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

APOTEX INC., Plaintiff, v. EISAI INC. and EISAI CO., LTD., Defendants.	Civil Action No. 09-cv-00477

MEMORANDUM OF LAW
IN SUPPORT OF DEFENDANTS EISAI'S MOTION TO DISMISS
FOR LACK OF SUBJECT MATTER JURISDICTION

For the reasons set forth below, Defendants Eisai Co., Ltd. and Eisai Inc. ("Eisai") move for dismissal of the Complaint pursuant to Fed. R. Civ. P. 12(b)(1).

STATEMENT OF THE CASE

This case concerns Eisai's pharmaceutical product Aricept®, used in the treatment of Alzheimer's disease. Plaintiff Apotex Inc. ("Apotex") is one of sixteen companies that submitted to the U.S. Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") requesting approval to market a generic version of the drug after November 25, 2010, when U.S. Patent No. 4,895,841 covering the drug's active ingredient expires.

Apotex has filed its Complaint seeking a declaratory judgment of noninfringement of four other Eisai patents that Eisai has never asserted against Apotex or any other company: U.S. Patent Nos. 5,985,864; 6,140,321; 6,245,911; and 6,372,760 ("the DJ Patents"). Two of those patents have been disclaimed pursuant to 35 U.S.C. § 253. Since Apotex notified Eisai of this suit, Eisai has given Apotex an express covenant, set

forth below, that it has no intention of enforcing any of these patents against Apotex's ANDA product.

Apotex does not actually allege a substantial adverse legal relationship between Eisai and Apotex with respect to the DJ Patents. Instead, Apotex's alleged purpose for this lawsuit is to obtain an advisory opinion from this Court regarding issues of patent infringement, so that Apotex can use that opinion at the FDA to eradicate a statutory right earned by two other generic drug companies who acted more promptly than Apotex in seeking FDA approval for generic Aricept®.

The United States District Court for the District of New Jersey recently addressed an effort by another generic drug company, Teva Pharmaceuticals USA, Inc. ("Teva"), to bring a suit to accomplish a similar result. After reviewing the Hatch-Waxman Act statutes and regulations, that court dismissed Teva's Complaint for lack of subject matter jurisdiction. *Teva Pharms. USA, Inc. v. Eisai Co., Ltd.*, Civ. No. 08-2344, 2009 WL 2905534 (D.N.J. Sept. 9, 2009). For the Court's convenience, a copy of this decision is attached to the Declaration of Anthony Michael, filed concurrently herewith, as Exhibit 1 ("Michael Ex."). In the present case, Apotex acted with even more delay than did Teva, and Apotex admits that it cannot market a generic version of Aricept® before November 2010 irrespective of any substantive ruling on the DJ Patents.

Because Apotex has not established that Eisai and Apotex have real and substantial adverse legal interests with respect to the DJ Patents and that Apotex is suffering actual and immediate injury caused by Eisai's conduct, Apotex has failed to demonstrate a case or controversy sufficient for subject matter jurisdiction. Moreover, even if Apotex satisfied the case or controversy standard, Eisai respectfully requests that the Court exercise its discretion to decline to hear this lawsuit.

STATEMENT OF FACTS

I. Eisai's NDA for Aricept®

Eisai is the holder of New Drug Application ("NDA") No. 20-690 for the drug product Aricept® (donepezil hydrochloride), approved by the FDA on November 25, 1996 for the treatment of Alzheimer's disease. (Michael Exs. 2 and 3.)

As mandated by 21 U.S.C. § 355(b)(1), Eisai listed five patents relating to Aricept® in the FDA's "Orange Book," namely U.S. Patent Nos. 4,895,841 ("the '841 patent"); 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").[1] (Michael Ex. 4.) Failing to list the patents could have potentially subjected Eisai to various penalties. *E.g.*, 21 U.S.C. § 355(e)(4); 21 C.F.R. § 314.53(b), (c), § 314.150(a)(2)(v).

In 2006 and 2007, respectively, Eisai filed statutory disclaimers of the '321 and '864 patents pursuant to 35 U.S.C. § 253. (Compl. Exs. B and C, last page.) Formal disclaimers of patents "ha[ve] the effect of canceling the claims from the patent[s] and the patent[s] [are] viewed as though the disclaimed claims had never existed in the patent[s]." *Teva*, 2009 WL 2905534, at *4 (quoting *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996)).

