IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

APOTEX INC.,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	1:09CV477
	)	
	)	
	)	
EISAI INC. & EISAI CO., LTD.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

This matter is before the Court on a Motion to Dismiss Pursuant to Rule 12(b)(1) [Doc. #13] filed by Defendants Eisai, Inc. and Eisai Co., Ltd. (collectively, "Eisai"). In its Complaint, Plaintiff Apotex, Inc. ("Apotex") seeks a declaratory judgment of noninfringement with respect to four patents filed by Eisai (the "DJ Patents"), as well as a finding of exceptional case pursuant to 35 U.S.C. § 285, and an award of costs, expenses, and attorneys' fees. Eisai maintains in its Motion to Dismiss that Apotex's Complaint does not present a justiciable Article III controversy, and that even if Article III jurisdiction does exist in this case, the Court should decline to exercise jurisdiction over this claim within the Court's discretion. For the reasons discussed below, the Court will grant Eisai's Motion to Dismiss.

I. THE HATCH-WAXMAN ACT

This declaratory judgment action arises under the Hatch-Waxman Act,[1] which provides the regulatory approval mechanism for new and generic pharmaceutical drugs. The Hatch-Waxman Act was enacted with the purpose of balancing "two competing interests in the pharmaceutical industry: '(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" Jannsen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1355 (Fed. Cir. 2008) (quoting Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002)). To accomplish the first of these objectives, the Hatch-Waxman Act requires a drug company to prepare and file a New Drug Application ("NDA"), which must be approved by the U.S. Food and Drug Administration ("FDA") prior to marketing the new drug. See 21 U.S.C. §§ 355(a), (b). As part of the NDA approval process, applicants must submit information regarding the drug's safety and efficacy and identify all patents that "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), (c)(2). When an NDA is approved, the FDA lists this patent information along with the approved drug in a publication commonly referred to as the "Orange Book." See 21 U.S.C. §§ 355(b)(1), (j)(2)(A)(ii).

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

With respect to the second objective of the Hatch-Waxman Act, that is, enabling competitors to bring low-cost, generic copies of those drugs to market, generic drug companies may obtain expedited approval of generic drugs by preparing and filing an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. §§ 355(j). Once an ANDA applicant demonstrates bioequivalence of its generic drug to the NDA drug, it is not required to conduct its own independent clinical trials to prove safety and efficacy. 21 U.S.C. §§ 355(j)(2)(A)(iv), (j)(8)(B). In addition, an ANDA applicant must also include a certification as to each patent listed in the Orange Book with respect to the listed drug that either: (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 the FDA's approval of the ANDA should be deferred until expiration; or (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. 21 U.S.C. § 355(j)(2)(A)(vii). Respectively, these filings are referred to as Paragraph I, II, III, and IV certifications.

The FDA's approval of an ANDA is dependent upon the type of certification sought by the generic drug manufacturer, with the approval of a Paragraph IV ANDA dependent upon two factors: "(1) whether the pioneer drug company brings an infringement action within 45 days of learning of the Paragraph IV ANDA filing, and (2) whether the company seeking approval was the first one to file an ANDA containing a Paragraph IV Certification to a listed patent." Jannsen, 540 F.3d at 1356. Under the Hatch-Waxman Act, in the interests of the early resolution of patent disputes involving the manufacture of generic drugs, the filing of a Paragraph IV certification constitutes an "artificial" act of patent infringement, "for purposes

of establishing jurisdiction in the federal courts." 35 U.S.C. § 271(e)(2); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678, 110 S. Ct. 2683, 2692, 110 L. Ed. 2d 605, 624 (1990); Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351 (Fed. Cir. 2004). Upon filing a Paragraph IV certification, an ANDA filer must provide notice of the factual and legal bases for the Paragraph IV certification to the patentee and the NDA holder. 21 U.S.C. § 355(j)(2)(B). Within 45 days of receiving this notice, the patentee and NDA holder may bring suit against the Paragraph IV filer for patent infringement, which triggers an automatic stay of the ANDA's approval for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does file an infringement suit within 45 days, the FDA may not approve the ANDA until either the 30 month stay has expired or a court rules that the patent is invalid or not infringed by the ANDA. 21 U.S.C. §§ 355(c)(3)(C). If however, the patentee does not bring suit within that period, the FDA may issue a final approval of the ANDA once the requirements for approval have been satisfied. Id.

