UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiff, v. MYLAN INC. AND MYLAN PHARMACEUTICALS INC., Defendants.	Case No.: 14-CV-00314-LHK Consolidated and Related Cases: 13-CV-04001-LHK 13-CV-04002-LHK ORDER GRANTING PARTIAL MOTION TO DISMISS

Plaintiffs Takeda Pharmaceutical Co. Ltd., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") filed this patent infringement action against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan"). *See* Compl. (ECF No. 1). Takeda's claims relate to Mylan Pharmaceuticals Inc.'s filing of an Abbreviated New Drug Application ("ANDA") for a generic form of Takeda's branded drug Dexilant®, for treatment of gastroesophageal reflux disease. In its Complaint, Takeda pleaded two Counts. Count I is a claim for infringement under the Hatch-Waxman Act pursuant to 35 U.S.C. § 271(e)(2). *Id.* ¶¶ 29-31. Count II seeks a declaratory judgment of infringement under 28 U.S.C.

§ 2201, "[p]ursuant to 35 U.S.C. § 271(a), (b), or (c)." *Id.* ¶¶ 32-38.

Mylan moves to dismiss Count II under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction or, alternatively, for an order terminating the automatic stay of the Food and Drug Administration's ("FDA") approval of Mylan's ANDA. *See* ECF No. 13 ("Mot.") at 1. Mylan argues that the Court lacks jurisdiction over Count II under the Declaratory Judgment Act because there is no controversy of "sufficient immediacy and reality." *Id.* at 6-10. Additionally, Mylan argues that the Court should not exercise its discretion to hear Count II because it would undermine congressional intent in enacting the Hatch-Waxman Act. *Id.* at 10-12.

On April 14, 2014, Takeda opposed Mylan's Motion to Dismiss. ECF No. 19-3 ("Opp'n"). On April 24, 2014, Mylan replied. ECF No. 26-4 ("Reply"). The Court held a hearing on July 31, 2014. Having considered the parties' submissions and the relevant law, the Court GRANTS Mylan's motion to dismiss Count II. Consequently, Mylan's alternative request for an order terminating the automatic 30-month stay of the FDA's approval of ANDA No. 205-205 is DENIED as moot.

I. BACKGROUND

A. The Hatch-Waxman Act

The Hatch-Waxman Act's framework for generic drugs and resolution of related patent infringement disputes has been explained repeatedly in detail. *See generally Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1282-86 (Fed. Cir. 2008) (explaining ANDA procedures and patent infringement claims under the Hatch-Waxman Act). The Court notes only relevant parts of this legal background for purposes of this motion.

The Food, Drug, and Cosmetic Act ("FDCA") requires a drug manufacturer to submit a New Drug Application ("NDA") to the 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. *Id.* § 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, commonly known

as the "Orange Book." *See id.* §§ 355(b)(1), 355(j)(7)(A)(i)-(iii). The Orange Book must list "each drug which has been approved for safety and effectiveness" through an NDA. *Id.* § 355(j)(7)(A)(i)(I). If a patent claiming the drug or method of using the drug issues after the NDA is approved, the NDA holder must submit the patent information to the FDA within 30 days of issuance for publication in the Orange Book. *Id.* § 355(c)(2).

The Hatch-Waxman Act amended the FDCA to provide for the ANDA process, which allows drug manufacturers to obtain FDA approval for generic versions of previously approved drugs without repeating the extensive testing required for an NDA. *See id.* § 355(j). When submitting an ANDA to the FDA, the generic manufacturer must make one of four certifications for each patent listed in the Orange Book for the reference-listed drug: (1) that no patent information has been filed, (2) that the patent has expired, (3) that the patent will expire on a specific date, 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). *Id.* § 355(j)(2)(A)(vii). If a generic manufacturer makes a Paragraph IV certification in its ANDA, the Hatch-Waxman Act requires that the applicant give 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 by the applicant's proposed generic drug. *Id.* § 355(j)(2)(B). If the ANDA contains a Paragraph IV certification, the patent owner may sue the generic applicant for infringement under 35 U.S.C. § 271(e)(2) within 45 days after receiving notice, which triggers a 30-month stay of FDA approval of the ANDA. *Id.* § 355(j)(5)(B)(iii).[1]

