

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**HOFFMAN-LA ROCHE INC.,**

**Plaintiff,**

**v.**

**MYLAN INC., and MYLAN PHARMS. INC.,**

**Defendants.**

**Civil Action Number: 2:09-01692**

**OPINION**

**HON. WILLIAM J. MARTINI**

**MEMORANDUM OPINION**<sup>1</sup>

**I. INTRODUCTION**

On April 8, 2009, Plaintiff Hoffman-La Roche (“Roche”) filed a complaint against Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (“Mylan”) alleging that Mylan infringed United States Patent No. 5,472,949 (the “949 Patent”), (Doc. No. 1-2), and seeking “to enforce its patent rights covering Xeloda® capecitabine 150 mg and 500 mg tablets.” Complaint 2, (Doc. No. 1). Mylan filed an Abbreviated New Drug Application (“ANDA”) No. 90-943 seeking FDA “approval to market a 150 mg and 500 mg generic copy of Roche’s Xeloda® brand capecitabine drug product prior to expiration of Roche’s patent rights.”

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<sup>1</sup> For the convenience of the reader of this document in electronic format, hyperlinks to the Court’s record and to authority cited herein may be inserted. No endorsement of any provider of electronic or other resources is intended by the Court’s practice of using hyperlinks.

Complaint 6. Roche claims this is an act of infringement under [35 U.S.C. §§ 271\(a\)](#), 271 (b), 271(c), 271(e)(2). Complaint 7-9. Mylan claims the ‘949 Patent “is invalid, unenforceable, or would not be infringed by its generic product.” Complaint 6. Mylan has since filed an Answer and Counterclaim, (Doc. No. 16), and an Amended Answer and Amended Counterclaim, (Doc. No. 33). Roche subsequently filed an Answer to Counterclaim, (Doc. No. 19), and an Amended Answer to Counterclaim, (Doc. No. 34).

Before this Court is Plaintiff’s Motion to Dismiss Defendants’ Defenses and Counterclaims Relating to Unasserted Claims 1-5 of the Patent-In-Suit (the “Motion”), (Doc. No. 38 (notice of motion); Doc. No. 38-1 (“Opening Brief”)), Defendants’ Brief in Opposition to Motion to Dismiss All Claims and Defenses Related to Claims 1-5 of U.S. Patent 5,472,949 (“Opposition Brief”), (Doc. No. 46), and Plaintiff’s Reply in Support of its Motion to Dismiss Defendants’ Defenses and Counterclaims to Unasserted Claims 1-5 of the ‘949 Patent-In-Suit (“Reply Brief”), (Doc. No. 49). The matter is fully briefed.

Having considered the parties’ filings, federal statutory law and rules, including local patent rules, case law, and persuasive scholarly authority, the Court, for the reasons elaborated below, will **GRANT** Plaintiff’s Motion to Dismiss.

## **II. CONTENTIONS OF THE PARTIES**

In accordance with a prior scheduling order and local rules, Roche identified only claim 6 as infringed by Mylan’s ANDA (Roche’s “Infringement Contentions”).

Subsequently, Roche provided Mylan with a covenant not to sue (the “Covenant”) for infringement of the remaining claims, i.e., claims 1, 2, 3, 4, and 5 of the ‘949 Patent. Based on the Infringement Contentions and Covenant, Roche argues that the Court is without subject matter jurisdiction to determine any controversy, claims, counterclaims, or defenses involving only claims 1, 2, 3, 4, and 5. Mylan takes the contrary position and argues that the Court retains jurisdiction over claims 1 through 5, i.e., the unasserted claims, notwithstanding the Infringement Contentions and the Covenant.

### III. STANDARD OF REVIEW

The Plaintiff’s motion to dismiss is brought pursuant to the provisions of [Fed. R. Civ. P. 12\(b\)\(1\)](#) (dismissal based on lack of subject matter jurisdiction). In adjudicating a Rule 12(b)(1) motion, “[a court] review[s] only whether the allegations on the face of the complaint, taken as true, allege facts sufficient to invoke the jurisdiction of the district court.” [Common Cause of Penn. v. Pennsylvania, 558 F.3d 249, 257 \(3d Cir. 2009\)](#). “[T]he parties invoking the federal courts’ jurisdiction, bear the burden of establishing their standing.” [Common Cause of Penn., 558 F.3d at 257](#).

