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

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

For the reasons set forth below and in Defendants Eisai Co., Ltd. and Eisai Inc.'s ("Eisai's") opening brief ("Eisai Br.," D.I. No. 14), Eisai respectfully requests that the Court grant its motion to dismiss the Complaint of Plaintiff Apotex Inc. ("Apotex") pursuant to Fed. R. Civ. P. 12(b)(1).

INTRODUCTION

Apotex's opposition brief ("Apotex Br.") demonstrates that there is no actual case or controversy, no threat or risk of infringement suit against Apotex, and no dispute allowing this Court to retain jurisdiction. Apotex asks this Court to issue substantive rulings about four patents that Apotex admits have never been in dispute between the parties. Apotex also concedes that the patents are subject to a covenant-not-to-sue or are disclaimed, and that there is no risk that Apotex would ever be sued on them. These admissions should determine the issue – the case should be dismissed. But there is more. There are at least five additional reasons why this action should be dismissed.

First, Apotex has dramatically changed positions from those alleged in the Complaint. In the Complaint, Apotex conceded that Ranbaxy was entitled under the Hatch-Waxman Act to a 180-day exclusivity period commencing in November 2010 upon the expiration of the '841 active ingredient Aricept® patent, as a reward for being the first-filing applicant. (Compl. ¶¶ 19, 30, 31.) Apotex also conceded that it filed a Paragraph III certification as to the '841 patent, and had only the "***right to enter the generic donepezil hydrochloride market 180 days after the '841 patent expires, namely 180 days after November 25, 2010***." (Compl. ¶ 54.) Apotex's theory of harm was that it allegedly would not be able to enter the market in May 2011 (*i.e.*, "180 days after November 25, 2010") because the 180-day exclusivity period would not be triggered in November 2010. (Compl. ¶¶ 34, 38-39, 48, 50, 54.) In Eisai's motion, Eisai showed that Apotex's allegations were baseless and unsupported speculation, because, among other things, Ranbaxy's FDA approval in fact has not been revoked, its two manufacturing facilities allegedly having FDA problems are not reported to be connected to donepezil, and, even if they were, Apotex still did not show such problems would hinder Ranbaxy's ability to market donepezil *over a year from now* in November 2010. (Eisai Br. at 5 and 15-16, citing Michael Exs. 7-11.) Moreover, Teva is another generic drug company who could alternatively trigger the 180-day exclusivity period, and Teva already has final FDA approval to sell donepezil. (Eisai Br. at 8 and 16-18, citing Michael Ex. 16.)

Apotex offers no evidence to support the jurisdictional allegations in the Complaint. Instead, Apotex changes positions. Apotex argues, for the first time, that it is being harmed by not being able to enter the market in November 2010, not 180 days after November 25, 2010. (Apotex Br. at 1, 2, 10-11, 15-16, 18.) Apotex's new argument has

no merit. But more fundamentally, Apotex cannot establish subject matter jurisdiction by making an unsupported argument in an opposition brief (*i.e.*, that Apotex is hurt by having to wait until 180 days after November 2010 to enter the market), which is contrary to the allegations in the Complaint that formed the basis for the lawsuit (*i.e.*, that Apotex's *right* was to enter the market *180 days after November 25, 2010*).

Second, Apotex's new argument that it is being harmed by having to wait to market until May 2011, when Ranbaxy's 180-day exclusivity period expires, is not an injury cognizable by Article III of the Constitution: it is the intended operation of the Hatch-Waxman Act. Apotex lost this same argument of harm in *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008); *accord Teva Pharms. USA v. Eisai Co.*, 2009 WL 2905534, *10 (D.N.J. Sept. 9, 2009) (interpreting *Janssen* as rejecting this type of harm, in dismissing a declaratory judgment action on the same patents as here).

Third, Apotex's new theory of harm wrongly asserts that Eisai should not have listed the DJ Patents in the Orange Book. But, as a matter of law, the Federal Circuit has held that generic drug companies may not bring a declaratory judgment action for patent noninfringement and make such claims. And, as a matter of fact, Apotex's arguments are unsupported and misleading in that Eisai listed the patents in the Orange Book years before they were disclaimed and years before Apotex's generic drug application even existed. This listing has been acknowledged repeatedly, without complaint, by Apotex itself (before its opposition brief) and by some fifteen other generic drug companies.