35 U.S.C. § 271(e) defines infringement under the Hatch-Waxman Act with regard to a generic manufacturer's use of a patent for purposes of developing an ANDA and seeking FDA approval. A generic drug manufacturer enjoys a "safe harbor" from infringement suits for use of the patent during development and submission of an ANDA: "It 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

[1] If the patentee does not sue within 45 days, the generic manufacturer can sue "under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5).

information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." § 271(e)(1). 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, § 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 or the use of which is claimed in a patent before the expiration of such patent." 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 Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004) ("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 § 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").

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." *Id.* at 1330. Thus, 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.

B. Procedural Background

Takeda asserts U.S. Patent No. 7,339,064 (the "'064 Patent"), which issued on March 4, 2008 and will expire on July 15, 2020. *See* Compl. ¶¶ 17, 18. The '064 Patent is entitled "Benzimidazole Compound Crystal" and claims crystalline forms of benzimidazole derivatives in a pharmaceutical composition for treating or preventing digestive ulcers. '064 Patent col.1 ll.38-59. Takeda asserts that the '064 Patent claims "hydrate and sesquihydrate crystal forms of dexlansoprazole," which is the active ingredient in Dexilant®. Opp'n at 3-4. The '064 Patent is not currently listed in the Orange Book for Dexilant®. Takeda explains that it has not submitted the required data to the FDA showing that the crystal forms claimed in the '064 Patent are bioequivalent to the crystal form in Dexilant®. *See id.* at 4.

Mylan Pharmaceuticals Inc. submitted ANDA No. 205-205 to the FDA, seeking approval to market a generic version of Dexilant® in 30 mg and 60 mg dosage forms prior to expiration of the '064 Patent. *See* Compl. ¶ 21. In July 2013, Takeda received notice letters from Mylan with a Paragraph IV Certification that certain Takeda Orange Book patents are invalid, unenforceable, and/or not infringed by Mylan's anticipated generic drug. *See id.* ¶¶ 23-25.

Prior to commencing this suit, on August 28, 2013, Takeda filed two separate infringement cases against Mylan, involving other patents related to Dexilant®. *See Takeda Pharm. Co. v. Mylan Inc.*, No. 13-CV-04001-LHK (N.D. Cal.); *Takeda Pharm. Co. v. Mylan Inc.*, No. 13-CV-04002-LHK (N.D. Cal.). In those two cases, Takeda asserted a total of seven other patents listed in the Orange Book, and Mylan counterclaimed against an eighth Orange Book patent. Under the Hatch-Waxman Act, Takeda's assertion of the Orange Book patents triggered an automatic 30-month stay against FDA approval of Mylan's ANDA, which will keep Mylan's product off the market until January 2016 unless Mylan first prevails in these litigations. *See* § 355(j)(5)(B)(iii); Opp'n at 12 n.7. On January 21, 2014, Takeda filed this current suit, asserting the '064 Patent. *See* Compl. ¶¶ 26-27. On February 7, 2014, the Court consolidated these three cases for all purposes. ECF No. 8.[2]

[2] Takeda is also involved in two other sets of lawsuits in this district against other ANDA filers for Dexilant®. *E.g.*, *Takeda Pharm. Co. v. Handa Pharms., LLC*, No. 11-CV-00840-JCS (N.D. Cal.); *Par Pharm., Inc. v. Takeda Pharm. Co.*, No. 13-CV-01927-LHK (N.D. Cal.).

In Count I of the current suit, Takeda asserts a claim against Mylan pursuant to § 271(e)(2) for infringement of the '064 Patent. *See* Compl. ¶¶ 29-31. In Count II, Takeda seeks a declaration pursuant to 28 U.S.C. § 2201 that Mylan will infringe the '064 Patent directly or indirectly under 35 U.S.C. § 271(a), (b), and/or (c). *See id.* ¶¶ 32-38. Specifically, Takeda alleges:

> 36. Pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Defendants' commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the ANDA Products would constitute infringement of the '064 Patent.
>
> 37. Plaintiffs are informed and believe, and thereupon allege, that Defendants' infringing commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the ANDA Products complained of herein will begin following FDA approval of ANDA No. 205-205.