“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. When resolving a factual challenge, the court may consult materials outside the pleadings ....”

[Koronthaly v. L'Oreal USA, Inc., Civil Action No. 07-5588, 2008 WL 2938045, at \\*2 \(D.N.J. July 29, 2008\)](#) (citations omitted).

This Court has subject matter jurisdiction both over Plaintiff's patent infringement claims pursuant to [35 U.S.C. 1](#) et seq., [28 U.S.C. §§ 1331](#), 1338(a), and [35 U.S.C. §§ 271](#). This Court has subject matter jurisdiction over Mylan's counterclaims (that is, according to Mylan, albeit this is contested by Roche) seeking declaratory judgment under [35 U.S.C. § 1](#) et seq., [28 U.S.C. §§ 1331](#), 1338(a) and, of course, under the Declaratory Judgment Act, [28 U.S.C. § 2201](#). (Doc. No. 33 at 16.) Since this action arises under the patent laws of the United States, i.e., [35 U.S.C. § 1](#) et seq., the Court must apply the precedents of the United States Court of Appeals for the Federal Circuit, which has jurisdiction over any appeal of this judgment. See [28 U.S.C. § 1295\(a\)](#); [\*Daiichi Sankyo Co., Ltd. v. Mylan Pharms. Inc., Civil Action Nos. 06-3462, 07-3039, 08-2752, 2009 WL 2356879, at \\*5 \(D.N.J. July 30, 2009\)\*](#) (Martini, J.).<sup>2</sup>

#### IV. ANALYSIS

“A party [such as Mylan] seeking to base jurisdiction on the Declaratory Judgment Act bears the burden of proving that the facts alleged, under all the circumstances, show that

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<sup>2</sup> Plaintiff suggests that *Daiichi* is on-point with the instant litigation. But the *Daiichi* opinion does not hold that a covenant not to sue extending only to some, but not all, patent claims divests the Court of jurisdiction of the unasserted claims (and counterclaims thereto). Tellingly, Plaintiff in this litigation does not argue for the application of claim or issue preclusion against Mylan based on *Daiichi*.

there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” [Benitec Austl., Ltd. v. Nucleonics, Inc.](#), 495 F.3d 1340, 1343 (Fed. Cir. 2007) (citing [MedImmune, Inc. v. Genentech, Inc.](#), 549 U.S. 118, 127 S. Ct. 764, 771 (2007)) (quotation marks omitted).<sup>3</sup> Moreover, a case or controversy “must be extant at all stages of review, not merely at the time the complaint [was] filed.” [Benitec](#), 495 F.3d at 1345 (citing [Steffel v. Thompson](#), 415 U.S. 452, 459 n. 10 (1974)); see also [Akzona Inc. v. E.I. du Pont de Nemours & Co.](#), 662 F. Supp. 603, 610 & n.17 (1987) (noting that issue had been left open by *Webb*, but holding that “an actual ‘case’ or ‘controversy’ within the meaning of article III must exist at all times

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<sup>3</sup> The *MedImmune* Court’s test represented a rejection of the Federal Circuit’s prior “reasonable apprehension of suit” or “reasonable apprehension of imminent suit” tests. [Benitec](#), 495 F.3d at 1343 n.2; see also [Indium Corp. of Am. v. Semi-Alloys, Inc.](#), 781 F.2d 879 (Fed. Cir. 1985):

Declaratory judgment jurisdiction under [28 U.S.C. § 2201](#) exists when an examination of the totality of the circumstances indicates that an actual controversy exists between the parties involved. In the case of an action seeking a declaratory judgment of patent invalidity or noninfringement, the actual controversy requirement is satisfied when a defendant’s [that is, the party defending against the declaratory judgment action] conduct has created on the part of the declaratory plaintiff a *reasonable apprehension* that it will face an infringement suit if it commences or continues the activity in question and when the plaintiff has ‘actually produced the accused device’ or has ‘prepared to produce such a device.’