Because there was no other drug product in the United States that contained the active ingredient donepezil hydrochloride, the FDA awarded Eisai a New Chemical Entity ("NCE") exclusivity that permitted generic drug companies to file ANDAs

[1] The '841 patent is directed to the active ingredient in Aricept® (donepezil hydrochloride) and its use. The '321, '864, and '911 patents are later patents directed to various "polymorph" (crystalline) forms of donepezil. The '760 patent is a later patent directed to a formulation including donepezil. (Compl. Exs. A-E.)

containing a patent challenge beginning on November 25, 2000 (one year before the end of the NCE exclusivity). (Michael Ex. 5; *see also* 21 C.F.R. § 314.108(b)(2).)

Further discussion of the statutory and regulatory framework in which this case operates appears in *Teva*, 2009 WL 2905534, at *1-2.

Accordingly, despite knowing the precise day when it could qualify as the first to file a generic drug application (November 25, 2000), Apotex did not do so.

II. Ranbaxy Files the First Generic Drug Application, and Gets Tentative Approval from the FDA to Sell Generic Aricept®

Shortly before August 26, 2003, Ranbaxy Laboratories Ltd. ("Ranbaxy"), another generic drug company, became the first to file an ANDA for generic Aricept®. (Compl. ¶ 30.) Ranbaxy filed Paragraph IV invalidity and/or noninfringement challenges to the patents now referred to as the DJ Patents. (Michael Ex. 6.)[2] Ranbaxy, however, agreed to wait until the '841 patent expired in November 2010 to market a generic drug, thus making a Paragraph III certification as to that patent. (Michael Ex. 6; *see also Teva*, 2009 WL 2905534, at *3.) As the first filer of a Paragraph IV challenge, Ranbaxy was eligible by statute to be awarded upon final FDA approval a 180-day marketing exclusivity as against other generic drug application filers. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). After receiving notice of Ranbaxy's ANDA, Eisai chose not to sue Ranbaxy.

After examining the substance of Ranbaxy's ANDA, on February 23, 2005 and again on December 5, 2007, the FDA granted Ranbaxy tentative approval to sell generic Aricept®. (Compl. ¶ 31; Michael Ex. 7.) The tentative approval can become final

[2] Because an ANDA containing a Paragraph IV certification was first filed in August 2003, amendments made to the Hatch-Waxman Act effective December 2003 are not applicable to this case. *See Teva*, 2009 WL 2905534, at *2 n.2.

approval in November 2010, when the '841 patent expires. 21 U.S.C. § 355(j)(2)(A)(vii)(III), (j)(5)(B)(ii).

In or around September 2008, the FDA issued a warning letter to Ranbaxy concerning two of its manufacturing facilities. (Compl. ¶ 32.) In February 2009, the FDA informed Ranbaxy it would halt further review of certain drug applications pending resolution of certain issues with these two facilities. (*Id.* ¶ 33.) Ranbaxy has announced that it expects to resolve the issues with the FDA within a period of months. (Michael Ex. 9.) Ranbaxy has already resolved similar issues to the satisfaction of certain regulatory agencies outside the United States. (Michael Exs. 8, 9.)

Because Ranbaxy's ANDA for donepezil has tentative approval, the FDA has already completed its substantive review of that application. (Compl. ¶ 31; *see also* 21 C.F.R. § 314.105(c), (d).) The FDA publicly released a list of Ranbaxy drugs that were affected by the investigation of the two facilities discussed above, and that list did ***not*** include Aricept®/donepezil. (Michael Ex. 10.) As of today, the FDA still lists Ranbaxy as having tentative approval for its generic donepezil ANDA. (Michael Ex. 7.) Analyst reports describe expected marketing of generic Aricept® upon the expiration of the '841 patent in November 2010. (Michael Ex. 11 at 2-3.)

III. Teva Files a Generic Drug Application, Receives Final FDA Approval to Sell Generic Aricept® and Brings a DJ Action That is Dismissed for Lack of Subject Matter Jurisdiction

In October 2004, Teva, a generic drug company, filed an ANDA for generic Aricept® that, like Ranbaxy's, included a Paragraph III certification as to the '841 patent (agreeing to wait until November 2010 to market a generic drug), and Paragraph IV certifications challenging the DJ Patents. (Michael Ex. 13.) *Teva*, 2009 WL 2905534, at *3. As with Ranbaxy, Eisai did not sue Teva upon receiving this notice.

