NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC.,	**Hon. Dennis M. Cavanaugh**
Plaintiff,	**OPINION**
v.	Civil Action No. 10-CV-06554 (DMC-JAD)
PFIZER INC., PHARMACIA & UPJOHN COMPANY LLC, and PFIZER HEALTH, AB,	
Defendants.	

DENNIS M. CAVANAUGH, U.S.D.J.

This matter comes before the Court upon motion by Defendants Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB's (collectively, "Defendants") to dismiss Plaintiff Impax Laboratories' ("Plaintiff") complaint for lack of subject matter jurisdiction, pursuant to FED. R. CIV. P. 12(b)(1), and in the alternative for failure to raise a compulsory counterclaim in an action currently pending between the parties before this court. Pursuant to FED. R. CIV. P. 78, no oral argument was heard. After considering the submissions of all parties, it is the decision of this Court for the reasons herein expressed that Defendants' motion to dismiss is **granted**.[1]

[1]On March 12, 2011, Plaintiff Impax filed a motion to strike portions of Defendant Pfizer's reply brief on the grounds that it raised new arguments that should have been included in the opening brief and requested leave of this court to file a surreply. We grant Plaintiff's motion to Strike, but deny the request to file a surreply.

I. BACKGROUND[2]

A. The Hatch-Waxman Act

This case comes before this court as a declaratory judgment action under the Hatch-Waxman Act.[3] The Hatch-Waxman Act governs the Food and Drug Administration's ("FDA") approval of new and generic drugs. Pursuant to Hatch-Waxman, a drug company who is the first to develop and market a drug must file a New Drug Application. ("NDA") 21 U.S.C. § 355(a), (b). As part of this application, the manufacturer is required to disclose to the FDA those patents which the holder believes cover the drug, as well as the methods for using it. 21 U.S.C. § 355(b)(2)(A). In so doing, the NDA applicant notifies the FDA of those patents for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Caraco Pharm. Labs. Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1282 (Fed. Cir. 2008). The FDA in turn lists all such patents in a publication titled the "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." ("Orange Book").

Subsequent manufacturers seeking to market a generic version of an NDA approved drug must file an "Abbreviated New Drug Application. ("ANDA") 21 U.S.C. § 355(j). In completing the ANDA application, the generic drug manufacturer must first demonstrate bioequivalence of its

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[2] The facts set-forth in this Opinion are taken from the Parties' statements in their respective moving papers.

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

drug with the existing NDA drug, as well as file certifications for each of the NDA holder's Orange Book patents that it believes cover the listed drug. U.S.C. § 355(j)(2)(A)(ii),(vii). For each identified patent, the ANDA applicant must include a certification that either (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii). The filing of a Paragraph IV certification constitutes a challenge to the validity or noninfringement of the existing patent, and is by definition an act of patent infringement. 35 U.S.C. § 271(e)(2)(A); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). Upon receipt of notice of a Paragraph IV Certification, the NDA holder may institute an action for patent infringement against the ANDA filer who challenged the patent. U.S.C. § 355(c)(3)(C). If, however, the NDA holder fails to bring suit within 45 days of receiving notice of the certification, the ANDA filer may bring a declaratory judgment action that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval. 21 U.S.C. § 355(c)(3)(D)(i)(II). An ANDA filer who files Paragraph IV Certifications may not market their generic drug until the expiration or finding of invalidity of the listed patents. 21 U.S.C. § 355(j)(5)(B)(iii).

As an additional incentive to the development of generic drugs, Hatch-Waxman provides for a 180-day period of market exclusivity to the first manufacturer to file an ANDA application raising Paragraph IV Certifications ("first-filer"). 21 U.S.C. § 355(j)(5)(D). The market exclusivity period commences upon the date of the first commercial marketing of the generic drug and prohibits the FDA from approving any subsequently filed ANDAs for the duration of the 180 day period. 21

U.S.C. § 355(j)(5)(B)(iv). This period of exclusivity, however, may be forfeited upon the occurrence of one of several enumerated forfeiture events. 21 U.S.C. § 355(j)(5)(D). One such forfeiture event occurs when the manufacturer fails to market its generic drug within 75 days of a final judgment that all of the patents against which it filed Paragraph IV Certifications are invalid or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Such final judgment need not be achieved by the first-filer, but may be achieved by a subsequent filer if such filer has received tentative approval. Id. Upon forfeiture, the FDA will be permitted to approve subsequent ANDA applications immediately upon the expiration of the NDA patents. Id.

