NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI CO., LTD. and EISAI INC., Plaintiffs, v. MUTUAL PHARMACEUTICAL CO., INC. and UNITED RESEARCH LABORATORIES, INC., Defendants.	)	Hon. Harold A. Ackerman Civil Action No. 06-3613 (HAA) **OPINION AND ORDER**

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ACKERMAN, Senior District Judge:

This matter comes before the Court on the motion (Docket No. 53) by Defendants Mutual Pharmaceutical Co., Inc. and United Research Laboratories, Inc. (collectively "Mutual") to dismiss the Amended Complaint filed by Plaintiffs Eisai Co., Ltd. and Eisai Inc. (collectively "Eisai"). Mutual has also filed an appeal (Docket No. 57) from Magistrate Judge Salas's denial of its request to stay discovery pending disposition of the motion to dismiss. For the following reasons, Mutual's motion to dismiss is GRANTED, and Mutual's appeal of Magistrate Judge Salas's order is dismissed as moot.

Background

Before discussing the facts of this pharmaceutical patent case, it is necessary to review the complicated statutory and regulatory framework that governs the marketing of drugs in the United States.

I. The FDCA and the Hatch-Waxman Act.

A. NDAs and Orange Book listing

The Federal Food, Drug, and Cosmetic Act ("FDCA") requires that before a drug manufacturer can market a new drug, it must submit a New Drug Application ("NDA") to the

Food and Drug Administration ("FDA") for approval. 21 U.S.C. § 355(a). In addition to extensive testing and safety information concerning the drug, the manufacturer must also submit the patent number and expiration date of any patent that claims the drug or a method of using the drug with respect to which a claim of patent infringement could reasonably be asserted. 21 U.S.C. § 355(b)(1). Once the NDA is approved, the FDA lists this patent information with the approved drug in its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly known as the "Orange Book." *See* 21 U.S.C. §§ 355(b)(1), 355(j)(A)(ii)-(iii). The Orange Book must list "each drug which has been approved for safety and effectiveness" through an NDA. 21 U.S.C. § 355(j)(A)(ii). If a patent claiming the drug or method of using the drug is approved after the NDA is approved, the NDA holder must submit the patent information, within 30 days after the patent's issuance, to the FDA for publication in the Orange Book. 21 U.S.C. § 355(c)(2). FDA regulations also require that all patent information for each patent that claims the drug must be submitted either in the original NDA or within 30 days after issuance of the ANDA. 21 C.F.R. § 314.53(c). An NDA applicant must use FDA Form 3542a for submitting patent information in a NDA; for submissions after approval of the NDA, the NDA holder must use FDA Form 3542. 21 C.F.R. § 314.53(c)(2)(i), (ii). The FDA relies on the information submitted in these forms in listing patents in the Orange Book, and "will not accept the patent information unless it is complete and submitted on the appropriate forms, FDA Forms 3542 or 3542a." 21 C.F.R. § 314.53(c)(1).

B. ANDAs and patent certifications

In 1984 Congress adopted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act." This statute amended the FDCA to provide for

an Abbreviated New Drug Application ("ANDA"), allowing manufacturers to obtain FDA approval for generic versions of previously-approved drugs without having to repeat the extensive testing required for a new drug application. *See* 21 U.S.C. § 355(j). When submitting an ANDA to the FDA, the generic manufacturer must make one of the following four certifications with respect to each of the patents listed in the Orange Book for the drug for which the applicant seeks approval: (1) that no patent information has been filed (a "Paragraph I" certification), (2) that the patent has expired (a "Paragraph II" certification), (3) that the patent will expire on a specific date (a "Paragraph III" certification), or (4) that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application is submitted" (a "Paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). If a generic drug applicant makes a Paragraph IV certification in its ANDA, the Hatch-Waxman Act requires that the applicant give notice to the patent owner ("ANDA Notice") setting forth the factual and legal basis for the applicant's opinion that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B). The instant motions require this Court to consider the importance and consequences of a Paragraph IV certification, or more precisely, the lack thereof.

FDA regulations set out the circumstances under which an ANDA applicant is required to amend its ANDA certification in light of a newly-listed patent. If a relevant patent is listed in the Orange Book after an ANDA is filed, but before approval, the ANDA applicant must amend its certification. 21 C.F.R. § 314.94(a)(12)(viii)(C)(1). No amendment is required if a patent is listed after the ANDA is approved. 21 C.F.R. § 314.94(a)(12)(viii)(C)(2). However, if the patent holder submits relevant patent information untimely – i.e., more than 30 days from the issuance of the patent or approval of the NDA – an ANDA applicant who submitted an ANDA

with an appropriate certification *before* the patent owner's submission is not required to file an amended certification. 21 C.F.R. § 314.94(a)(12)(vi).[1] If an ANDA is filed *after* the patent owner's late patent submission, the ANDA applicant must amend its certification. *Id.* Thus, if an ANDA contains a correct patent certification at the time of filing, and a patent is *untimely* added to the Orange Book for the drug in question after the ANDA has been filed, the ANDA applicant need not update its ANDA to certify against the newly and untimely-listed patent. As will be seen, such is the scenario here.

The timing of when the FDA may approve an ANDA depends upon the nature of an applicant's ANDA patent certification. If the ANDA contains a Paragraph IV certification, a patent owner's filing of an infringement action within 45 days after receiving an ANDA Notice Letter triggers a 30-month stay of FDA approval, running from the date of receipt of the ANDA Notice letter. 21 U.S.C. § 355(j)(5)(B)(iii).[2] This infringement action may be brought pursuant to 35 U.S.C. § 271(e)(2); the interpretation of this statute is one of the primary issues before the

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[1]This regulatory provision states, in relevant part:

> Late submission of patent information. If a patent on the listed drug is issued and the holder of the approved application for the listed drug does not submit the required information on the patent within 30 days of issuance of the patent, an applicant who submitted an abbreviated new drug application for that drug that contained an appropriate patent certification before the submission of the patent information is not required to submit an amended certification.

21 C.F.R. § 314.94(a)(12)(vi).

[2]In addition, the first applicant who submits an ANDA containing a Paragraph IV certification regarding a patent generally is eligible for a 180-day period of market exclusivity for that generic drug; no other ANDAs from competing generic manufacturers could be approved for 180 days from the time the first applicant hits the market. 21 U.S.C. § 355(j)(5)(B)(iv).

Court.[3]

C. The safe harbor and infringement provisions of 35 U.S.C. § 271(e)

35 U.S.C. § 271(a) defines an action for patent infringement: "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." Section 271(e) delimits the act of infringement with regard to a generic drug manufacturer's use of the patent for purposes of developing an ANDA and seeking FDA approval to market the generic drug. Prior to filing an ANDA, a generic drug manufacturer enjoys a "safe harbor" from infringement suits for use of the patent during the development and submission of an ANDA. 35 U.S.C. § 271(e)(1). This provision states that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." In other words, § 271(e)(1) "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990). Once an ANDA is filed, however, 35 U.S.C. § 271(e)(2) makes such a filing an act of infringement "if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent

[3]The FDA may approve an ANDA immediately if the ANDA contains a Paragraph I or Paragraph II certification. 21 U.S.C. § 355(j)(5)(B)(I). In practice, FDA approval is not "immediate," but generally takes a period of months. If the ANDA contains a Paragraph III certification, the FDA may approve the ANDA on the certified date of patent expiration. 21 U.S.C. § 355(j)(5)(B)(ii).

or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2).[4]

Thus, § 271(e)(2) makes the "paper act" of filing an ANDA an act of infringement. This provision, according to the Supreme Court, created "a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications." *Eli Lilly*, 496 U.S. at 676; *see also Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1551 (Fed. Cir. 2004) (stating that "35 U.S.C. § 271(e)(2) is designed to create an artificial act of infringement for purposes of establishing jurisdiction in the federal courts"). Because § 271(e)(1) exempts generic manufacturers from an infringement suit during ANDA development, § 271(e)(2) "permit[s] patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue." *Apotex*, 376 F.3d at 1351; *see also Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995) (stating that infringement action pursuant to § 271(e)(2) "makes it possible for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent").

Patent holders usually employ Section 271(e)(2) as the "hook" for seeking a declaratory judgment of infringement because the provision serves to provide patentees with "a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity," *Glaxo Inc. v. Novopharm, Ltd.*, 110

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[4]Section 271(e) specifies the exclusive injunctive remedy available for a suit against a generic manufacturer for a not-yet-marketed product. The patent owner may obtain injunctive relief barring the generic manufacturer from marketing the infringing product, but may not recover any monetary damages. 35 U.S.C. § 271(e)(4).

F.3d 1562, 1569 (Fed. Cir. 1997). The Federal Circuit has held that § 271(e)(2) "is not a jurisdictional statute in the strict sense of the word" because in a suit under § 271(e)(2), district courts have subject matter jurisdiction pursuant to 28 U.S.C. § 1338(a), which provides for original jurisdiction in the district courts for any civil action "arising under any Act of Congress relating to patents." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003) (quoting 28 U.S.C. § 1338(a)). However, § 271(e)(2) "makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed," *Allergan*, 324 F.3d at 1330, and therefore the Federal Circuit has deemed § 271(e)(2) to be "primarily a jurisdictional-conferring statute that establishes a case or controversy in a declaratory judgment action." *Apotex*, 376 F.3d at 1351.[5]

As will be seen, one of the two issues raised by Mutual's instant motion concerns whether an infringement action pursuant to § 271(e)(2) may be maintained if the ANDA does not contain a Paragraph IV certification against the allegedly infringed patent.