In October 2005, Teva amended its ANDA to include, for the first time, a Paragraph IV challenge to the '841 patent. (Michael Ex. 14.) By amending its ANDA to include a Paragraph IV challenge to the '841 patent, Teva became eligible to share 180-day exclusivity with Ranbaxy. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000). In other words, Teva became the first-filer against the '841 patent, and Ranbaxy was the first-filer on the remaining patents, resulting in Teva and Ranbaxy both having 180-day exclusivity against other generic drug application filers. *Id.*; *see also Teva*, 2009 WL 2905534, at *3 ("Teva's Paragraph IV certification against the '841 patent in its amended ANDA allowed Teva to share in the 180-day exclusivity period with Ranbaxy, as both Teva and Ranbaxy were first-filers with regard to Orange Book patents for Aricept®.").

After Eisai received notice of the amended ANDA, in December 2005, Eisai sued Teva for infringement of the '841 patent in the United States District Court for the District of New Jersey. *Teva*, 2009 WL 2905534, at *3. Consistent with its prior actions, Eisai did not sue Teva on the DJ Patents. *Id.*; Compl. ¶ 36. Eisai's lawsuit against Teva involving the '841 patent is styled *Eisai Co., Ltd. v. Teva Pharmaceuticals USA, Inc.*, Civ. Nos. 05-5727, 07-5489 (D.N.J.). On March 28, 2008, the District of New Jersey issued a preliminary injunction, preventing Teva from selling generic Aricept® until the expiration of the '841 patent in November 2010. *Eisai Co., Ltd. v. Teva Pharms. USA, Inc.*, 2008 WL 1722098 (D.N.J. Mar. 28, 2008). The lawsuit remains pending.

On April 28, 2008, the FDA granted Teva final approval to sell generic Aricept®. (Michael Ex. 15.) Accordingly, Teva has no FDA-related bar to selling generic Aricept®. *See Teva*, 2009 WL 2905534, at *4.

In May 2008, Teva filed a declaratory judgment suit against Eisai on the same DJ Patents that are at issue in this case. *Id.* On September 9, 2009, the *Teva* court granted

Eisai's motion to dismiss for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). *Id.* at *13. The *Teva* court found that Teva had not shown an actual case or controversy as to the DJ Patents, and that, even if Teva did, the court would exercise its discretion to decline declaratory judgment jurisdiction. *Id.* at *7-13.

IV. Apotex Becomes One of Fifteen Other Later-Filing Generic Drug Applicants Making Paragraph III Certifications as to the '841 Patent

In July 2007, over six years after it could have first done so, Apotex sent Eisai a letter informing Eisai that Apotex had filed a generic drug application for Aricept®. (Compl. ¶ 42.) Like Ranbaxy, Apotex made a Paragraph III certification as to the '841 patent agreeing that "it would not sell its generic product until, at least, the date the '841 patent expired, namely November 25, 2010." (Compl. ¶ 41.) Like Ranbaxy, Apotex included Paragraph IV certifications asserting that its generic drug product did not infringe the DJ Patents. (*Id.*) As with Ranbaxy, Eisai never sued Apotex.

On July 1, 2009, some two years after filing its ANDA, Apotex filed the instant suit seeking a declaratory judgment of noninfringement of the DJ Patents. (*See* Docket Entry No. 1, Compl.) Apotex never gave Eisai any prior notice that it intended to file this suit.

Having now had notice of this suit, Eisai, by and through its undersigned counsel, hereby unconditionally covenants that Eisai is not now asserting and will not in the future assert the DJ Patents against Apotex or any of its customers, distributors or successors with respect to the donepezil hydrochloride product described in Apotex's ANDA No. 78-841. By this covenant, Eisai confirms what was previously made clear through the parties' actions – Eisai has no intention of suing Apotex on the DJ Patents with respect to Apotex's ANDA (and could not sue in any event on the disclaimed patents).