Apotex also ignores that Eisai's act of listing these patents did not block any particular drug company from selling drugs. Teva already has FDA approval to market generic Aricept®, and Ranbaxy will have final FDA approval in November 2010. Any

generic drug company had the opportunity to become a first-filer with a right to launch in November 2010, by promptly submitting a generic drug application.

Fourth, Apotex improperly requests that this Court issue advisory opinions about the question of patent scope and patent infringement. Such opinions are prohibited by the United States Constitution, a waste of this Court's resources, and a burden to Eisai.

Fifth, Apotex ignores Eisai's showing that this Court should exercise its discretion to decline declaratory judgment jurisdiction, even if Apotex had established that such jurisdiction existed (which Apotex did not).

Eisai respectfully requests that the Court grant its motion to dismiss. If the Court would find it helpful, Eisai would welcome oral argument on this motion.

ARGUMENT

I. Dismissal is Justified by Apotex's Failure to Support the Jurisdictional Allegations Forming the Basis of Its Complaint

The harm alleged in Apotex's Complaint, forming the basis of this suit, was supposedly not being able to start marketing in May 2011, because Ranbaxy allegedly had problems with two manufacturing facilities and Teva would not be able to obtain final FDA approval to sell generic Aricept®, preventing them from triggering the 180-day exclusivity in November 2010. (Compl. ¶¶ 19, 30, 34, 38-39, 48, 50, 54.) In Eisai's motion, Eisai refutes these allegations, showing they are legally insufficient, factually unsupported and speculative, and contrary to the record, including Apotex's admissions in a Citizen's Petition filed with the FDA. (Eisai Br. at 14-18.) In response, Apotex did not come forward with any factual evidence to support the original alleged harm. In two instances, Apotex just cites back to the Complaint. (Apotex Br. at 6, 11.) Apotex also

tries to change positions with contradictory arguments. (*See* pages 2-3, above.) Apotex's failure to produce evidence in support of the allegations of the Complaint alone requires dismissal. *Cedars-Sinai Med. Ctr. v. Watkins*, 11 F.3d 1573, 1584 (Fed. Cir. 1993) ("Once challenged, allegations alone are insufficient to meet the complainant's burden."); *Panavise Prods., Inc. v. Nat'l Prods., Inc.*, 306 F. App'x 570, 573 (Fed. Cir. 2009).

Apotex also does not dispute that it was never threatened with the DJ Patents, that two of them are disclaimed, and that Apotex has been given a covenant-not-to-sue. (Apotex Br. at 7.) Indeed, after receiving Eisai's motion, Apotex requested a copy of the covenant on a single sheet of paper for "providing customers or potential customers." (*See* Exhibit 34 to the Reply Declaration of Anthony Michael ("Reply Ex.") at 5, filed herewith.) Apotex's use of the covenant-not-to-sue with its customers and potential customers further confirms there is no case or controversy between Eisai and Apotex about the DJ Patents. (Eisai Br. at 9-12.) *Janssen*, 540 F.3d at 1363 (relying on the covenant-not-to-sue in finding no subject matter jurisdiction).

II. Apotex's Orange Book Listing Arguments are Not a Basis for a Declaratory Judgment Action of Patent Noninfringement

Apotex spends most of its brief discussing Eisai's listing of its patents in the FDA's Orange Book pursuant to FDA regulations, as part of some supposed plan to prevent generic competition by Apotex. (Apotex Br. at 1-2, 5-8, 10-12, 14, 18, 19-20.) This argument is frivolous, both legally and factually.

As a legal matter, a generic drug applicant cannot file a declaratory judgment action claiming improper listing of patents in the Orange Book, particularly where as here it was not sued for patent infringement. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d

1368, 1373-74, 1378 (Fed. Cir. 2002). Apotex's arguments are improper as a matter of law in these proceedings.

