

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

PFIZER INC.,	)	
PFIZER IRELAND PHARMACEUTICALS,	)	
WARNER-LAMBERT COMPANY, and	)	
WARNER-LAMBERT COMPANY LLC,	)	
	)	
Plaintiffs,	)	Case No.: 08-cv-7231
	)	(consolidated with no. 09-cv-6053)
	)	
v.	)	Judge Robert M. Dow, Jr.
	)	
APOTEX INC. and	)	
APOTEX CORP.,	)	
	)	
Defendants.	)	

**MEMORANDUM OPINION AND ORDER**

Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company LLC (collectively “Pfizer”) filed this patent infringement action against Defendants Apotex Inc. and Apotex Corp. (collectively “Apotex”) for infringement of United States Patent No. 5,273,995 (“the ‘995 patent”). After Pfizer filed its initial complaint, the ‘995 patent was reissued in part as U.S. Patent No. 40,667 (“the ‘667 patent”). Pfizer has since amended its complaint to include a claim for infringement of the ‘667 patent.

Pfizer’s suit was prompted by Apotex’s filing of an Abbreviated New Drug Application (“ANDA”), in which it seeks permission from the Food and Drug Administration (“FDA”) to market a generic copy of Pfizer’s pharmaceutical product, Lipitor<sup>®</sup>. Apotex answered and filed counterclaims [110] asserting non-infringement and invalidity of the ‘995 and ‘667 patents, as well as three other Pfizer patents: U.S. Patent Nos. 5,686,104 (“the ‘104 patent”), 5,969,156 (“the ‘156 patent”), and 6,126,971 (“the ‘971 patent”) (collectively “the Unasserted Patents”).

Currently before the Court is Pfizer’s motion to dismiss [113] Counts III-VIII of Apotex’s counterclaims for lack of subject matter jurisdiction and for failure to state a claim pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).<sup>1</sup> For the reasons stated below Pfizer’s motion to dismiss [113] Apotex’s counterclaims is denied. The dismissal is without prejudice as to Pfizer’s motion to dismiss for failure to make the statutorily-required *bona fide* offer of confidential access.

## **I. Background**

### **A. Statutory Framework**

The approval of prescription drugs is governed by the applicable provisions of the Federal Food, Drug, and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the “Hatch-Waxman Act”), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”). The Hatch-Waxman Act requires pharmaceutical companies seeking to market new, previously unapproved drugs to file a New Drug Application (“NDA”) with the FDA. 21 U.S.C. § 355(a), (b). As part of its NDA, an applicant must provide certain information to the FDA about “any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1). The FDA publishes the patent information in the *Approved Drug Products With Therapeutic Equivalence Evaluations*, which is commonly referred to as the “Orange Book.” 21 U.S.C. § 355(j)(7)(A). Drugs approved by the FDA are known as “listed drugs.” 21 U.S.C. § 355(j)(2)(A)(i).

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<sup>1</sup> Counts III-VIII (“the Unasserted Patent counterclaims”) assert declaratory judgment claims for invalidity and non-infringement of the ‘104, ‘156, and ‘971 patents.

In 1984, with the enactment of the Hatch-Waxman Act, Congress created “an expedited approval process known as an Abbreviated New Drug Application (ANDA)” in order “[t]o encourage the development of generic versions of listed drugs.” *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355-56 (Fed. Cir. 2008); see also 21 U.S.C. § 355(j). The Hatch-Waxman Act allows generic drug companies to rely on the FDA’s previous approval of a listed drug if the generic drug company demonstrates in its ANDA that its generic drug product is bioequivalent to the NDA drug. 21 U.S.C. § 355(j)(2)(A). An ANDA applicant also must include a certification to each patent listed in the Orange Book covering the listed drug. 21 U.S.C. § 355(j)(2)(A)(vii). There are four types of patent certifications: (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; and (IV) in the opinion of the ANDA applicant, 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); *Janssen*, 540 F.3d at 1356.

The timing of ANDA approval by the FDA depends on the types of certifications contained in the ANDA. An ANDA with a Paragraph III certification cannot be approved until the expiration of the last to expire of any patent that is the subject of that certification. 21 U.S.C. § 355(j)(5)(B)(ii). Where an ANDA contains a Paragraph IV certification, the timing of approval depends on two events: (i) whether the holder of the listed patent brings an infringement suit within 45 days of receiving notice of the ANDA filing, and (ii) whether the company seeking approval was the first to file an ANDA with a Paragraph IV certification to the listed patent. 21 U.S.C. § 355(j)(5)(B)(iii).

With respect to the first potential event, the Hatch-Waxman Act provides that the filing

of a Paragraph IV certification is an act of patent infringement. 35 U.S.C. § 271(e)(2)(A). If the patentee or NDA holder does not bring suit within 45 days of receiving notice of the Paragraph IV certification, the statute mandates that FDA “shall” approve the ANDA immediately. 21 U.S.C. § 355(j)(5)(B)(iii). If the brand name company does bring suit within 45 days, the FDA may not approve the ANDA for 30 months, unless a court decides that the patent(s)-in-suit are invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii).

With respect to the second potential event, to encourage generic pharmaceutical companies to challenge Orange Book listed patents, the Hatch-Waxman Act grants the first company to submit a Paragraph IV ANDA a 180-day period of generic marketing exclusivity during which time FDA will not approve a later-filed Paragraph IV ANDA based on the same NDA. 21 U.S.C. § 355(j)(5)(B)(iv). Under the version of Hatch-Waxman Act that is applicable to this case, the start of the 180-day exclusivity period is triggered by the earlier of two events: (1) the first-filer’s commercial marketing of its generic drug product; or (2) a court decision of non-infringement or invalidity. *Id.* § 355(j)(5)(B)(iv)(I)-(II) (2000).<sup>2</sup> A court decision of non-infringement or invalidity can come in any court action, including one involving a subsequent Paragraph IV ANDA applicant. Consequently, “subsequent Paragraph IV ANDA filers have a strong incentive to generate a triggering event allowing the FDA to approve their subsequent Paragraph IV ANDAs 181 days after the triggering event,” while “NDA holders have a strong incentive to prevent a triggering event, because subsequent Paragraph IV ANDAs cannot be

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<sup>2</sup> In 2003, Congress enacted the MMA, which amended the Hatch-Waxman provisions governing the commencement of the 180-day exclusivity period. However, grandfather provisions within the MMA make the amended triggering provisions inapplicable to (1) Paragraph IV ANDAs filed before the date of the enactment of the MMA, and (2) subsequent Paragraph IV ANDAs filed after the enactment of the MMA if the first Paragraph IV ANDA was filed prior to enactment of the MMA. See *Janssen*, 540 F.3d at 1357 n.2 (explaining the grandfather provisions). Here, Ranbaxy filed the first Paragraph IV ANDA in 2002, such that the MMA amendments governing the commencement and forfeiture of the 180-day exclusivity period do not apply to this case.

approved until the exclusivity period [is triggered and] expires.” *Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278, 1284 (Fed. Cir. 2008).