B. Factual Background

Defendant Pharmacia & Upjohn LLC is the current holder of an approved NDA for tolerodine tartrate extended-release capsules in 2 and 4 mg doses. Defendant Pfizer currently sells drug products pursuant to this NDA under the registered name Detrol® LA. In completing it's NDA application, Pfizer listed U.S. Patent No. 5,382,600 ("600 Patent"), U.S. Patent No. 6,630,162 ("162 Patent"), U.S. Patent No. 6,770, 295 ("295 Patent"), and U.S. Patent No. 6,911,217 ("217 Patent"). These patents were subsequently listed in the Orange Book by the FDA.

Teva was the first to file an ANDA for generic Detrol® LA. Pursuant to its ANDA filing, Teva included Paragraph IV Certifications for each of Pfizer's four listed patents. As first ANDA filer, Teva is eligible for a 180-day period of generic marketing exclusivity upon the expiration of the relevant patents, during which no subsequent ANDA filing may be approved by the FDA. However, Teva may forfeit such market exclusivity upon the occurrence of one of the enumerated "forfeiture events" provided under 21 U.S.C. § 355(j)(5)(D)(i), and thereby open the door to FDA approval for subsequently filed ANDAs.

On December 12, 2007 Plaintiff Impax submitted an ANDA seeking approval to engage in the manufacture, use, or sale of its Tolterodine Extended-Release Capsules. In its application, Impax provided information that it believed to demonstrate bioequivalence with Detrol® LA, as well as Paragraph IV certifications that Impax's manufacture, use, importation, sale, or offer for sale of Impax's proposed Tolterodine ER Capsules will not infringe any valid or enforceable claim of the '600, '162, '295, and '217 patents. As required by Hatch-Waxman, Impax provided Pfizer with its Notice letter in which it provided a detailed statement of the factual and legal bases that the '600, '162, '295, and '217 patents are invalid, unenforceable, or not infringed. Upon receiving notice of the certifications, Pfizer filed an infringement action under 35 U.S.C. § 271(e)(2)(A) asserting the '600, '162, and '295 Patents against Impax in the Southern District of New York.[4] ("First Impax Action"). Pfizer did not commence an infringement action regarding the '217 patent.

During the pendency of the first Impax action, Pfizer was in litigation with first-filer Teva regarding the validity of the '600 patent. ("IVAX Action"). In December of 2009, Impax and Pfizer moved to consolidate the First Impax Action with Pfizer's infringement suit against Teva. Pursuant to the Stipulation Order entered by this court on December 23, 2009, the cases were consolidated and the parties agreed to be bound by any decision regarding the validity or non-infringement of the '600 patent rendered in the IVAX action. (Cunning Decl. Ex. E, ECF No.23-1) Specifically, the parties agreed and stipulated "to be bound, individually and collectively, and in all respects, by the Court's decisions in Pfizer, Inc., et al. v. IVAX Pharms., Inc. et al., Civil Action No. 07-0174." The parties further agreed and stipulated

[4]Pfizer's infringement action was transferred to the U.S. District for the District of New Jersey on April 29, 2008.

> "that when a final judgment concerning the validity and enforceability of the '600 patent is entered in Civil Action No. 07-0174, a like judgment should be entered in the Consolidated Action. In the event that a final judgment on the '600 patent is vacated, modified, affirmed, or reversed prior to appeal, on appeal or upon remand from an appeal, the parties agree that such judgment shall be applied in the same manner to any judgment entered in the Consolidated Action."

[Johnson Decl. Ex. C, 1-2, ECF No. 27-1]

On December 16, 2010, more than 45 days from the date Pfizer received notice of filing regarding Impax's ANDA (sent January 29, 2008), Impax brought this action for a declaratory judgment of non-infringement regarding the '217 patent. Impax seeks a declaration that the manufacture, use, offer for sale, or sale of Impax's proposed Tolterodine ER capsules will not infringe any valid claim of the '217 patent. On January 28, 2011, Pfizer granted Impax a covenant not to sue with respect to the '217 patent.[5] Defendant Pfizer subsequently filed a motion to dismiss, alleging lack of subject matter jurisdiction for failure to allege a case or controversy, and in the alternative failure to raise a compulsory counterclaim in the preceding Impax litigation.