*Id.* at 882-83 (quoting [Jervis B. Webb Co. v. S. Sys., Inc.](#), 742 F.2d 1388, 1398-99 (Fed. Cir. 1984)) (emphasis added).

during the action,” as opposed to only when the suit was first filed).<sup>4</sup>

The Federal Circuit has held that in litigation seeking a declaratory judgment to the effect that a patent is invalid, as Mylan seeks here, “the existence of a case or controversy must be evaluated on a claim-by-claim basis.” [Webb., 742 F.2d at 1399 \(Fed. Cir. 1984\)](#); [PharmaNet, Inc. v. DataSci Ltd. Liability Co., Civil Action No. 08-2965, 2009 WL 396180, at \\*3 \(D.N.J. Feb. 17, 2009\)](#) (Brown, C.J.) (same) (citing *Webb, supra*).<sup>5</sup>

A. Do Roche’s Infringement Contentions Divest the Court of Subject Matter Jurisdiction?

Plaintiff’s complaint alleged that Mylan infringed the ‘949 Patent. The patent encompassed six claims. *See* ‘949 Patent (noting that the patent has “6 Claims, [and] No Drawings”), (Doc. No. 1-2 at 2). It appears that at this stage Plaintiff was asserting that each of the six claims were infringed. (As Mylan notes, Plaintiff’s language to the effect that this Court has been “divested” of jurisdiction in regard to the unasserted claims indicates that the Court had jurisdiction over them, at least, initially.) Subsequent to filing its Complaint, Plaintiff filed, per local patent rules, its Infringement Contentions in which Plaintiff took the position that only claim 6 is at issue. Plaintiff’s position, then, is that although the Court originally had jurisdiction over patent claims 1 to 5 (including counterclaims and defenses

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<sup>4</sup> Prior case law, *expressly* left open whether or not jurisdiction at the start of litigation was a sufficient basis “to sustain the case or controversy requirement to the conclusion of the action ....” [Webb, 742 F.2d at 1398 n.6](#). This issue now appears to be settled.

<sup>5</sup> *See generally* 8 DONALD S. CHISUM, CHISUM ON PATENTS § 21.02[1][d][iii][C], at 21-126 n.255 (2005) (collecting case law).

relating to the unasserted claims), its Infringement Contentions divested the Court of jurisdiction because there is no longer a concrete present controversy in regard to those claims. Opening Brief 5-7. Roche primarily relies on [\*Jervis B. Webb Co. v. S. Sys., Inc.\*, 742 F.2d 1388, 1398-99 \(Fed. Cir. 1984\)](#), and [\*Super Sack Mfg. Corp. v. Chase Packaging Corp.\*, 57 F.3d 1054, 1058 \(Fed. Cir. 1995\)](#). Although both cases have broad language consistent with Plaintiff's position, Mylan correctly points out that neither of these two cases squarely holds that where a party generally alleges that a patent has been infringed or identifies a set of patent claims as infringed but subsequently asserts only that a more limited set of patent claim as being infringed, then the limitation divests the court of jurisdiction with regard to the unasserted (or no longer asserted) patent claims . Furthermore, Mylan points out that Roche's position was rejected by [\*Lear Automotive Dearborn, Inc. v. Johnston Controls, Inc.\*, 528 F. Supp. 2d 654 \(E.D. Mich. 2007\)](#).

Although *Webb* and *Super Sack*, *supra*, are not on-point, other case law is on-point. In [\*Teradyne Inc. v. Hewlett-Packard Co.\*, Civil Action No. 91-0344, 1994 WL 317560 \(N.D. Cal. June 21, 1994\)](#) (Patel, J.), Hewlett-Packard ("HP") alleged that Teradyne infringed HP's '814 Patent. Teradyne counterclaimed that the '814 was invalid or otherwise not infringed. As in the instant litigation, HP did not initially specify which patent claims of the '814 patent had been infringed by Teradyne. Subsequently, HP notified Teradyne that it was only asserting patent claims 3, 9, and 10; and argued that there was no longer a live case or controversy in regard to claims 1 to 2 and 4 to 7, the unasserted claims. Shortly thereafter,

Teradyne brought a summary judgment motion seeking to base invalidity on the unasserted claims. The District Court for the Northern District of California held:

The burden is on Teradyne to establish that such a case or controversy existed at the filing of its request for declaratory judgment and continues to the present time. Since HP is no longer asserting claims 1-2 and 4-7 against Teradyne, *Teradyne must demonstrate that it has a reasonable apprehension that HP will do so in the future; otherwise jurisdiction is lacking.* Teradyne has not attempted to make this showing and indeed it seems likely that HP would be estopped from asserting these claims in the future, now that it has limited its challenge to claims 3, 9 and 10.