On December 8, 2003, the Hatch-Waxman Act was amended by Title XI of the MMA, which, among other things, includes a provision for a “civil action to obtain patent certainty.” 21 U.S.C. § 355(j)(5)(C). That provision “allows a Paragraph IV ANDA filer a right to bring a declaratory judgment action for non-infringement or invalidity of the relevant listed patents against the patentee and NDA holder, if the patentee has not brought an infringement action within the 45-day notice period.” *Janssen*, 540 F.3d at 1357. See also 21 U.S.C. § 355(j)(5)(C)(i)(II) (authorizing “a civil action to obtain patent certainty” under 28 U.S.C. § 2201 “for a declaratory judgment that the [listed] patent is invalid or will not be infringed by the drug for which the applicant seeks approval”). The MMA was enacted “to prevent NDA holders from ‘gaming’ the Hatch-Waxman Act by forestalling the resolution of patent disputes with ANDA filers.” *Caraco*, 527 F.3d at 1285. In addition, in 35 U.S.C. § 271(e)(5) – a 2003 amendment to the patent statute that works in conjunction with the 2003 amendment to the Hatch-Waxman Act – Congress extended federal court jurisdiction over declaratory judgment actions to obtain patent certainty “to the extent consistent with the Constitution.” See *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1335 (Fed. Cir. 2007); *Janssen*, 540 F.3d at 1357. Therefore, federal courts have jurisdiction over ANDA declaratory judgment actions to the extent that they present an Article III case or controversy. *Janssen*, 540 F.3d at 1357.

## **B. Factual Background<sup>3</sup>**

At issue in this case is the prescription drug atorvastatin, which Pfizer markets under the brand-name Lipitor<sup>®</sup>. Pfizer holds an approved NDA for Lipitor<sup>®</sup>. The Orange Book originally

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<sup>3</sup> For purposes of Pfizer’s motion to dismiss, the Court assumes as true all well-pleaded allegations set forth in the Apotex’s counterclaims. See, e.g., *Killingsworth v. HSBC Bank Nevada, N.A.*, 507 F.3d 614, 618 (7th Cir. 2007).

listed five patents for Lipitor®: the ‘995 patent, the ‘971 patent, the ‘104 patent, the ‘156 patent, and U.S. Patent No. 4,681,893 (“the ‘893 patent”). On March 17, 2009, the ‘995 patent was reissued in part as U.S. Patent No. 40,667 (“the ‘667 patent”); Pfizer has since listed the ‘667 patent in the Orange Book as well.

The first generic drug company to seek FDA approval to market a generic version of Lipitor® was Ranbaxy, which filed its ANDA in August 2002. Ranbaxy’s ANDA included Paragraph IV certifications as to all five patents listed at that time – the ‘893, ‘995 ‘104, ‘156, and ‘971 patents. In response, Pfizer sued Ranbaxy for infringement of only the ‘893 patent and the ‘995 patent. The district court found both patents to be valid and infringed. The Federal Circuit affirmed with respect to the ‘893 patent, but reversed with respect to the ‘995 patent. See *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495 (D. Del. 2005), *aff’d in part*, 457 F.3d 1284 (Fed. Cir. 2006).

Because it was the first to file an ANDA with a Paragraph IV certification, Ranbaxy is entitled to 180 days of marketing exclusivity. That period of exclusivity has not yet been triggered because (1) Ranbaxy has not yet begun to market its product, and (2) no court decision of non-infringement or invalidity has been issued with respect to the ‘104, ‘156, and ‘971 patents. The ‘893 patent expired on March 24, 2010, and therefore no longer bars Ranbaxy from marketing its generic drug. However, in 2008, Pfizer and Ranbaxy entered a settlement agreement whereby Ranbaxy agreed not to market its product until November 30, 2011. Therefore, Ranbaxy’s exclusivity period will not begin to run until that date at the earliest, unless, in litigation involving a subsequent ANDA filer, a court determines that the ‘104, ‘156, ‘971, and ‘667 patents are not infringed or are invalid.

Generic companies Teva Pharmaceuticals USA, Inc. and Cobalt Pharmaceuticals Inc.

also have filed atorvastatin ANDAs. Teva and Cobalt filed Paragraph III certifications as to the ‘893 patent, and Paragraph IV certifications as to the other listed patents. Pfizer sued Teva and Cobalt for infringement of the ‘995 patent only. Each of those cases settled prior to judgment, and therefore did not trigger Ranbaxy’s 180-day exclusivity period.

Apotex filed its ANDA for atorvastatin on November 4, 2008, and provided Pfizer with the statutorily mandated notice. Apotex’s ANDA includes Paragraph IV certifications to the ‘995, ‘104, ‘156, and ‘971 patents, and a Paragraph III certification as to the ‘893 patent. Initially, Pfizer sued Apotex on only the ‘995 patent. Following the issuance of the ‘667 reissue patent, Apotex filed a Paragraph IV certification to the ‘667 patent, and Pfizer amended its complaint to assert the ‘667 patent as well.

Apotex filed ten counterclaims, including claims for a declaratory judgment of non-infringement and invalidity of the ‘104, ‘156, and ‘971 patents (“the Unasserted Patents”) under the Declaratory Judgment Act, 28 U.S.C. § 2201, and the MMA to the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).<sup>4</sup> Apotex’s hope is to obtain a decision from this Court that the Unasserted Patents are invalid or are not infringed by Apotex’s product, thereby triggering Ranbaxy’s exclusivity period. Absent such a court ruling (either in this case or in litigation involving another subsequent ANDA filer), Apotex will not be able to market its generic atorvastatin drug until 180 days after Ranbaxy begins marketing its drug, which, as a result of the settlement agreement between Pfizer and Ranbaxy, will not occur until November 2011 at the earliest.