The issue before this court is whether Plaintiff Impax has sufficiently alleged a cognizable injury-in-fact upon which this court may sustain subject matter jurisdiction.

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[5]The original covenant not to sue was challenged by Plaintiffs in their opposition to Defendant's Motion to Dismiss as insufficient to remove any patent uncertainty. Plaintiff found insufficient the provision of the covenant that expressly excluded "licensees, sublicensees, and customers of Impax and Impax Affiliates, and any successor or assign of Impax or any Impax Affiliate." Impax argues that such limitations do not remove a threat of suit against Impax's customers and other related entities. On March 29, 2011, Pfizer issued a second covenant by which it unconditionally covenanted not to enforce the '217 patent against Impax's "licensees, sublicensees, customers, suppliers, importers, manufacturers, distributors, or insurers" in connection with the manufacture, use, offer for sale, or importation of the products described in Impax's ANDA. As the sufficiency or import of the covenants are not relevant to the disposition of this case, we do not address parties' arguments raised regarding the covenant not to sue.

Plaintiff has provided two separate injuries-in-fact upon which they maintain declaratory judgment jurisdiction is proper: ANDA approval delay and patent uncertainty. For the following reasons, this court finds that the injuries alleged fail to present a cognizable case or controversy. Jurisdiction is therefore improper and Defendants' Motion to Dismiss is **granted.**

II. MOTION TO DISMISS

A. LEGAL STANDARD

1. Standard of Review for Motion to Dismiss for Lack of Subject Matter Jurisdiction Pursuant to Rule 12(b)(1)

Rule 12(b)(1) provides for dismissal of an action based on lack of subject matter jurisdiction. See Fed.R.Civ.P. 12(b)(1). When the existence of subject matter jurisdiction is challenged under Rule 12(b)(1), the plaintiff bears the burden to show that the court has the requisite jurisdiction to hear the case. See, e.g., Hedges v. United States, 404 F.3d 744, 750 (3d Cir.2005); Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir.1977). In adjudicating such a Rule 12(b)(1) motion, the court may not presume that the plaintiff's allegations are true, but instead, must conduct an evaluation of the merits of the jurisdictional claims. See, e.g., Hedges, 404 F.3d at 750. "Accordingly, unlike a Rule 12(b)(6) motion, consideration of a Rule 12(b)(1) jurisdiction-type motion need not be limited; conflicting written and oral evidence may be considered and a court may 'decide for itself the factual issues which determine jurisdiction." Id. (citing Williamson v. Tucker, 645 F.2d 404, 413 (5th Cir.) Cert. denied, 454 U.S. 897 (1981)). When a federal court concludes that it lacks subject-matter jurisdiction, "the only function remaining to the court is that of announcing the fact and dismissing the cause." Steel Co. V. Citizens for a Better Env't, 523 U.S. 83, 94 (1998) (quoting Ex parte McCardle, 7 Wall. 506, 514 (1869).

2. Subject Matter Jurisdiction Over a Declaratory Judgment Action Under Hatch-Waxman

The Medicare Prescription Drug, Improvement and Modernization Act of 2002 (MMA), amended the Hatch-Waxman Act to authorizes a "civil action" under 28 U.S.C. § 2201 "for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval." 21 U.S.C. § 355(j)(5)(C)(i)(II). A declaratory judgment action may be brought by an ANDA filer who raised Paragraph IV challenges if the NDA holder fails to sue the challenger within 45 days of receipt of notice of certification. Caraco, 527 F.3d at 1285. (citing 21 U.S.C. § 355(j)(5) (C)).

Federal jurisdiction over declaratory judgments under the MMA has been granted to the full extent consistent with the Constitution. Id. (citing 35 U.S.C. § 271(e)(5)). Implicit in this grant is the notion that jurisdiction may not extend beyond Constitutional limits. Therefore, federal courts may only exercise jurisdiction to the extent that an MMA declaratory judgment action presents an Article III case or controversy. Id., see also Teva Pharm. USA Inc. v. Novartis Pharm. Corp., 482 F.3d 1330 (Fed. Cir. 2007).