In the interests of encouraging generic pharmaceutical companies to challenge suspect patents listed in the Orange Book, the Hatch-Waxman Act grants the first party to submit an ANDA containing a Paragraph IV certification (the "first-filer") a 180-day period of generic marketing exclusivity. 21 U.S.C. §§ 355(j)(2)(A)(iv). Particularly relevant to the case presently before the Court, the first-filer of a Paragraph IV certification may obtain this 180-day exclusivity period regardless of whether or not it successfully establishes that the challenged patents are invalid or not infringed by the drug described in its ANDA. "All that is required for the first Paragraph IV ANDA filer to receive the 180-day exclusivity period is that it submits a substantially complete ANDA that contains a Paragraph IV Certification." Jannsen, 540 F.3d

at 1356 (citing 21 U.S.C. § 355 (j)(5)(B)(iv)(II)(bb)). Accordingly, once a first-filer obtains this marketing exclusivity, the commencement of the 180-day period may be triggered by the earlier of two events: "(1) the date on which the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application; or (2) the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed." Apotex, Inc. v. Food and Drug Admin., 414 F. Supp. 2d 61, 64 (D.D.C. 2006) (citing 21 U.S.C. § 355(j)(5)(B)(iv) (internal quotation marks omitted)) aff'd 226 Fed. Appx. 4 (Fed. Cir. 2007).

The FDA, which is the administrative agency responsible for administering the Hatch-Waxman Act's drug approval mechanism, has interpreted the Act to create "patent-based" exclusivity in the case of multiple ANDA filers, whereby "multiple exclusivity periods . . . may be conferred in connection with a single drug product." Id. Under this patent-based interpretation, a 180-day exclusivity period may be awarded to each individual ANDA-applicant who is the first to make a Paragraph IV certification against a listed patent, where, as here, multiple patents underlie a single drug.[2] The FDA's adoption of a patent-based approach to exclusivity is entitled to deference, and as recognized by the U.S. Court of Appeals for the Federal Circuit, the FDA's patent-based approach is a reasonable interpretation of the Hatch-

[2] An alternative interpretation of the Hatch-Waxman Act's marketing exclusivity period, which has not been adopted by the FDA, is a "drug-based" exclusivity period, also known as the "first-filer" approach. Apotex, 414 F.Supp. 2d at 64 n.2; see also Apotex, Inc. v. FDA, 393 F.3d 210, 211 (D.C. Cir. 2004). Under the "drug-based" approach, only the first ANDA applicant to file a Paragraph IV certification with respect to any patent underlying a pharmaceutical drug may be awarded a 180-day exclusivity period for the marketing of that drug, regardless of whether other ANDA applicants are the first to file Paragraph IV certifications with respect to other listed patents underlying the drug.

Waxman Act. Apotex, Inc. v. Food & Drug Administration, et al., 226 Fed. Appx. 4 (Fed. Cir. 2007); see also Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1278-80 (Fed. Cir. 2004).

In 2003, the Hatch-Waxman Act was amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, 2457-60. The MMA amended the statutory provisions governing the triggering of the 180-day exclusivity period to allow for the forfeiture of the first Paragraph IV filer's exclusivity period for various reasons, including the failure to begin marketing the generic drug within a certain period of time after it first becomes eligible to commence marketing of that drug. 21 U.S.C. § 355(j)(5)(D). However, the MMA also contains a grandfather provision, which limits the scope of the forfeiture provisions to affect only parties who filed Paragraph IV ANDAs after the December 2003 enactment of the amendment. See MMA, Pub. L. No. 108-173, § 1102(b), 117 Stat. 2066 (2003). In addition, the MMA permits Paragraph IV ANDA filers to bring a civil action in federal district court, seeking a declaratory judgment "that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II). Federal courts have jurisdiction over these declaratory judgment actions to the extent that they provide a justiciable case or controversy pursuant to Article III of the Constitution. See Caraco Pharm. Labs. v. Forest Labs., 527 F.3d 1278, 1285 (Fed. Cir. 2008); 35 U.S.C. § 271(e)(5).

II. FACTUAL BACKGROUND

Eisai holds NDA No. 20-690 for the pharmaceutical drug Aricept® (donepezil hydrochloride), which was approved by the FDA on November 25, 1996 for the treatment of

