

[Dkt. Ents. 742, 744, 801, 819]

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

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ASTRAZENECA LP and  
ASTRAZENECA AB,

Plaintiffs,

v.

BREATH LIMITED,

Defendant.

Consolidated Civil Action  
No. 08-1512 (RMB/AMD)

Member cases:

09-1518

09-4115

10-5785

11-3626

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ASTRAZENECA LP and  
ASTRAZENECA AB,

Plaintiffs,

v.

APOTEX, INC. and APOTEX  
CORP.,

Defendants.

**OPINION**

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Plaintiffs,

v.

SANDOZ, INC.,

Defendant.

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ASTRAZENECA LP and  
ASTRAZENECA AB,

Plaintiffs,

v.

WATSON LABORATORIES, INC.

Defendant.

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APPEARANCES

John E. Flaherty, Esquire  
McCarter & English, LLP  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102

and

Denise L. Loring, Esquire  
Michael P. Kahn, Esquire  
Marc A. Cavan, Esquire  
Richard T. McCaulley, Esquire  
Lewis Fogel, Esquire  
Ropes & Gray LLP  
1211 Avenue of the Americas  
New York, New York 10036

And

Mariam Koodhary, Esquire,  
Inhouse Counsel

Attorneys for Plaintiffs  
AstraZeneca, LP and  
AstraZeneca AB

Katherine Ann Escanlar, Esquire  
Saiber LLC  
One Gateway Center, 10<sup>th</sup> Floor  
Newark, New Jersey 07102-5311

and

William A. Rakoczy, Esquire  
Amy D. Brody, Esquire  
Tara M. Raghavan, Esquire  
Heinz J. Salmen, Esquire  
Natasha White, Esquire  
Rakoczy Molino Mazzochi  
Siwik LLP  
6 West Hubbard Street, Suite 500  
Chicago, Illinois 60654

Eric I. Abraham, Esquire  
Christina L. Saveriano, Esquire  
Hill Wallack LLP  
202 Carnegie Center  
Princeton, New Jersey 08543

and

Richard J. Basile, Esquire  
David W. Aldrich, Esquire  
Benjamin J. Lehberger, Esquire  
Erin R. Woelker, Esquire  
Alyson J. DiLena, Esquire  
St. Onge Steward Johnson &  
Reens, LLC  
989 Bedford Street  
Stamford, Connecticut 06905-  
5619

Attorneys for Defendants/  
Counterclaim' Plaintiffs  
Apotex,  
Inc. and Apotex Corp.

Sheila Raftery Wiggins, Esquire  
Duane Morris LLP  
744 Broad Street, Suite 1200  
Newark, New Jersey 07102

and

Taras A. Gracey, Esquire  
Mark H. Remus, Esquire  
Abby Parsons, Esquire  
Steptoe & Johnson LLC  
115 S. LaSalle Street, Suite  
3100

Attorneys for Defendant/  
Counterclaim-Plaintiff Sandoz,

Inc.

Attorneys for  
Defendant/Counterclaim  
Plaintiffs Breath Limited and  
Watson Laboratories, Inc.

**Bumb**, United States District Judge:

Plaintiffs AstraZeneca AB and AstraZeneca LP ("AstraZeneca") and defendants Apotex, Inc., and Apotex Corp. ("Apotex") have filed motions asking the Court to amend or correct its Opinion and Order of Judgment, dated April 1, 2013.<sup>1</sup> [Dkt. Ents. 744, 801.] For the reasons that follow, AstraZeneca's motion is GRANTED and Apotex's motion is GRANTED IN PART and DENIED IN PART. Additionally, defendant Sandoz, Inc. ("Sandoz") has filed a letter advising the Court that its decision not to resolve certain counterclaims of invalidity, in light of its finding of non-infringement, may hamper the progression of the pending appeal. [Dkt. Ent. 819.] The Court therefore DISMISSES these counterclaims without prejudice for the reasons set forth below.

#### **LEGAL STANDARD**

Federal Rule of Civil Procedure 59(e) permits a party to file a motion to alter or amend a judgment "no later than 28 days

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<sup>1</sup> Although the defendants Breath Limited and Watson Laboratories, Inc., originally joined in Defendants' motion for reconsideration [Dkt. Ent. 742], Apotex subsequently filed an amended motion for the same relief, which excluded them. The parties have proceeded as though the original motion was abandoned, and the Court therefore DISMISSES that motion. [Dkt. Ent. 742.]

after the entry of the judgment." In the District of New Jersey, Local Civil Rule 7.1(i) governs motions for reconsideration. Agostino v. Quest Diagnostics, Inc., Civ. No. 04-4362, 2010 WL 5392688, \*5 (D.N.J. Dec. 22, 2010) (citing Bryan v. Shah, 351 F. Supp. 2d 295, 296 n.2 (D.N.J. 2005)). Local Rule 7.1(i) "creates a procedure by which a court may reconsider its decision upon a showing that dispositive factual matters or controlling decisions of law were overlooked by the court in reaching its prior decision." Id. (citing Bryan, 351 F. Supp. 2d at 296 n.2).