II. Eisai's NDA and Other FDA Submissions.

In 1990, the United States Patent and Trademark Office granted approval to Eisai for U.S. Patent No. 4,895,841 (the '841 patent), which claims the active ingredient donepezil hydrochloride and the use of that compound in the treatment of Alzheimer's disease. In 1996, Eisai submitted an NDA (No. 20-690; the "1996 NDA") for a donepezil hydrochloride tablet which Eisai markets under the name Aricept® or Aricept® RDT (for "Rapidly Disintegrating

[5]In its initial Complaint, Eisai brought a direct action pursuant to § 271(e)(2). In its Amended Complaint, it has added a declaratory judgment claim based on §271(a).

Tablet"). In its NDA, Eisai filed information for the '841 patent as well as certain other patents not at issue in this case. On November 25, 1996, the FDA approved Aricept® and subsequently listed the patent information, including the '841 patent, in the Orange Book for Aricept®. Eisai launched Aricept® in the United States in 1997.

The original form of Aricept®, the subject of the 1996 NDA, was for a tablet to be swallowed with water. In 2003, Eisai developed a form of Aricept® which consisted of a tablet that disintegrates in the mouth. On December 17, 2003, Eisai submitted an NDA (No. 21-720; the "2003 NDA") for this new form of Aricept®, called Aricept® ODT (for "Orally Disintegrating Tablet"). This second NDA was approved by the FDA on March 31, 2005. Total annual domestic sales of Aricept® products are at least $1 billion.

Just as for its Aricept® NDA, Eisai was required to file the patent information for Aricept® ODT with the FDA, so that the FDA could publish the patent information in the Orange Book. However, Eisai apparently failed to file this information correctly. As discussed, an NDA applicant must use Form 3542a for its initial declaration of patents, and an NDA owner must submit post-NDA-approval patent information on Form 3542. In its 2003 NDA for Aricept® ODT, Eisai included exact copies of two Forms 3542a that it submitted with its 1996 NDA. The Forms 3542a submitted in the 2003 NDA listed NDA Number 20-690, the number of the 1996 NDA, rather than 21-720, the number for the 2003 NDA. One of the Forms 3542a declared U.S. Patent No. 6,140,321 (the '321 patent), and the other listed the '841 patent at issue here. Again, however, both forms were an exact duplicate of the form submitted in the 1996 NDA and were not updated in any way for submission in the 2003 NDA. Because they were duplicates of the 1996 NDA forms, the forms listed the trade name for the drug as Aricept® RDT, rather than

Aricept® ODT. Aricept® RDT and Aricept® ODT are indeed very similar drugs: "Both tablets include the same active ingredient – donepezil hyrdochloride – and indeed share the same package insert." (Eisai Br. at 13.) Thus, because the same patents claim both forms of the drug, Eisai's decision to simply resubmit the 1996 NDA Forms has a rational explanation, but Eisai appears to not have taken sufficient care to ensure that the relevant forms, NDA numbers, and drug names were changed. The FDA approved the 2003 NDA for Aricept® ODT in October 2004; apparently due to the irregularity in Eisai's patent submission, the FDA failed to list the '841 patent in the Orange Book for Aricept® ODT.

The FDA contacted Eisai on March 31, 2005 to request resubmission of the required patent information for the 2003 NDA for Aricept® ODT. On April 1, 2005, Eisai sent a letter to the FDA with an "exact duplicate of the patent information provided in the initial application." (Michael Decl., Ex. 13 at 1.) This "exact duplicate," however, was a duplicate of the forms submitted for the 1996 NDA, listing the 1996 NDA number and Aricept® RDT instead of Aricept® ODT. Thus, Eisai appears to have repeated its initial mistake. Furthermore, Eisai's "resubmission," while not only again listing the wrong NDA and drug, also employed Form 3542a (the form for initial submissions) rather than Form 3542 (the form for post-approval submissions). In what Eisai describes as a "clerical error" attributable to "us[ing] the wrong form in submitting the patent information due to a recent change in FDA regulations" (Eisai Br. at 13), the FDA still did not list the '841 patent in the Orange Book for Aricept® ODT. But as will be seen, Eisai's error here was more than merely "clerical."

III. Mutual's ANDA.

On August 17, 2005, Mutual wrote to Eisai requesting a listing of all Eisai patents with regard to donepezil hydrochloride which Eisai reasonably believed could be asserted to be infringed if donepezil hydrochloride was manufactured, used, offered for sale, sold or imported into the United States by an unauthorized party. Eisai responded in an August 24, 2005, letter, attaching a list of seven patents under the heading "Aricept® (Donepezil Hydrochloride) Process Patents." (Michael Decl., Ex. 16 at 3.) This list included the two patents submitted with regard to the 2003 NDA – the '841 and '321 patents – along with six other patents. Eisai provided no information specifically identified as relating to Aricept® ODT.

On November 7, 2005, Mutual filed an ANDA with the FDA, seeking approval to market a generic version of Aricept® ODT. Based on a subsequent ANDA Notice letter sent to Eisai by Mutual, the ANDA contained Paragraph IV certifications[6] against four patents, including the '321 patent listed by Eisai on the wrong form and with the wrong heading in its 2003 Aricept® ODT NDA. These Paragraph IV certifications were made despite the fact that, at the time, none of the patents were listed in the Orange Book for Aricept® ODT. Notably, Mutual did *not* make any Paragraph IV certification (or any other ANDA certification) against the '841 patent.

On January 18, 2006, Mutual sent a letter to Eisai inquiring as to why the five patents listed in the Orange Book for Aricept® (including the '841 and '321 patents) were not also listed in the Orange Book for Aricept® ODT and asking whether or not those patents had been filed with the FDA. Mutual thus appears to have recognized that none of the patents were listed for

[6]As stated earlier, a Paragraph IV certification states that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Aricept® ODT at the time it filed its ANDA more than two months earlier. Eisai's response to Mutual, if any, is not in the record. Instead, on February 9, 2006, Mutual wrote to the FDA to express its belief that Eisai had failed to submit required patent information for Aricept® ODT. Mutual asked the FDA to take appropriate action to confirm that the lack of patent listings in the Orange Book for Aricept® ODT was accurate or to have Eisai correct the information. On February 27, 2006, the FDA informed Eisai of the challenge to the submission of patent information for Aricept® ODT. The FDA requested that Eisai either confirm that the Orange Book data was correct or to submit any corrections that needed to be made.

On April 10, 2006, Eisai informed the FDA by letter that the Orange Book listing was inaccurate and that the '841 patent should be listed in association with Aricept® ODT. Eisai acknowledged that its own error in failing to submit the correct form prevented the '841 patent from being listed in the Orange Book at the proper time. (Eisai Br. at 15 ("Eisai explained the clerical error to the FDA and again requested that the FDA list the '841 patent in the Orange Book for Aricept® ODT."; *id.* at 13 (recognizing that "due to clerical error (Eisai used the wrong form in submitting the patent information due to a recent change in FDA regulations)," the FDA did not list the '841 patent at the time the NDA was filed).) Along with the letter, Eisai correctly provided the FDA with Form 3542 for the '841 patent, this time properly referencing Aricept® ODT and the corresponding NDA No. 21-720. Subsequent to Eisai's letter, the FDA listed the '841 patent for Aricept® ODT in the Orange Book. It is not clear precisely when the FDA listed the '841 patent; however, it did not occur until at earliest after Eisai's letter to the FDA in April 2006. As noted above, Mutual filed its ANDA in November 2005, at a time when no patents were properly listed in the Orange Book for Aricept® ODT.

On June 28, 2006, Mutual mailed Eisai an ANDA Notice letter informing Eisai of Mutual's November 7, 2005, ANDA submission to the FDA to obtain approval to engage in the commercial manufacture, use or sale of a generic version of Aricept® ODT. As noted earlier, at the time of Mutual's ANDA submission on November 7, 2005, no patents were listed in the Orange Book for Aricept® ODT and thus Mutual was not required to make any Paragraph II, III, or IV certifications in its ANDA. *See* 21 U.S.C. § 355(j)(2)(A)(vii). Mutual would only have been required to submit a Paragraph I certification stating that no patents were listed in the Orange Book for Aricept® ODT, at which point the FDA could have immediately granted approval to Mutual's ANDA. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I), 355(j)(5)(B)(I). At the time of Mutual's ANDA submission there were five patents (the '841, '321, '864, '911, and '760 patents) listed in the Orange Book for Aricept® (RDT). Mutual was not required to make certifications against the five patents listed for Aricept® (RDT) because Mutual's ANDA was for a generic version of Aricept® ODT and not Aricept®.[7] Despite this fact, as noted earlier, Mutual chose to make Paragraph IV certifications against four of the five patents listed for Aricept®, but not against the '841 patent.