Alzheimer's disease. Eisai listed five patents in support of its NDA in the Orange Book: U.S. Patent No. 4,895,841 ("the '841 patent") and the DJ Patents (5,985,864 ("the '864 patent"); 6,140,321 ("the '321 patent"); 6,245,911 ("the '911 patent"); and 6,372,760 ("the '760 patent")). A generic drug manufacturer, Ranbaxy Laboratories Ltd. ("Ranbaxy"), filed the first ANDA for donepezil hydrochloride in August 2003, which included a Paragraph III certification as to the '841 Patent, and Paragraph IV certifications against the four remaining DJ Patents.[3] Eisai elected not to sue Ranbaxy for infringement of the DJ Patents, and because it was the first Paragraph IV filer with respect to those patents, Ranbaxy became eligible for the 180-day marketing exclusivity period for the DJ Patents. The FDA later granted Ranbaxy tentative approval to sell generic Aricept®, which is eligible for final approval upon the expiration of the '841 Patent in November 2010. However, in September 2008, Ranbaxy was issued a warning letter by the FDA regarding alleged regulatory non-compliance and problems with two of its pharmaceutical manufacturing facilities outside the United States. Apotex maintains that the FDA will reject Ranbaxy's ANDA on account of these deficiencies, and that Ranbaxy's tentative approval to market generic Aricept® will also be revoked.

In October 2004, another generic drug manufacturer, Teva Pharmaceuticals USA ("Teva"), filed an ANDA, which originally contained a Paragraph III certification as to the '841 Patent and Paragraph IV certifications against the DJ Patents. In October 2005, Teva amended its ANDA to include a Paragraph IV certification against the '841 Patent, challenging its validity and constituting a technical act of infringement. Due to the FDA's adoption of a

[3] Ranbaxy filed these Paragraph IV certifications in August 2003, before the December 2003 enactment of the forfeiture provisions of the MMA.

patent-based approach to exclusivity, Teva thus became eligible to share in Ranbaxy's 180-day marketing exclusivity period for generic Aricept® because it was the first ANDA filer to include a Paragraph IV certification against the '841 Patent. See Apotex, 226 Fed. Appx. at 4; Mylan Labs, 389 F.3d at 1278-80. Like Ranbaxy, Eisai did not sue Teva for infringement of the DJ Patents, however Eisai did file suit against Teva for patent infringement regarding its Paragraph IV certification against Patent '841. Because Eisai filed its infringement action within 45 days of learning of Teva's Paragraph IV certification, a 30-month stay of FDA approval for Teva's ANDA was triggered pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Although Eisai's infringement suit is still presently pending, the District of New Jersey has awarded Eisai a preliminary injunction which prevents Teva from marketing generic Aricept® prior to the November 2010 expiration of the '841 Patent. See Eisai Co., Ltd. v. Teva Pharms. USA, Inc., 2008 WL 1722098 (D.N.J. Mar. 28, 2008). The FDA granted Teva final approval to market generic Aricept® on April 28, 2008, however the preliminary injunction issued by the District of New Jersey prevents Teva from doing so until November 2010 at the expiration of the '841 Patent.

In 2006 and 2007, Eisai filed statutory disclaimers of two of the DJ Patents ('321 & '864) pursuant to 35 U.S.C. § 253, which resulted in these claims being treated as if they had never existed in patent. See Guinn v. Kopf, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (citing Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp., 294 U.S. 477, 492 55 S. Ct. 544, 461, 79 L. Ed. 1005 (1935)). However, in May 2008, Teva, through its Gate Pharmaceuticals division, filed a new declaratory judgment action against Eisai, seeking a judgment of non-infringement of the four DJ Patents. In response, Eisai provided Teva an express covenant-not-to-sue regarding Teva's

use of the remaining undisclaimed DJ Patents ('911 & '760) in its ANDA products. See Teva Pharms. USA, Inc. v. Eisai Co., Ltd., No. 08-2344, 2009 WL 2905534 (D.N.J. Sept. 9, 2009). As a result, the District of New Jersey dismissed Teva's declaratory judgment action for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1), finding that no substantial and sufficiently immediate controversy existed between adverse parties so as to create Article III jurisdiction. Id.

Thereafter, several other generic pharmaceutical manufacturers including Par Pharmaceuticals, Inc., Roxanne Laboratories, Inc., and Apotex filed ANDAs, seeking to market donepezil hydrochloride. In July 2007, Apotex filed its ANDA, filing a Paragraph III certification as to the '841 Patent and Paragraph IV certifications against the DJ Patents. Eisai did not sue Apotex regarding its Paragraph IV certifications against the DJ Patents, and it has also granted Apotex a covenant-not-to-sue regarding its use of the two nondisclaimed DJ Patents. On July 1, 2009, Apotex brought the instant declaratory judgment action, seeking a declaration of noninfringement by the court with regard to the DJ Patents.