Two weeks after Apotex filed the present suit, on July 14, 2009, Apotex filed a Citizen Petition with the FDA requesting that the administrative agency revoke Teva's final FDA approval to sell generic Aricept®. (Michael Ex. 16.) In its filing, Apotex concedes that Teva in fact has final FDA marketing approval to sell generic Aricept®, and that "Teva's launch status is now solely within its hands." (*Id.* at 4, 5.)

In addition to Ranbaxy and Apotex, fourteen other generic drug companies have submitted ANDAs containing Paragraph III certifications as to the '841 patent, agreeing to wait until after the '841 patent expires on November 25, 2010 to begin selling generic donepezil. (Michael Exs. 6 and 17-31.) Eisai has not threatened or sued any of those companies for infringement of the DJ Patents. None of those companies has filed a declaratory judgment action.

STATEMENT OF THE QUESTIONS PRESENTED

1. Did Apotex establish that an actual case or controversy exists between Eisai and Apotex required under the law for subject matter jurisdiction?

2. Even if Apotex did prove the existence of subject matter jurisdiction, should the Court decline to accept this declaratory judgment action in the exercise of its discretion?

ARGUMENT

I. LEGAL STANDARDS FOR A MOTION TO DISMISS UNDER RULE 12(B)(1)

Federal Rule of Civil Procedure 12(b)(1) permits a party to move for dismissal of an action based on a lack of subject matter jurisdiction. FED. R. CIV. P. 12(b)(1). In this motion, Eisai makes a factual attack on Apotex's assertion of subject matter jurisdiction. *See Dye v. Hatfield*, Civ. No. 03-1077, 2004 WL 3266029, at *2 (M.D.N.C. Aug. 26, 2004) (procedure for an attack on the truth of the jurisdictional allegations), *aff'd*, 122 F. App'x 649 (4th Cir. 2005); *Walker v. U.S. Dep't of the Army*, 60 F. Supp. 2d 553, 555

(E.D. Va. 1999); *Merck & Co., Inc. v. Apotex, Inc.*, Civ. No. 06-5789, 2007 WL 4082616, at *4 (D.N.J. Nov. 15, 2007), *aff'd*, 292 F. App'x 38 (Fed. Cir. 2008).

Accordingly, no presumptive truthfulness attaches to the nonmovant's allegations, the Court may consider evidence beyond the pleadings, and the existence of disputed material facts will not preclude the Court from evaluating the merits of jurisdictional claims. *Dye*, 2004 WL 3266029, at *2; *Walker*, 60 F. Supp. 2d at 555 (E.D. Va. 1999) (citing *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977)); *Teva*, 2009 WL 2905534, at *6. Plaintiff Apotex has the burden of proving the existence of subject matter jurisdiction. *Dye*, 2004 WL 3266029, at *2; *Williams v. United States*, 50 F.3d 299, 304 (4th Cir. 1995); *Teva*, 2009 WL 2905534, at *6.[3]

II. APOTEX HAS NOT ESTABLISHED DECLARATORY JUDGMENT JURISDICTION

A. Under the Supreme Court's *MedImmune* "All-the-Circumstances" Test, There Is No Case or Controversy and No Declaratory Judgment Jurisdiction

The Declaratory Judgment Act provides that, "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not relief is or could be sought." 28 U.S.C. § 2201(a).

[3] Whether Apotex has proven a legally cognizable case or controversy between it and Eisai is a question that goes to the subject matter jurisdiction of the Court and is proper for a Rule 12(b)(1) motion. *E.g.*, *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1359 (Fed. Cir. 2008); *Vesture Corp., v. Thermal Solutions, Inc.*, Civ. No. 03-0080, 2003 WL 22326607, at *1 (M.D.N.C. Sept. 30, 2003) ("The long established rule of law is that a declaratory judgment plaintiff must establish an actual controversy on the 'totality of the circumstances.'").

The Supreme Court recently reaffirmed an "all-the-circumstances" test set forth in its prior precedent. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1334 (Fed. Cir. 2008) (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)). In particular, under *MedImmune*, the question of whether declaratory judgment jurisdiction exists in a patent case turns on "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." *MedImmune*, 549 U.S. at 127 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

The Supreme Court further held that Article III of the Constitution:

> require[s] that the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.

Id. (citing *Aetna Life Ins. Co., v. Haworth*, 300 U.S. 227, 240-241 (1937)) (internal quotations omitted).