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<sup>4</sup> At issue on Pfizer’s motion to dismiss are Counts III-VIII of Apotex’s counterclaims. Count III sets forth a claim for a declaratory judgment of non-infringement of the ‘104 patent; Count IV sets forth a claim for a declaratory judgment of invalidity of the ‘104 patent; Count V sets forth a claim for a declaratory judgment of non-infringement of the ‘156 patent; Count VI sets forth a claim for a declaratory judgment of invalidity of the ‘156 patent; Count VII sets forth a claim for a declaratory judgment of non-infringement of the ‘971 patent; and Count VIII sets forth a claim for a declaratory judgment of invalidity of the ‘971 patent.

At the time that Pfizer filed its motion to dismiss in this case, it had never asserted any of the Unasserted Patents against any ANDA filer. However, in the intervening months, Pfizer has sued three other subsequent ANDA-filers – Mylan, KUDCO, and Dr. Reddy's Laboratories – on the '156 patent.

Pfizer seeks dismissal of the Unasserted Patent counterclaims on jurisdictional grounds, contending that those counterclaims do not present an Article III case or controversy. In the alternative, Pfizer argues that the Court lacks jurisdiction over Apotex's claims because Apotex failed to make the statutorily required *bona fide* offer of confidential access to its ANDA. Finally, Pfizer claims that Apotex's counterclaims warrant dismissal pursuant to Rule 12(b)(6) because they do not meet the pleading requirements of Rule 8(a).

## **II. Legal Standards**

Pfizer has moved to dismiss Apotex's counterclaims for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), and for failure to state a claim under Rule 12(b)(6). The purpose of a motion to dismiss is not to decide the merits of the case. A Rule 12(b)(6) motion tests the sufficiency of the complaint or counterclaims, *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990), while a Rule 12(b)(1) motion tests whether the Court has subject matter jurisdiction. *Long v. Shorebank Development Corp.*, 182 F.3d 548, 554 (7th Cir.1999). In reviewing a motion to dismiss under either rule, the Court takes as true all factual allegations in Apotex's counterclaims and draws all reasonable inferences in its favor. *Killingsworth*, 507 F.3d at 618; *Long*, 182 F.3d at 554.

To survive a Rule 12(b)(6) motion to dismiss, the counterclaims first must comply with Rule 8(a) by providing "a short and plain statement of the claim showing that the pleader is entitled to relief" (Fed. R. Civ. P. 8(a)(2)), such that the defendant is given "fair notice of what



the \* \* \* claim is and the grounds upon which it rests.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Second, the factual allegations in the counterclaims must be sufficient to raise the possibility of relief above the “speculative level,” assuming that all of the allegations in the complaint are true. *E.E.O.C. v. Concentra Health Servs., Inc.*, 496 F.3d 773, 776 (7th Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). “Detailed factual allegations” are not required, but Apotex must allege facts that, when “accepted as true, \* \* \* ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, --- U.S. ----, 129 S.Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 555). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 129 S.Ct. at 1949. “[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint.” *Twombly*, 550 U.S. at 563. Surviving a Rule 12(b)(1) motion to dismiss is more difficult, as the party asserting the claims bears the burden of proving that the jurisdictional requirements have been met. *United Phosphorus, Ltd. v. Angus Chem. Co.*, 322 F.3d 942, 946 (7th Cir. 2003).

### **III. Analysis**

Pfizer raises three grounds for dismissal of Apotex’s counterclaims. First, Pfizer seeks to dismiss Apotex’s declaratory judgment counterclaims pursuant to Rule 12(b)(1) on the grounds that they do not present a “case” or “controversy” as required by Article III of the Constitution. Second, Pfizer argues that dismissal is warranted because Apotex failed to make the statutorily required *bona fide* offer of confidential access to its ANDA. Third, Pfizer claims that Apotex’s counterclaims should be dismissed pursuant to Rule 12(b)(6) because they do not meet the pleading requirements of Rule 8(a).

“It is axiomatic that a federal court must assure itself that it possesses jurisdiction over the subject matter of an action before it can proceed to take any action respecting the merits of the action.” *Scott Air Force Base Properties, LLC v. County of St. Clair, Ill.*, 548 F.3d 516, 520 (7th Cir. 2008) (citation omitted); see also *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83 (1998) (rejecting the proposition that a court may proceed to the merits question before resolving whether it has Article III jurisdiction); *Cook v. Winfrey*, 141 F.3d 322, 325 (7th Cir. 1998) (holding that the district court erred by dismissing case pursuant to Rule 12(b)(6) without reaching the jurisdictional challenge asserted under Rule 12(b)(1)); *Crawford v. United States*, 796 F.2d 924, 929 (7th Cir. 1986) (“once the district judge has reason to believe that there is a serious jurisdictional issue, he is obliged to resolve it before proceeding to the merits even if the defendant, whether as a matter of indolence or strategy, does not press the issue”). Therefore, the Court begins by addressing Pfizer’s jurisdictional challenges.

**A. Apotex’s Declaratory Judgment Claims Present an Article III Case or Controversy**

As discussed above, Congress has extended federal court jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201, to ANDA Paragraph IV disputes (21 U.S.C. § 355(j)(5)(C)), and has directed federal courts to exercise jurisdiction over such actions “to the extent consistent with the Constitution” (35 U.S.C. § 271(e)(5)). See *Janssen*, 540 F.3d at 1359. The Declaratory Judgment Act provides that, “[i]n a case of actual controversy within its jurisdiction \* \* \* any court of the United States \* \* \* 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). The phrase “case of actual controversy,” as it appears in the Declaratory Judgment Act, “refers to the type of ‘Cases’ and ‘Controversies’ that are justiciable under Article III.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

In *MedImmune*, the Supreme Court explained that, in determining whether a justiciable declaratory judgment action exists, “the question \* \* \* is whether 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.” *Id.* at 771 (citation omitted). “In applying the all-the-circumstances test \* \* \*, [courts are] guided by the Supreme Court’s three-part framework for determining whether an action presents a justiciable Article III controversy.” *Caraco*, 527 F.3d at 1291. Pursuant to that framework, an action is justiciable under Article III where (1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case has not been rendered moot. *Id.* (citations omitted).