The "purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence." Harsco Corp. v. Zlotnicki, 779 F.2d 906, 909 (3d Cir. 1985), cert. den'd, 476 U.S. 1171 (1986) (internal citation omitted). Reconsideration is appropriate if: (1) there has been an intervening change in the controlling law; (2) evidence not available when the Court issued the subject order has become available; or (3) it is necessary to correct a clear error of law or fact or to prevent manifest injustice. Max's Seafood Café v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999) (internal citations omitted).

#### **ANALYSIS**

Apotex asks the Court to reconsider its ruling on certain kit claims and method claims. AstraZeneca asks the Court to clarify its Order of Judgment to specify the asserted claims. In

a letter dated May 30, 2013, Sandoz advised the Court that certain counterclaims remain pending, thus calling into question whether the Court's Order of Judgment constitutes a final judgment for purposes of appeal. The Court considers each issue in turn.

### **1. Kit Claims**

This is a patent infringement action, which culminated in a two-month long bench trial in November and December of 2012. After extensive post-trial briefing, the Court issued a 143-page Bench Opinion and Order of Judgment on April 1, 2013, resolving the case in favor of the defendants. AstraZeneca LP v. Breath Ltd., Civ. No. 08-1512, 2013 WL 1385224, \*4, n.11 (D.N.J. Apr. 3, 2013) (issued under temporary seal on April 1, 2013). AstraZeneca then filed an emergent motion for an injunction pending appeal to preclude the defendants from launching their generic drug products. The Court denied that motion, but in consideration of the significance of the interests at stake, afforded AstraZeneca a ten-day injunction to seek the same relief from the Federal Circuit. On May 24, 2013, the Federal Circuit granted the injunction, without prejudice to the ultimate disposition of the case by a merits panel.

In a footnote within the April 1st Opinion, the Court addressed the parties' dispute as to whether certain kit claims

and counterclaims remained in the case.<sup>2</sup> The Court found that AstraZeneca had withdrawn these kit claims and issued covenants not to sue, which appeared to moot the defendants' counterclaims for a declaratory judgment that the kit claims are invalid. The Court retained its power to revisit the issue upon motion by the defendants, however.

Apotex now argues that AstraZeneca could not withdraw the kit claims from this action because the Court's preliminary injunction decision and the Federal Circuit's opinion affirming that decision firmly determined the invalidity of these claims. Apotex contends, in the alternative, that even if the preliminary injunction decisions did not determine the invalidity of the kit claims, Apotex's counterclaims remained in the case, because AstraZeneca's covenants not to sue did not strip the Court of its jurisdiction over them. Apotex further argues that it proved the invalidity of the kit claims twice, at the preliminary injunction stage and at trial.

Article III of the U.S. Constitution grants federal courts the authority to adjudicate "Cases" and "Controversies." "[A]n 'actual controversy' must exist not only at the time the complaint is filed, but through 'all stages' of the litigation."

Already, LLC v. Nike, Inc., -- U.S. --, 133 S. Ct. 721, 726

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<sup>2</sup> The "kit claims" are claims 29-30 of U.S. patent 6,598,603 (the "'603 patent") and claims 17, 18, 20, 21, and 24-27 of U.S. patent 6,899,099 (the "'099 patent").

(2013) (citations omitted). "A case becomes moot – and therefore no longer a 'Case' or 'Controversy' for purposes of Article III – when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." Id. (internal quotations omitted).

At the outset of this litigation, both parties had standing to pursue their claims. AstraZeneca had standing to sue because Apotex was allegedly infringing its rights under patent law. Apotex had standing to file its counterclaim because AstraZeneca was allegedly pressing an invalid patent to prevent Apotex's legitimate business activity. Id. at 727 (citing MedImmune v. Genentech, Inc., 549 U.S. 118, 126-37 (2007) for the proposition that "a genuine threat of enforcement of intellectual property rights that inhibits commercial activity may support standing").

At the preliminary injunction stage, this Court found the kit claims invalid. The Federal Circuit affirmed. AstraZeneca LP v. Apotex, Inc., 623 F. Supp. 2d 579, 588-92 (D.N.J. 2009), aff'd, 633 F.3d 1042 (Fed. Cir. 2010). AstraZeneca subsequently withdrew its claims of infringement as to the kit claims<sup>3</sup> and gave Apotex a covenant not to sue on these claims. AZ Ex. B, Dkt. Ent. 802-1.