Eisai disclaimed the '864 and '321 patents. (Compl. Exs. B and C, last page.) By statute, a disclaimer is considered as though it were "part of the original patent." 35 U.S.C. § 253. Eisai cannot enforce disclaimed patents against Apotex or anyone else. There is no "substantial controversy" between Eisai and Apotex as to these disclaimed patents, and Eisai and Apotex do not have any "adverse legal interests" with regard to the disclaimed patents. *See MedImmune*, 549 U.S. at 127.

Courts have long held, including after *MedImmune*, that they lack subject matter jurisdiction to provide substantive opinions regarding disclaimed patents. *E.g.*, *Belk, Inc. v. Meyer Corp.*, Civ. No. 07-168, 2008 WL 2704792, at *3-4 (W.D.N.C. July 7, 2008)

(dismissing declaratory judgment claim as to a disclaimed patent); *Teva*, 2009 WL 2905534, at *12 ("Eisai's statutory disclaimers of the '864 and '321 patents prevent any substantial controversy regarding those patents."); *Merck*, 2007 WL 4082616, at *5 ("Thus, because Merck has formally disclaimed the '735 and '443 patents, and can no longer enforce any claims as to these patents, there is no justiciable case or controversy to support jurisdiction in an action for a declaratory judgment here."); *White Mule Co. v. ATC Leasing Co.*, 540 F. Supp. 2d 869, 881 (N.D. Ohio 2008) (the patentee's formal disclaimer "leaves [the court] with no 'actual controversy' to adjudicate"); *W.L. Gore & Assocs., Inc. v. Oak Materials Group, Inc.*, 424 F. Supp. 700, 702 (D. Del. 1976) ("As plaintiff has formally disclaimed all claims of the patent, there is no longer a justiciable case or controversy before the Court with respect to the validity of any of those claims."); *Technimark, Inc. v. Crellin, Inc.*, 14 F. Supp. 2d 762, 763, 767 (M.D.N.C. 1998) (dedication of the patent under § 253 after suit filed rendered moot counterclaims of patent noninfringement and invalidity);[4] *see also Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 525 F. Supp. 2d 680, 686 (D. Del. 2007) ("The existence of issued and presently enforceable patent claims against a declaratory judgment plaintiff is a necessary prerequisite to the continued litigation of a declaratory judgment action.").

For this reason, the Court should dismiss Apotex's claims that seek a declaratory judgment as to the disclaimed '864 and '321 patents.

Moreover, Eisai never threatened or sued Apotex (or anyone else) on any of the DJ Patents, and Eisai has confirmed expressly in the covenant above its prior actions making clear that it has no intention to do so. (*See* pages 4-8, above.) In light of the

[4] Under § 253, a "disclaimer" has the same effect as a "dedication" to the public. *W.L. Gore*, 424 F. Supp. at 702.

totality of circumstances – including the fact that Eisai never threatened or sued Apotex, never threatened or sued any of the other fifteen generic companies filing Paragraph III certifications as to the '841 patent, and provided an express covenant-not-to-sue Apotex herein – Eisai and Apotex do not have adverse legal interests, or any real and substantial controversy of immediacy and reality, with regard to the DJ Patents. *MedImmune*, 549 U.S. at 127.

District courts, including after *MedImmune*, have held that a covenant-not-to-sue given by the patentee to a declaratory judgment plaintiff may show the lack of an actual controversy between the parties. *See, e.g.*, *Fortinet, Inc. v. Trend Micro Inc.*, Civ. No. 08-5371, 2009 WL 1814598, at *2-3 (N.D. Cal. June 24, 2009); *Ameritox, Ltd. v. Aegis Servs. Corp.*, Civ. No. 07-80498, 2009 WL 790116, at *3 (S.D. Fla. Mar. 24, 2009); *Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 425-26 (D. Del. 2007), *vacated as moot*, 287 F. App'x 884 (Fed. Cir. 2008); *Pfizer*, 525 F. Supp. 2d at 686; *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, Civ. No. 06-1020, 2007 WL 3014702, at *3 (D.N.J. Oct. 11, 2007), *aff'd*, 540 F.3d 1353, 1363 (Fed. Cir. 2008).[5]

For this additional reason, the Court should dismiss Apotex's claims as to all the DJ Patents.