III. STANDARD OF REVIEW

A. Declaratory Judgments Under the Hatch-Waxman Act

The burden is on the party claiming declaratory judgment jurisdiction of establishing that jurisdiction exists both at the time of filing and throughout the pendency of the case. See, e.g., Benitec Austl., Ltd. v. Nucleonics, Inc., 495 F. 3d 1340, 1344 (Fed. Cir. 2007). In the pharmaceutical patent setting, the Hatch-Waxman Act and the MMA authorize parties to bring declaratory judgment actions to the full extent consistent with the Constitution. Accordingly,

the Court has subject matter jurisdiction over declaratory judgment claims brought pursuant to the Hatch-Waxman Act to the extent that a case or controversy is presented under Article III of the Constitution. See Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 57 S. Ct. 461, 81 L. Ed. 617 (1937). Article III jurisdiction exists over a declaratory judgment action when a dispute is "definite and concrete, touching the legal relations of parties having adverse legal interests, . . . real and substantial and admit[s] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts. Id., at 240-241, 57 S. Ct. (internal quotation marks and alteration omitted). When determining whether an action presents a justiciable Article III controversy, the courts utilize an all-the-circumstances standard. MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127, 127 S. Ct. 764, 771, 166 L. Ed. 2d 604, 615 (2007). "Basically, the question in each case 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. (quoting Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273, 61 S. Ct. 510, 85 L. Ed. 826 (1941)). In applying the "all-the-circumstances" test to determine whether a court has jurisdiction over a declaratory judgment action, the Supreme Court has enunciated a three-part framework. An action presents a justiciable case or controversy where: "(1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case is not rendered moot at any stage of the litigation." Caraco, 527 F.3d at 1291. Moreover, even if a plaintiff properly establishes that Article III jurisdiction exists over a declaratory judgment action properly brought pursuant to the Hatch-

Waxman Act, a court may decline to exercise jurisdiction over the matter within its discretion. See Brillhart v. Excess Ins. Co., 316 U.S. 491, 497-98, 62 S. Ct. 1173, 1176-77, 86 L. Ed. 1620 (1942); see also Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F. 3d 1330, 1338 n.3 (Fed. Cir.2007) (holding that under both the Declaratory Judgment Act and the Hatch-Waxman Act that "the district court is not required to exercise jurisdiction to address the merits of the action, as it retains discretion . . . to decline declaratory judgment jurisdiction"). As set out in the following discussion, the Court will find that Apotex has not presented a justiciable Article III controversy in the present case, and that even if it had, the Court within its discretion would decline to exercise jurisdiction over this claim.

B. Standing

In order to meet the "irreducible constitutional minimum of standing," Apotex, as the party claiming declaratory judgment jurisdiction, must meet three requirements: "First and foremost, there must be alleged (and ultimately proved) an 'injury in fact' – a harm suffered by the plaintiff that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical.' Second, there must be causation – a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability – a likelihood that the requested relief will redress the alleged injury." Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 103-04, 118 S. Ct. 1003, 1016-17, 140 L. Ed. 2d 210 (1998) (internal citation omitted).

IV. DISCUSSION

In its Complaint, Apotex initially alleged that it has Article III standing to bring this declaratory judgment action on the grounds that its ability to enter the generic Aricept® market will be "delayed indefinitely," "because Ranbaxy will not be able to launch its generic product," and following 180 days after the November 2010 expiration of the '841 Patent, there will be "no opportunity for a triggering event and subsequent generic entry to the market." (Compl. ¶¶ 35, 50). The Complaint argues that Apotex's entry into the donepezil hydrochloride market will face indefinite delay because Eisai's failure to bring suit for patent infringement prevents a court holding that the DJ Patents are invalid or not infringed, and Ranbaxy, the first-filer, will be unable to initiate marketing generic Aricept® due to its issues with the FDA. Id. at ¶¶ 50, 58. Effectively, Apotex maintains that it will be injured because neither of the statutory triggers for the 180-day exclusivity period pursuant to 21 U.S.C. § 355(j)(5)(B)(iv) will be met at any definite point following the expiration of the '841 Patent. Id.

However, in its Response Brief to Eisai's Motion to Dismiss [Doc. #19], Apotex appears to have altered the theory upon which it argues that Article III jurisdiction exists. Apotex amends its theory of injury from one that it initially alleged was based on"indefinite delay," to one that is based upon its "inability to promptly launch." In the Response Brief, Apotex argues that its injury stems not from any purported delay in the triggering of Ranbaxy's exclusivity period, but that "Eisai's procedural manipulation of Hatch-Waxman creates a situation wherein Eisai can delay Apotex's market entry by at least half a year" after the expiration of the '841 Patent in November 2010 – and *before* a period of 180-days thereafter. (Resp. Opp. Mot. to