IV. The Instant Suit.

On August 3, 2006, Eisai filed a patent infringement suit under 35 U.S.C. § 271(e)(2) against Mutual, alleging that the filing of Mutual's ANDA for a generic Aricept® ODT infringes the '841 patent. On September 27, 2006, Mutual filed a motion to dismiss the Complaint for

[7]An ANDA applicant is only required to make certifications "with respect to each patent which claims the listed drug . . . *for which the applicant is seeking approval.*" 21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added).

failure to state a claim.[8] Mutual contended in that initial motion that § 271(e)(2) does not authorize a patent infringement suit regarding the '841 patent because: the '841 patent was not listed in the Orange Book for Aricept® ODT at the time of Mutual's ANDA submission; Mutual therefore did not include a Paragraph IV certification in its ANDA; and a suit pursuant to § 271(e)(2) may not be brought if the ANDA does not contain a Paragraph IV certification.

On September 6, 2007, while Mutual's initial motion to dismiss was pending, Eisai filed an Amended Complaint, adding a claim for a declaratory judgment of patent infringement pursuant to 35 U.S.C. § 271(a). Eisai asserts it amended its Complaint to add a declaratory judgment action largely in response to comments made by Mutual's counsel at an August 29, 2007 hearing before Magistrate Judge Salas. This hearing concerned Mutual's motion to stay discovery pending this Court's resolution of Mutual's initial motion to dismiss. According to Eisai, Mutual's counsel suggested that FDA approval of Mutual's ANDA would occur relatively shortly and that Mutual could use the threat of approval as leverage to seek a settlement with Eisai. Eisai's Amended Complaint includes the identical § 271(e)(2) claim as was presented in its initial Complaint, and adds the declaratory judgment claim.

Mutual subsequently filed the instant motion to dismiss. In this motion, it reasserts its argument to dismiss the § 271(e)(2) claim; indeed, the parties' submissions on the instant motion with regard to § 271(e)(2) repeat their prior submissions almost verbatim. To the extent that the briefing on the second motion to dismiss presents additional arguments regarding the § 271(e)(2) claim, this Court has carefully considered these "updated" arguments as well as those made in the

[8]In addition to the Paragraph IV issue, Mutual also moved in its first motion to dismiss for lack of personal jurisdiction pursuant to Rule 12(b)(2). After jurisdictional discovery, Mutual withdrew this portion of its motion to dismiss.

briefing on the first motion to dismiss. In the instant motion, Mutual also moves to dismiss Eisai's new declaratory judgment claim for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1).

Around the same time that Mutual filed its motion to dismiss, the parties entered into a stipulation (Docket No. 54) pursuant to which Mutual agreed to provide Eisai, during the period prior to the expiration of the patent, with 45-days' written notice before "market[ing], offer[ing] to sell or sell[ing]" a generic Aricept® product under its ANDA. (Stipulation and Order Oct. 10, 2007 at ¶ 1.) In exchange, Eisai agreed to not seek a preliminary injunction or temporary restraining order until it receives such notice.

Following the August 2007 hearing, Magistrate Judge Salas denied Mutual's motion to stay discovery pending resolution of the motion to dismiss. Mutual has filed an appeal (Docket No. 57) from this ruling.

Analysis

I. Standard of Review Pursuant to Rule 12(b)(6).

Mutual filed its initial motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), and it seeks to dismiss Eisai's § 271(e)(2) claim in the instant motion pursuant to that Rule as well. On a Rule 12(b)(6) motion, a court generally may only consider matters attached to the complaint or referenced in the complaint. In opposition to Mutual's motion, Eisai submitted the Declaration of Anthony Michael, to which was attached several exhibits containing copies of letters and other documents not attached to, or explicitly referenced in, the Complaint. These documents provide much of the factual background regarding the non-listing of the '841 patent

in the Orange Book and the absence of a Paragraph IV certification against the '841 patent in Mutual's ANDA. If matters outside the pleadings are presented to the court and the court exercises its discretion to consider such matters, then generally the court must convert the motion into one for summary judgment pursuant to Rule 56, and "[a]ll parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." Fed. R. Civ. P. 12(c).

However, because Eisai itself submitted the extraneous material, the Court will decline to convert the motion and may resolve it pursuant to Rule 12(b)(6). On a motion to dismiss, a court may consider "matters integral to or upon which plaintiff's claim is based." *In re Bayside*, 190 F. Supp. 2d at 760. Because Eisai itself presented the documents in the Michael Declaration, the Court shall construe these materials as "integral" to Eisai's claim of infringement. This Court need not convert the motion because "[t]he reason that a court must convert a motion to dismiss to a summary judgment motion if it considers extraneous evidence submitted by the defense is to afford the plaintiff an opportunity to respond." *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). When a complaint relies on a document or the plaintiff submits the document in opposition to a motion to dismiss, "the plaintiff obviously is on notice of the contents of the document, and the need for a chance to refute evidence is greatly diminished." *Pension Ben.*, 998 F.2d at 1196-97. Eisai has submitted and relies upon the documents in the Michael Declaration, and thus conversion of the motion for the protection of Eisai is not necessary.[9]

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[9]Furthermore, Mutual also has challenged this Court's subject matter jurisdiction over Eisai's declaratory judgment claim. "[I]n a factual attack under Rule 12(b)(1), the court may consider and weigh evidence outside the pleadings to determine if it has jurisdiction." *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000). Because the parties dispute jurisdictional facts which provide the basis for Eisai's declaratory judgment claim – particularly

Rule 12(b)(6) permits a court to dismiss a complaint, or a count therein, for failure to state a claim upon which relief may be granted. In evaluating a motion to dismiss pursuant to Rule 12(b)(6), the court must "accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the plaintiff." *Kanter v. Barella*, 489 F.3d 170, 177 (3d Cir. 2007) (quoting *Evancho v. Fisher*, 423 F.3d 347, 350 (3d Cir. 2005)); *see also, e.g.*, *Labov v. Lalley*, 809 F.2d 220, 221 (3d Cir. 1987). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007) (internal citations omitted). A complaint must contain "enough facts to state a claim to relief that is plausible on its face" and the "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true." *Twombly*, 127 S. Ct. at 1974, 1965. A court need not accept "'unsupported conclusions and unwarranted inferences,'" *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (quoting *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997)), and "[l]egal conclusions made in the guise of factual allegations . . . are given no presumption of truthfulness," *Wyeth v. Ranbaxy Labs., Ltd.*, 448 F. Supp. 2d 607, 609 (D.N.J. 2006) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)); *see also Kanter*, 489 F.3d at 177 ("[A] court need not credit either 'bald assertions' or 'legal conclusions' in a complaint when deciding a motion to dismiss.") (quoting *Evancho*, 423

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with regard to potential FDA approval and the timing of any potential decision by Mutual to hit the market – Mutual presents a factual challenge, and this Court may consider matters outside the pleadings. Thus, the extraneous material must be considered by this Court.

F.3d at 351).

II. This Court Must Dismiss Eisai's § 271(e)(2) Claim Because Mutual's ANDA Did Not Contain a Paragraph IV Certification.

A. Plain reading of the statute

"[I]n any case of statutory construction, our analysis begins with the language of the statute . . . [a]nd where the statutory language provides a clear answer, it ends there as well." *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) (quotation and citations omitted); *see also Langston v. OPM*, 395 F.3d 1349, 1351 (Fed. Cir. 2005) ("In construing a statute, our analysis begins with the language of the statute, and where the statutory language is clear and unambiguous, it generally ends there as well."). This Court must "presume that [the] legislature says in a statute what it means and means in a statute what it says there." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004) (quoting *Conn. Nat. Bank v. Germain*, 503 U.S. 249, 253-54 (1992)). Where the language of a statute is plain, "the sole function of the courts – at least where the disposition required by the text is not absurd – is to enforce it according to its terms." *Lamie v. United States Tr.*, 540 U.S. 526, 534 (2004) (quoting *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000)).

Eisai brings its direct claim for patent infringement pursuant to 35 U.S.C. § 271(e)(2). This section states:

> It shall be an act of infringement to submit -- (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary

> biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). Section 505(j), to which the provision refers, is the ANDA provision codified at 21 U.S.C. § 355(j).[10] Thus, to show the artificial act of infringement established by § 271(e)(2), the plain text of the statute sets forth three seemingly straightforward requirements. A patent holder must show that: 1) the alleged infringer submitted an ANDA; 2) the ANDA was for a drug claimed in a patent or the use of which was claimed in a patent; and 3) the purpose of the ANDA must have been to obtain approval for the commercial manufacture, sale, or use of the drug before the expiration of such patent.

The plain text of § 271(e)(2) does not require that the alleged infringer file an ANDA with a Paragraph IV certification, or that the patent that the drug claims be listed in the Orange Book. At first blush, based on the plain language of the statute, Eisai appears to have made out a claim of infringement. Mutual submitted an ANDA for Aricept® ODT; that ANDA was for a drug the active ingredient of which – donepezil hydrochloride – is claimed in the '841 patent; and Mutual filed the ANDA to obtain FDA approval to market a generic version of the drug allegedly claimed in the '841 patent before the expiration of that patent.[11]

Mutual asks this Court to look beyond the plain language of § 271(e)(2) to the entire structure of the Hatch-Waxman Act. The Federal Circuit has recognized that "'[w]hen

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[10]The Federal Circuit, in quoting §271(e)(2), has explicitly stated that "an application under 505(j)" in § 271(e)(2) is an ANDA: "'It shall be an act of infringement to submit-(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [codified at 21 U.S.C. § 355(j); i.e., an ANDA]' . . . ." *Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1326 (Fed. Cir. 2003) (quoting 35 U.S.C. § 271(e)(2)).