Id. ¶¶ 36, 37. Thus, Takeda seeks a declaration that Mylan will directly or indirectly infringe the '064 Patent when it begins making, using, or selling its generic product in the future, after the FDA approves Mylan's ANDA. Takeda pleaded similar counts for the seven other patents it asserted in the two consolidated cases, but Mylan has not moved to dismiss any of those counts. In this case, however, Mylan now seeks to dismiss Count II for lack of subject matter jurisdiction, or to terminate the automatic 30-month stay against FDA approval of ANDA No. 205-205.

Mylan filed its motion on March 10, 2014. ECF No. 13. On April 14, 2014, Takeda filed an opposition. ECF No. 19-3. On April 24, 2014, Mylan replied. ECF No. 26-4. The Court held a hearing on July 31, 2014.

II. LEGAL STANDARDS

A. Motion to Dismiss Under Rule 12(b)(1)

Generally, dismissal for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) "is a procedural question not unique to patent law," and is therefore governed by regional circuit law. *Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1380 (Fed. Cir. 2002). However, "[w]hether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law." *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1378 (Fed. Cir. 2005), *overruled on other grounds*, 549 U.S. 118 (2007).

A jurisdictional challenge may be facial or factual. *See Safe Air for Everyone v. Meyer*, 373

F.3d 1035, 1039 (9th Cir. 2004). Where the attack is facial, the court determines whether the complaint's allegations are sufficient on their face to invoke federal jurisdiction, accepting all material allegations as true and construing them in favor of the party asserting jurisdiction. *See Warth v. Seldin*, 422 U.S. 490, 501 (1975). Where the attack is factual, "the court need not presume the truthfulness of the plaintiff's allegations." *Safe Air*, 373 F.3d at 1039. In resolving a factual dispute regarding subject matter jurisdiction, a court may review extrinsic evidence beyond the complaint without converting a motion to dismiss into one for summary judgment. *See id.*; *McCarthy v. United States*, 850 F.2d 558, 560 (9th Cir. 1988) (holding that a court "may review any evidence, such as affidavits and testimony, to resolve factual disputes concerning the existence of jurisdiction"). Once a party has moved to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), the opposing party bears the burden of establishing the Court's jurisdiction. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *Chandler v. State Farm Mut. Auto. Ins. Co.*, 598 F.3d 1115, 1122 (9th Cir. 2010).

Generally, if the Court grants a motion to dismiss, leave to amend will be denied only if amendment would unduly prejudice the opposing party, cause undue delay, or be futile, or if the moving party has acted in bad faith. *Leadsinger, Inc. v. BMG Music Publ'g*, 512 F.3d 522, 532 (9th Cir. 2008); *see also Lopez v. Smith*, 203 F.3d 1122, 1127-28 (9th Cir. 2000) (leave should be granted unless "the pleading could not possibly be cured by the allegation of other facts").

B. Declaratory Judgment Jurisdiction

The Declaratory Judgment Act states: "In a case of actual controversy within its jurisdiction . . . any court of the United States . . . 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). A party seeking to base subject matter jurisdiction on the Declaratory Judgment Act bears the burden of showing an "actual controversy." *Crossbow Tech., Inc. v. YH Tech.*, 531 F. Supp. 2d 1117, 1120 (N.D. Cal. 2007). Jurisdiction is proper only where "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) (citing *Md. Cas. Co. v.*

Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)).

Under the Supreme Court's "all the circumstances" test, courts have "unique and substantial discretion in deciding whether to declare the rights of litigants." *Id.* at 136 (internal citations omitted). "[D]istrict 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." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995). Courts must act "in accordance with the purposes of the Declaratory Judgment Act and the principles of sound judicial administration" in exercising discretion over jurisdiction in suits for declaratory judgment. *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed. Cir. 2005) (citation omitted).