Dism. [Doc. #19] at 2). In effect, Apotex now seems to claim that its injury stems from the fact that it will be unable to promptly launch its product immediately after the November 2010 expiration of the '841 Patent, regardless of any first-filer's 180-day exclusivity period. The Court notes that although parties are generally entitled to amend their pleadings once as a matter of course pursuant to Federal Rule of Civil Procedure 15(a), amended pleadings must be filed in accordance with the provisions of Federal Rule of Civil Procedure 7 and the Local Rules of this District. Local Rule 7.3(j)(5) states that parties do not need to separately brief motions to amend, however, Local Rule 7.3(a) requires that "[e]ach motion shall be set out in a separate pleading." To the extent that Apotex has altered the type the injury it alleges was caused by Eisai, Apotex has not filed a separate motion to amend its Complaint, as required by the local rules. However, the Court notes that for the reasons set out below, even if Apotex had properly amended its Complaint to reflect this change, the Court would nevertheless grant Eisai's Motion to Dismiss on the grounds that Apotex has failed to establish standing to bring this declaratory judgment action, specifically, that it has not demonstrated an injury-in-fact which is redressible by a ruling from the Court.

In bringing the present declaratory judgment action, Apotex bears the burden of establishing that it has standing and that Article III jurisdiction exists over this claim. Benitec, 495 F. 3d at 1344. Preliminarily, the Court notes that it does not appear that the present dispute between Apotex and Eisai "touch[es] the legal relations of parties having *adverse* legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, 549 U.S. at 127, 127 S. Ct. at 771 (emphasis added). Eisai has disclaimed two of

the DJ Patents ('321 & '864), which requires that these patents be treated as if they were never filed, and Eisai has also granted Apotex a covenant-not-to-sue with respect to the other two remaining DJ Patents ('911 & '760). See Guinn, 96 F.3d at 1422. Therefore, it does not appear the parties in the present case have adverse legal interests with respect to the issue of whether Apotex has infringed the DJ Patents, since both parties agree that Apotex has not.

However, Apotex maintains that a justiciable Article III controversy exists due to Eisai's alleged manipulation of the Hatch-Waxman's approval mechanism, resulting in regulatory-blocking injuries, which it claims are redressible by this Court in the form a declaratory judgment of non-infringement with respect to the DJ Patents. In this regard, Apotex alleges in its Response Brief, that it is injured by its inability to obtain a "prompt launch" of its generic pharmaceutical. Under this theory, Apotex alleges that Eisai's actions, in listing the DJ Patents in the Orange Book and declining to file suit for infringement, have blocked Apotex, along with other prospective donepezil hydrochloride manufacturers, from receiving ANDA approval from the FDA and promptly entering the pharmaceutical market. Apotex maintains that it is thereby injured by its inability to enter the generic Aricept® market promptly upon the expiration of the '841 Patent, and consequently, prior to the expiration of the exclusivity periods belonging to Ranbaxy and Teva. In addition, Apotex claims in its Complaint that it will be injured under a theory of "indefinite delay," "because Ranbaxy will not be able to launch its generic product [when] Eisai's '841 patent expires and Eisai has refused to sue any generic Paragraph IV filer for infringement of its '864, '321, '911 and '760 patents." (Compl. ¶ 50). Apotex argues that its entry into the generic Aricept® market will face indefinite delay because neither Ranbaxy nor

Teva will be able to market generic Aricept® and commence their exclusivity periods following the expiration of the '841 Patent. Apotex argues under this theory of injury that if it prevails, and the Court issues a declaration of non-infringement, "the exclusivity period would be triggered and Ranbaxy's exclusivity period would no longer present a regulatory barrier for Apotex and other subsequent ANDA filers." (Resp. Opp. Mot. to Dism. at 15).

In support of these claims, Apotex cites the Federal Circuit case of Caraco Pharm. Labs v. Forest Labs., Inc., wherein the court held that Caraco, a generic drug manufacturer, had Article III standing to bring a declaratory judgment action against Forest, a brand name manufacturer, for a "regulatory blocking injury" it suffered due to Forest's failure to bring a suit for infringement against Caraco with respect to Orange-Book listed pharmaceutical patents. Caraco, 527 F.3d 1278. In Caraco, the court held that a justiciable Article III controversy was present where "Forest's actions effectively prevent[ed] the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market." Id. at 1297. The patents-at-issue in that case were two patents listed by Forest in the Orange Book related to its NDA, one of which expired in 2012 ("the 2012 Patent"), and another in 2023 ("the 2023 Patent"). Caraco was not a first-filer with respect to those patents. Instead, another generic drug manufacturer, Ivax, was the first to file Paragraph IV certifications against both the 2012 and 2023 Patents. Forest chose not to sue Ivax for infringing the 2023 Patent, but it did sue Ivax for infringing the 2012 Patent and ultimately obtained a court judgment that the 2012 Patent was valid and infringed. The district court therefore enjoined Ivax from making products infringing the 2012 Patent, which prevented Ivax from triggering its exclusivity period at any point prior to the expiration of the

2012 Patent. Nevertheless, a subsequent ANDA filer would have been able to trigger Ivax's exclusivity period before 2012 if it could obtain a court judgment that both the 2012 and 2023 Patents were invalid or not infringed.