[5] A covenant-not-to-sue made as part of a brief filed with the Court is an effective form of covenant. *Super Sack Mfg. Corp., v. Chase Packaging Corp.*, 57 F.3d 1054, 1059 (Fed. Cir. 1995), *abrogated on other grounds*, *MedImmune*, 549 U.S. at 127 (overruling a "reasonable apprehension of imminent suit" test); *Vesture*, 2003 WL 22326607, at *1-2 (covenant-not-to-sue included in a party's motion to dismiss).

B. Apotex's Lawsuit is Also Subject to Dismissal Under the Federal Circuit's Ruling in *Janssen*

Apotex's Complaint makes allegations similar to those which the Federal Circuit held – in a prior action by Apotex – failed to establish subject matter jurisdiction. *Janssen Pharmaceutica, N.V. v. Apotex, Inc*., 540 F.3d 1353 (Fed. Cir. 2008).

In *Janssen*, like here, Apotex was a late-filing generic drug applicant who was therefore subject to the 180-day exclusivity period of a more prompt ANDA first-filer (in that case, Teva). *Id.* at 1358. In *Janssen*, Apotex could not enter the market at the time of the lawsuit because it had stipulated to the validity and enforceability of the patent covering the active ingredient of the drug (there, the '663 patent). *Id.* Therefore, Apotex had to wait until that patent expired to enter the market. *Id.* at 1357, 1360. The same result is present here – Apotex made a Paragraph III certification with respect to the '841 active ingredient patent "stating [Apotex] would not sell its generic product until, at least, the date the '841 patent expired, namely November 25, 2010." (Compl. ¶ 41.) Thus, Apotex cannot now enter the market because it acquiesced to Eisai's active ingredient patent.

In *Janssen*, like here, Apotex was not sued on the declaratory judgment patent, and further received a covenant-not-to-sue from the patentee as to that patent. *Janssen*, 540 F.3d at 1358.

In *Janssen*, like here, Apotex's real motivation in suing the patent holder was to trigger the first-filer's statutory 180-day marketing exclusivity period at a time before the first-filer could market its drug. *Id.* at 1361; *see* Compl. ¶ 58. The court rejected Apotex's arguments and dismissed the case for lack of subject matter jurisdiction: "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." *Janssen*, 540 F.3d at 1361; *see also Teva*, 2009 WL 2905534, at *11 ("Rather, as in *Janssen*, any delay occasioned here by Teva's inability to market the Gate version during Ranbaxy's exclusivity period, once that period is triggered, results from the operation of the Hatch-Waxman Act and its grant of an exclusivity period, not any act by Eisai.").

The same reasoning applies here. Apotex's inability to promptly launch its generic Aricept® product because of the first-filing generic drug companies' 180-day exclusivity period is not a cognizable controversy with Eisai under Article III of the Constitution, but instead is the result of the operation of the Hatch-Waxman Act. Indeed, when describing the operation of the Hatch-Waxman Act in its Complaint, Apotex admits that a first-to-file generic drug company "can obtain a 180-day period of exclusivity, during which time the FDA will not approve any other ANDAs containing Paragraph IV certifications that list the same pioneer drug." (Compl. ¶ 19.)

The Federal Circuit further found that "Apotex cannot claim that at the time of the district court's dismissal it was being excluded from selling a noninfringing product by an invalid patent." *Janssen*, 540 F.3d at 1361. Even if Apotex prevailed in its declaratory judgment action, Apotex still "cannot obtain FDA approval until the expiration of the '663 [active ingredient] patent because of its stipulations with respect to that patent." *Id.*

That quotation applies almost literally here. At the time Apotex filed suit, it was not being excluded from selling a noninfringing product because of an invalid patent. Even if Apotex were to prevail in this action with respect to the DJ Patents, Apotex still cannot obtain FDA approval until after the expiration of the '841 (active ingredient)

patent because of its Paragraph III certification with respect to that patent – "stating [Apotex] would not sell its generic product until, at least, the date the '841 patent expired, namely November 25, 2010." (*See* Compl. ¶¶ 41, 47.)[6]

Apotex also speculates that it could be harmed in the future, because Ranbaxy may not be able to launch its generic drug due to alleged FDA regulatory problems. Apotex speculates that, over a year from now, Ranbaxy will not be able to launch its generic drug and that, without Ranbaxy launching, the 180-day period will not be triggered right away. (Compl. ¶ 34.) These allegations contradict established facts, misinterpret the law, and, even if true, involve events so far out into the future as to be too remote to support jurisdiction in the present action.