At issue here is whether Apotex has alleged a controversy of sufficient “immediacy and reality” so as to be justiciable under Article III. The immediacy inquiry can be viewed either through the lens of standing (*i.e.*, whether plaintiff alleges an actual or imminent injury caused by the defendant that can be redressed by judicial relief) or through one of the prongs of the ripeness doctrine (*i.e.*, whether withholding court consideration would cause hardship to the parties). See *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 n.6 (Fed. Cir. 2008); *MedImmune*, 549 U.S. at 127. In either case, “the underlying inquiry [is] rooted in the requirement that Article III courts cannot issue advisory opinions.” *Prasco*, 537 F.3d at 1338 n.6.

## **1. Standing**

To establish standing, a plaintiff must demonstrate (1) an injury-in-fact, (2) that is fairly traceable to the defendant’s conduct, and (3) that can be redressed by the court. See *Novartis*, 482 F.3d at 1340. The Court addresses each element of the standing analysis below.

**a. Apotex Alleges a Judicially Cognizable Injury-in-Fact**

For purposes of the standing inquiry, an injury-in-fact is a harm that is concrete, as well as actual or imminent, not conjectural or hypothetical. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Apotex's alleges two injuries-in-fact, both of which essentially can be characterized as the inability to market a non-infringing product. First, Apotex contends that, by not suing Apotex on the Unasserted Patents while reserving the right to do so in the future, Pfizer has created uncertainty as to Apotex's legal rights under its ANDA. According to Apotex, that uncertainty, as well as the threat of future litigation based on the Unasserted Patents, are injuries-in-fact. See *Novartis*, 482 F.3d at 1341, 1345 (stating that the "threat of litigation" on unasserted patents and the "legal uncertainty" caused when a patent holder fails to sue an ANDA filer on all Paragraph IV Certified patents constitute "present injur[ies] sufficient for a justiciable controversy"). Second, according to Apotex, Pfizer has erected a barrier to FDA approval of its product, thereby barring Apotex from entering the market. See *Caraco*, 527 F.3d at 1285 (prevention of generic drug company from selling non-infringing generic drug by patent holder's actions is a sufficient Article III injury-in-fact); *Prasco*, 537 F.3d at 1339 (holding that a patentee creates an immediate injury or threat of future injury by "creating a barrier to the regulatory approval of a product that is necessary for marketing"). In particular, Apotex points to Pfizer's refusal to litigate the Unasserted Patents, which prevents the triggering of Ranbaxy's exclusivity period by a court decision of non-infringement or invalidity. Apotex also points to Pfizer's settlement agreement with Ranbaxy, which delays the triggering of the exclusivity period by the only other possible avenue – Ranbaxy's commercial marketing of its generic product.

Pfizer contends that Apotex's alleged injuries are not sufficiently imminent to establish standing in light of Apotex's Paragraph III certification to the '893 patent, which prevents the

FDA from approving Apotex's ANDA until the '893 patent expires. According to Pfizer, because Apotex's Paragraph III certification prevented immediate FDA approval when Apotex filed its counterclaims, any delay in FDA approval (and concomitant injury) related to the Unasserted Patents was not imminent at that time.<sup>5</sup>

At the time Apotex filed its counterclaims, the delay in FDA approval caused by Pfizer's actions was not a present injury, because the Paragraph III certification constituted an independent barrier to FDA approval. However, "the injury required for standing need not be actualized. A party facing prospective injury has standing to sue where the threatened injury is real, immediate, and direct." *Davis v. Federal Election Com'n*, 128 S.Ct. 2759, 2769 (2008). Here, Apotex's alleged injury was prospective when it filed its pleading. In particular, the injury Apotex identifies is its inability to obtain FDA approval (and sell its product) between the March 2010 expiration of the '893 patent and 180 days after the date Ranbaxy begins marketing its product sometime after November 2011. The Federal Circuit has recognized, in the context of the Hatch-Waxman Act, that the creation of "an independent barrier to the drug market" by a brand drug company "that deprives [the generic company] of an economic opportunity to compete" satisfies the injury-in-fact and causation requirements of Article III standing. *Caraco*, 527 F.3d at 1285. See also *Prasco*, 537 F.3d at 1339 (holding that a patentee creates an immediate injury or threat of future injury by "creating a barrier to the regulatory approval of a

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<sup>5</sup> The '893 patent expired in March of 2010 and therefore no longer constitutes a barrier to FDA approval of Apotex's ANDA. However, as the party seeking to establish declaratory judgment jurisdiction, Apotex must demonstrate that such jurisdiction existed at the time that it filed its claims for declaratory relief. See *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974); *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007) ("The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since"); *Int'l Med. Prosthetics Research Assocs. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575 (Fed. Cir. 1986). Apotex filed its counterclaims on October 28, 2009 [110]. Therefore, if Pfizer is correct about the significance of Apotex's Paragraph III Certification to the '893 patent, then dismissal for lack of subject matter jurisdiction would be appropriate despite the fact that the '893 patent no longer poses a barrier to FDA approval.

product that is necessary for marketing”). Thus, Apotex has alleged a potentially cognizable injury. The question before the Court is whether the threatened delay in its ability to go to market was imminent when Apotex filed its counterclaims.

The Supreme Court has explained that the purpose of the imminence requirement “is to ensure that the alleged injury is not too speculative for Article III purposes – that the injury is ‘*certainly* impending.’” *Lujan*, 504 U.S. at 564 n.2 (citation omitted) (emphasis in original). Pfizer, relying on the Federal Circuit’s decision in *Janssen*, contends that Apotex’s delay argument is “too speculative.” The Court disagrees. In *Janssen*, the patent holder (Janssen) listed three patents in the Orange Book in relation to an approved NDA for its drug Risperdal<sup>®</sup> Oral Solution. 540 F.3d at 1357. Teva Pharmaceuticals USA, Inc. (“Teva”) was first to file an ANDA to make a generic version of risperidone oral solution. *Id.* at 1358. Teva filed a Paragraph III certification as to one of the patents (the ‘663 patent), and a Paragraph IV certification as to the other two. *Id.* As the first-filer of a Paragraph IV certification, Teva secured the 180 days of generic market exclusivity. Janssen did not sue Teva for infringement. Therefore, the FDA would be permitted to approve Teva’s generic version of risperidone oral solution upon the expiration of the ‘663 patent. *Id.* Subsequently, Apotex filed an ANDA including a Paragraph IV certification as to all three patents. 540 F.3d at 1358. Janssen sued Apotex for infringing the ‘663 patent, but did not bring suit as to the other two patents. *Id.* As in the instant case, Apotex asserted counterclaims for declaratory judgment of non-infringement of the two unasserted patents. *Id.* After filing its declaratory judgment counterclaims, Apotex stipulated to the validity, infringement, and enforceability of the ‘663 patent. *Id.* at 1360. As a result, if Apotex prevailed on its declaratory judgment claims, it could obtain FDA approval on the same date as Teva – when the ‘663 patent expired. 540 F.3d at 1361. Absent a declaratory

judgment action, Apotex would have to wait until the expiration of Teva's 180-day exclusivity period for FDA approval.