As a factual matter, Apotex never, at any time before the opposition brief, asserted that Eisai should not have listed the patents in the Orange Book. To the contrary, Apotex acknowledged the listing in the Orange Book without criticism in July 2007, when Apotex filed its generic drug application (Michael Ex. 19), and again in July 2009, when it filed the instant Complaint (Compl. ¶¶ 25-29). In its July 2009 Citizen Petition pending with the FDA, Apotex not only acknowledges the listing, but is trying to use it affirmatively to convince the FDA to make Teva (like Apotex) wait until May 2011 to begin marketing. (Michael Ex. 16 at 1-2, 4-5.) Similarly, fifteen generic drug companies other than Apotex have filed certifications against the DJ Patents and none of them asserted improper listing. (Michael Exs. 6, 13, 17-18, 20-30.)

Apotex cites no *evidence* to support these arguments. Apotex states in conclusory fashion that a "reasonable opportunity for discovery" will likely establish that Aricept® lacks a significant amount of the polymorph claimed in the '911 patent. (Apotex Br. at 5.) But Aricept® has been FDA-approved and available on the market for ***almost 13 years*** (Michael Ex. 2) and Apotex admittedly has known of Aricept® since at least 2007 (Compl. ¶ 42). Apotex could have tested for and likely already knows the polymorphic form of Aricept®. Yet, not only did Apotex not raise any listing issue with the FDA, Apotex is currently relying on the listing in arguments before the FDA. (*See* Michael Ex. 16.)

Apotex's argument also is illogical. By regulation, Eisai listed the patents in the Orange Book after they issued, from 2000-2002, respectively. (Reply Michael Ex. 35.)

Eisai then requested that the FDA delist one of them. (*See* Michael Ex. 4; Compl. ¶ 29.) These acts occurred years before Apotex's generic drug application even first existed in 2007. (Compl. ¶ 42.) And, the patents were listed years before two were disclaimed. (*See* Compl. Exs. B and C, last page.) Eisai thus did not list disclaimed patents, and could not have listed with Apotex's application in mind, as Apotex argues without support. Finally, Apotex is wrong that Eisai's listing prevents generic drug entry – any company had the opportunity to promptly file a generic drug application to obtain or share a 180-day exclusivity period and market in November 2010. (*See* Eisai Br. at 3-4.) As it turns out, Ranbaxy and Teva filed applications, while Apotex delayed years, giving those companies the statutory reward of a 180-day exclusivity period. (*Id.* at 4-7.)

To the extent Apotex's complaint is that the FDA continues to list the disclaimed patents, Apotex's complaint has nothing to do with a patent infringement dispute between Eisai and Apotex. The reason the FDA continues to list the patents is to preserve the 180-day exclusivity of the first-filing generic. *See Ranbaxy Labs. v. Leavitt*, 469 F.3d 120, 123, 126 (D.C. Cir. 2006). Apotex's desire to use an advisory opinion of this Court as a device to eradicate the 180-day exclusivity of the first-filers is therefore also in tension with precedent requiring that the FDA continue the listing of the DJ Patents in the Orange Book specifically in order to preserve the first-filer's 180-day exclusivity. *Id.*

III. The Federal Circuit Rejected Apotex's *Caraco* Arguments in *Janssen*

Quoting *Caraco* out of context, Apotex argues that Eisai's listing of the DJ Patents in the Orange Book deprives Apotex of an economic opportunity to market during the 180-day exclusivity period of the first-filing generic, thereby creating subject matter

jurisdiction for a patent infringement action. (Apotex Br. at 14.) Apotex lost these same arguments in *Janssen*, also citing *Caraco*. *See Janssen*, 540 F.3d at 1359, 1361-62.