To determine whether a declaratory judgment action satisfies the Article III case or controversy requirement, Courts must look to whether "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007), quoting Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 279, 273 (1941). The dispute must be "definite and concrete, touching the legal relations of parties having adverse legal interests"; and be "real and substantial" and

"admi[t] of specific relief through a decree of a conclusive character." Id. quoting Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240-241 (1937)). Finally, Plaintiff's injury must be "fairly traceable" to the defendant's conduct, and the requested relief must be likely to redress the alleged injury. Steel Co., 523 U.S. at 102-03. Jurisdiction over a declaratory judgment action must be present "at all stages of review, not merely at the time the complaint is filed" and "the burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." Benitec Austl., Ltd. v. Nucleonics, Inc. 495 F.3d 1340, 1344. (2007); Steffel v. Thompson, 415 U.S. 452, 459 n.10 (1974).

Declaratory Judgment Jurisdiction under the Hatch-Waxman Act has been found proper when a judgment in Plaintiff's favor regarding the validity, infringement, or enforceability of an NDA covered patent would "clear the path to FDA approval" which would otherwise be denied by the actions of the NDA holder. Caraco, 527 F.3d at 1293; see also Novartis, 482 F.3d at 1340. (*holding that where an NDA holder brings an infringement suit against a Paragraph IV ANDA filer on only one of several Orange-Book-listed patents covering its NDA, the ANDA filer has standing to seek a declaratory judgment on any of the NDA holder's remaining Orange-Book-listed patents for that NDA*). The injury-in-fact must be fairly traceable to the conduct of the NDA holder, and not the result of Plaintiff's own actions or the inherent framework of the Hatch-Waxman Act. Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1361 (Fed. Cir. 2008); Teva Pharms. USA, Inc. v. Eisai Co., 620 F.3d 1341, 1347 (Fed. Cir. 2010); Caraco, 527 F.3d at 1292. Therefore, declaratory judgment jurisdiction is proper when a judgment in Plaintiff's favor would eliminate the potential for the NDA listed patents to exclude the ANDA

filer from the market." Id. However, any harm that gives rise to jurisdiction over declaratory judgment action under Hatch-Waxman will cease to exist upon the stipulation to the validity, infringement, or enforceability of a relevant NDA covered patent. Janssen, 540 F.3d at 1360.

B. DISCUSSION

Defendants assert that Plaintiff has failed to allege a justiciable case or controversy, and that declaratory judgment jurisdiction is therefore improper. Specifically, Defendants allege that Plaintiff has not presented a controversy regarding the '217 patent that is traceable to Defendant's conduct.[6] (Def. Br. Supp. Mot. Dismiss, Feb. 3, 2011, ECF No. 16-1)

As previously discussed, Plaintiff claims two separate injuries. First, Plaintiff claims a "patent uncertainty injury" arising from the absence of a judicial declaration regarding the validity of the '217 patent. Second, Plaintiff claims an "approval delay injury" resulting from the marketing exclusivity period for which first-filer Teva is eligible. Defendants counter that Plaintiff suffers no patent uncertainty injury, as Pfizer has granted Impax an irrevocable covenant not to sue on the '217 patent, and no approval delay injury attributable to the '217 patent, as Impax has voluntarily decided to forego its challenge to Pfizer's '600 patent, thereby deferring approval of its ANDA until September 25, 2012 at the earliest, when the patent is set to expire.

The pivotal fact for Impax's claim of injury lies in the stipulation to be bound by the IVAX adjudication of the validity of the '600 patent. To the extent this stipulation is binding on Impax, Impax cannot allege any patent uncertainty nor approval delay injury until the expiration

[6]Defendant also asserts in the alternative that Plaintiff's complaint should be dismissed for failure to bring the sole claim at issue as a compulsory counterclaim in a 2008 actions currently pending between the parties in this Court. As this Court now grants Defendants' motion to dismiss on the grounds of lack of subject matter jurisdiction, we do not address their alternative grounds for dismissal.

or finding of invalidity of the '600 patent. In spite of the fact that the current judgment may be modified or overturned in the impending appeal, this court finds that Impax is currently bound by the final judgment of the District Court of the validity of the '600 patent. Therefore, Plaintiff has failed to allege an injury-in-fact traceable to the '217 patent.

1. The '600 Patent

Pursuant to the Consolidation and Stipulation Order consented to by the parties, a Final Judgment Order was entered in the Consolidated Case upon the finding of validity of the '600 patent in the IVAX action. (Johnson Decl. Ex. C, 1-2, ECF No. 27-1) Therefore, as noted in the Final Judgment Order, the earliest effective date of any approval of Impax's ANDA will be the date of the expiration of the term of the '600 patent, set for September 25, 2012.