III. DISCUSSION

Mylan's motion raises the issue of whether the owner of a pharmaceutical patent may simultaneously assert a claim for infringement under § 271(e)(2) and a claim pursuant to the Declaratory Judgment Act for infringement under § 271(a)-(c). The Federal Circuit has not resolved this issue. Moreover, the Federal Circuit has not addressed the question of whether district courts may exercise jurisdiction over a claim asserting future infringement of a non-Orange Book patent under the Declaratory Judgment Act when such a claim is based solely on the filing of an ANDA by a generic manufacturer. As discussed below, the legal precedent regarding these questions is unsettled. However, even assuming that a sufficiently immediate and real controversy exists for purposes of Count II, the Court exercises its discretion to decline declaratory judgment jurisdiction because Count II is duplicative of Count I and serves no useful purpose in this case.

A. Existence of a Controversy

Mylan argues that "As a matter of law, Takeda's allegations in Count I, preclude declaratory judgment jurisdiction over Count II." Mot. at 6. Mylan contends that there can be no immediate controversy because the 30-month stay lasts until January 2016, trial is scheduled for November 2015, the FDA has not approved Mylan's ANDA, and Mylan has not declared its intent to launch its generic product. *See id.* at 6-7, 9-10. Mylan insists that courts "consistently" dismiss duplicative declaratory judgment claims. *Id.* at 7. Mylan further notes that Takeda's Count II

contains few facts and recites only the bare allegation that Mylan has "made and will continue to make substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import" its generic product prior to expiration of the '064 Patent. Compl. ¶¶ 21-28, 32-38.

In opposition, Takeda argues it is entitled to maintain a declaratory judgment claim simultaneously with a § 271(e)(2) claim. According to Takeda, current precedent establishes that "filing of an ANDA typically provides a sufficient basis to establish a justiciable controversy." Opp'n at 8. Takeda also contends that the filing of the ANDA demonstrates that Mylan has made substantial preparations towards infringement, pointing to certain FDA correspondence (not referenced in or attached to the Complaint). *See* Takahashi Decl. Ex. B (ECF No. 19-4).

Contrary to the parties' representations about established precedent, the case law does not conclusively resolve this dispute. The Federal Circuit has provided some guidance about the relationship between infringement under § 271(e)(2) and infringement under § 271(a)-(c). "The very act of submitting an ANDA is an act of infringement." *Teva Pharms. USA v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007). Generally, infringement suits under § 271(e)(2) should not be "treated any differently than patent infringement suits under 35 U.S.C. § 271(a)." *Abbott Labs. v. Torpharm, Inc.*, 503 F.3d 1372, 1379 (Fed. Cir. 2007). Additionally, the Federal Circuit has advised that if a controversy exists for purposes of declaratory judgment jurisdiction for one party, it necessarily exists for the opposing party: "It logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party." *Teva*, 482 F.3d at 1342.

The Federal Circuit has also analyzed specific circumstances where either the branded or generic manufacturer may bring a declaratory judgment claim to resolve potential infringement. In *Teva*, the Federal Circuit examined whether a generic manufacturer (Teva) who was sued on only one of five Orange Book patents could pursue claims for declaratory judgment of noninfringement under § 271(e)(5) for the four unasserted patents. *Id.* at 1335. The court determined that Teva's ANDA created an immediate controversy under *MedImmune* for all Orange Book patents, and that the branded manufacturer (Novartis) should not be allowed to insulate some of those patents from litigation by choosing not to assert them. The Federal Circuit noted that "[t]here is no question that

under 35 U.S.C. § 271(e)(2), Novartis would have an immediate justiciable controversy against Teva as soon as Teva submitted the ANDA; indeed, that is exactly what occurred in this case." *Id.* at 1342. Moreover, the court listed a combination of circumstances that necessarily establishes declaratory judgment jurisdiction in a Hatch-Waxman case:

> A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.