Subsequently, Caraco filed an ANDA which included Paragraph IV certifications against both the 2012 and 2023 Patents. Again, Forest only sued Caraco for infringement on the 2012 Patent and did not bring suit on the 2023 Patent. Although Forest also granted Caraco a covenant-not-to-sue on the 2023 Patent, Forest refused to concede that the 2023 Patent was invalid or not infringed by the generic drug described in Caraco's ANDA. Under these facts, the Federal Circuit concluded that looking to all the circumstances of the case, "Forest's covenant not to sue does not eliminate the controversy with Caraco, because the controversy can only be resolved by a judgment that determines whether Forest's . . . patent is infringed by the drug described in Caraco's ANDA." Id. In that case, the court held that Caraco was injured by Forest's failure to sue for infringement of the 2023 Patent, because absent a court ruling on the validity or infringement of the 2023 Patent, there was no prospect of triggering Ivax's exclusivity period prior to the expiration of the 2012 Patent. The Federal Circuit thus found that Caraco had established Article III standing because Forest's failure to sue for infringement of the 2023 Patent prevented Caraco from entering the market in "a manner that is unique to the Hatch-Waxman context." Id. at 1296.

Apotex maintains that it, like Caraco, has standing to bring the present action because it is injured by Eisai's failure to bring suit for infringement of the DJ Patent, and that a finding of non-infringement or invalidity would redress this injury because it would commence

Ranbaxy's exclusivity period with respect to the DJ Patents. The Court notes that although the Federal Circuit in Caraco did hold that under certain confined circumstances, a patent-holder's failure to bring suit for infringement may provide an ANDA-filer with an Article III controversy, the facts of Caraco are distinguishable from the present case in one key regard: in Caraco, Article III jurisdiction was present only because a declaratory judgment in favor of Caraco "would clear the path to FDA approval that Forest's actions would otherwise deny Caraco – namely, using the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) to activate [the first-filer's] exclusivity period." Id. at 1293.

Here, however, Apotex has failed to establish that any declaratory judgment by this Court could possibly "clear the path" to the FDA's approval of its ANDA, because any such approval of Apotex's donepezil hydrochloride ANDA would necessarily, and by express design of the Hatch-Waxman Act, occur after the first-filers' exclusivity periods have expired, particularly with regard to the '841 Patent, whose validity Apotex does not challenge. Accordingly, the holding in Caraco is inapplicable to the facts of this case, because even, assuming *arguendo*, this Court could exercise Article III jurisdiction over this declaratory judgment action and find that the DJ Patents are not infringed, Apotex would still be unable to obtain FDA approval for its donepezil hydrochloride ANDA absent a finding of invalidity or non-infringement with respect to the '841 Patent, because Apotex expressly recognizes the validity of the '841 Patent through its Paragraph III certification. In other words, if the Court provided Apotex a judgment of non-infringement with regard to the DJ Patents, such a ruling would only have the effect of triggering Ranbaxy's 180-day exclusivity period with regard to the DJ Patents, and would not, however, trigger Teva's

exclusivity period, which is based upon its Paragraph IV certification against the '841 Patent. Teva's ANDA has been approved by FDA, but its marketing of donepezil hydrochloride was enjoined until the November 2010 expiration of the '841 Patent or a prior finding of non-infringement. Following that point, Teva enjoys a 180-day exclusivity-period to market generic Aricept®. Hence, even if the Court declared the DJ Patents invalid or unenforceable and triggered Ranbaxy's exclusivity period, Apotex's ANDA would still not be eligible for FDA approval until 180 days after either November 2010 or an earlier court ruling of the '841 Patent's invalidity, which are the exact same time constraints Apotex's ANDA currently faces. Therefore, even if Apotex could obtain a declaration of non-infringement of the DJ Patents, the relief it presently seeks would not "clear a path" to the FDA's approval of Apotex's ANDA.