In *Janssen*, Apotex argued that if its declaratory judgment action was dismissed, FDA approval of its product could be indefinitely delayed because Teva might not commercially launch its product (thereby triggering the exclusivity period) immediately after the expiration of the '663 patent. *Id.* at 1362. The court held that, at the time that the district court entered final judgment in the case, Apotex's alleged harm of indefinite delay was speculative because Teva still was precluded from launching at that time, and there was no "basis to conclude that Teva will, or is likely to, delay in bringing its generic product to market in the future." *Id.* at 1362-63.

By contrast, here, the alleged delay in marketing between March 2010 and November 2011 is not a mere risk but a certainty. At the time that Apotex filed its counterclaims, there was no doubt that, following the March 2010 expiration of the '893 patent, Apotex would be precluded from obtaining FDA approval and going to market until at least November 2011. Contrary to Pfizer's contention, Apotex is not "suspicious that Ranbaxy might not launch its generic atorvastatin product upon its first opportunity to do so." Rather, Apotex knows that Ranbaxy will not launch its product until November 2011 as a result of Ranbaxy's settlement agreement with Pfizer, resulting in a delay in FDA approval of Apotex's product. Thus, unlike in *Lujan*, where "the plaintiff allege[d] only an injury at some indefinite future time," Apotex alleges an injury at a very specific time in the future. 504 U.S. at 564 n.2. Consequently, Apotex has alleged an injury that is sufficiently imminent for purposes of the injury-in-fact requirement of the standing inquiry.<sup>6</sup>

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<sup>6</sup> The gist of Pfizer's imminence argument is that any decision by this Court on the Unasserted Patents would be premature because such a decision would not allow Apotex to enter the market immediately; Apotex would still need to wait for the '893 patent to expire. That argument might be better analyzed under the ripeness doctrine, the purpose of which "is to prevent the courts, through avoidance of

**b. Apotex's Injury is Traceable to Pfizer's Conduct**

Pfizer contends that, to that extent that Apotex can establish any delay in FDA approval of its product, the injury attendant to that delay is not traceable to Pfizer's conduct, but to Ranbaxy's statutorily-mandated 180-day exclusivity period. Once again, Pfizer relies on *Janssen*. As noted above, in *Janssen* – in a move that the court found to be dispositive – Apotex stipulated to the validity, infringement, and enforceability of the '663 patent. Consequently, in *Janssen*, if Apotex prevailed on its declaratory judgment claims, the earliest date on which it could obtain FDA approval was after the '663 patent expired. *Id.* at 1361. Significantly, the expiration of the '663 patent also marked the date on which Teva could first obtain FDA approval. *Id.* The Federal Circuit explained that, as a result of the stipulation, the sole cause of Apotex's claimed injury (*i.e.*, its exclusion from selling its allegedly noninfringing product) was "Teva's 180-day exclusivity period – a period which Teva [was] entitled to under the Hatch-Waxman Act." *Id.* The court held that "Apotex's inability to promptly launch its generic risperidone product because of Teva's 180-day exclusivity period is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act." *Id.* Put differently, Apotex's injury – its inability to market its product during the 180-day exclusivity period – was traceable to the Hatch-Waxman Act, not to Janssen's actions.

Here, however, Apotex is not seeking merely to bypass Ranbaxy's 180-day exclusivity period. Rather, Apotex also seeks to avoid an entirely separate delay – namely, the delay in going to market that it will face between March 2010 and at least November 2011 absent a court ruling regarding the Unasserted Patents. That delay is not attributable to the Hatch-Waxman Act. Indeed, delays such as the one Apotex has identified are precisely what Congress sought to

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premature adjudication, from entangling themselves in abstract disagreements." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967). See also *Tokyo Kikai Seisakusho, Ltd. v. U.S.*, 529 F.3d 1352, 1362 (Fed. Cir. 2008). The Court addresses whether Apotex's declaratory judgment action is ripe below.



eliminate when it enacted the MMA amendments. See 149 Cong. Rec. S15885 (Nov. 25, 2003) (explaining that where a brand drug company has several patents listed in the Orange Book with respect to a particular drug and brings suit on only one patent and holds the others in reserve, thereby “introduc[ing] uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market[,] \* \* \* generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period” by bringing a declaratory judgment action). Here, it is Pfizer’s “actions in the context \* \* \* of the Hatch-Waxman framework” that are the source of the complained-of delay. *Caraco*, 527 F.3d at 1292. In particular, Pfizer’s listing of the Unasserted Patents in the Orange Book, combined with its refusal to litigate their validity and the Pfizer-Ranbaxy settlement agreement create “an independent barrier to the drug market that deprives [Apotex] of an economic opportunity to compete. It is well established that the creation of such barriers to compete satisfies the causation requirement of Article III standing.” *Id.*

A Delaware district court reached the same conclusion on similar facts in *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355 (D. Del. 2009). In *Dey*, Sepracor, a pioneer drug company, listed six patents in the Orange Book for the drug at issue. 595 F. Supp. 2d at 358. A generic drug company, Breath, filed an ANDA with a Paragraph IV certification for all six patents. Sepracor sued Breath on all six patents, but the parties settled before any decision on the merits was issued. *Id.* Pursuant to the settlement agreement, Breath agreed not to market its generic product until August of 2012. *Id.* After Breath filed its ANDA, thereby securing the right to 180 days of exclusivity, Dey filed an ANDA with Paragraph IV certifications for all six patents. *Id.*

