the NDA or a method of using that drug "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1), (c)(2). The FDA is then required to publish this information in its "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 U.S.C. § 355(b)(1); 21 C.F.R §§ 314.3(b), 314.53(e).

The Hatch-Waxman Act also provides that a generic drug manufacturer may rely upon the data submitted by an NDA holder for an approved drug to market a generic copy of that drug by submitting an Abbreviated New Drug Application ("ANDA") with the FDA. *See* 21 U.S.C. § 355(j). As part of its ANDA, the generic applicant must submit one of four certifications against each Orange Book listed patent relating to the drug that it seeks to copy. *See* 21 U.S.C. § 355(j)(2)(A)(vii). If the generic applicant seeks to market its drug before the expiration of any of the listed patents, it must submit a "Paragraph IV certification" asserting "that such patent is invalid or will not be infringed by the manufacture, use, or sale" of the generic product and must notify the NDA holder of this certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (j)(2)(B). The filing of an ANDA including a Paragraph IV certification against a listed patent constitutes an act of patent infringement if the generic product described in the ANDA would infringe that patent. 35 U.S.C. § 271(e)(2).

The first ANDA applicant to submit a Paragraph IV certification against a listed patent is granted 180 days of exclusivity to market its drug ("180-day exclusivity") once its ANDA is

[2] The Hatch-Waxman Act is the name commonly used to refer to the amendments made to the Federal Food, Drug and Cosmetic Act by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (codified at scattered sections of titles 21 and 35 of the United States Code).

approved. 21 U.S.C. § 355(j)(5)(B)(iv) (2000).[3] During the 180-day exclusivity period, the FDA will not approve an ANDA that includes a later-filed Paragraph IV certification against that patent. 21 U.S.C. § 355(j)(5)(B)(iv) (2000).[4] A 180-day exclusivity period will begin upon the occurrence of one of two "triggering events": (1) the first commercial marketing of the generic product by the first-filer, or (2) a court decision holding the listed patent invalid or not infringed by a generic product described in an ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000). At the end of this period, however, if no other exclusivity periods remain in effect, competitors may receive approval of their ANDAs and begin marketing their generic products.

Defendant Forest is the holder of NDA No. 21,323 for LEXAPRO® brand escitalopram oxalate tablet products, which was approved by the FDA on August 14, 2002. As part of its initial NDA filing, Forest submitted information to the FDA regarding U.S. Patent No. Re. 34,712 (the "'712 patent"), which the FDA published in the Orange Book. The '712 patent, entitled "Pharmaceutically Useful (+)-1-(3-Dimethylaminopropyl)-1-(4'-Fluorophenyl)-1,3-Dihydroisobenzofuran-5-Carbonitrile And Non-Toxic Acid Addition Salts Thereof," includes claims covering substantially pure escitalopram, the active ingredient of LEXAPRO®.

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[3] Though the governing statute is ambiguous, the FDA has adopted a "patent-based" approach to the 180-day exclusivity provisions, awarding a separate exclusivity period for the first Paragraph IV certification against each listed patent. *See Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 63-64, 67-74 (D.D.C. 2006) (describing and upholding FDA's "patent-based" approach). Under this approach, when there are multiple listed patents, multiple exclusivity periods will be awarded. *See id.* at 64.

[4] The Hatch-Waxman Act provisions relating to 180-day exclusivity were amended in 2003 by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("Medicare Amendments"). However, these provisions are not retroactive and apply only to ANDAs seeking to copy drugs against which no Paragraph IV certification had been made as of December 8, 2003. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(b), 117 Stat. 2066, 2460. Because a Paragraph IV certification against LEXAPRO® was made on or around August 5, 2003, the preamendment version of 21 U.S.C. § 355(j)(5)(B)(iv) applies to any 180-day exclusivity periods awarded in connection with LEXAPRO®.

On or before August 5, 2003, Ivax Pharmaceuticals, Inc. ("Ivax") filed an ANDA for generic escitalopram including a Paragraph IV certification against the '712 patent. As the first Paragraph IV filer against the '712 patent, Ivax was awarded a 180-day exclusivity period ("'712 exclusivity"). Defendants received notice of Ivax's ANDA filing and paragraph IV certification and promptly filed a action against Ivax for infringement of the '712 patent in the U.S. District Court for the District of Delaware ("the Delaware litigation") on September 22, 2003.