First, Apotex is speculating about Ranbaxy. As discussed above, Ranbaxy's tentative approval of donepezil is still reported on the FDA website, contrary to Apotex's allegation that Apotex thinks the FDA revoked that tentative approval. (*See* page 5, above.) And, even if the FDA did revoke tentative approval, Ranbaxy is actively working on resolving the issues concerning two of its manufacturing facilities (and has already done so in Europe). There is no basis in fact for speculating that Ranbaxy will not, in over a year's time, be able to correct issues it might have now, or be able to

[6] In upholding the dismissal of Apotex's suit, the Federal Circuit distinguished and limited a prior case, *Caraco Pharmaceutical Labs., Ltd. v. Forest Labs., Inc.* 527 F.3d 1278 (Fed. Cir. 2008). *See Janssen*, 540 F.3d at 1361-62 (in *Caraco*, a favorable ruling on the declaratory judgment action patent would have cleared the path to immediate generic entry by the plaintiff); *Teva*, 2009 WL 2905534, at *10. *Caraco* is distinguishable from the present case for the same reasons *Janssen* supports dismissal – there is no actual controversy between Eisai and Apotex about the DJ Patents and Apotex suffers barriers to presently entering the market irrespective of the DJ Patents. (*See* Compl. ¶¶ 41, 47.)

manufacture or source donepezil even if the issues persist. (*See* page 5, above.)[7] In *Janssen*, Apotex similarly tried to argue that Teva would, in the future, not be able to launch and trigger the 180-day exclusivity. The Federal Circuit held that Apotex's speculation about a first-filer's potential future inability to launch a generic drug did ***not*** support subject matter jurisdiction. *Janssen*, 540 F.3d at 1362-63; *see MedImmune*, 549 U.S. at 127 (a dispute must be immediate and real, and not based on a hypothetical state of facts). Thus, there is no basis for the Court to issue an advisory opinion about the DJ Patents now, based on Apotex's unsupported hypothetical speculation that Ranbaxy will be unable to launch generic Aricept® over a year from now.

A second, independent reason why Apotex is wrong in speculating that it will not be able to market generic drug in the future is that Teva, in addition to Ranbaxy, may also be able to trigger the 180-day exclusivity period. Teva presently has final FDA approval to sell generic Aricept®. (*See* page 6, above.) In its Citizen Petition filed in the FDA, Apotex admitted that Teva has final FDA approval and that Teva's "launch status is now solely within its hands." (Michael Ex. 16 at 4, 5.) Apotex further admitted that, if Teva were to launch a generic drug, "the other ANDA applicants [including Apotex] will be a Day 181 launch in May 2011." (*Id.* at 5.) Thus, Apotex's Citizen Petition admits, in contrast to the speculative allegations in its Complaint, that Apotex ***will*** be able launch its drug in May 2011, 181 days after the '841 patent expires, based on Teva marketing Teva's generic drug. (*Id.*)

Apotex alleges that Teva is "poised" to obtain final FDA approval of its generic donepezil drug application, and an "attempt by the FDA to finally approve Teva's

[7] Indeed, Apotex is having certain issues with the FDA as well. (Michael Exs. 32 and 33.)

application is not likely to be successful" because the FDA was mistaken in considering Teva a first-filer. (Compl. ¶ 38.) This is in error because, as Apotex correctly admits elsewhere, Teva already has obtained final FDA approval. (*See* Michael Exh. 16 at 4; Michael Exh. 15.) Moreover, Apotex relies on *ipse dixit* when it alleges it will be harmed if the FDA was mistaken in giving final approval to Teva – when Apotex is the one trying to convince the FDA that it should revoke Teva's final approval. (Michael Ex. 16.) Apotex cannot try to create its own harm and cite that to this Court as a basis for jurisdiction. *Union Cosmetic Castle, Inc. v. Amorepacific Cosmetics USA, Inc.*, 454 F. Supp. 2d 62, 71 (E.D.N.Y. 2006) ("A plaintiff cannot establish Article III standing to pursue a cause of action where that plaintiff is the primary cause of its own alleged injury."); *Taylor v. FDIC*, 132 F.3d 753, 767 (D.C. Cir. 1997); *Bhd. of Locomotive Eng'rs & Trainmen v. Surface Transp. Bd.*, 457 F.3d 24, 28 (D.C. Cir. 2006).