Plaintiffs maintain that the stipulation to be bound does not remove jurisdiction, as the judgment is currently on appeal and therefore subject to modification. As a result, Plaintiffs argue that patent uncertainty and approval delay injuries persist, providing Plaintiffs with a cognizable injury-in-fact. In support for this proposition, Plaintiffs rely on the case of Janssen Pharmaceutica N.V. v. Apotex, Inc., previously decided before this court and affirmed by the Federal Circuit. 2007 WL 3014702 (D.N.J. 2007), aff'd, 540 F.3d 1352 (Fed. Cir. 2008)

2. Janssen

Plaintiff's reliance on Janssen is misplaced. Plaintiffs read Janssen as standing for the proposition that a stipulation to be bound by a judgment regarding patent validity will *only* be final once all appellate rights in the case have been exhausted. (Pl.'s Br. Opp'n Mot. Dismiss, March 18, 2011, ECF No. 23) In Janssen, it was held that Plaintiff's stipulation to the validity, enforceability, and infringement of an asserted patent divested this court of jurisdiction over the

matter. 540 F.3d at 1361. However, Janssen did not state, nor does this court hold now, that *only* upon exhaustion of appellate review will a stipulation to be bound be considered final.[7] Moreover, the plain language of the stipulation order directs us to conclude otherwise. The Consolidation and Stipulation Order provides: "when a final judgment concerning the validity and enforceability of the '600 patent is entered in [the IVAX action], a like judgment should be entered in the Consolidated Action." (Johnson Decl. Ex. C, 1-2, ECF No. 27-1). The Order goes on to provide further instructions in the event that the judgment is vacated, modified, affirmed, or reversed prior to appeal, on appeal, or upon remand from the appeal, providing that "such judgments shall be applied in the same manner to any judgment entered in the Consolidated Action." Id. Therefore, the Stipulation Order by its own terms contemplates that once a final judgment is entered in the District Court, such judgment would be entered and therefore binding on the parties pending a subsequent judgment on appeal.

While the holding of Janssen does not provide Plaintiff with the support that it seeks, Janssen is controlling in this case by virtue of Plaintiff's stipulation to be bound. Janssen stands for the proposition that a stipulation to be bound will divest a federal court of declaratory judgment jurisdiction, as such stipulation is not fairly traceable to the Defendant's actions and will prevent a judgment in Plaintiff's favor from redressing the injury alleged. see generally, 540 F.3d 1353.

[7]Although the Court in Janssen noted that the stipulation took effect on the date that the Federal Circuit affirmed the holding of the District Court, it did not provide any further explanation that an exhaustion of appeals was required before a district court finding of validity would be binding on the parties to the stipulation. 540 F.3d at 1358.

In Janssen, as here, a generic drug company was the second to file an ANDA for an NDA Approved Drug. Id. at 1358. Pursuant to the generic company's ANDA application, Paragraph IV certifications were filed for each of the NDA holder's patents. Id. The NDA holder in turn sued the ANDA filer for infringement of one of the three Orange-Book listed patents ("the '663 patent"). In that same suit, the ANDA filer asserted counter-claims seeking a declaratory judgment of non-infringement for the remaining unasserted patents. Id. The NDA holder then granted the ANDA filer a covenant not to sue on the unasserted patents and requested that the counterclaims be withdrawn for lack of case or controversy. Id. at 1358-59. While the declaratory judgment action was pending, the ANDA filer stipulated to be bound to the judgment of a separate action regarding the validity of the '663 patent. Id. at 1358.

The Plaintiffs in Janssen advanced similar injuries to those alleged in the present action. There, as here, the ANDA filer argued that it was being prevented from launching its generic drug as soon as possible and that a lack of a judgment regarding the unasserted patent subjected the company's affiliates, suppliers, and customers to patent uncertainty. Id. at 1359. Plaintiff argued that a declaratory judgment in its favor would trigger the first-filer's exclusivity period at a time when it could not exercise it, thereby allowing the subsequent filer to receive approval for its ANDA immediately upon expiration of the '663 patent. Id. at 1360. The court rejected the notion that an inability to launch its generic product immediately upon the expiration of the '663 patent constituted an injury-in-fact, rather finding such delay to be a result envisioned by the Hatch-Waxman Act. Id. Regardless of a judgment in its favor, the ANDA filer would still be prevented from entering the market until the expiration of the '663 patent. Id. at 1361. Declaratory judgment jurisdiction was therefore no longer proper, as the harm that created a

justiciable Article III case or controversy ceased to exist upon the Plaintiff's stipulation. Id.