482 F.3d at 1344. Thus, *Teva* indicates that the filing of an ANDA with a Paragraph IV certification and the assertion of an Orange Book patent always create an immediate and real controversy under *MedImmune*.

Other courts have held that the filing of an ANDA also permits the branded manufacturer to file a § 271(e)(2) claim for patents that are *not* listed in the Orange Book. Indeed, in recent litigation between Takeda and other generic manufacturers regarding Dexilant®, Judge Spero reached this conclusion: "[T]his Court joins a number of other district courts in concluding that there is no requirement under the Hatch-Waxman Act that a patent must be listed in the Orange Book in order for a drug manufacturer to bring an infringement action based on that patent against an ANDA applicant." *Takeda Pharm. Co. v. Handa Pharms., LLC*, No. 11-CV-00840-JCS, 2013 U.S. Dist. LEXIS 74126, at *63 (N.D. Cal. Apr. 8, 2013) (collecting cases).[3]

The handful of district courts that have addressed the propriety of asserting both Hatch-Waxman and declaratory judgment claims for infringement have reached varying results. Some courts have permitted a patentee to maintain declaratory judgment infringement claims against a generic manufacturer. For example, in the District of Delaware, Judge Robinson has addressed similar claims on multiple occasions. In *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, generic manufacturers moved to dismiss the patentee's declaratory judgment claims for indirect

[3] At the July 31, 2014 hearing, Takeda stated that this ruling is currently on appeal to the Federal Circuit, and that Takeda has maintained Count II in this case partly because an adverse ruling on appeal could foreclose Takeda's § 271(e)(2) claim on the '064 Patent, which is not listed in the Orange Book.

infringement under § 271(b) or (c), where the patentee had also filed § 271(e)(2) claims. 629 F. Supp. 2d 338, 350-51 (D. Del. 2009) (Robinson, J.). The court denied the motions, finding a "real and immediate controversy" because "Defendants have filed the ANDA and have declared their intent to manufacture, market, and sell potentially infringing products in the event that the FDA approves the ANDA." *Id.* at 351.

The same court later followed *Watson* in denying a motion to dismiss a patentee's declaratory judgment infringement claims. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 418-19 (D. Del. 2010) (Robinson, J.). In *Cyclobenzaprine*, the branded manufacturer filed both § 271(e)(2) and declaratory judgment infringement counts. Judge Robinson denied the generic manufacturers' motion to dismiss the declaratory judgment claims without prejudice, finding that the ANDA applicant had concealed its intentions by effectively denying access to confidential information in the ANDA. *See id.* at 419.

Then, in *Cephalon, Inc. v. Sandoz, Inc.*, Judge Robinson dealt with a situation where the patentee failed to timely list in the Orange Book two patents that issued after the generic manufacturer filed its ANDA. Civ. No. 11-821-SLR, 2012 WL 682045, at *1-2 (D. Del. Mar. 1, 2012) (Robinson, J.). The generic manufacturer moved to dismiss the infringement claims for those two patents, but the patentee argued that declaratory judgment jurisdiction existed "regardless of whether § 271(e)(2) is applicable to the facts of record." *Id.* at *2. The court agreed with the patentee, finding that the generic manufacturer had notice of the two new patents and had engaged in activities sufficient to create a controversy, concluding: "I do not understand the administrative paradigm of the Hatch-Waxman Act to preclude a patent holder from establishing jurisdiction under 28 U.S.C. § 2201(a)." *Id.* at *5. Thus, Judge Robinson decided that a § 271(e)(2) claim does not prevent a duplicative declaratory judgment infringement claim. *See also Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, No. 08-C-0953, 2009 WL 6337911, at *13-14 (E.D. Wis. Sept. 24, 2009) (finding Article III controversy in connection with an Abbreviated New Animal Drug Application because "FDA may approve the ANADA in the immediate future").