Apotex also wrongly asks this Court to find that the FDA was erroneous in providing final FDA approval to Teva's generic drug application. (Compl. ¶ 38.) Apotex is effectively trying to avoid exhausting its administrative remedies by having this Court rule – in a *patent infringement* suit between *Eisai and Apotex* – whether the FDA's regulatory actions with respect to a third-party, Teva, were legally erroneous. If Apotex believes the FDA's actions were wrong, Apotex's recourse is first to petition the FDA to revoke its position, and, if that fails, sue the FDA.[8] As Apotex admits, unless and until Apotex succeeds in an action against the FDA, Teva continues to possess final FDA

[8] Indeed, Apotex previously ***did*** sue the FDA to challenge its patent-based approach of providing shared 180-day exclusivity – and lost that suit. *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 72, 74 (D.D.C. 2006) ("FDA's choice of [the patent-based] approach is reasonable and entitled to deference"), *aff'd*, 226 F. App'x. 4 (D.C. Cir. 2007).

approval to sell generic donepezil, and Apotex will be able to launch its drug 181 days after Teva does, in accordance with the intended operation of the Hatch-Waxman Act. (Compl. ¶ 38.) "Apotex's exclusion from the market because of Teva's entitlement to this statutory exclusionary period does not present a justiciable Article III controversy." *Janssen*, 540 F.3d at 1362.

In any event, Apotex is speculating about the consequences of whether Teva will be able to launch over a year from now, which again lacks sufficient immediacy and reality to support subject matter jurisdiction in the present action. *Janssen*, 540 F.3d at 1363; *see MedImmune*, 549 U.S. at 127.

III. EVEN IF THE COURT IS NOT REQUIRED TO DISMISS THIS ACTION, THE COURT SHOULD EXERCISE ITS DISCRETION TO DO SO

"Since its inception, the Declaratory Judgment Act has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995); *MedImmune*, 549 U.S. at 136; 28 U.S.C. § 2201(a) (using the permissive phrase "may declare"). District courts are vested with this broad discretion "because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp." *MedImmune*, 549 U.S. at 136 (citations omitted).

Apotex's failure to prove that this Court has subject matter jurisdiction requires dismissal. *Telectronic Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1526 (Fed. Cir. 1992). But, even if Apotex could prove that jurisdiction exists, this Court should still exercise its substantial discretion to decline to hear this action. *Id.* Sixteen generic drug companies, including Ranbaxy and Apotex, are respecting the '841 patent by waiting until after November 2010 to market generic Aricept®. Fifteen generic drug companies,

Apotex being one, also must respect Ranbaxy's and Teva's status as first-filers and respect their 180-day statutory exclusivity under the Hatch-Waxman Act.

Apotex delayed years to file its ANDA. In the meantime, other generic drug companies became first-filers. Apotex's Complaint is devoid of any real case or controversy over patent infringement issues between Eisai and Apotex. This Court should not use scarce judicial resources to issue advisory opinions about patents that have never been in issue, or are disclaimed, because Apotex has a separate agenda to eviscerate the statutory 180-day exclusivity period of a third-party. The Court should exercise its broad discretion to avoid this wasteful and unnecessary litigation. *E.g.*, *Impax Labs., Inc. v. Medicis Pharm. Corp.*, Civ. No. 08-253, 2008 WL 1767044, at *4 (N.D. Cal. Apr. 16, 2008) (exercising discretion to decline to hear a declaratory judgment action where the action would promote unnecessary litigation and reduce worthwhile incentives); *Teva*, 2009 WL 2905534, at *13 (exercising discretion to decline to hear Teva's declaratory judgment action as to the DJ Patents).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that Eisai's Motion to Dismiss be granted, and Apotex's Complaint be dismissed for lack of subject matter jurisdiction.

Respectfully submitted on this the 25th day of September 2009.

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CERTIFICATE OF SERVICE

I hereby certify that on September 25, 2009, I electronically filed the foregoing Memorandum of Law in Support of Defendants Eisai's Motion to Dismiss for Lack of Subject Matter Jurisdiction with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following counsel of record.

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