The Court finds that the constraints currently facing Apotex's ability to market generic Aricept® would exist regardless of any favorable declaratory judgment by the Court, since they arise pursuant to the intended operation of the ANDA approval mechanism of the Hatch-Waxman Act. This conclusion is consistent with Federal Circuit's decision in Jannsen Pharm., N.V. & Jannssen, L.P. v. Apotex, Inc., where the court declined to extend Caraco and found no justiciable Article III controversy when a generic drug manufacturer was unable to launch its generic drug product because of the first-filer's 180-day exclusivity period. Jannsen Pharm., N.V. & Jannsen, L.P. v. Apotex, Inc., 540 F. 3d 1353 (Fed. Cir. 2008). Although Jannsen related to a different set of patents underlying another pharmaceutical drug, the case involved several of the same parties and issues present in the instant case.

In particular, in Jannsen, Teva was the first to file Paragraph IV certifications against two patents ('425 & '587) and a Paragraph III certification to a third patent ('663), all relating to an ANDA for a generic version of the name brand pharmaceutical drug, Risperdal®, manufactured by the patent-holder Jannsen. Jannsen chose not to sue Teva for infringement with respect to either the '425 Patent or the '587 Patent. Therefore, Teva secured a 180-day marketing exclusivity period which would commence following the earlier of either: (a) Teva's first marketing of generic Risperdal® after the expiration of the '663 Patent, or (b) a court finding of invalidity or non-infringement of the '425 and '587 Patents. In the same case, Apotex, also seeking to market generic Risperdal®, later filed Paragraph IV certifications against all three patents ('425, '587 & '663). Like Teva, Jannsen chose not to sue Apotex for infringement of the '425 and '587 Patents, however, it did file suit against Apotex for infringing the '663 Patent. In the infringement action, Apotex asserted several counterclaims, including claims seeking a declaratory judgment of noninfringement of the '425 and '587 Patents. In response, Jannsen provided Apotex covenants-not-to-sue for the '425 and '587 Patents, but Apotex refused to withdraw its declaratory judgment claims. Much like the present case, Apotex alleged that it was injured by Jannsen's failure to bring a suit for infringement under a theory of a possible "indefinite delay" before Teva began marketing, and by being prevented from enjoying a "prompt launch" of its generic Risperdal® product due to first-filer Teva's exclusivity period.

The district court in Jannsen granted Jannsen's motion to dismiss Apotex's declaratory judgment claims for lack of subject matter jurisdiction, finding that no justiciable Article III controversy was presented. In the Federal Circuit's opinion affirming that dismissal, the court

held that with respect to its "inability to promptly launch" claim, Apotex did not have standing to bring such a claim because "Apotex's inability to promptly launch its generic risperidone product because of [first-filer] Teva's 180-day exclusivity period is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act." Id. at 1361. "The key difference between Caraco and [Jannsen]," the court explained, "is that the harm that gave rise to the jurisdiction over the declaratory judgment claim in Caraco ceased to exist once Apotex stipulated to the validity, infringement, and enforceability of the '663 Patent," because "the harm to Apotex that has continuously existed is its exclusion from selling its alleged noninfringing product *during* Teva's statutorily entitled 180-day exclusivity period." Id. (emphasis in original). With respect to Apotex's alleged injury for the indefinite delay facing the approval of its ANDA, the Federal Circuit again affirmed the district court, concluding that Apotex did not have standing to bring a declaratory judgment action on those grounds because "Apotex's alleged harm of indefinite delay of approval was too speculative to create an actual controversy to warrant the issuance of a declaratory judgment." Id. at 1363.

In the present case, the Court notes that, as in Jannsen, Apotex's alleged inability to promptly launch its donepezil hydrochloride product stems from the 180-day exclusivity periods obtained by first-filers Ranbaxy and Teva, which is an intended consequence and a "result envisioned" by the Hatch-Waxman Act. Id. at 1361. Accordingly, any injury flowing from Apotex's inability to "promptly launch" its generic pharmaceutical or obtain FDA approval of its ANDA application prior to the exhaustion of the first-filers' exclusivity period does not

present the Court with an injury that may redressed by means of a declaratory judgment.[4] As stated by the Jannsen court, "the import of the 180-day exclusivity period is clear, we hold that Apotex's exclusion from the market because of [the first-filer's] entitlement to this statutory exclusionary period does not present a justiciable Article III controversy." Id. at 1362. Therefore, this Court likewise concludes with regard to Apotex's alleged "inability to promptly launch" injury that no Article III case or controversy jurisdiction exists.