Other courts, however, have declined jurisdiction over similar claims. In another District of Delaware case, then-Magistrate Judge Stark addressed facts nearly identical to those presented

here. *In re Rosuvastatin Calcium Patent Litig.*, MDL 08-1949, 2008 WL 5046424 (D. Del. Nov. 24, 2008) (Stark, M.J.), *adopted by* 2009 WL 87409 (D. Del. Jan. 12, 2009). There, the patentee filed both "a standard ANDA patent infringement action pursuant to § 271(e)" and "a non-ANDA patent infringement declaratory judgment action pursuant to § 271(a)" for an Orange Book-listed patent. *Id.* at *4, 12. Judge Stark acknowledged that there was "no case expressly considering whether both types of actions may be maintained simultaneously," *id.* at *13, but granted defendants' motion to dismiss the declaratory judgment count, citing multiple reasons. First, "[n]othing in the Hatch-Waxman Act appears to contemplate that a patentee, at the same time it pursues the § 271(e) action created for it by the Act, would also pursue an ordinary § 271(a) patent infringement action on the same patent and based on all the same facts." *Id.* Second, there was no immediate controversy because of the pending 30-month stay and the remaining time to trial. *Id.* Third, a § 271(a) action would be "inconsistent with Congressional intent" because "Congress evidently believed that a patentee in AstraZeneca's position did not have a cause of action under § 271(a)." *Id.* at *13. Fourth, the patentee's two counts were duplicative because they would provide identical relief. *Id.* Other district courts have reached similar conclusions about lack of declaratory judgment jurisdiction over claims based only on filing of an ANDA. *See Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 938 (N.D. Ill. 1995) (finding no controversy under pre-*MedImmune* standards due to uncertainty of FDA approval of generic); *Eisai Co. v. Mut. Pharm. Co.*, No. 06-3613, 2007 U.S. Dist. LEXIS 93585, at *62 (D.N.J. Dec. 20, 2007) (dismissing declaratory judgment claims because "[a]t least until the ANDA is approved, however, the controversy is not sufficiently immediate").

Moreover, Judge Spero has already addressed this issue in connection with Takeda's asserted patents—a ruling that the parties omitted from their briefs. In the first wave of cases in this district between Takeda and other generic manufacturers, the parties presented this issue in post-trial briefing. *See Takeda Pharm. Co. v. Handa Pharms., LLC*, No. 11-CV-01609-JCS, 2013 U.S. Dist. LEXIS 187604, at *198-205 (N.D. Cal. Oct. 17, 2013). Takeda asserted a declaratory judgment claim against defendant TWi for infringement of U.S. Patent No. 7,737,282 (the "'282 Patent"), which was not listed in the Orange Book, and TWi contested jurisdiction over this claim.

See id. at *143, 203. Judge Spero discussed some of the case law above, observing that this question "is the subject of considerable disagreement among the lower courts and has not been addressed in any precedential opinion by the Federal Circuit." *Id.* at *200. Noting "the scant record in this case as to the immediacy of the controversy," Judge Spero declined jurisdiction as a matter of discretion because Takeda's declaratory judgment infringement claims were wholly duplicative of its § 271(e)(2) infringement claims. *Id.* at *204-05.[4] Thus, a number of courts have reached different conclusions about jurisdiction over declaratory judgment claims in similar circumstances.

In addition to the foregoing case law, the parties also dispute whether the safe harbor provisions of § 271(e)(1) preclude jurisdiction over Count II. Mylan insists that Takeda cannot establish an actual controversy based on Mylan's activities for preparing its ANDA, *see* Mot. at 8, while Takeda contends otherwise, *see* Opp'n at 14. Again, the case law contains conflicting statements about whether a patentee can cite safe harbor activities as the basis for declaratory judgment jurisdiction over claims regarding anticipated infringement. The *Eisai* court concluded that "[a]ctivities protected by the safe harbor provision cannot serve as the basis for a declaratory judgment of actual future infringement." *Eisai*, 2007 WL 4556958, at *17. In an earlier nonprecedential case, the Federal Circuit reached a similar conclusion, finding that activities under § 271(e)(1) cannot support declaratory judgment claims, reasoning: "To permit Ventritex 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.*, No. 92-1076, 1993 WL 87405, at *4 (Fed. Cir. Feb. 22, 1993). However, more recently, the Federal Circuit suggested a different conclusion: "the protected status of Novopharm's activities leading to its submissions to the FDA does not by itself prevent the district court from considering Glaxo's request for declaratory relief because such relief is directed to the time after the ANDA is approved, when § 271(e)(1) no longer provides a shelter against infringement liability." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997). Notably, *Glaxo* dealt with a

[4] The first-wave cases are currently on appeal to the Federal Circuit. However, at the hearing in this case, Takeda indicated that it does not plan to appeal Judge Spero's decision to decline declaratory judgment jurisdiction over the '282 Patent as to TWi.