In *Caraco*, the first-filer, Ivax, had made Paragraph IV certifications as to all the Orange Book patents. *Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278, 1286 (Fed. Cir. 2008). Thus, Ivax, the first-filer, was seeking to enter the market immediately by challenging each of the patents. *See id.* Accordingly, the later-filer, Caraco, "wanted to be able to challenge both patents and if successful, this would trigger Ivax's 180-day exclusivity period ***at a time when Ivax [the first-filer] could obtain FDA approval and then launch its product.***" *Janssen*, 540 F.3d at 1361 (explaining *Caraco*) (emphasis in original). Here, unlike *Caraco*, the first-filer, Ranbaxy, has made a Paragraph III certification as to the '841 patent, meaning that Ranbaxy cannot begin marketing until November 2010 when that patent expires. (Apotex Br. at 5-6.) Apotex, as a later-filer who also made a Paragraph III certification as to the '841 patent, can begin marketing following 180 days after November 25, 2010. (Compl. ¶¶ 41, 54.) This reward of the 180-day exclusivity period to Ranbaxy for being a first-filer is a fundamental component of the incentive system of the Hatch-Waxman Act. *Janssen*, 540 F.3d at 1356; *Ranbaxy*, 469 F.3d at 126.[1]

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[1] Indeed, Apotex wrongly assumes (Apotex Br. at 11) that in a hypothetical world where the patents were never listed, and no company had the incentive of a 180-day exclusivity period, there still would have been generic drug applications promptly filed. *Ranbaxy*, 469 F.3d at 123 (referring to the "pro-competitive effect of the incentive for a generic drug manufacturer to be the first to challenge a patent listed in the Orange Book and thereby introduce generic competition to a branded drug"); *accord* Apotex Br. at 4.

Apotex's request for a declaratory judgment for the purpose of running out Ranbaxy's 180-day exclusivity period now – at a time when Ranbaxy and even Apotex cannot go to market (*see* Apotex Br. at 12) – thus violates the express statement of the Federal Circuit in *Janssen* that "[a later-filer's] inability to promptly launch its generic [drug] product because of [a first-filer'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 *2, 10.[2]

IV. Apotex Improperly Requests an Advisory Opinion

Apotex asserts that, if the motion to dismiss is denied, Apotex will "seek summary judgment of non-infringement," and that, "[b]ecause of Eisai's statutory disclaimers and covenant not to sue, Eisai will be hard pressed to argue that Apotex's product infringes any of these patents." (Apotex Br. at 2.) In other words, Apotex wants this Court make substantive rulings on the scope of the patents and the question of infringement, arguing that, even though Eisai has not admitted non-infringement, Eisai will simply decline to fight because the patents are disclaimed or subject to covenants.

The Fourth Circuit has developed criteria to ensure that a case does not call for an advisory opinion: "First, the case must pit against each other 'adverse parties whose contentions are submitted to the court for adjudication.' Second, a decision in the case

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[2] Apotex's citation to *Minn. Mining & Mfg. v. Barr Labs.*, 289 F.3d 775 (Fed. Cir. 2002) is misplaced. There, unlike here, the patentee had actually filed suit alleging patent infringement, which obviously created subject matter jurisdiction, and then admitted non-infringement, and the parties were disputing whether the voluntary dismissal of that suit should be with or without prejudice. *Id.* at 779-80. None of those facts are present here.

must be likely to have some effect on the dispute." *United States v. McClure*, 241 F. App'x 105, 108 (4th Cir. 2007) (citations omitted); *see also Muskrat v. United States*, 219 U.S. 346, 357 (1911). Apotex suggests summary judgment will be appropriate precisely because Eisai and Apotex will not be pitted against each other with conflicting adverse contentions on infringement submitted for adjudication. Because Apotex's action seeks an advisory opinion on the question of patent scope and infringement, Apotex fails to establish subject matter jurisdiction.

V. Even If The Court Is Not Required To Dismiss This Action, The Court Should Exercise Its Discretion To Do So

Apotex failed to respond to Eisai's argument that the Court should exercise its discretion to decline jurisdiction, even if Apotex had established that jurisdiction existed, which Apotex has not. (*See* Eisai Br. at 8 (Question 2) and 18-19.)

For the reasons stated in Eisai's opening brief, the action should be dismissed. Indeed, the fact that Apotex's theory of harm in its opposition brief contradicts the theory in its Complaint further supports the Court's discretionary denial of subject matter jurisdiction over this wasteful action. (*See* pages 2-3, above.)

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.

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CERTIFICATE OF SERVICE

I hereby certify that on November 13, 2009, I electronically filed the foregoing **REPLY MEMORANDUM OF LAW IN FURTHER 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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