On July 12, 2005, the '941 patent was issued to Defendant Lundbeck. The '941 patent is entitled "Crystalline Composition Containing Escitalopram," and generally covers crystalline particles of escitalopram oxalate with a median particle size of 40 microns (μm) or more, dosage forms containing particles in this size range, and methods for manufacturing particles in this size range. Forest submitted the required information about the '941 patent to the FDA for listing in the Orange Book.

Ivax was also the first party to file a Paragraph IV certification against the '941 patent, for which it was awarded another 180-day exclusivity period ("'941 exclusivity").[5] Between July 18, 2005 and November 8, 2006, Forest received notice of thirteen Paragraph IV certifications against the '941 patent from twelve ANDA applicants. On May 24, 2006, Forest received notice of Caraco's Paragraph IV certification against the '941 patent.[6] In its notice letter, Caraco represented that its proposed generic products would not infringe the '941 patent because the escitalopram oxalate crystals in its proposed generic products had a median particle size between

[5] Forest received notice of Ivax's Paragraph IV certification against the '941 patent on July 18, 2005. Despite receiving this notice over one and a half years ago, Defendants have never brought an action against Ivax for infringement of this patent.

[6] A copy of Caraco's notice letter is attached at Exhibit B.

1.94 μm and 2.30 μm, "much, much less than 40 μm," the lower bound of the range recited in the '941 patent. *See* Ex. B at 5.

Based on Caraco's representation, even though Forest has been aware of Caraco's Paragraph IV certification against the '941 patent since receiving its May 24, 2006 notice letter, Forest has never brought an action against Caraco for infringement of that patent. In fact, Forest has never sued any ANDA applicant or any other party for infringement of the '941 patent. Forest has never communicated any intention to sue Caraco for infringement of the '941 patent, nor has Forest had any communication whatsoever with Caraco regarding this patent or Caraco's Paragraph IV certification against it.

In its May 24, 2006 notice letter, Caraco also notified Forest of its Paragraph IV certification against the '712 patent. Unlike the '941 patent, which claims escitalopram oxalate particles of a particular size, the '712 patent claims substantially pure escitalopram, the active ingredient in Caraco's proposed generic products.[7] Accordingly, in its notice letter, Caraco did not deny that its proposed generic products would infringe the '712 patent, but instead asserted that the infringed claims were invalid. Because these claims are not invalid and in fact have already been found valid, enforceable, and infringed in the Delaware litigation, Forest filed an action in the U.S. District Court for the Eastern District of Michigan for infringement of the '712 patent on July 10, 2006.[8]

On February 20, 2007, Caraco filed a complaint in the Eastern District of Michigan seeking a declaratory judgment that its proposed generic products do not infringe the '941 patent.

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[7] The '712 patent also includes claims directed towards pharmaceutical compositions containing escitalopram, methods of using escitalopram for the treatment of depression, and a method for preparing escitalopram.

[8] On February 23, 2007, this Court stayed the action relating to the'712 patent until July 21, 2007. (D.I. 48.)

See Compl. ¶¶ 83-84. In its complaint, Caraco explained that it filed this action to obtain a court decision that would trigger the 180-day exclusivity period awarded to Ivax as the first filer of a Paragraph IV certification against the '941 patent. *See* Compl. ¶¶ 78-82.

ARGUMENT

I. SUBJECT MATTER JURISDICTION OVER THIS ACTION EXISTS ONLY IF CARACO IS UNDER A REASONABLE APPREHENSION OF BEING SUED BY DEFENDANTS FOR INFRINGEMENT OF THE '941 PATENT

Article III of the U.S. Constitution limits the jurisdiction of the federal courts to "cases" and "controversies," language which has been interpreted as requiring "'concrete, living contests between adversaries.'" U.S. Const. Art. III; *Aqua Marine Supply v. AIM Machining, Inc.*, 247 F.3d 1216, 1220 (Fed. Cir. 2001) (quoting *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 20 (1998)). This limitation on federal subject matter jurisdiction applies identically to actions seeking declaratory relief under the Declaratory Judgment Act, which by its terms requires an "actual controversy within [the federal court's] jurisdiction." 28 U.S.C. § 2201(a); *see also Reichhold Chems., Inc. v. Travelers Ins. Co.*, 544 F. Supp. 645, 649 (E.D. Mich. 1982) ("Congress . . . only enlarged the remedies that are available in the Federal Courts but it did not expand the jurisdiction of the Court itself.").