[11]Mutual does not dispute that it seeks approval of its ANDA prior to the '841 patent's expiration.

interpreting a statute, the court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute (or statutes on the same subject) and the objects and policy of the law, as indicated by its various provisions, and give it such a construction as will carry into execution the will of the Legislature.'" *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1355 (Fed. Cir. 2003) (quoting *Kokoszka v. Belford*, 417 U.S. 642, 650 (1974)). Statutory interpretation is a "holistic endeavor," and therefore "[a] provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme." *United Sav. Ass'n of Tex v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988). This Court must heed the "cardinal rule that a statute is to be read as a whole, since the meaning of statutory language, plain or not, depends on context," and cannot read the terms of § 271(e)(2) without reference to the "entire statute." *26 Bloomfield Ave. Corp. v. City of Newark*, 904 F. Supp. 364, 368 (D.N.J. 1995) (quoting *King v. St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991)).

Based on these principles, Mutual urges that § 271(e)(2) cannot be interpreted without consideration of the provisions of 21 U.S.C. § 355(j), the ANDA provision referenced in § 271(e)(2). Section 355(j) requires an ANDA applicant to submit a certification "in the opinion of the applicant and to the best of his knowledge, with respect to each patent" which claims a "*listed* drug" or a "use for such *listed* drug" and "for which information is required to be filed under subsection (b) or (c) of this section." 21 U.S.C. § 355(j)(2)(A)(vii) (emphases added). Subsections (b) and (c) – 21 U.S.C. §§ 355(b) and (c) – concern the listing of patents in the Orange Book. For example, 21 U.S.C § 355(b)(1) requires an NDA applicant holder to submit to the FDA, for listing in the Orange Book, the patent number and expiration date for any patent

that claims the drug for which the NDA applies or that claims a use of such drug for which a claim of patent infringement could reasonably be asserted if the drug was manufactured or sold by an unlicensed person. Thus, an ANDA applicant must make a certification with respect to claimed patents listed in the Orange Book. The entire structure of the ANDA process depends in part on Hatch-Waxman's patent listing and certification requirements.

Based on this reading of § 355, Mutual goes a step further and contends that § 271(e)(2) – the infringement provision pursuant to which Eisai brings the instant suit – must be read together with § 355(j)'s patent listing and certification requirements. According to Mutual, such consideration of the entire structure of the Hatch-Waxman statutory scheme dictates that § 271(e)(2) does not allow for a patent infringement suit where the patent is not listed in the Orange Book and, consequently, the ANDA does not include a Paragraph IV certification against the patent.

In the absence of controlling caselaw to the contrary, this Court would be tempted to conclude that Mutual's reading goes a bridge too far. Section § 271(e)(2) requires "an application" under § 355(j), but says nothing regarding any certification that § 355(j) might require for an ANDA in a given circumstance. Based on a plain reading of § 271(e)(2), which is where the Court must begin its analysis, an ANDA can still be a valid "application" under § 355(j) without a Paragraph IV certification. The certification and listing provisions of § 355 do not change the statutory language of § 271(e)(2). Section 355(j) indeed requires a certification in an ANDA with respect to patents listed in the Orange Book for the drug in question, but it does not require any ANDA certifications for unlisted patents, such as the '841 patent at the time Mutual's ANDA was filed. While § 355(j) cross-references the patent listing and certification

requirements, § 271(e)(2) simply does not state that the patent necessarily must be listed and certified against pursuant to these provisions for an infringement action to lie.[12]

B. Controlling Federal Circuit precedent and other persuasive authority

No matter how this Court may read the statute in the first instance, this Court does not consider this question against a blank slate. Rather, this Court must heed the interpretations of the statute suggested by our highest court, the Supreme Court of the United States, and by the court of appeals charged with interpreting patent law, the Federal Circuit. These august authorities have read § 271(e)(2) to require an ANDA with a Paragraph IV certification against a listed patent.

The Supreme Court offered guidance on the instant question in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). Commenting on the Hatch-Waxman statutory scheme, the

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[12]If Congress had intended "to limit the artificial act of infringement created by § 271(e)(2) to ANDAs containing Paragraph IV certifications . . . it could have easily done so. The provision might have read, for example, 'It shall be an act of infringement to submit an application containing a certification described in § 355(j)(2)(a)(vii)(IV).'" *Teva Pharm. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829-30 (N.D. Ill. 2004). But Congress did not do so. Instead, the provision simply requires an "application under [§355(j)]" without any mention of certifications or any other limitation on the form of § 355(j) application which would suffice. *See id.* at 829 ("The language of § 271(e)(2)(A) does not require that the ANDA contain a certification to constitute an act of infringement. It only requires that the application be filed under § 355(j).")

Both *Teva* and *Glaxo Group Ltd. v. Apotex, Inc.*, 272 F. Supp. 2d 772, 775 (N.D. Ill. 2003), adopted this plain reading and held that § 271(e)(2) did not require a Paragraph IV certification. However, both these cases concerned infringement suits regarding "old antibiotics," which were formerly governed by a different regulatory regime than were other drugs, and to which the patent listing and ANDA certification requirements of Hatch-Waxman do not apply. Thus, while these courts' statutory analyses are persuasive, the cases arose in distinguishable contexts, and in any event this Court must follow the guidance of the Federal Circuit and reach a different conclusion than the courts did in these two cases. The Court shall return to the "old antibiotics" issue and the relevance of "old antibiotics" caselaw later in this Opinion.

Supreme Court stated in *Eli Lilly*:

> This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. And that was precisely the disability that the new 35 U.S.C. § 271(e)(1) imposed with regard to use of his patented invention only for the purpose of obtaining premarketing approval. Thus, an act of infringement had to be created for these ANDA and paper NDA proceedings. *That is what is achieved by § 271(e)(2) – the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.*

Id. at 678 (emphasis added). This language, strongly suggesting that the act of infringement defined by § 271(e)(2) consists of an ANDA with a Paragraph IV certification, is dicta and the Court did not engage in detailed analysis on this question.[13] However, this Court does not take statements by the Supreme Court lightly. Moreover, as will be seen, neither has the Federal Circuit.

The Federal Circuit has never squarely faced the question before this Court. However, in several opinions, the Federal Circuit has provided detailed explanations of the workings of the

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[13]The Court in *Eli Lilly* determined "whether 35 U.S.C. § 271(e)(1) renders activities that would otherwise constitute patent infringement noninfringing if they are undertaken for the purpose of developing and submitting to the Food and Drug Administration (FDA) information necessary to obtain marketing approval for a medical device under § 515 of the Federal Food, Drug, and Cosmetic Act (FDCA)." *Eli Lilly*, 496 U.S. at 663-64 (citations omitted); *see also id.* at 665 ("The parties dispute whether [§271(e)(1)] exempts from infringement the use of patented inventions to develop and submit information for marketing approval of medical devices under the FDCA."). One district court has stated that "[i]t is clear from the Court's discussion [in *Eli Lilly*] that the only issue before it was whether § 271(e)(1) covered medical devices other than drugs. What constitutes infringement under § 271(e)(2), and whether a paragraph IV certification is necessary before § 271(e)(2) can apply, were not before the Court." *Glaxo Group Ltd. v. Apotex, Inc.*, 272 F. Supp. 2d 772, 778 (N.D. Ill. 2003), *aff'd in part and rev'd in part on other grounds*, 376 F.3d 1339 (Fed. Cir. 2004).

Hatch-Waxman Act and the ANDA process. These recitations make clear that, according to the Federal Circuit, § 271(e)(2) depends upon the filing of an ANDA containing a Paragraph IV certification. First, in *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, the court commented:

> *Inclusion of a paragraph IV certification in an ANDA, however, is deemed an act of infringement.* The statute, *referring to an ANDA containing a paragraph IV certification*, states: "It shall be an act of infringement" to submit an application under 21 U.S.C. § 355(j) "for a drug claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of [the] drug . . . before the expiration of [the] patent." 35 U.S.C.A. § 271(e)(2)(A).

69 F.3d at 1131 (emphasis added). The Court particularly notes that, despite the seemingly plain language of the statute, the Federal Circuit explicitly described the statute as "referring to an ANDA containing a paragraph IV certification." *Id.* Later in the same opinion, the Federal Circuit stated with even more clarity: "As seen above, the Hatch-Waxman Act gives a drug patent owner the right to bring an action for infringement *upon the filing of a paragraph IV certification.*" *Id.* at 1135 (emphasis added). Thus, the Federal Circuit specifically conditioned the act of infringement defined by § 271(e)(2) on the filing of a Paragraph IV certification, and not just an ANDA with any type of certification (or no certification). The court continued in its linkage of a § 271(e)(2) action to a Paragraph IV certification:

> In that action, *depending upon the nature of the certification that has been filed*, the district court determines the validity of the patent at issue and/or whether the drug sought to be marketed infringes the claims of that patent. "What is achieved by § 271(e)(2) [is] the creation of a highly artificial act of infringement that consists of submitting an ANDA . . . containing a [paragraph IV] certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Thus, section 271(e)(2)(A) makes it possible

> for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent. If the court determines that the patent is not invalid and that infringement would occur, and that *therefore the ANDA applicant's paragraph IV certification is incorrect*, the patent owner is entitled to an order that FDA approval of *the ANDA containing the paragraph IV certification* not be effective until the patent expires. *See* 21 U.S.C. § 355(j)(4)(B)(iii)(II); 35 U.S.C.A. § 271(e)(4)(A).