Teradyne argues, however, that since claims 3, 9 and 10 all depend from claims 1 and 2 there is still a live controversy with respect to those two claims. Although Teradyne may still attempt to prove that claims 3, 9 and 10 are invalid because they depend on claims 1 and 2, the court does not have power to enter a declaratory judgment that the latter claims are invalid. Therefore, since Teradyne's motion on the invalidity of the '814 concerned only claims that are no longer being asserted against it, that portion of Teradyne's motion is denied for lack of jurisdiction. For the same reasons, the court will only address that portion of Teradyne's non-infringement argument that relates to the claims that Teradyne is currently accused of infringing.

*Id.* at \*3 (emphasis added) (quotation marks and citations omitted). *But see* Opposition Brief 8 n.3 (suggesting that the jurisdictional status of patent claim 1 is in doubt “because claim 6 is a dependent claim that incorporates claim 1”). Although the “reasonable apprehension” has since been superseded by the *MedImmune* test, *see supra* note 3 and accompanying text, it is still clear that the *Teradyne* court took the view that merely because patent claims were at issue in one stage of a litigation, the court can nevertheless become divested of jurisdiction over those particular patent claims, even by a parties' voluntary action to limit the court's jurisdiction. The fact that particular patent claims were put in issue in a complaint or in an early stage of a litigation will not, without more, work to preserve the court's jurisdiction



over those patent claims at every subsequent stage. Furthermore, the position of the *Teradyne* court seems to have been espoused by other courts. *See, e.g., Howes v. Zircon Corp.*, 992 F. Supp. 957, 959-60 (N.D. Ill. 1998) (“As a preliminary matter I hold that I have no jurisdiction to address Zircon’s motion for summary judgment [for noninfringement] on claims 1 or 16 of the ‘578 patent. To be justiciable, there must be a controversy at present and not merely at the time the complaint was filed. The Plaintiffs *no longer allege infringement* of claims 1 and 16 and thus no present case or controversy exists regarding their infringement. Therefore I deny [defendant] Zircon’s motion for summary judgment on claims 1 and 16 because I lack jurisdiction over those claims.” (emphasis added) (citations omitted)); accord *Therma-Tru Corp. v. Peachtree Doors Inc.*, Civil Action No. 89-73028, 1992 WL 332100, at \*4 (E.D. Mich. Feb. 25, 1992), *aff’d in part, rev’d in part on other grounds*, 44 F.3d 988 (Fed. Cir. 1995) (“Where a plaintiff limits its charge of infringement to only some claims of a patent, there is no case or controversy as to the remaining claims.” (citing *Grain Processing Corp. v. Am. Maize-Products Co.*, 840 F.2d 902, 905-06 (Fed. Cir. 1988)) (emphasis added)).

Other courts have held that a claimant’s unilateral action will only divest the court of jurisdiction over the counterclaimant’s declaratory judgment in regard to no-longer or unasserted claims if the claimant, the party alleging infringement, dismisses *all* his discrete patent claims within a given patent, thereby “withdr[awing] the entire patent from controversy.” *Syngenta Seeds, Inc. v. Monsanto Co.*, Civil Action No. 02-1331, 2004 WL

[2790498](#), at \*1 n.1 (D. Del. Nov. 22, 2004); *see also* [F.B. Leopold Co., Inc. v. Roberts Filter Mfg. Co., Inc.](#), Civil Action No. 92-2427, 1995 WL 776945, \*1-2 (W.D. Pa. Aug. 2, 1995) (same).<sup>6</sup>