A plaintiff facing a Rule 12(b)(1) motion to dismiss must prove the existence of subject matter jurisdiction or its complaint will be dismissed. *See, e.g., Rogers v. Stratton Indus., Inc.*, 798 F.2d 913, 915 (6th Cir. 1986) ("[W]here subject matter jurisdiction is challenged under Rule 12(b)(1), as it was here, the plaintiff has the burden of proving jurisdiction in order to survive the motion."); *Hollins v. Methodist Healthcare, Inc.*, 474 F.3d 223, 225 (6th Cir. 2007).

Federal Circuit law governs the existence of subject matter jurisdiction in an action for a declaratory judgment regarding the validity or infringement of a defendant's patent. *See, e.g.,*

Microchip Tech. Inc. v. Chamberlain Group, Inc., 441 F.3d 936, 940 (Fed. Cir. 2006). The Federal Circuit has developed a two-part test to determine whether such an action presents a justiciable case or controversy. *See, e.g, Teva v. Pfizer*, 395 F.3d at 1332. Under this test, subject matter jurisdiction exists only if plaintiff proves that there has been "(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 by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity." *Id.*

A Rule 12(b)(1) motion to dismiss may be a "facial" or "factual" attack. *Mozdzierz Consulting, Inc. v. Mile Marker, Inc.*, No. 04-CV-74925-DT, 2006 WL 799222, at *2 (E.D. Mich. Mar. 28, 2006). While a facial attack merely challenges whether a plaintiff has sufficiently alleged the existence of subject matter jurisdiction in its pleadings, a factual attack denies that there is any underlying factual basis for subject matter jurisdiction. *Id.* As a result, allegations made in a plaintiff's complaint are not accepted as true when considering a factual attack on subject matter jurisdiction. *Id.* Instead, a court must resolve any factual disputes between the parties to determine whether or not plaintiff has met its burden of proving facts that show the existence of subject matter jurisdiction. *Id.* Defendants assert that there is no factual basis for subject matter jurisdiction over Caraco's declaratory judgment claims because nothing has occurred that would give rise to a case or controversy as required by Article III of the U.S. Constitution. Therefore, Defendants' motion is a factual attack on subject matter jurisdiction, and Caraco's allegations are not presumed true.

II. CARACO'S DECLARATORY JUDGMENT COMPLAINT SHOULD BE DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION

A. The Federal Circuit And District Courts Have Squarely Rejected Subject Matter Jurisdiction Over Declaratory Judgment Complaints In Similar Circumstances

There is no subject matter jurisdiction over an action for declaratory judgment based on Defendants' actions relating to the '941 patent. In *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, the Federal Circuit upheld the district court's dismissal of an ANDA filer's declaratory judgment action for lack of subject matter jurisdiction in nearly identical circumstances. 395 F.3d at 1331-38. In *Teva*, the plaintiff filed a Paragraph IV certification against defendant's listed patent, and the defendant did not bring an infringement action within forty-five days. *Id.* at 1329-30. The plaintiff then filed an action seeking a declaration of noninfringement and invalidity of the listed patent, and the defendant successfully moved to dismiss the action for lack of subject matter jurisdiction. *Id.* at 1330. The Federal Circuit upheld the district court's dismissal. *Id.* at 1327. Like Caraco, the *Teva* plaintiff argued that the mere listing of a patent in the Orange Book creates reasonable apprehension that any party that files a Paragraph IV certification against that patent will be sued for infringement.[9] *Id.* at 1332-33. The Federal Circuit unambiguously rejected this argument, holding that:

> The listing of a patent in the Orange Book by an NDA filer is the result of a statutory requirement. Without more, [defendant's] compliance with the Hatch-Waxman listing requirement should not be construed as a blanket threat to potential infringers as far as [defendant's] patent enforcement intentions are concerned . . . . We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent.

[9] Caraco states in its Complaint that a patentee's listing of a patent in the Orange Book "necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug before patent expiration." Compl. ¶ 36.

Id. at 1333; *see also Torpharm*, 2004 WL 1465756, at *9 ("[T]he mere listing of a patent in the Orange Book does not give plaintiffs reason to fear suit."); *Dr. Reddy's v. Pfizer*, 2003 WL 21638254, at *5 (stating that "the mere listing of . . . patents does not create declaratory judgment jurisdiction, especially in light of the fact that [plaintiff] cannot put its generic setraline to market [for nearly three more years].").