Sepracor filed suit against Dey on five of the six patents. Dey then brought a declaratory

judgment action for non-infringement of the sixth, unasserted patent. In addressing whether it had jurisdiction over the declaratory judgment action, the district court considered the Federal Circuit's decision in *Janssen*, and found it to be distinguishable. As noted above, the *Janssen* court considered Apotex's stipulation to be determinative. *Janssen*, 540 F.3d at 1360 ("We agree with the parties that if Apotex had not stipulated to the validity of the '663 patent, then *Caraco* would have been controlling.").<sup>7</sup> In *Dey*, the court observed that that stipulation put Apotex on "equal footing" with the first ANDA filer "with respect to the earliest date it could conceivably enter the market," such that "the only \* \* \* *non-speculative* harm to Apotex was the possibility of having to wait 180 days for Teva to enjoy its exclusivity period." 595 F. Supp. 2d at 362 (emphasis in original). By contrast, "Dey [had] not precluded itself from going to market prior to the primary ANDA filer," and thus there was "nothing equivalent to Apotex's stipulation." *Id.* Unlike Apotex in *Janssen*, "if Dey were to prevail on its declaratory judgment action, the sole effect would not be to simply destroy Breath's exclusivity period," but to allow "Dey [to] potentially go to market well in advance of August 2012, the earliest date that Breath could go to market under its settlement agreement with Sepracor." *Id.* The court concluded that, under those circumstances, Dey's declaratory judgment action presented a justiciable Article III controversy. *Id.*

Here, Pfizer argues that the Paragraph III certification is comparable to the stipulation in *Janssen*. But the Paragraph III certification does not put Apotex on equal footing with Ranbaxy. Consequently, as was the case in *Dey*, the statutory exclusivity period is not the sole delay that Apotex faces. Rather, absent a court decision, Apotex will be foreclosed from marketing until November 2011 as a result of Pfizer's listing of the Unasserted Patents in the Orange Book and

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<sup>7</sup> In *Caraco*, the Federal Circuit concluded that the generic drug company's declaratory judgment action for non-infringement of an unasserted patent presented an Article III controversy. 527 F.3d at 1297.

the Ranbaxy settlement agreement. The Court concludes that that delay is traceable to Pfizer.

**c. Apotex's Injury Is Redressible by a Favorable Judgment**

Finally, a judgment in Apotex's favor would redress the claimed injury by "eliminat[ing] the potential for the [unasserted] patent[s] to exclude [Apotex] from the drug market," *Caraco*, 527 F.3d at 1293, and making it possible for Apotex to obtain FDA approval upon the expiration of the '893 patent.

**2. Ripeness and the Prohibition on Advisory Opinions**

Pfizer argues that as a result of the Paragraph III certification to the '893 patent, "there is no injury to Apotex and no controversy between Apotex and Pfizer over the Unasserted Patents [because] even if Apotex prevailed against the Unasserted Patents tomorrow, the FDA may not approve its ANDA" until after March 2010. While Pfizer frames that argument in terms of whether Apotex has alleged an injury-in-fact, it is really an argument about the timing of the suit, and therefore might be better couched in terms of ripeness. See *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 140 (1974) ("ripeness is peculiarly a question of timing").

"The doctrine of ripeness focuses on the conduct of the defendant to determine whether the defendants actions have harmed, are harming, or are about to harm the plaintiff." *Novartis*, 482 F.3d at 1337. It is well established that "[o]ne does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough." *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 143 (1974) (quoting *Pennsylvania v. West Virginia*, 262 U.S. 553, 593 (1923)). For example, in the *Regional Rail Reorganization Act Cases*, the Court deemed ripe an action brought by eight major railroads challenging the conveyance of their property by operation of the Regional Rail Reorganization Act. Although a reorganization plan had not yet been formulated and a special court had not yet ordered the

conveyances, the Court reasoned that “where the inevitability of the operation of a statute against certain individuals is patent, it is irrelevant to the existence of a justiciable controversy that there will be a time delay before the disputed provisions will come into effect.” *Id.* at 143. Similarly, here, the harm to Apotex is inevitable, and the action is fit for judicial review, as further factual development would not “significantly advance [the court’s] ability to deal with the legal issues presented.” *Nat’l Park Hospitality Ass’n v. Dep’t of Interior*, 538 U.S. 803, 812 (2003). Therefore, contrary to Pfizer’s claims, the fact that there was “a time delay” between the filing of the counterclaims and the expiration of the ‘893 patent does not render the action premature, or otherwise deprive this Court of jurisdiction.

### **3. The Cases on which Pfizer Relies are Distinguishable**

Pfizer relies primarily on *Janssen and Teva Pharmaceuticals USA, Inc. v. Eisai Co., Ltd.*, No. 08-2344, 2009 WL 2905534 (D. N.J. Sept. 9, 2009), an unpublished decision by the district court of New Jersey. As demonstrated above, Pfizer’s reliance on *Janssen* is misplaced. The *Janssen* court’s decision turned on the fact that, as a result of Apotex’s stipulation, if Apotex prevailed, it would merely bypass the 180-day exclusivity period. Because such a result would thwart the statutory structure, the court found no case or controversy.

The reasoning of the court in *Teva* was similar. In *Teva*, the generic drug company – Teva – filed a declaratory judgment action seeking to trigger Ranbaxy’s exclusivity period, and thereby accelerate approval of its own ANDA (referred to in the opinion as “the Gate ANDA”) for a generic version of the drug donepezil. In a prior action, a court had entered a preliminary injunction precluding Teva from marketing any version of generic donepezil as covered by one of the listed patents for the drug, the ‘841 patent. 2009 WL 2905534, at \*11. As a result, even if Teva prevailed on its declaratory judgment action, it could not market its generic product until

the '841 patent expired. *Id.* Moreover, the “preliminary injunction place[d] Teva and Ranbaxy on an ‘equal footing’ with respect to the Gate ANDA” because Ranbaxy had filed a Paragraph III certification as to the '841 patent, which precluded Ranbaxy from launching its generic product until the '841 expired. *Id.* Consequently, as was the case in *Janssen*, if Teva prevailed, the result would merely be to allow it to circumvent Ranbaxy’s 180-day exclusivity period. Put differently, the only harm that Teva faced was its “inability to market [its drug] during Ranbaxy’s exclusivity period.” *Id.* The court concluded that, under those circumstances, “the harm to Teva from the delay in approval of [its drug did] not result from the inability to trigger the Ranbaxy exclusivity period absent a court judgment on the DJ patents,” but “from the operation of the Hatch-Waxman Act and its grant of an exclusivity period, not any act by Eisai.” 2009 WL 2905534, at \*11. As discussed above, here Apotex is not on equal footing with Ranbaxy. Therefore, both *Janssen* and *Teva* are inapposite.