Id. (emphasis added).[14]

In a subsequent case, the Federal Circuit reiterated its view of the act of infringement established by § 271(e)(2) as dependent on a Paragraph IV certification:

> Hatch-Waxman provides that *the act of filing a paragraph IV certification with respect to a patent* creates a cause of action for patent infringement in the patent holder. *See* 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit ... [an ANDA] . . . if the purpose of such submission is to obtain [FDA] approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent . . . before the expiration of such patent.").

aaiPharma Inc. v. Thompson, 296 F.3d 227, 232 (Fed. Cir. 2002) (emphasis added). Finally, the Federal Circuit again observed in a later opinion that an ANDA containing a Paragraph IV certification constitutes an act of infringement under § 271(e)(2): "As suggested by the certification process, a generic drug manufacturer may file an ANDA before a patent expires and, in so doing, allege non-infringement and invalidity of the patent. The Hatch-Waxman Act provides that, *in that situation*, the filing of the ANDA is an act of infringement." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1326 (Fed. Cir. 2003) (citing 35 U.S.C. § 271(e)(2)(A) and *Novopharm*, 110 F.3d at 1568-69) (emphasis added).

In the face of the Federal Circuit's direct statements, which rely in part on the Supreme

[14]Inexplicably, neither party cites these crucial passages from *Bristol-Myers*.

Court's comments in *Eli Lilly*, this Court must follow this authority, even if it might read the statute differently on its own.[15] This Court, of course, gives serious weight to any pronouncements by the Supreme Court, and the Federal Circuit controls the substantive interpretation of patent law based on its exclusive jurisdiction over appeals of cases relating to patents. 28 U.S.C. § 1295(a). "[D]ecisions of the Federal Circuit on substantive questions of patent law are binding precedent on district courts." *LG Elecs., Inc. v. First. Int'l Computer, Inc.*, 138 F. Supp. 2d 574, 582 (D.N.J. 2001) (citing *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1574-75 (Fed. Cir. 1984)); *see also, e.g., Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 182 F.3d 1356, 1359 (Fed. Cir. 1999). Several district courts, in varying contexts, have similarly read a Paragraph IV requirement into § 271(e)(2). *See, e.g., Kos Pharm., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 317 (S.D.N.Y. 2003); *Organon, Inc. v. Teva Pharm., Inc.*, 244 F. Supp. 2d 370, 374 (D.N.J. 2002); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 578 (D.N.J. 2001); *Pfizer Inc. v. Novopharm Ltd.*, No. 00-1475, 2001 WL 477163, at *3 (N.D. Ill. May 3, 2001); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 930 (N.D. Ill. 1995); *Abbott Labs. v. Zenith Labs., Inc.*, No. 94-6792, 1995 WL 117984, at *10 (N.D. Ill. Mar.

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[15]The Court notes that others have questioned the reading of the statute offered by the Supreme Court and the Federal Circuit:

> The first point to notice about the infringement provision is that it makes *absolutely no mention of a Paragraph IV certification* – a detail that appears to have inexplicably escaped the attention of most of the courts that have analyzed the provision . . . . Indeed, even the Supreme Court, in its construal of the statute in *Ely Lilly*, implies that the submission of a Paragraph IV certification is an essential element of the section 271(e)(2) infringement action.

David C. McPhie, "Old Drugs, New Uses: Solving a Hatch-Waxman Patent Predicament," 59 FOOD AND DRUG L.J. 155, 165 (2004) (emphasis in original) (footnotes omitted). However, this Court cannot disregard these precedents.

16, 1995). Thus, this Court holds that to establish an act of infringement pursuant to § 271(e)(2), the ANDA must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question. Here, Mutual's ANDA contained no such certification. Therefore, Eisai cannot bring a claim pursuant to § 271(e)(2).[16]

C. Practical considerations and the peculiar nature of the instant case

This interpretation of § 271(e)(2), without some further definition, could allow an ANDA applicant to insulate itself from an infringement action until it hits the market simply by failing to include a Paragraph IV certification. Such a failure would violate the Hatch-Waxman Act if 21 U.S.C. § 355(j)(2)(A)(vii) required a Paragraph IV certification in the given circumstance, but would still mean that the ANDA did not include a Paragraph IV certification, and hence no § 271(e)(2) action could ensue based on the filing of the ANDA. Eisai raises this concern as reason to read § 271(e)(2) as not requiring a Paragraph IV certification. (Eisai Br. at 26 n.8.) A court in this District recognized this problem, stating that "the use of the statute by individual patent owners would be almost impossible if they were dependent upon the applicant to first

[16]Eisai claims that the Federal Circuit implicitly recognized the validity of a § 271(e)(2) claim in the absence of Orange Book listing or a Paragraph IV certification by addressing a § 271(e)(2) claim on its merits in *Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.*, 468 F.3d 1366 (Fed. Cir. 2006). In that case, the Federal Circuit stated only that "[]under 35 U.S.C. § 271(e)(2), it is an act of infringement to submit an ANDA under 21 U.S.C. § 355(j) for a drug claimed in a patent before the patent's expiration." *Id.* at 1372. At the time that the generic manufacturer filed the ANDA in *Impax*, there was no patent listed in the Orange Book with respect to the drug in question, but the generic "became aware of the [] patent while preparing its ANDA." *Id.* at 1373. The Federal Circuit addressed the merits of the generic manufacturer's declaratory judgment action that it had not infringed pursuant to § 271(e)(2) without reference to the necessity of Orange Book listing or a Paragraph IV certification. Essentially, Eisai invites this Court to hold that, by *silence*, the Federal Circuit overruled its prior precedent that Orange Book listing of the patent and the consequent Paragraph IV ANDA certification is required. This Court declines Eisai's invitation.

include the existing patent in its certification." *Marion Merrell Dow, Inc. v. Hoechst-Roussel Pharm., Inc.*, No. 93-5074, 1994 WL 424207, at *2 (D.N.J. May 5, 1994). The court held that to determine whether a patent holder could maintain a § 271(e)(2) action absent a Paragraph IV certification against the patent, the court must ask "*should the certification have included the patent* and if so, is there an infringement of that patent?" *Id.* (emphasis added); *see also Ben Venue*, 146 F. Supp. 2d at 582; *Zenith*, 934 F. Supp. at 936. This standard accounts for the danger of artful certification (or lack of certification) by an ANDA applicant attempting to avoid an infringement suit.

Here, Eisai does not argue that Mutual *should have* made a Paragraph IV certification regarding the '841 patent. Rather, it has acknowledged that its own error resulted in the '841 patent not being listed in the Orange Book in association with Aricept® ODT. Only after filing the proper FDA forms did the FDA list the '841 patent for Aricept® ODT in the Orange Book, but this listing came well after Mutual filed its ANDA, without any Paragraph IV certification, on November 7, 2005. FDA regulations dictate that if an ANDA contains a correct patent certification at the time of filing, and a patent is *untimely* added to the Orange Book for the drug in question after the ANDA has been filed, the ANDA applicant need not update its ANDA to certify against the newly and untimely-listed patent. 21 C.F.R. § 314.94(a)(12)(vi). Eisai does not – and could not – argue that Mutual should have included a Paragraph IV certification; rather, it contends that no Paragraph IV certification was needed at all for Mutual's filing of its ANDA to constitute an act of infringement. The Federal Circuit's reading of § 271(e)(2) has effectively foreclosed this argument. *See, e.g.*, *aaiPharma*, 296 F.3d at 232; *Bristol-Myers*, 69 F.3d at 1131.

While the plain language of the statute might plausibly suggest a different result, the

readings of § 271(e)(2) offered by the Supreme Court and the Federal Circuit make sense as a practical matter. In the "usual" case, where an ANDA applicant seeks approval to market a generic version of a drug claimed by a properly filed, timely filed, non-expired patent, the ANDA must include a Paragraph IV certification.[17] An ANDA applicant making a Paragraph IV certification must also give ANDA Notice to the patent owner, setting forth the factual and legal basis for the applicant's opinion that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B). Without a Paragraph IV certification, the patent holder would not receive formal notice of the ANDA, and thus might not have any occasion to bring an infringement suit, or even be aware of the possibility of one, until the ANDA is approved and the generic drug hits the market. Thus, the Paragraph IV certification serves to protect the patent holder in that it enables notice of potential infringement. Moreover, a Paragraph IV certification triggers a 30-month stay of FDA approval of the ANDA if the patent holder, upon receiving ANDA Notice, files a § 271(e)(2) infringement action within 45 days. 21 U.S.C. § 355(j)(5)(B)(iii). Requiring a Paragraph IV certification to enable an infringement action, therefore, would be uncontroversial in most cases and not pose any problems for a patent holder.[18] Indeed, the patent holder would

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[17]Of the four possible § 355(j) certifications, only Paragraph IV is relevant here. A Paragraph I, II, or III certification could not be a requirement for an infringement suit, as these certifications would mean that the patent in question was never filed, has expired, or will expire before the ANDA applicant will market its drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(III); *see also Marion Merrell Dow*, 1994 WL 424207, at *2 n.1 ("The Court notes that [] Sections 355(b)(2)(A)(i)-(iii) would not provide a cause of action for infringement because those sections refer solely to patents which have expired, will expire or have not been filed with [the] FDA.").