In addition, the Court finds that Apotex's other theory of injury, that its entry into the donepezil hydrochloride market will be "indefinitely delayed," is too speculative at this point to implicate "the bedrock rule that a case or controversy must be based on a *real* and *immediate* injury . . . an objective standard that cannot be met by a purely subjective or speculative fear of future harm." Prasco, LLC v. Medicis Pharm. Corp., 537 F. 3d 1329, 1339 (Fed. Cir. 2008) (emphasis in original). Although Ranbaxy's ANDA is not subject to the MMA's forfeiture provisions, because it was filed before the December 2003 enactment of the amendment, the Court nonetheless finds that Apotex has failed to present any basis upon which the Court could conclude that both first-filers, Ranbaxy and Teva, will, or are likely to, delay in bringing the

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[4] In Jannsen, one key basis for the court's finding of no subject matter jurisdiction was that Apotex stipulated to the validity and enforceability of the underlying patent. Jannsen, 540 F. 3d at 1361. Here, Apotex attempts to avoid an outcome similar to Jannsen by stating that it "does not admit to the validity, enforceability, or infringement of the '841 patent."(Resp. Opp. Mot. to Dism., at 5 n.1). However, filing a Paragraph III certification to a patent is done for the purposes of declaring, and serves as recognition of the fact, that the patent is valid and enforceable. See, e.g., Jannsen, 540 F. 3d at 1358 (holding that Teva's filing of a Paragraph III certification respected the patent's validity). Accordingly, although Apotex claims in its pleadings not to "admit to" the validity of the '841 Patent, it has already recognized the validity and enforceability of this Patent through its Paragraph III certification, and it has not in any proceeding affirmatively contested or disputed the validity of the '841 Patent.

generic product to market following the expiration of the '841 Patent. See Jannsen, 540 F. 3d at 1363; cf. Caraco, 527 F. 3d at 1296 n.14 (holding that although Caraco had Article III standing to bring its "inability to promptly launch" claim, its claim based upon "indefinite delay" was too speculative to create a justiciable Article III controversy, even though the first-filer was not subject to the forfeiture provisions of the MMA). Eisai's '841 Patent does not expire until November 2010, and Apotex has neither shown that Ranbaxy's regulatory complications are likely to indefinitely prevent its marketing of donepezil hydrochloride,[5] nor that Teva will fail to begin marketing the generic drug at that point, both of which would be required showings to demonstrate such an injury under these facts.[6] For these reasons, the Court finds that with respect to its alleged "indefinite delay" claim, Apotex has failed to establish that any delay preventing its entry into the donepezil hydrochloride market following the expiration of the '841 Patent is sufficiently real or immediate so as to present this Court with a justiciable Article III controversy.

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[5] As compared to a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), in considering a motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), the Court may look to evidence submitted in record in order to determine if subject matter jurisdiction exists. See Adams v. Bain, 697 F. 2d 1213, 1219 (4th Cir. 1982). The Court has considered the evidence submitted in the present case as it relates to Ranbaxy's alleged inability to market donepezil hydrochloride. The Court nevertheless finds that Apotex has failed to establish that Ranbaxy will be unable to begin marketing generic Aricept® following the November 2010 expiration of the '841 Patent.

[6] Further, with regard to Teva, the Court notes that Teva's ANDA was filed after the MMA's forfeiture provisions came into effect. Therefore, even if Teva, against its business and economic interests, continued to unreasonably delay entry into the market, the MMA would provide statutory recourse for subsequent ANDA filers seeking to enter the donepezil hydrochloride market.

Finally, the Court notes that even if this claim had properly satisfied the jurisdictional requirements of Article III, the Court would exercise its broad discretion to decline to exercise jurisdiction over this claim. See Novartis, 482 F. 3d at 1338 n.3 (noting that courts have discretion to decline to entertain declaratory judgment actions brought under the Hatch-Waxman Act). With respect to Apotex's "indefinite delay" claim, the Court would decline to exercise jurisdiction over this claim because there has been no showing that Ranbaxy will be unwilling or unable to begin marketing donepezil hydrochloride following the November 2010 expiration of the '841 Patent, and in the event Teva unreasonably delays marketing, its exclusivity period is subject to forfeiture under the provisions of the MMA. In addition, the Court would in its discretion decline to entertain Apotex's "inability to promptly launch" claim on the grounds that Apotex was not a first-filer with regard to any of the patents underlying Eisai's Aricept® NDA, and for this reason, it is appropriate that Apotex will be unable to enter the generic Aricept® market until the expiration of the first Paragraph IV filers' exclusivity periods. Therefore, the Court will grant Eisai's Motion to Dismiss Pursuant to Rule 12(b)(1).

V. CONCLUSION

For the reasons stated above, IT IS HEREBY ORDERED that Eisai's Motion to Dismiss Pursuant to Rule 12(b)(1) [Doc. #13] is GRANTED, and this case will be dismissed.

An Order and Judgment consistent with this Memorandum Opinion will be filed contemporaneously herewith.

This, the 27th day of August, 2010.

United States District Judge