Teva also makes clear that the fact that Defendants have previously sued Caraco and Ivax for infringement of a different patent (the '712 patent) does not support subject matter jurisdiction. The court in *Teva* rejected plaintiff's attempt to base subject matter jurisdiction on the defendant's history of enforcing its patent rights. *Teva v. Pfizer*, 395 F.3d at 1333. In fact, in *Teva* subject matter jurisdiction did not exist even though the defendant had previously sued another generic manufacturer for infringement of the *same* patent that was the subject of the declaratory judgment complaint. *Id.* at 1330. By contrast, Defendants have never sued any party for infringement of the '941 patent.[10]

Both before and after the *Teva* decision, numerous district courts have come to the same conclusion as the Federal Circuit and held that there is no subject matter jurisdiction over declaratory judgment actions in similar factual contexts. In circumstances essentially identical to those presented in this motion, two separate decisions by the U.S. District Court for the District of New Jersey have found that no reasonable apprehension of suit existed. In *Glaxo Group Ltd. v. Dr. Reddy's Laboratories, Ltd.*, the court found no subject matter jurisdiction based on defendant's submission of its patent for Orange Book listing, enforcement of other patents

[10] The additional fact that Defendants have never affirmatively stated to Caraco that they will not sue for infringement of the '941 patent likewise does not support subject matter jurisdiction over this action. This factor was also considered in *Teva*, where there was no subject matter jurisdiction even though defendant had refused plaintiff's request for a covenant not to sue. *Teva v. Pfizer*, 395 F.3d at 1331.

(including actions for other listed patents against the declaratory judgment plaintiff and other generic manufacturers), and refusal to covenant not to sue. 325 F. Supp. 2d at 506-07. Likewise, in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, the court found no subject matter jurisdiction based on defendant's submission of its patent for Orange Book listing, infringement action against plaintiff on another listed patent, history of litigation against plaintiff and other generic manufacturers, and refusal to provide a covenant not to sue. 2005 WL 3619389, at *2-4.

Other courts have dismissed actions for lack of subject matter jurisdiction even where defendants engaged in conduct beyond that alleged by Caraco in its complaint. For example, in *Torpharm, Inc. v. Pfizer, Inc.*, the District of Delaware dismissed a declaratory judgment action for lack of subject matter jurisdiction where the defendant had submitted its patent for Orange Book listing, refused to covenant not to sue the plaintiff, issued a press release stating its intent to enforce its patent rights, filed an infringement action against plaintiffs involving a different product, and sued for infringement of the patent that was the subject of the declaratory judgment action against a different generic manufacturer. 2004 WL 1465756, at *8-12.[11] By contrast, Defendants have merely submitted the '941 patent for Orange Book listing, as required by law, and filed actions for infringement of a different patent. Caraco's complaint should be dismissed because it is firmly established by binding Federal Circuit precedent and numerous district court decisions that a declaratory judgment plaintiff cannot be under a reasonable apprehension of suit based on these facts.

[11] Many other district courts have reached this same conclusion based on similar facts. *See, e.g., Mutual Pharm. Co., v. Pfizer Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004); *Mylan Pharms. Inc. v. Merck & Co.*, No. 05-CV-1416, 2005 WL 2850137 (M.D. Pa. Oct. 28, 2005); *Eon Labs, Inc. v. Pfizer, Inc.*, No. 05-CV-0002LAP, 2005 WL 1705295 (S.D.N.Y. July 19, 2005); *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005); *Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. 03-CV-10167-RGS, 2003 WL 22888848 (D. Mass. Dec. 8, 2003); *Dr. Reddy's Labs., Ltd. v. Pfizer, Inc.*, No. 03-CV-726 (JAP), 2003 WL 21638254 (D.N.J. July 8, 2003).