Although the cases appear to be in conflict, this Court believes that they can be largely, if not entirely, reconciled. In [Jervis B. Webb Co. v. S. Sys., Inc.](#), 742 F.2d 1388 (Fed. Cir. 1984), the United States Court of Appeals for the Federal Circuit explained:

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<sup>6</sup> As explained above, the decision of the District Court for Eastern District of Michigan in *Lear, supra*, seems to support Mylan's position. In *Lear*, plaintiff Lear asserted that Johnson Controls Inc. ("JCI") infringed its patent, and defendant JCI asserted noninfringement and invalidity in regard to patent claims 1 and 4. After the close of discovery, in its opposition brief to JCI's summary judgment motion, Lear made the argument, for the first time, that the Court was divested of jurisdiction over patent claim 1. Lear argued that it had not and would not assert that claim 1 had been infringed by JCI, and furthermore, Lear's counsel made a proffer at oral argument to provide a covenant to that effect, which it subsequently did. [Lear](#), 528 F. Supp. at 669. In this situation, the *Lear* court held:

To the contrary, it is difficult to view Lear's tactics in this case as anything other than an eleventh-hour attempt to pull the jurisdictional rug out from under a counterclaim that it could not defend against on the merits. *The parties having proceeded through discovery without Lear having affirmatively withdrawn its allegation of infringement of claim 1*, and [defendant] JCI having filed a motion seeking summary judgment in its favor as to the invalidity of this claim, the Court believes that it is far too late in the day for Lear to now contend, after JCI's motion has been fully briefed and argued, that the Court should refrain from deciding this matter.

*Id.* at 674 (emphasis added). The fairness considerations which animated the *Lear* court are not at play in the instant litigation. Plaintiff has made no eleventh-hour submission. Roche limited the patent claims in dispute in a written filing well prior to the end of discovery, and at a time consistent with the local rules, and Roche has actively sought to litigate the limitation before proceedings advanced. This opinion responds to Roche's motion, not Mylan's.

Since Webb only asserted and *litigated* the infringement of claims 1, 3, 4, 8, 9 and 11, and *the evidence in the record is inadequate to indicate the existence of a case or controversy regarding the remaining claims in the invalidity declaratory judgment counterclaim*, we vacate that portion of the district court’s holding regarding the invalidity of claims 2, 5-7, 10 and 12.

*Id.* at 1399 (emphasis added).<sup>7</sup> This Court understands the Federal Circuit to mean that when a claimant alleges infringement with regard to a claim within a patent, *and litigates that claim*, its infringement claim creates a live case or controversy<sup>8</sup> under the Declaratory Judgment Act so that a counterclaimant could assert invalidity or noninfringement in regard to that particular patent claim. (In the instant litigation, Roche is seeking *not* to litigate the unasserted claims.) A counterclaimant seeking a declaratory judgment for invalidity or noninfringement can bring a counterclaim in regard to a particular patent claim even if the claimant does not allege infringement in regard to that particular claim, if and only if the counterclaimant could otherwise establish jurisdiction in regard to that particular patent

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<sup>7</sup> Cf. [\*Shelcore, Inc. v. Durham Indus., Inc.\*, 745 F.2d 621 \(Fed. Cir. 1984\)](#) (“Durham asserts that all of the claims of the ‘831 utility patent are invalid under section 103. We disagree. The district court held only claims 1-12 invalid. By voluntarily dismissing with prejudice claim 13 of the ‘831 utility patent, Shelcore removed the issue of *infringement* of claim 13 from the trial court’s consideration. But Shelcore could not *unilaterally* remove the validity issue because Durham’s counterclaim put validity of all the claims in issue.” (emphasis added) (footnotes omitted)). Shelcore’s actions had no unilateral effect to the extent that Durham could otherwise show jurisdiction remained.