#### **4. Allowing Apotex’s Declaratory Judgment Action Furthers the Purpose of the Hatch-Waxman Act**

Finally, Apotex’s declaratory judgment action is consistent with the primary goal of the Hatch-Waxman Act, “which is to balance the need for pharmaceutical innovation with the need for generic drug competition.” *Caraco*, 527 F.3d at 1294. As the Federal Circuit explained in *Caraco*, “a significant part of this carefully crafted dialectic balance is encouraging the early resolution of patent disputes when subsequent Paragraph IV ANDA filers are ‘blocked by a first generic applicant’s 180-day exclusivity.’” *Id.* (citation omitted). That is precisely what Apotex seeks to do here.

#### **B. Bona Fide Offer of Confidential Access to the ANDA**

Pfizer contends that dismissal of Apotex’s counterclaims also is required because Apotex failed to make a *bona fide* offer of confidential access to its ANDA as the statute requires.

Under the MMA’s declaratory judgment provisions, no declaratory judgment action may be brought by an ANDA applicant unless the applicant provides the NDA-holder/patent owner with “an offer of confidential access” to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(cc), 355(j)(5)(C)(III).<sup>8</sup> The statute further provides that “the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.” 21 U.S.C. § 355(j)(5)(C)(III). If a patent holder requests “access to an application under an offer of confidential access[, that request] shall be considered acceptance of the offer of confidential access with the restrictions \* \* \* contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract.” *Id.*

Here, Apotex’s offer of confidential access imposed a number of restrictions, including:

- (1) only outside counsel for Pfizer could access the information provided;
- (2) only outside counsel for Pfizer who do not engage in any patent prosecution for Pfizer could access the information provided;
- (3) only outside counsel for Pfizer who do not engage in any FDA counseling, litigation or other activities before or involving FDA (involving Pfizer or not) could access the information provided;
- (4) the outside attorneys shall not disclose any of the information provided to any

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<sup>8</sup> In particular, the statute states:

No action may be brought under section 2201 of Title 28, by an applicant referred to in subsection (b)(2) of this section for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless-- \* \* \* (cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

21 U.S.C. § 355(j)(5)(C)(i)(I)(cc). Subclause (III) in turn sets forth the offer of confidential access requirement. 21 U.S.C. § 355(j)(5)(C)(i)(III).

person or entity, including any employee of Pfizer or to any outside scientific consultants or to any other outside counsel for Pfizer without prior consent of Apotex;

(5) all information disclosed to Pfizer's outside counsel and any copies be returned before any suit is filed.

While the statute expressly allows ANDA applicants to impose restrictions on ANDA access, Pfizer argues that the restrictions in Apotex's offer far exceed what the statute permits, thereby rendering the offer illusory. Furthermore, according to Pfizer, a *bona fide* offer of confidential access is a jurisdictional prerequisite, such that dismissal should be for lack of jurisdiction pursuant to Rule 12(b)(1).

Apotex presents a number of arguments in response. First, Apotex maintains that its offer meets the statutory requirements. Second, Apotex contends that the offer of confidential access requirement is not jurisdictional. Finally, Apotex argues that even if the offer of confidential access requirement is jurisdictional and the Court finds that Apotex has failed to satisfy that requirement, the Court nevertheless has jurisdiction under the Declaratory Judgment Act.

First, the Court considers whether an offer of confidential access is a jurisdictional prerequisite. The plain language of the statute, which provides that "[n]o action may be brought under section 2201 of Title 28" absent an offer of confidential access, suggests that it is. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(cc), 355(j)(5)(C)(i)(III). While it appears that no court has considered whether a deficient offer can deprive a court of jurisdiction, at least one court has referred to the offer of confidential access requirement as a "jurisdictional prerequisite." *Apotex, Inc. v. Novartis AG*, 2007 WL 5493499, at \*3 (E.D. Va. Sept. 4, 2007). Based on the statutory text, it appears that a court may not exercise jurisdiction over an ANDA declaratory judgment action absent an offer of confidential access. But even if that supposition is incorrect, it would

have no bearing on the proper disposition of this motion because the Court concludes that Apotex has at least preliminarily satisfied the requirement to make its offer of confidential access.

In assessing the adequacy of Apotex's offer, the Court again finds a dearth of authority addressing the propriety of restrictions imposed in offers of confidential access in the specific context of the Hatch-Waxman framework. However, "[i]n evaluating whether \* \* \* counsel should have access" to an opposing party's confidential information more generally, courts "balance the risk of inadvertent disclosure of trade secrets to competitors against the risk of impairing the process of litigation by denying access." *Interactive Coupon Marketing Group, Inc. v. H.O.T! Coupons, LLC.*, 1999 WL 618969, at \*2 (N.D. Ill. Aug. 9, 1999) (citations omitted). "Risk of inadvertent disclosure of trade secrets exists where the factual circumstances show that an attorney acts as a competitive decision-maker." *SmartSignal Corp. v. Expert Microsystems, Inc.*, 2006 WL 1343647, at \*5 (N.D. Ill. May 12, 2006). See also, *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 (Fed. Cir. 1984) (stating that "the factual circumstances surrounding each individual counsel's activities, association, and relationship with a party, whether counsel be in-house or retained, must govern any concern for inadvertent or accidental disclosure" and that involvement in "competitive decisionmaking" serves as the basis for denial of access). The Federal Circuit has defined the term "competitive decisionmaking" as "shorthand for a counsel's activities, association, and relationship with a client that are such as to involve counsel's advice and participation in any or all of the client's decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor." *U.S. Steel*, 730 F.2d at 1468 n.3. Courts also have held that "access to confidential information [can] not be denied solely because of counsel's in-house status." *Matsushita Elec. Indus. Co., Ltd. v.*



*United States*, 929 F.2d 1577, 1579 (Fed. Cir. 1991).