B. The Medicare Amendments Did Not Change The Requirement That An ANDA Applicant Must Be Under A Reasonable Apprehension Of Suit Before Bringing A Declaratory Judgment Action

Caraco asserts in its complaint that this Court must find that it has subject matter jurisdiction over this matter because the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Amendments") "direct the district court to exercise subject matter jurisdiction" in a declaratory judgment action such as this one. Compl. ¶ 57. This argument was also specifically addressed and rejected by the Federal Circuit in *Teva*, which noted that, while the Medicare Amendments include a provision permitting an ANDA applicant to bring a declaratory judgment action under certain conditions, the statute explicitly states that courts will have subject matter jurisdiction over these actions "to the extent consistent with the Constitution," and that this language "compels the conclusion that the Amendments were not meant to automatically bestow district court jurisdiction over actions such as [plaintiff's]." *Teva v. Pfizer*, 395 F.3d at 1336. The court further rejected the plaintiff's argument that the reasonable apprehension test was not a Constitutional test. *Id.* at 1335. The court finally reviewed the legislative history of the Medicare Amendments and concluded that "Congress did not intend for the Medicare Amendments to cause courts to alter the requirement . . . that a declaratory judgment plaintiff must demonstrate a 'reasonable apprehension' of suit to establish Article III jurisdiction." *Id.* at 1336-37; *see also, e.g., Mylan Pharms. Inc. v. Merck & Co.*, No. 05-CV-1416, 2005 WL 2850137, at *8 (M.D. Pa. Oct. 28, 2005) (noting that Federal Circuit had squarely addressed and rejected plaintiff's argument that reasonable apprehension was not required after enactment of Medicare Amendments); *Apotex Inc. v. Pfizer, Inc.*, 385 F. Supp. 2d 187, 192-93 (S.D.N.Y. 2005) ("The Medicare Amendments do not disturb the Federal Circuit's consistent holding that the constitutional limits of an Article III court's jurisdiction in anticipatory patent infringement declaratory judgment actions are defined by the two-part

reasonable apprehension test."); *Torpharm,* 2004 WL 1465756, at *7 ("The court does not read the plain language of either 21 U.S.C. § 355(j)(5)(C)(i)(II) or 35 U.S.C. § 271(e)(5) as eliminating the Federal Circuit's two-part test.").[12]

C. Defendants Have Taken No Action To Create Reasonable Apprehension Of Suit On The Part Of Caraco

Caraco cannot satisfy the Federal Circuit's test for subject matter jurisdiction because Defendants did not make any "explicit threat or other action" that could possibly lead Caraco to reasonably anticipate being sued for infringement of the '941 patent. *Teva v. Pfizer*, 395 F.3d at 1332. The test specifically requires "action *by the patentee*" creating a reasonable apprehension of suit. *Id.* at 1332 (emphasis added); *see also State of Tex. v. West Pub. Co.*, 681 F. Supp. 1228, 1230 (W.D. Tex. 1988), *aff'd*, 882 F.2d 171 (5th Cir. 1989) ("[A]n objectively reasonable apprehension of litigation can only be created by the defendant's actions rather than unilateral conduct on the part of the plaintiff."); *Int'l Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1211 (7th Cir. 1980) ("[R]easonable apprehension, however, must be the product of defendant's statements or conduct; a reasonable apprehension alone, if not inspired by defendant's actions, does not give rise to an actual controversy.").

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[12] A recent Supreme Court decision, *MedImmune, Inc. v. Genentech, Inc.*, --- U.S. ----, 127 S. Ct. 764 (2007), addressed the issue of whether subject matter jurisdiction exists over an action brought by a patent licensee seeking a declaratory judgment on the licensed patent's validity, enforceability or infringement when the licensee continues to pay royalties under the license and therefore cannot be sued for infringement by the patentee. The Court held that subject matter jurisdiction existed in this unusual factual setting. *Id.* at 777. The decision also included dicta, in a footnote, noting that the Federal Circuit's reasonable apprehension test was in conflict with other Supreme Court decisions. *Id.* at 774 n.11. The Court did not reject the reasonable apprehension test, nor did it in any way call into question the continuing applicability of the test to an action like this one, brought by an ANDA applicant under the declaratory judgment provision of the Hatch-Waxman Act. *See WS Packaging Group, Inc. v. Global Commerce Group, LLC,* No. 06-C-674, 2007 WL 205559, at *2 n.3 (E.D. Wis. Jan. 24, 2007) ("[Plaintiff] argues that the United States Supreme Court recently set forth a new jurisdictional test for declaratory judgment actions in *MedImmune* . . . . However, I do not read *MedImmune* so broadly."); *Merchandising Techs., Inc. v. Telefonix, Inc.*, No. 05-CV-1195-BR, 2007 WL 464710, at *4-6, 12 (D. Or. Feb. 7, 2007) (citing *MedImmune* and applying reasonable apprehension test without comment).