<sup>8</sup> The recent shift away from the Federal Circuit’s reasonable apprehension test to the Supreme Court’s *MedImmune* test did not change who has the burden to establish jurisdiction under the Declaratory Judgment Act and when that burden must be met. *See supra* note 3. Thus pre-*MedImmune* Federal Circuit authority remains informative, if not controlling. *MedImmune* changed what the standard is in regard to what a counterclaimant seeking to establish jurisdiction must show, but not in regard to who must make the showing and when that showing must be made.

claim. See [Webb, 742 F.2d at 1399 n.8](#) (noting that a counterclaimant can seek a declaratory judgment on all claims, even if the patentee “asserted the infringement of less than all of the claims where the declaratory plaintiff is [otherwise] able to meet ... the case or controversy requirement”). Nor does this result change if reasonably early in the litigation, a party changes his litigation position from one generally alleging that a patent or all its claims have been infringed to one alleging that only a subset of the claims have been infringed. In regard to those claims that have not been asserted or were never asserted, the counterclaimant seeking a declaratory judgment in regard to the unasserted claims must meet its burden under *MedImmune* and show that a live case or controversy exists and continues to exist on a claim-by-claim basis and at every stage of the litigation. Thus a claimant’s unilateral action to change its litigation position, its decision to no longer assert that particular claims are infringed, does not, standing alone, divest a court of jurisdiction over the counterclaimant’s declaratory judgment relating to the unasserted claims. But once the claimant changes its litigation position, the counterclaimant cannot go forward with its declaratory judgment action in regard to the unasserted claims unless it show the existence of a live case or controversy. If the counterclaimant fails to make the requisite showing, then the court will lack jurisdiction to reach the merits of any invalidity or noninfringement claim connected to those discrete claims. In short, the claimant’s change of position without more does *not* divest the district court of jurisdiction, but should a claimant change its position in this manner, the counterclaimant must otherwise show jurisdiction continues to exist as to those

claims.<sup>9</sup>

Here, Mylan, the counterclaimant argues that Roche's new litigation does not divest the Court of jurisdiction. Mylan is correct as a doctrinal matter. Roche's new litigation position, as put forward in its Infringement Contentions did not, standing alone, divest this Court of jurisdiction over Mylan's counterclaims related to the unasserted claims. But Mylan has failed to make a showing that there is otherwise a live case or controversy as to those claims. Mylan is correct about the doctrinal point, but it appears that it has failed to meet its burden.

Mylan's position is not, as the Court understands it, that had Roche originally served a complaint asserting only claim 6 and continued with that position to date, that the Court would have jurisdiction to hear counterclaims relating to the unasserted claims. Rather, Mylan's position is that once a claimant asserts a particular claim or asserts infringement with regard to a patent in its entirety, then subsequent limitations by the claimant leave the court's jurisdiction unchanged. Such a rule makes little policy sense. It would encourage claimants to make the most limited infringement claims at the opening of litigation and to amend pleadings and contentions to make more expansive infringement claims as the

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<sup>9</sup> See 8 CHISUM, *supra* note 5, at 21-126 to 129 ("The existence of an actual controversy must be evaluated on a patent by patent and claim by claim basis. The patent owner may threaten suit or actually sue for infringement as to specified claims. The accused may respond with a suit or counterclaim for a declaratory judgment of invalidity or noninfringement as to other patents or claims if but only if an actual controversy is found to exist as to those other patents and claims." (footnote omitted)).

litigation progresses. This result would seem to undermine notice pleading and punish parties for presenting alternative (i.e., expansive) theories of liability at early stages in litigation. *Cf. [MedImmune, Inc. v. Genentech, Inc., 535 F. Supp. 2d 1000, 1007 \(C.D. Cal. 2008\)](#)* (“[T]he policy and fairness concerns underlying covenants not to sue do not turn on whether or not a plaintiff initially asserted all or only some claims.”).