It is not clear from the briefing which particular attorneys Pfizer believes should be permitted to access Apotex's ANDA that would not be allowed access under the terms of Apotex's offer. Nor is there any way for the Court to determine, based on the pleadings, whether there exists an adequate basis for the denial of access to those attorneys (*i.e.*, involvement in "competitive decisionmaking"). All that is clear is that Apotex has made an offer that Pfizer contends is too broad. The Court concludes that the adequacy of Apotex's offer does not provide grounds for the dismissal of Apotex's counterclaims, at least in the first instance. Rather, the parties are directed to attempt to negotiate – with the Court's assistance, if necessary – a protective order regarding access to the ANDA that conforms to the principles outlined above. For example, while Apotex's current offer denies all in-house counsel access to the ANDA, as noted above, "access to confidential information [can] not be denied solely because of counsel's in-house status." *Matsushita*, 929 F.2d at 1579. To the extent that Apotex seeks to preclude all of Pfizer's in-house attorneys from accessing the ANDA, Apotex will need to identify some basis for denying access to those attorneys apart from their status as in-house counsel. In the unlikely event that the efforts of the parties (and the Court, if necessary) fail to yield an appropriate protective order, Pfizer may renew its request for dismissal based on Apotex's failure to provide Pfizer with confidential access to the ANDA. But for the time being, Pfizer's motion to dismiss for failure to make the statutorily-required *bona fide* offer of confidential access is denied without prejudice.

**C. Apotex's Counterclaims Are Sufficiently Pled Under Rule 8(a)**

Finally, Pfizer contends that Apotex's counterclaims and defenses of non-infringement and invalidity warrant dismissal pursuant to Rule 12(b)(6) because Apotex has not met the pleading requirements of the Federal Rules of Civil Procedure. Rule 8(a)(2) requires that

pleadings contain “a short and plain statement of the claim showing that the pleader is entitled to relief,” Fed. R. Civ. P. 8(a)(2), such that the opposing party is given “fair notice of what the \* \* \* claim is and the grounds upon which it rests.” *Twombly*, 550 U.S. at 555. Apotex’s counterclaims adhere to that standard.

Apotex’s counterclaims for a declaratory judgment of non-infringement (Counts III, V, and VII) allege that the product described in the ANDA will not infringe any valid and/or enforceable claim of the Unasserted Patents. Counterclaims, ¶¶ 104, 112, 120. Pfizer has the burden of proof as to infringement of the Unasserted Patents. See *Under Sea Indust., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) (“The burden is always on the patentee to show infringement”); *Schinzing v. Mid-States Stainless, Inc.*, 415 F.3d 807, 814 (8th Cir. 2005) (where defendant counterclaimed for a declaratory judgment of non-infringement, patent holder “was obligated to counterclaim for infringement and had the burden to show infringement”); *Advance Transformer Co. v. Levinson*, 1986 WL 84365, at \*25 (N.D. Ill. June 17, 1986), *rev’d in part on other grounds*, 837 F.2d 1081 (Fed. Cir. 1988) (“Even in a declaratory judgment action where the plaintiff pleads non-infringement, the patentee-defendant still has the burden of proving infringement”). As discussed above, Apotex has made an “offer of confidential access” to its ANDA. Once an appropriate protective order is in place, Pfizer may review the ANDA in order to “evaluat[e] possible infringement of the [Unasserted P]atent[s].” 21 U.S.C. § 355(j)(5)(C)(i)(III). Therefore, Pfizer is on notice as to Apotex’s non-infringement counterclaims. See *Elan Pharma Intern. Ltd. v. Lupin Ltd.*, 2010 WL 1372316, at \*4 (D. N.J. March 31, 2010) (concluding that non-infringement counterclaims merely averring that the defendant’s product did not infringe the listed patents satisfied Rule 8(a) and put the plaintiff on full notice of the defendant’s claims of non-infringement).

Apotex's invalidity counterclaims (Counts IV, VI, and VIII) allege that the Unasserted Patents are "invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code." Counterclaims, ¶¶ 108, 116, 124. While brief, those allegations are sufficient to put Pfizer on notice of what Apotex is claiming – invalidity of the Unasserted Patents – and the grounds upon which this claim rests – failure to satisfy one or more of the conditions of patentability.

Moreover, dismissal of Apotex's counterclaims for failure to satisfy Rule 8(a) would undermine the Local Patent Rules, which require more detailed disclosures at a later stage. Pursuant to Local Patent Rules 2.2 and 2.3, both parties will be required to disclose of certain information regarding their theories of the case. Of particular relevance here is Local Patent Rule 2.3, which will require Apotex to serve "Initial Non-Infringement, Unenforceability and Invalidity Contentions" stating the basis for its non-infringement and invalidity counterclaims.

In analogous cases, other district courts have concluded that local patent rules requiring similar disclosures militate against dismissal of counterclaims for failure to meet the pleading requirements of Rule 8(a). For example, in *Elan Pharma Intern. Ltd. v. Lupin Ltd.*, Lupin, the defendant in an ANDA case, asserted counterclaims of non-infringement and invalidity as to all the listed patents. Lupin's counterclaims were similar to Apotex's in their brevity. Lupin's counterclaims asserting non-infringement simply alleged that "the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim' of the [listed] patents." 2010 WL 1372316, at \*1. Its counterclaims asserting invalidity alleged that "the claims of the [listed] patents \* \* \* [were] 'invalid under one or more provisions of 35 U.S.C. §§ 101-105.'" *Id.* Elan moved to dismiss the counterclaims on the grounds that they did not meet the pleading

requirements of Rule 8. The district court for the district of New Jersey denied that motion based largely on that district's local patent rules, which required disclosures substantially identical those required by LPR 2.2 and 2.3. The court reasoned that granting the motion to dismiss would "undermine[] the logic" and render "superfluous" the District of New Jersey Local Patent Rules. *Id.* at \*5. Similarly, here, granting Pfizer's motion to dismiss on pleading grounds would be inconsistent with the Local Patent Rules. See also *Teirstein v. AGA Medical Corp.*, 2009 WL 704138, at \*5 (E.D. Tex. March 16, 2009) (denying motion to dismiss counterclaim for declaratory judgment of patent invalidity for failure to meet the requirements of Rule 8(a)(2) where counterclaim alleged invalidity of a patent "for failing to satisfy one of more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112," reasoning that requiring more "would undermine the purpose of the Court's Local Patent Rules," which required additional disclosures).

#### **IV. Conclusion**

For the foregoing reasons, Pfizer's motion to dismiss [113] Apotex's Unasserted Patent counterclaims is denied. The dismissal is without prejudice as to Pfizer's motion to dismiss for failure to make the statutorily-required *bona fide* offer of confidential access. The parties are directed to negotiate a protective order governing access to Apotex's ANDA that is consistent with the principles set forth above.



Dated: June 30, 2010

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Robert M. Dow, Jr.  
United States District Judge