"method of making" patent that the patentee could not assert under § 271(e)(2), such that jurisdiction "was necessarily based upon the Declaratory Judgment Act." *Id.* at 1570.

As Judge Spero noted, this issue "implicates important and unresolved questions as to the interaction between the Declaratory Judgment Act and the Hatch-Waxman Act." *Takeda*, 2013 U.S. Dist. LEXIS 187604, at *204. In light of the unsettled precedent above and Judge Spero's prior resolution of the same question, this Court does not decide whether an immediate and real controversy exists. Rather, assuming an immediate and real controversy, the Court declines jurisdiction for the reasons below.

B. Discretion

Even if Takeda has alleged facts sufficient to establish a justiciable controversy, this Court may decline declaratory judgment jurisdiction as a matter of discretion. *See Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008) (citing *Wilton*, 515 U.S. at 289). A district court, when deciding whether to exercise its discretion, should determine whether hearing the case would "serve the objectives for which the Declaratory Judgment Act was created." *Id.* (citation omitted). "The reason for giving this discretion to the district court is to enable the court to make a reasoned judgment whether the investment of judicial time and resources in a declaratory action will prove worthwhile in resolving a justiciable dispute." *Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 672 (Fed. Cir. 1991). "Situations justifying exercise of the court's discretion to issue a declaratory judgment include '(1) when the judgment will serve a useful purpose in clarifying and settling the legal relations in issue, and (2) when it will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding.'" *Id.* at 672-73 (quoting E. Borchard, Declaratory Judgments, 299 (2d ed. 1941)).

Here, the Court finds that exercising jurisdiction over Count II serves no useful purpose and will not resolve any issues that adjudication of Count I will not also resolve. First, permitting Takeda to proceed on Count II appears unnecessary in light of (if not contrary to) the Hatch-Waxman Act. Congress enacted § 271(e)(2) to permit resolution of infringement disputes stemming from the ANDA process. As the Supreme Court explained, "an act of infringement had to be created for these ANDA . . . 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 . . . 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." *Eli Lilly*, 496 U.S. at 678. This suggests that an infringement suit under the Declaratory Judgment Act was not otherwise available to branded manufacturers or—at minimum—is now unnecessary in light of § 271(e)(2). Judge Stark observed in *Rosuvastatin* that "to permit the § 271(a) action to proceed seems to me to be inconsistent with Congressional intent. Congress evidently believed that a patentee in AstraZeneca's position did not have a cause of action under § 271(a)—indeed, the lack of such an action was a motivating factor in creating the § 271(e)(2) action." 2008 WL 5046424, at *13. Furthermore, § 271(e)(2) permits Takeda to pursue theories of indirect infringement. *See Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003) ("[S]ection 271(e)(2) may support an action for induced infringement.").

Second, Count II will not "serve a useful purpose" or "terminate and afford relief from the uncertainty, insecurity, and controversy" here because it is duplicative of Count I. Section 271(e)(4) provides relief for infringement under § 271(e)(2) and permits Takeda to obtain an order delaying the effective date of the FDA's approval of Mylan's ANDA until after expiration of the '064 Patent, along with any appropriate injunctive or monetary relief. *See Eli Lilly*, 496 U.S. at 678 ("Quite obviously, the purpose of (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend."). At the hearing, Takeda stated that Count II offers "extra protection" by providing damages for any actual infringement by Mylan after the FDA approves the ANDA and before final resolution of this litigation. However, § 271(e)(4)(C) states that in connection with a § 271(e)(2) claim, a court may award "damages or other monetary relief . . . if there has been commercial manufacture, use, offer to sell, or sale within the United States . . . of an approved drug . . . ." The parties have not otherwise explained how Counts I and II differ in any material respect for purposes of this litigation, as both involve resolution of whether Mylan's anticipated generic product will infringe the '064 Patent upon FDA approval. *See Glaxo*, 110 F.3d at 1568 (infringement under § 271(e)(2) "focuse[s] on what is likely to be sold following FDA approval"). In declining jurisdiction over a similar claim, Judge Spero found that "resolution