B. Does Roche’s Covenant not to Sue Divest the Court of Jurisdiction?

Likewise, Roche argues that Roche’s Covenant not to sue, (Doc. No. 38-4 Ex.A), also divests the Court of jurisdiction to hear Mylan’s counterclaims and defenses relating exclusively to the unasserted claims. The Covenant states, in part, that Roche “irrevocably agrees, promises and covenants not to sue, assert any claims of infringement of, or otherwise enforce or attempt to enforce claims 1 through 5 of the ‘949 patent.” *Id.* at 3. In its moving papers, Roche explains that the covenant “promis[es] that it would not assert claims 1 through 5 against Mylan for the manufacture, use, sale, offer for sale, or importation for the product capecitabine that is the subject of ANDA No. 90-493.” Opening Brief 7; *see also* Reply Brief 1 (“The covenant provides Mylan with full immunity from suit for Claims 1 through 5 of the ‘949 patent under Mylan’s ANDA, regardless of whether the cause of action arises under 35 U.S.C. §§ 271(a), (b) or (c).”); *id.* at 3 (“[T]he covenant is **not** limited to any specific causes of action (*i.e.*, sections 271(a), (b), (c) or (e)(2)) ....” (emphasis in the original)). Statements of counsel at oral argument and in briefs are binding. *See [Super Sack Mfg. Corp., 57 F.3d at 1058](#)* (explaining that a party is bound by the “statement of [its]

counsel in motion papers and briefs”).

“Whether a covenant to sue will divest the trial court of jurisdiction depends on what is covered by the covenant.” [Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 556 F.3d 1294, 1297 \(Fed. Cir. 2009\)](#).<sup>10</sup> As a matter of first impression, the Covenant seems sufficiently broad, at least, to effectuate a voluntary dismissal of Roche’s claims grounded in claims 1 through 5. It would also appear to divest the Court of subject matter jurisdiction of Mylan’s counterclaims and defenses connected exclusively to those claims.

Mylan’s responses are not convincing. *First*, Mylan argues that although the Federal Circuit has held that a covenant not to sue divests a court of jurisdiction over counterclaims, those cases involved a claimant that covenanted not to sue in regard to an entire patent. Opposition Brief 6, 8. In other words, Federal Circuit authority does not specifically address partial covenants. *See* [Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353 \(Fed. Cir. 2008\)](#); [Merck & Co., Inc. v. Apotex, Inc., 287 Fed. Appx. 884 \(Fed. Cir. 2008\)](#). Mylan’s brief correctly restates the holdings of the cases of the Federal Circuit, but Mylan puts forward no principled reason for distinguishing a partial covenant and a covenant covering an entire patent. *See* [Genentech, Inc., 535 F. Supp. 2d at 1008](#) (“The Federal Circuit has not suggested

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<sup>10</sup> Unhelpfully, Roche’s brief argues that “[a] covenant not to sue does not need to cover potentially infringing activities in the future as long as it covers past and present activities that constitute actual controversies between the parties.” Opening Brief 7. *But see* *Teradyne*, Civil Action No. 91-0344, 1994 WL 317560, at \*3. A covenant need not extend to hypothetical or speculative future contingencies, but it must cover “planned [future] activities” in addition to past and present activities otherwise subject to an infringement claim. [Revolution Eyewear, 556 F.3d at 1297](#).

that a different rule should apply where partial covenants are involved.”). *But cf. id.* at 1005 n.1 (“Though *Benitec* and other Federal Circuit cases do not make the distinction, a *partial* covenant not to sue may limit the scope of an invalidity counterclaim [in regard to particular claims] but not the scope of an unenforceability counterclaim [relating to the patent in its entirety].”).

*Second*, Mylan argues that the covenant uses “vague, ambiguous, and [uses] unusual language,” and that Roche’s several filings confusingly change terms, sometimes referring to the “drug capecitabine,” and other times referring to the “product capecitabine.” Opposition Brief 8. Even if this were so, Roche’s counsel stated in its brief:

[T]he covenant is *not* limited to any specific causes of action (*i.e.*, sections 271(a), (b), (c) or (e)(2)), but, instead, reflects Roche’s ‘unconditional and irrevocable’ agreement ‘not to sue assert [sic] *any claim of infringement* of, or otherwise enforce or attempt to enforce Claims 1 through 5 of the ‘949 patent ...’ as it relates Mylan’s ANDA No. 90-493. No exceptions or limitations exist. Thus the covenant covers *all* causes of action related to the subject matter of this litigation – Mylan’s ANDA No. 90-493.