[18]"[I]t is perhaps not surprising that a Paragraph IV certification would get read into section 271(e)(2) considering how such certification inherently presupposes an applicant's contemplation of commercial activity before the expiration of a patent (even while asserting that the patent is invalid or otherwise will not be infringed by such activity)." McPhie, 59 FOOD AND DRUG L.J. at 165.

welcome such a certification as it would allow it the protection of the 30-month stay if the patentee timely filed an infringement action.

However, the case before the Court is not a "normal" case. Here, Eisai admits that it is not entitled to the 30-month stay of ANDA approval that a Paragraph IV certification would allow; rather, it only seeks to bring an infringement action and resolve the question, *before* Mutual hits the market, of whether Mutual's generic drug infringes the '841 patent. Also, the ANDA Notice provided to Eisai by Mutual gave notice of Paragraph IV certifications as to four Eisai patents but not the '841 patent. Thus, Eisai brought this suit after essentially not receiving notice, or receiving "negative" notice, regarding the patent at issue. The Court is troubled by Mutual's decision to make Paragraph IV certifications against four of the patents listed for Aricept® but not against the '841 patent, where *none* of these patents were listed in the Orange Book for Aricept® ODT. This behavior could be construed as an attempt to avoid a § 271(e)(2) suit specifically on the '841 patent. Despite the lack of Orange Book listing, Mutual knew of the '841 patent and that, based on Eisai's letter to Mutual, the patent potentially claimed against some form of Aricept®. Against this background, Eisai's inability to take advantage of § 271(e)(2) here may be viewed as strange.

However, Eisai can blame itself for its predicament. It allowed Mutual this opportunity by its repeated oversights in filing the wrong forms and wrong information with the FDA. Due to the unusual developments which led to the instant dispute, the Court is confident that this situation does not and will not occur with any great frequency, and the reading of § 271(e)(2) offered by the Supreme Court and the Federal Circuit and adopted by this Court will pose little practical difficulties for patent holders or generic manufacturers.

For the reasons stated above, this Court will grant Mutual's motion to dismiss the first Count of Eisai's Amended Complaint because Eisai, as a matter of law, cannot maintain an infringement action pursuant to 35 U.S.C. § 271(e)(2) where the allegedly infringed patent was not listed in the Orange Book for the drug at issue and the ANDA contained no Paragraph IV certification against the patent.[19]

III. This Court Must Dismiss Eisai's Claim for a Declaratory Judgment of Infringement.

In its Amended Complaint, Eisai added a claim seeking a declaratory judgment of "future actual infringement" pursuant to 35 U.S.C. § 271(a). Mutual argues in the instant motion, pursuant to Rule 12(b)(1), that this Court lacks subject matter jurisdiction over Eisai's declaratory judgment action because the claim is based on future actions that lack sufficient reality and immediacy. "[I]n a factual attack under Rule 12(b)(1), the court may consider and weigh evidence outside the pleadings to determine if it has jurisdiction." *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000).

A. Declaratory judgment jurisdictional standard

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 further relief is or could be sought." 28 U.S.C. § 2201(a) (emphasis added). No

[19]The parties devote considerable attention to debating the meaning of the legislative history of § 271(e)(2) and various statements made in administrative rulings and other documents by the FDA. This Court need not address these arguments in light of the definitive interpretations pronounced by the Supreme Court and the Federal Circuit.

bright-line rule governs whether a case presents an actual controversy. The Supreme Court has required only that dispute be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] 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.'" *MedImmune, Inc. v. Genetech, Inc.*, 127 S. Ct. 764, 771 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)). "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." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). The declaratory judgment plaintiff bears the burden of proof. *Id.* at 272. Even if this Court has subject matter jurisdiction, it retains the discretion pursuant to the Declaratory Judgment Act to decline declaratory judgment jurisdiction. *See, e.g., Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995) (stating that "district courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites").

Most declaratory judgment actions in patent cases are brought by "potential infringers against patentees seeking a declaration of noninfringement or invalidity or both." *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 763 (Fed. Cir. 1990). Until recently, the Federal Circuit applied a two-part jurisdictional test in such a declaratory judgment action brought by potential infringers: 1) "whether conduct by the patentee creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and 2) whether conduct by the declaratory judgment plaintiff amounts to infringing activity or demonstrates concrete

steps taken with the intent to conduct such activity." *SanDisk Corp v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1379 (Fed. Cir. 2007). In *MedImmune*, the Supreme Court abrogated the Federal Circuit's "reasonable apprehension of suit" prong based on its conflict with *Aetna Life* and other cases. *MedImmune*, 127 S. Ct. at 774 n.11. The Federal Circuit has recognized the Supreme Court's "rejection of our reasonable apprehension of suit test." *See, e.g.*, *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1283-84 (Fed. Cir. 2007); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007); *SanDisk*, 480 F.3d at 1380. In the wake of *MedImmune*, the Federal Circuit has not precisely defined the "outer boundaries of declaratory judgment jurisdiction, *Sony*, 497 F.3d at 1284, but has held that "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise," *SanDisk*, 480 F.3d at 1381.

Of course, the instant matter is not the usual case where the potential infringer is the declaratory judgment plaintiff and seeks a declaration of noninfringement. Rather, Eisai seeks a declaratory judgment that Mutual's marketing of generic Aricept® ODT "will infringe" the '841 patent under a theory of future actual infringement. (Am. Compl. Prayer for Relief ¶ (b).) "Declarations of infringement sought by patentees against parties who will allegedly infringe in the future have been less frequently requested, but have nevertheless been allowed to proceed." *Lang*, 895 F.2d at 761; *see also, e.g.*, *Centocor, Inc. v. MedImmune, Inc.*, No. 02-3252, 2002 WL 31465299, at *1 (N.D. Cal. Oct. 22, 2002) ("Although it is unusual for a court to grant declaratory relief to a patent owner, the Federal Circuit has acknowledged that in rare cases, such relief may be appropriate."). In *Lang*, the Federal Circuit established a two-part test for "future

infringement" suits brought by patentees: "(1) the defendant must be engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a), or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming." *Id.* at 764. The court explained:

> The first prong is identical to one of the requirements in a patent declaratory judgment action where the threatened infringer is the plaintiff. It looks to the accused infringer's conduct and ensures that the controversy is sufficiently real and substantial. The second prong requires conduct by both the accused infringer and the patentee and is similar to the reasonable apprehension prong in the normal action. It ensures that the controversy is definite and concrete between parties having adverse legal interests.

Id. (citations omitted).

The second prong of the *Lang* test incorporates the very "reasonable apprehension of suit" standard that the Supreme Court rejected in *MedImmune*. Considering that the Federal Circuit acknowledged that the second prong of the *Lang* test is "similar to the reasonable apprehension prong in the normal action," it appears that the second *Lang* prong has been abrogated as well. *See Geisha, LLC v. Tuccillo*, No. 05-5529, 2007 WL 2608558, at *8 (N.D. Ill. Sept. 4, 2007) ("Given the close similarity between the two-part test articulated in *Lang* and the traditional reasonable-apprehension-of-suit test that has been abandoned after *MedImmune*, the court concludes that the *Lang* test likewise is no longer good law.").

The parties here contest the impact of *MedImmune* on the *Lang* standard. Eisai claims that *MedImmune* eliminates the second *Lang* prong and thus makes the test "less stringent."

(Eisai Br. at 32.) In its opening brief, Mutual also states that the second element is "no longer good law." (Mutual Br. at 18.) Curiously however, in its reply brief, Mutual claims that its initial assertion in its opening brief was "erroneous[]," because *MedImmune* dealt with the reasonable apprehension of suit test as it applies to suits brought by potential infringers, not by patent holders. (Mutual Reply Br. at 8.) Mutual argues that the rejected standard concerns "conduct by the *patentee*," but the test in *Lang* "turns on the *accused infringer's conduct, not its state of mind*, in the face of a threatened infringement action." (*Id.* (emphasis in original).) This Court agrees with Eisai that because the Federal Circuit equated the second *Lang* prong with the now-rejected reasonable apprehension of suit in a "normal" declaratory judgment action, the second *Lang* prong is no longer good law.

This does not mean, however, that the "imminence" factor addressed by the second prong must go completely unconsidered. Rather, under the Supreme Court's formulation of the standard, the Court must determine whether "there is a substantial controversy, between parties having adverse legal interests, of sufficient *immediacy* and *reality* to warrant the issuance of a declaratory judgment." *Md. Cas.*, 312 U.S. at 273 (1941); *see also Teva Pharm.*, 482 F.3d at 1338 ("[A] declaratory judgment plaintiff is only required to satisfy Article III, which includes standing and ripeness, by showing under 'all the circumstances' an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of 'sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" (quoting *MedImmune*, 127 S. Ct. at 771)). Thus, both "reality" and "immediacy" must be satisfied.