of Takeda's infringement claim under § 271(a) and the Declaratory Judgment Act will not 'serve a useful purpose in clarifying and settling the legal relations in issue' because the Court has already found that it has jurisdiction over Takeda's infringement claims under the Hatch-Waxman Act." *Takeda*, 2013 U.S. Dist. LEXIS 187604, at *204-05. Other district courts have also noted the redundancy of such claims. *See Rosuvastatin*, 2008 WL 5046424, at *13 ("There is no relief Plaintiffs could be awarded by prevailing on Count II that they would not also be able to obtain if they prevail on Count I."); *Watson*, 629 F. Supp. 2d at 351 n.19 (noting "it is not entirely clear to the court why these counts have been included"). Indeed, at the hearing, Takeda stated that it is not appealing Judge Spero's jurisdictional ruling for the '282 Patent because Takeda can obtain all necessary relief in that case from its § 271(e)(2) claim.

As noted above, Takeda indicated that it may need to pursue Count II if the Federal Circuit decides that § 271(e)(2) claims do not apply to patents not listed in the Orange Book, including the '064 Patent. However, Takeda admitted that it could re-file Count II at a later time if necessary. Thus, there is no apparent practical reason for Takeda to maintain Count II at this time.

For these reasons, the Court concludes that investment of judicial time and resources to resolve Count II of Takeda's complaint is unwarranted. Accordingly, Count II is DISMISSED WITHOUT PREJUDICE.

The analysis above also applies to the declaratory judgment counts that Takeda has pleaded against Mylan for the seven additional asserted patents in the two other consolidated cases. *See* Case No. 13-CV-04001-LHK, Compl. ¶¶ 47-53 (Count III); Case No. 13-CV-04002-LHK, Compl. ¶¶ 60-66 (Count VI).[5] At hearing, the Court gave the parties an opportunity to explain why those counts differ from Count II in this case, for purposes of declaratory judgment jurisdiction. The parties did not identify any reason why those counts should not also be dismissed, should the Court dismiss Count II for the '064 Patent. Accordingly, it is further ordered that Takeda's Count III in Case No. 13-CV-04001-LHK and Count VI in Case No. 13-CV-04002-LHK are DISMISSED WITHOUT PREJUDICE. *See Rosuvastatin*, 2008 WL 5046424, at *13 n.14 (dismissing additional

[5] Mylan filed counterclaims for judgments of invalidity and noninfringement of U.S. Patent No. 8,105,626.

declaratory judgment claims under similar circumstances).

Finally, Mylan requests in the alternative that the Court terminate the 30-month stay of FDA approval. Mylan's theory is that the stay prevents an actual controversy, so declaratory judgment jurisdiction cannot exist "unless Takeda wishes to waive the automatic stay." Mot. at 2. Because the Court grants Mylan's partial motion to dismiss Count II, Mylan's alternative request to terminate the stay is DENIED as moot.

IV. CONCLUSION

For the foregoing reasons, the Court declines to exercise declaratory judgment jurisdiction over Count II. Mylan's partial motion to dismiss is GRANTED, and Count II of Takeda's complaint is DISMISSED WITHOUT PREJUDICE. Count III in Case No. 13-CV-04001-LHK and Count VI in Case No. 13-CV-04002-LHK are also DISMISSED WITHOUT PREJUDICE.

IT IS SO ORDERED.

Dated: August 1, 2014

Lucy H. Koh

LUCY H. KOH
United States District Judge