3. Caraco

Caraco Pharm. Labs. Ltd. v. Forest Labs., Inc., is not controlling in this case for the reasons laid out by the Federal Circuit in Janssen. 540 F.3d at 1361. Caraco found a cognizable injury-in-fact traceable to the NDA holder when the act of listing patents in the Orange Book created an *independent barrier* to the marketplace depriving the ANDA filer the opportunity to compete.[8] 527 F.3d at 1293. The court in Caraco expressed concern that an NDA holder's failure to sue on listed patents could result in the exclusion of an ANDA filer from selling a noninfringing product. Id. at 1293. However, Janssen, specifically distinguished Caraco by virtue of the stipulation, holding that Caraco *would have been controlling,* but for the ANDA filer's stipulation to the validity of the '663 patent. Janssen, 540 F.3d at 1360. (*finding the harm that gave rise to declaratory jurisdiction ceased to exist once the ANDA filer stipulated to the validity of an NDA covered patent*). Here, as in Janssen, the stipulation to be bound presents yet *another* obstacle to FDA approval, preventing Plaintiff from obtaining FDA approval until the expiration or finding of invalidity of the stipulated to patent. Declaratory judgment jurisdiction cannot, therefore, be supported on the grounds of clearing the path to FDA approval.

4. Eisai

Plaintiff's analogy to the preliminary injunction in Teva Pharmaceuticals USA, Inc. v. Eisai Co., Ltd. is similarly unconvincing. In Eisai, the Federal Circuit found that a preliminary

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[8]Of particular note, the court found that the NDA holder's grant of a covenant not to sue in lieu of suing on the patent-in-suit was not sufficient to remove the injury-in-fact when the unasserted patent was the only barrier to FDA approval. This court does not address the covenant not to sue granted by Defendant in this case.

injunction barring the marketing of the drug in question was insufficient to remove jurisdiction over a declaratory judgment action. 620 F.3d 1341 (Fed. Cir. 2010) (*vacated on other grounds*). The court confirmed the holding in Caraco that an actual controversy existed when a favorable judgment would eliminate the potential for NDA covered patents to exclude the ANDA filer from the drug market. Id. at 1347. However, the Court in Eisai again specifically distinguished Janssen on the grounds of the stipulation by observing that in Janssen "the subsequent filer's alleged harm, inability to enter the market, was not 'fairly traceable' to the listing of the subject patents in the Orange Book. Rather, the cause was the stipulation.". Id. at 1347-48. In distinguishing the stipulation in Janssen, the court emphasized that the injunction in Eisai was *preliminary* and was therefore not comparable to the *final* determination of validity, infringement, and enforceability provided by the stipulation in Janssen. Id. 1348.

It can not be said that the judgment entered into this case pursuant to the stipulation agreed to by the parties is comparable to a preliminary injunction, regardless of whether the determination underlying the order is potentially subject to modification on appeal. The terms of the stipulation specifically direct "that when a final judgment concerning the validity and enforceability of the '600 patent is entered in Civil Action No. 07-0174, a like judgment should be entered in the Consolidated Action." Pursuant to parties' request, a judgment of validity was entered. They may not now argue that it should have no effect.

IV. CONCLUSION

Accordingly, this case is controlled by the rationale articulated in Janssen. Impax is presently bound by their stipulation to the holding of the IVAX action, which found the '600 patent to be valid.

Although the underlying determination of validity is subject to modification on appeal, the parties are bound as it stands. Therefore, a favorable judgment in Impax's favor would not clear the path to FDA approval and does not provide the basis for declaratory judgment jurisdiction. Defendant's motion to dismiss for lack of subject matter jurisdiction is therefore **granted**.[9]

S/ Dennis M. Cavanaugh
DENNIS M. CAVANAUGH, U.S.D.J.

Date: September 30 . 2011
cc: All Counsel of Record
Hon. J. A. Dickson, U.S.M.J.
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[9]We do not reach Defendant's arguments regarding the failure to raise compulsory counterclaims as they are not required for the disposition of this case.