B. Eisai does not satisfy the jurisdictional standard based on activities protected by the Hatch-Waxman safe harbor

Even under the arguably "less stringent" standard post-*MedImmune*, Eisai has not met the jurisdictional prerequisites for declaratory judgment relief. The irregularities that prevent Eisai from maintaining a § 271(e)(2) action also doom its declaratory judgment claim. Eisai seeks a declaratory judgment that Mutual is violating 35 U.S.C. § 271(a), which defines as infringement the making, using, offering to sell, or selling of any patented invention without authority during the term of the patent. The safe harbor provision, 35 U.S.C. § 271(e), expressly exempts these potentially infringing activities from liability "if performed solely for uses reasonably related to the development of information for FDA approval." *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992). Section 271(e)(2) defines the filing of an ANDA with a Paragraph IV certification as infringement so that a patent holder may seek pre-market determination of its rights, while the safe harbor provision accommodates Congress's interest in fostering competition.[20] Thus, activities protected by the safe harbor provision cannot serve as the basis for a declaratory judgment of actual future infringement. *Id.* at 1523-25.

C. Eisai's allegations of future potential infringement are insufficient

Beyond those activities protected by § 271(e)(1), Eisai claims actual future infringement on the basis of statements made by Mutual's representatives and counsel. Eisai alleges:

> In the mid-2006 time period, Mutual through its Vice President of Intellectual Property and General Counsel, informed counsel for Eisai that the Mutual ANDA was not subject to an automatic 30 month stay

[20] "To permit [an ANDA filer] to be protected from direct suit for infringement and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical." *Intermedics, Inc. v. Ventritex Co.*, 991 F.2d 808 (Fed. Cir. 1993) (table) (unpublished opinion).

> of FDA approval, that Mutual might launch its product at risk as soon as it obtained approval from the FDA and that, as a result, Eisai should speak with Mutual about a business arrangement. . . .
>
> On August 29, 2007, Mutual represented through its counsel in open court that, under typical timelines for the FDA's approval of Abbreviated New Drug Applications, final approval of Mutual's ANDA is imminent. Mutual further represented in open court through its counsel that, upon FDA approval of Mutual's ANDA, Mutual could launch a generic version of ARICEPT® ODT giving rise to a claim of damages by Eisai for actual patent infringement.

(Am. Compl. ¶¶ 24, 26.)[21]

Eisai also alleges in its Amended Complaint that "[i]n response to questioning by the Court on August 29, 2007, Mutual through its counsel refused to agree to stipulate that the '841 patent is valid and that Mutual would not market a generic donepezil product until after the '841 patent expires." (Am. Compl. ¶ 28.) After subsequent negotiations, the parties have entered into a stipulation (Docket No. 54) pursuant to which Mutual agreed to provide Eisai, during the period prior to the expiration of the patent, with 45-days' written notice before "market[ing], offer[ing] to sell or sell[ing]" a generic Aricept® product under its ANDA. (Stipulation and Order Oct. 10, 2007 at ¶ 1.) In exchange, Eisai agreed to not seek a preliminary injunction or temporary restraining order until it receives such notice.

These allegations, combined with the post-Complaint stipulation, do not present the immediacy necessary for declaratory judgment jurisdiction. The alleged future infringement

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[21]Eisai also mentions that Mutual's counsel appeared to invite the added declaratory judgment claim during this hearing, stating that "To the extent that a threat is actionable, it is actionable in a DJ action. And as we sit here today, Eisai certainly, I guess, is free to pursue that, but the case they've got on file [the initial Complaint containing only the § 271(e)(2) claim] should be dismissed." (Michael Decl. Ex. 5 at 22:22-25.) Of course, this remark by counsel does not rise to the level of a waiver.

depends on two contingent future events: FDA approval of Mutual's ANDA, and Mutual's decision to market a generic version of Aricept® ODT pursuant to that ANDA. At least until the ANDA is approved, however, the controversy is not sufficiently immediate. Indeed, Congress created the §271(e)(2) action specifically to provide a jurisdictional "hook" for patentees to go to court and seek a declaratory judgment of infringement prior to ANDA approval. *See Apotex*, 376 F.3d at 1551 (stating that "35 U.S.C. § 271(e)(2) is designed to create an artificial act of infringement for purposes of establishing jurisdiction in the federal courts" and "permit[s] patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue"). Section 271(e)(2) provides patentees "with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity," *Novopharm*, 110 F.3d at 1569, and is "primarily a jurisdictional-conferring statute that establishes a case or controversy in a declaratory judgment action," *Apotex*, 376 F.3d at 1351; *see also Allergan*, 324 F.3d at 1330 (stating that § 271(e)(2) "makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed").

As discussed previously in this Opinion, Eisai cannot avail itself of § 271(e)(2) here. It therefore cannot establish the immediacy required for a declaratory judgment action without § 271(e)(2)'s "artificial" act of infringement. Even accepting Eisai's allegations regarding Mutual's representations as true, Eisai has alleged only that Mutual might hit the market upon FDA approval of its ANDA. However, only § 271(e)(2) allows Eisai to seek judicial resolution of its patent claims prior to ANDA approval. Mutual's agreement to give Eisai 45-days notice of its intent to market a generic Aricept® after ANDA approval only further undercuts the

immediacy of the controversy here. Where "the FDA has not given [Mutual] approval to market a generic form of [Aricept® ODT]," the "fact that [Mutual] has not indicated that it does not plan to enter the market is not sufficient to show that [Mutual] intends to enter the market." *Zenith*, 934 F. Supp. at 938. "[A] controversy will only materialize if the FDA approves the accused drug and if [Mutual] decides to market the drug." *Id.* at 939; *see also Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 05-590, 2006 WL 2375035, at *3 (D. Del. Aug. 16, 2006) (dismissing declaratory judgment claim for lack of sufficient reality and immediacy where FDA had not approved defendant's product, where defendant could not predict but only "expect" FDA approval within a certain time frame, where product could change based on FDA's determination in approving product, and where defendant had not "distributed sales literature, prepared to solicit orders, or engaged in any sales or marketing activity").

Eisai identifies only two cases, upon which it relies heavily, in which a court held that declaratory jurisdiction existed over a patentee's claim prior to ANDA approval. Both these cases are distinguishable. In *Novopharm*, the Federal Circuit affirmed jurisdiction over a declaratory judgment infringement action based on threats by the generic manufacturer that it intended to hit the market prior to patent expiration. 110 F.3d at 1570-71. However, *Novopharm* concerned a "method of making" patent claim, which is not covered by § 271(e)(2); Section 271(e)(2) only applies to a "drug claimed in a patent or the use of which is claimed in a patent." *Id.* at 1570. Thus, the patentee had to resort to the Declaratory Judgment Act rather than § 271(e)(2). The Federal Circuit stated that some of the acts by defendant which served as the basis for plaintiff's claim, as here, "are of course protected from liability under § 271(e)(1)." *Id.* at 1571. However, because plaintiff's claim for relief was "directed to the time after the ANDA

is approved, when § 271(e)(1) no longer provides a shelter against infringement liability," the Federal Circuit found that the district court properly exercised jurisdiction over plaintiff's claim. *Id.*

Eisai makes repeated analogies to this case, as it also seeks relief for Mutual's potential infringement "upon FDA approval." (Am. Compl. ¶ 29.) However, the Federal Circuit explicitly limited its holding in *Novopharm* to "method of making" patents: "Accordingly, declaratory relief is available to the patentee *asserting a 'method of making' claim* if . . . sufficient facts are alleged to create an actual case or controversy. Such allegations may include . . . imminent FDA approval and actual threats of future infringement." *Id.* (emphasis added). Thus, "imminent FDA approval and actual threats of future infringement" suffice only with regard to a "method of making" claim, where § 271(e)(2) does not apply. Here, § 271(e)(2) applies, but Eisai cannot make out a case under that provision due to the lack of a Paragraph IV certification. *Novopharm* does not aid Eisai here.

In *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006 (N.D. Ill. 2001), the district court found jurisdiction over plaintiff's declaratory judgment claim of future infringement. The court found that the reality and immediacy requirements had been met based on the following:

> First, defendant has filed and the FDA has accepted for filing the ANDA, which, as both parties recognize, means that defendant is ready or has at least made meaningful preparations to be ready to market the allegedly infringing product. *See Novopharm*, 110 F.3d at 1570-71. Second, even accepting defendant's timetable, the ANDA is likely to be approved by June 2002, over a year before the patent expires. Obviously, the threat of defendant entering the market is not "years away," *see Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992), nor, in light of defendant's steadfast refusal to reply to plaintiff's demand letters, is there any real doubt that defendant plans to sell some form of

> cefuroxime axetil once the ANDA is approved.

Id. at 1008-09 (citations omitted). Eisai argues that the same logic applies here.