The fact that Defendants received notice of Caraco's Paragraph IV certification against the '941 patent over nine months ago, yet did not sue Caraco and have never sued any other generic manufacturer for infringement of this patent, clearly demonstrates that Caraco is under no reasonable apprehension of being sued for infringement for its ANDA filing under 35 U.S.C. § 271(e).[13] *See, e.g., Mylan v. Merck*, 2005 WL 2850137, at *2, 6 (finding no reasonable apprehension of suit where patentee had not sued any Paragraph IV filer for infringement of patents-in-suit, including a patent for a "particular crystalline form" of the active ingredient); *Glaxo v. Dr. Reddy's*, 325 F. Supp. 2d at 507 (finding no subject matter jurisdiction where patentee chose not to sue ANDA applicant during statutory 45-day window and had never sued any generic manufacturer for infringement of the patents-in-suit). Furthermore, Caraco can be under no reasonable apprehension of being sued for infringement under 35 U.S.C. § 271(a) and/or (b) for making, marketing, and selling its generic products because at the present time, approval of its ANDA is blocked until the later of: (1) the expiration of Ivax's 180-day exclusivity period; and (2) an adjudication in its favor on the '712 patent or the mid-2009 expiration of the thirty month stay. There is no possibility of imminent infringement by Caraco.

In fact, Defendants here have not communicated at all with Caraco regarding the '941 patent, and the only correspondence of any sort between the parties regarding the '941 patent was the Paragraph IV notice letter sent to Forest by Caraco. *See, e.g., West Interactive Corp.*, 972 F.2d at 1297-98 (finding record indicating no contact between patentee and declaratory judgment plaintiff to be insufficient to create a reasonable apprehension of suit); *Torpharm*, 2004 WL

[13] Caraco implies that Defendants are motivated by an improper anticompetitive purpose in failing to sue Caraco for infringement of the '941 patent, stating that "Defendants' refusal to litigate the . . . '941 patent is purposefully preventing a court decision . . . which would trigger Ivax's 180-day exclusivity period for the '941 patent, thereby allowing generic competition . . ." This suggestion that Defendants' decision *not to sue* is anticompetitive is both peculiar and baseless. Defendants have not asserted the '941 patent because, based on Caraco's own representations, Caraco's proposed generic products would not infringe the '941 patent.

1465756, at *11 (holding that where defendant "stood silent throughout the . . . litigation" and the only communication between the parties was correspondence from plaintiffs, "plaintiffs cannot complain that they feared that defendants would sue them for patent infringement."); *Mutual Pharm. v. Pfizer*, 307 F. Supp. 2d at 95 (finding no reasonable apprehension of suit where "the plaintiff has not alleged that there have been any communications whatsoever from the defendant to the plaintiff with regard to the [patent-in-suit]").

Caraco's notice letter, the only communication between the parties regarding the '941 patent, provides further evidence that Caraco is not under a reasonable apprehension of suit. In this letter, Caraco denies that its proposed generic products will infringe the '941 patent and states that these products will contain particles approximately *one-twentieth* of the size required for literal infringement of the '941 patent. *See* Ex. B at 5. Accordingly, Defendants have never asserted that Caraco's proposed generic products would infringe the '941 patent. Caraco cannot claim that it is somehow under a reasonable apprehension of suit despite the fact that neither party has claimed that the proposed generic products would infringe the '941 patent. *See Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings*, 787 F.2d 572, 575 (Fed. Cir. 1986) ("It is difficult to conceive of a justiciable controversy when *neither* party says there is any possibility of infringement. . . . ").

Because no one currently asserts that Caraco's proposed generic products would infringe the '941 patent, the only basis for Caraco's claim that an actual controversy is presented here is the existence of the '941 patent and a statutory provision that requires Defendants to inform the FDA of the existence of this patent. However, as discussed above, the listing of a patent in the Orange Book has already been definitively rejected as a basis for subject matter jurisdiction. *Teva v. Pfizer*, 395 F.3d at 1333. Furthermore, the Federal Circuit has recognized that the mere

existence of a patent cannot be the basis for subject matter jurisdiction. *See Int'l Med. Prosthetics*, 787 F.2d at 576 ("[T]hat a patent exists does not alone create a right to challenge its validity in court. Absent an actual controversy, such a challenge is an abuse of the judicial process."). Caraco can cite no threat, action, or communication by Defendants that could possibly create a reasonable apprehension of suit. Any allegations that Caraco is nonetheless under a subjective belief that it is likely be sued are not credible and do not establish reasonable apprehension of suit in any case. *See, e.g., Torpharm*, 2004 WL 1465756, at *6 ("Subjective impressions of the declaratory judgment plaintiff, however, are insufficient to satisfy the [reasonable apprehension] requirement. The court must find objective facts considering the totality of the circumstances at the time the complaint was filed."); *Mutual Pharm. v. Pfizer*, 307 F. Supp. 2d at 95 ("[T]he plaintiff's 'purely subjective apprehension of an infringement suit is insufficient to satisfy the actual controversy requirement.'").