Reply Brief 3 (citation omitted) (emphasis in the original). Because Roche’s counsel has taken the position that the covenant is without “exceptions or limitations,” counsel’s position here and the underlying covenant disposes of Mylan’s argument grounded in alleged ambiguity. Opposition Brief 8. It also would appear to dispose of several other arguments made by Mylan, including: (1) the covenant was not fully effective because it was conditioned on Mylan’s “defenses and [the] ANDA remaining static,” Opposition Brief 9; and (2) the covenant does not include all causes of action in the complaint, *id.*



C. The *Teva* Litigation.

Mylan notes that Roche has brought suit in this Court against Teva for infringement of the '949 patent and Mylan believes that Roche may move to consolidate the two actions. Mylan argues that this is some reason for the Court to retain jurisdiction over the unasserted claims. Opposition Brief 13. Mylan's speculative position as to Roche's future filings, much less what this Court may order in response thereto, is not a substantial basis for this Court to exercise or retain jurisdiction over Mylan's counterclaims – even assuming its predictions come to pass. Moreover, the Court is aware of no policy interest that is furthered by its exercising jurisdiction on the basis of future consolidation. And Mylan puts forward no law on this point.

D. Other Relief Sought By Mylan

Mylan seeks a variety of other relief in its opposition brief. Some of the relief sought relates to discovery. Roche argues that there is no concrete discovery dispute before the Court and so Mylan's request for relief is premature. The Court agrees.

Mylan also argues that if the Court dismisses its counterclaims, it should be without prejudice. As explained, the Court will dismiss Mylan's counterclaims arising exclusively under claims 1 through 5 for lack of jurisdiction. Dismissal based on lack of jurisdiction means that the Court has *not* reached the merits of those claims. As the Third Circuit has explained: "If a court then determines that it lacks subject matter jurisdiction, it cannot decide the case on the merits. It has no authority to do so. A federal court can only exercise that

power granted to it by Article III of the Constitution and by the statutes enacted pursuant to Article III.... The disposition of such a case will, however, be without prejudice.” *In re Orthopedic “Bone Screw” Products Liability Litigation*, 132 F.3d 152, 155 (3d Cir. 1997). It would seem that the same rule would apply to discrete claims: if the Court is without power to hear them, i.e., dismisses for lack of subject matter jurisdiction, its dismissal is without prejudice. *Cf. Winslow v. Walters*, 815 F.2d 1114, 1116 (7th Cir.1987) (holding that “a ruling granting a motion to dismiss for lack of subject matter jurisdiction is not on the merits; its res judicata effect is limited to the question of jurisdiction”).

Finally, Mylan argues that Roche’s infringement claims connected to the unasserted claims should be dismissed with prejudice. Mylan’s argument comes absent case law or any other supporting authority. Opposition Brief 16. Mylan’s protection against future suit from Roche is coextensive with Roche’s covenant, Roche’s Infringement Contentions, and the representation of Roche’s counsel – under various doctrines, including law of the case, judicial estoppel,<sup>11</sup> and once this case goes to final judgment, claim and issue preclusion.<sup>12</sup> If these doctrines are insufficient protection against meritless suit, Mylan has failed to explain why.

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<sup>11</sup> *See Teradyne*, Civil Action No. 91-0344, 1994 WL 317560, at \*3 (“[I]t seems likely that HP would be estopped from asserting these claims in the future, now that it has limited its challenge to claims 3, 9 and 10.”).

<sup>12</sup> *See Webb*, 742 F.2d at 1399.

## V. CONCLUSION

For the reasons elaborated above, the Court holds that no subject matter jurisdiction exists for claims 1, 2, 3, 4, and 5 of the '949 patent; and orders that all claims, counterclaims, and defenses arising exclusively under claims 1, 2, 3, 4, and 5 of the '949 patent are dismissed from this action for lack of subject matter jurisdiction; and, the Court, therefore, **GRANTS** the Motion.

An appropriate order accompanies this memorandum opinion. Although the Court's order constructively amends Roche's pleadings, Roche is **ORDERED** to serve amended pleadings consistent with this opinion, such amended pleadings shall be served within 20 days of the entry of the order filed contemporaneously with this opinion.

s/ William J. Martini  
**William J. Martini, U.S.D.J.**

**DATE: December 9, 2009, 2009**