First, however, Mutual's Vice President of Marketing and Strategic Analysis has attested that "Mutual has made no preparations for launch of donepezil ODT," that "Mutual has not made a decision to launch donepezil ODT," and "[f]rom a time a decision were made to launch donepezil ODT, it would take Mutual at least six months to launch the product." (Foster Decl. ¶¶ 8-10.) Thus, the facts are not as clear here as they were in *Glaxo*. In *Glaxo*, defendant "ha[d] refused to change the course of its actions in the face of plaintiff's acts to preserve its patent rights." *Glaxo*, 130 F. Supp. 2d at 1009. Such is not the case here. In one case where the court determined that the jurisdictional prerequisites were satisfied, the court based that decision on the court's findings that "there is no doubt about the Defendants' plans to market [its product] at the earliest opportunity, in the face of [plaintiff's] patent claims. Nor is there any question about its immediate capacity to do so upon FDA approval." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112 (D. Mass. 1998) (finding jurisdictional requirements met but nonetheless declining to exercise declaratory judgment jurisdiction). The Court cannot make such findings here.[22]

Another important distinction exists between the instant matter and the *Glaxo* district court case upon which Eisai relies. *Glaxo* concerned an antibiotic drug. So-called "old

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[22]In any event, the court in *Amgen* declined to exercise jurisdiction even though plaintiff met the jurisdictional requirements. *Id.* The court reasoned that "numerous considerations militate against exercising" jurisdiction, including: 1) "FDA approval is uncertain;" 2) "the process or the product may itself be altered during the interval in ways that are material to an infringement analysis;" and 3) "subjecting the Defendants to an infringement litigation at present may run afoul of the Congressional policy underlying the section 271(e)(1) exemption." *Amgen*, 3 F. Supp. 2d at 112. Similar considerations apply here.

antibiotic" drugs are exempt from the patent listing and certification requirements of the Hatch-Waxman Act.[23] Because patent listing and certification requirements do not apply to old antibiotics, some courts have held that a Paragraph IV certification in an ANDA is not required to maintain a § 271(e)(2) action in an old antibiotics case. *Teva Pharm. USA, Inc. v. Abbott*

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[23]At the time that the Hatch-Waxman Act was enacted in 1984, the regulatory process for approval of antibiotic drugs was governed by 21 U.S.C. § 357, a separate section of the FDCA that has now been repealed. Generic manufacturers seeking approval to market antibiotic drugs sought such approval pursuant to § 357, not § 355(j). Section 357 did not contain the Orange Book patent listing and ANDA certification requirements of § 355. When the Hatch-Waxman Act added 35 U.S.C. § 271(e)(2) to the FDCA, that provision's specific reference to an "application under Section [355(j)]" meant that § 271(e)(2) did not apply to antibiotics. Hatch-Waxman did not create an act of infringement based on an application under § 357. However, § 271(e)(1), establishing the safe harbor from infringement for the purposes of developing an application for FDA approval, *does* apply to antibiotics because it did not limit the safe harbor to activities in preparation of an application under any specific provision. Thus, this "loophole" for antibiotic drugs benefitted generic manufacturers at the expense of patent holders: "Generic manufacturers of 'old antibiotics' would be able to take advantage of § 271(e)(1) to manufacture, use, or sell a drug if done solely for the submission of an ANDA without violating the pioneer patent. However, the patent holder of the old antibiotic would not be permitted to maintain a suit under § 271(e)(2)(A) against the generic manufacturer that submitted an ANDA until the marketing of the generic drug was imminent." *Teva Pharm. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 830 (N.D. Ill. 2004). "It is unclear why the FDCA treated antibiotics differently than other drugs, and equally unclear whether Congress recognized the discrepancy when it passed § 271(e)(2)." *Glaxo Group Ltd. v. Apotex, Inc.*, 272 F. Supp. 2d 772, 777 (N.D. Ill. 2003).

Congress addressed this inconsistency in 1997 by passing the Food and Drug Modernization Act of 1997 ("Modernization Act"). The Modernization Act repealed § 357 and brought antibiotics into the Hatch-Waxman regime. "As a result, antibiotics are treated like any other drug, and generic manufacturers of antibiotics must now apply for ANDAs under § 505(j), which makes 35 U.S.C. § 271(e)(2) applicable." *Id.* However, because the repealed § 357 did not require patent listing or ANDA certifications for antibiotics, the Modernization Act "exempted drug manufacturers who had filed previously under § 357 ("old antibiotics") from Orange Book listing requirements, and also exempted ANDA applicants for generic versions of old antibiotics from the certification requirements under § 355(j)(2)(A)(vii)." *Id.* "Drug manufacturers who utilized Section 357 to obtain FDA approval are exempt from listing the patents related to their antibiotic in the Orange Book. ANDA applicants attempting to market generic versions of such antibiotics are not required to file a certification under 21 U.S.C. § 355(j)(2)(A)." *See Glaxo*, 376 F.3d at 1344 (citing Pub. L. 105-115, Title I, § 125(d), 11 Stat. 2326 (1997)).

Labs., 301 F. Supp. 2d 819, 829-30 (N.D. Ill. 2004); *Glaxo Group Ltd. v. Apotex, Inc.*, 272 F. Supp. 2d 772, 775 (N.D. Ill. 2003). Indeed, the same district court that issued the *Glaxo* opinion regarding declaratory judgment later so held. However, the drug at issue here is not an old antibiotic. Because the Hatch-Waxman patent listing and certification requirements apply, a Paragraph IV certification is required and Eisai therefore cannot make out a § 271(e)(2) action. Similarly, the *Glaxo* declaratory judgment opinion is distinguishable because it arose in the unique context of old antibiotics.[24]

Eisai contends that its declaratory judgment action should not depend on the availability, or lack thereof, of relief under § 271(e)(2) because the Declaratory Judgment Act allows for jurisdiction "whether or not further relief is or could be sought." 28 U.S.C. § 2201(a); *see also MedImmune*, 127 S. Ct. at 770. However, § 271(e)(2) provides the jurisdictional peg for infringement actions brought prior to ANDA approval, and, in the absence of this jurisdictional hook, jurisdiction is lacking.[25]

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[24]In *Glaxo*, plaintiff also presented a § 271(e)(2) claim, and the parties disputed whether plaintiff stated a claim under that provision because the old antibiotic drug was not listed, and need not have been listed, in the Orange Book. The court declined to reach this issue because "plaintiff seeks the same relief" under both § 271(e)(2) and its declaratory judgment claim. *Glaxo*, 130 F. Supp. 2d at 1009 n.4. Eisai apparently seeks to employ the same approach here by its filing of infringement claims pursuant to both § 271(e)(2) and the Declaratory Judgment Act, as the substantive analysis for each claim would be the same. However, as opposed to the old antibiotic in *Glaxo*, the drug at issue here is not exempt from the Hatch-Waxman patent listing and certification requirements. Therefore, based on the facts of this case, Eisai cannot proceed because it cannot bring a claim under § 271(e)(2) and the controversy is not sufficiently immediate to establish jurisdiction under the Declaratory Judgment Act.

[25]The Court notes that *Lang*, while applicable here, was not a drug case and did not involve an ANDA. Most of the drug patent cases applying *Lang* concern issues arising from licensing agreements or other situations not involving an ANDA. In the special context of an ANDA, which is governed by a detailed statutory and regulatory regime, the absence of many cases dealing with "actual future infringement" is not surprising because of the existence of §

For these reasons, this Court lacks subject matter jurisdiction over Eisai's declaratory judgment claim, and would decline jurisdiction even if it did. The Court will grant Mutual's motion to dismiss that claim pursuant to Rule 12(b)(1).

IV. The Court's Decision Does Not Permanently Prevent Eisai from Seeking Redress.

While this Court must dismiss Eisai's Amended Complaint at this time, Eisai is not without any remedy for Mutual's potential infringement. Eisai may bring an action for infringement upon learning, pursuant to the parties' stipulation, of Mutual's intent to market a generic version of Aricept® ODT. Because of the lack of timely patent listing and consequent lack of ANDA Paragraph IV certification, Eisai has lost its right to stay FDA approval of the ANDA for 30 months, and has lost its ability to litigate the infringement issue prior to Mutual hitting the market, or announcing its intent to hit the market. However, if and when Mutual – prior to the expiration of the '841 patent – decides to market a generic version of Aricept® ODT, the parties' stipulation allows sufficient time to resolve certain issues by way of an infringement action and a potential motion for preliminary relief, if Eisai so chooses. This framework would potentially allow Eisai to avoid the irreparable harm it claims would result from not being allowed to sue Mutual until Mutual hits the market with its generic product. Eisai is not mistaken in arguing that dismissal here would result in inefficiencies, especially in light of a similar action pending before this Court involving an ANDA for generic Aricept® and the '841

271(e)(2).

patent. *Eisai Co. v. Teva Pharm. USA, Inc.*, No. 05-5727 (HAA).[26] Yet the peculiar factual background of this case compels the result here. Practical considerations of potential inefficiency, although important, cannot change the law as it applies to this case.

V. Mutual's Appeal of Magistrate Judge Salas's Discovery Ruling Is Moot.

Mutual has filed an appeal from Magistrate Judge Salas's denial of its request to stay discovery pending disposition of the motion to dismiss. Because this Opinion and Order resolves the pending motion to dismiss, this Court need not address the merits of Mutual's appeal, and will dismiss the appeal as moot.

Conclusion and Order

For the aforementioned reasons, it is hereby ORDERED that Mutual's motion (Docket No. 53) to dismiss is GRANTED. Mutual's appeal (Docket No. 57) from Magistrate Judge Salas's denial of its request to stay discovery pending disposition of the motion to dismiss is hereby dismissed as moot. The Clerk shall mark this matter closed.

Dated: December 20, 2007
Newark, New Jersey

/s/ Harold A. Ackerman
U.S.D.J.

[26]Indeed, a motion to consolidate the instant matter with *Eisai v. Teva* is pending before this Court (Civil Action No. 05-5727, Docket No. 35), and will be mooted by the dismissal here.