D. Requiring Caraco To Be Under A Reasonable Apprehension Of Suit For This Court To Exercise Subject Matter Jurisdiction Is Entirely Consistent With The Goals Of The Hatch-Waxman Statutory Scheme

Enforcing the long established requirement that a declaratory judgment plaintiff must be under a reasonable apprehension of suit before the court may exercise subject matter jurisdiction is not inconsistent with, and in fact, promotes the goals of the Hatch-Waxman Act.

Ivax is entitled to 180 days of exclusivity as the first Paragraph IV filer against the '712 and '941 patents. In the event, however unlikely, that the '712 patent is invalidated before its expiration, Ivax's ANDA will be approved and its '712 exclusivity will be immediately triggered. However, Ivax will still receive a full 180 days of market exclusivity as first filer against the '941 patent, starting from the day it begins commercial marketing of its generic products. After 180 days, Caraco will receive approval of its ANDA (assuming all technical requirements are met)

and will be free to begin marketing its generic products. Caraco's statement that it will face "indefinite delays" in the approval of ANDA 78-219 is completely unfounded. Compl. ¶ 78. Caraco proposes, without explanation, that Ivax might receive approval of its ANDA but delay marketing its generic products until the expiration of the '941 patent in 2023, thereby blocking Caraco from marketing its own products until at least that time. Compl. ¶ 81. The suggestion that Ivax would decide to postpone marketing generic escitalopram until 2023 is simply illogical and implausible. Ivax's commercial marketing will not be delayed, because as the first filer, it has an enormous economic incentive to market as quickly as possible.

It is entirely consistent with the goals of the Hatch-Waxman statutory scheme to allow Ivax to control the timing of its commercial marketing and thereby receive the benefit of the full 180 days of exclusivity to which it is entitled. It is Caraco's proposal that would contravene the goals of the Hatch-Waxman statutory scheme by permitting Caraco to prematurely trigger and extinguish Ivax's market exclusivity as to the '941 patent. The 180-day exclusivity provision rewards the *first* party to file a Paragraph IV certification against a listed patent, as an incentive for generic manufacturers to expose themselves to potential litigation. *See, e.g, TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 83 n.15 (D.D.C. 2003). Ivax took this risk and filed its Paragraph IV certification immediately, while Caraco chose to wait. Caraco could have been the first filer against the '941 patent and assumed the accompanying risks and expenses. Instead, Caraco waited over ten months, until six other generic manufacturers had already filed Paragraph IV certifications without provoking litigation, and submitted its ANDA knowing that it was unlikely to be sued for infringement of the '941 patent. Yet Caraco now asks this Court to depart from binding case law precedent and the plain language of the statute and find subject matter jurisdiction where there is no reasonable apprehension of suit. Caraco may find it unfair that it

would be unable to compete with Ivax in the generic escitalopram market for 180 days, but subject matter jurisdiction is not created by Caraco's disagreement with the incentive structure of the Hatch-Waxman Act. *See Dr. Reddy's v. Pfizer*, No. 03-CV-7261 (JAP), 2003 WL 21638254, at *7 (D.N.J. July 8, 2003) ("[Plaintiff] seeks to nullify the statutory benefit given as an incentive for generic companies who take the greatest risk of being the first generic entrant on the market. This argument is entirely unpersuasive as a basis for this Court to exercise jurisdiction."). Because Caraco is under no reasonable apprehension of suit, there is no subject matter jurisdiction over this action for declaratory judgment, and Caraco's complaint should be dismissed.

CONCLUSION

For all the foregoing reasons, Defendants respectfully ask this Court to grant Defendants' Motion To Dismiss Plaintiff's Complaint For Lack Of Subject Matter Jurisdiction.

Dated: March 13, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 13, 2007, the foregoing document was electronically filed with the Clerk of Court using the CM/ECF system, which will send notification of such filing to the following email addresses on this 13 day of March, 2007:

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