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<sup>3</sup> The Court notes that the parties dispute whether AstraZeneca actually withdrew its claims at the December 2010 hearing. This is a moot point, however, since the critical question is whether Apotex's counterclaims were rendered moot by AstraZeneca's covenant not to sue.

Under the Supreme Court's recent opinion in Nike, AstraZeneca now has the "formidable burden" of showing that it "could not reasonably be expected" to resume its enforcement efforts against Apotex. 133 S. Ct. at 727.<sup>4</sup> If AstraZeneca can show that its covenant not to sue satisfies this burden, then Apotex's counterclaims are moot, and this Court lacks jurisdiction over them. Stated another way, the critical inquiry is "whether the facts alleged, under all the circumstances, show

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<sup>4</sup> AstraZeneca challenges the application of Nike to this case for two reasons. First, because it involved trademark infringement and dilution rather than patent infringement. AZ Opp. Br. 12 (citing Nike, 133 S. Ct. at 727). AstraZeneca points to a case that "questions" whether Nike applies to patent cases, Morvil Tech., LLC v. Medtronic Ablation Frontiers, LLC, Civ. No. 10-2088, 2013 WL 1562520, \*3 (S.D. Cal. April 11, 2013). AZ Opp. Br. 12. In Morvil, the district court simply noted that "even assuming Nike applies to patent cases, it is distinguishable from the present case." Id. The Court is not troubled by this statement. Indeed, the Federal Circuit recently cited Nike in the context of a patent case. In Arkema, Inc. v. Honeywell Intern., Inc., the Federal Circuit relied on Nike for the proposition that a plaintiff's decision not to grant a covenant not to sue suggested that an "active and substantial controversy" existed between the parties. 706 F.3d 1351, 1358 (Fed. Cir. 2013). The Court further notes that Nike addresses Article III standing issues, which are not specific to trademark law.

Second, AstraZeneca contends that Nike does not apply because it invoked the voluntary cessation doctrine, which precludes a party from engaging in unlawful conduct, stopping when sued to have the case declared moot, and then picking up where the party left off. AZ Opp. Br. 12. AstraZeneca contends that "the covenant would preclude AstraZeneca from suing Apotex for infringement of its generic BIS products that are the subject of its ANDA." Id. It seems AstraZeneca is simply arguing the merits - whether its covenant moots the counterclaims - not the propriety of applying the test set forth in Nike. Further undermining AstraZeneca's position is the fact that in its motion to dismiss, it cited Nike for support. Dkt. Ent. 683 at 4-6. Accordingly, the Court rejects these arguments.



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, 549 U.S. at 127.

In Nike, the Supreme Court concluded that the injury, “given the breadth of the covenant, cannot reasonably be expected to recur,” thus mooting the defendant’s counterclaims of invalidity. 133 S. Ct. at 732. Key factors in this determination included: (1) the covenant’s unconditional and irrevocable nature, (2) its prohibition on any claim or demand, (3) the inclusion of the covenant recipient’s distributors and customers, and (4) the breadth of the prohibition covering present and future designs. Id at 728.<sup>5</sup>

By contrast, the covenant here is considerably narrower. It states in relevant part:

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<sup>5</sup> Specifically, the Nike covenant provided:  
[Nike] unconditionally and irrevocably covenants to refrain from making any claim(s) or demand(s) ... against Already or any of its ... related business entities ... [including] distributors ... and employees of such entities and all customers ... on account of any possible cause of action based on or involving trademark infringement, unfair competition, or dilution, under state or federal law ... relating to the NIKE Mark based on the appearance of any of Already's current and/or previous footwear product designs, and any colorable imitations thereof, regardless of whether that footwear is produced ... or otherwise used in commerce before or after the Effective Date of this Covenant.  
Id. at 728 (emphasis in original).

AstraZeneca hereby covenants not to sue [Apotex] for infringement of the Kit Claims, as they now read, by Apotex's budesonide inhalation suspension, 0.25 mg/2ml and 0.5 mg/2ml as described in Apotex's Abbreviated New Drug Application No. 78-202, as approved and as it existed on March 30, 2009 . . . . The covenant does not reach other products or changes to Apotex's budesonide inhalation suspension, 0.25 mg/2ml and 0.5 mg/2ml, or uses of such products, as described in Apotex's ANDA No. 78-202 as approved and as it existed on March 30, 2009.

AZ Ex. B (emphasis added). Unlike in Nike, AstraZeneca's covenant does not state that it is unconditional and irrevocable and does not cover its suppliers, distributors, and customers. Further, and most importantly, it only covers Apotex's Abbreviated New Drug Application ("ANDA") as originally filed with the FDA as of a particular date. Apotex represents that it has already amended or supplemented its ANDA and that the relevant filing date has changed, so the covenant does not even cover its current ANDA.<sup>6</sup> Ap. Moving Br. 11; Ap. Reply Br. 10. AstraZeneca disputes this, responding that Apotex has not explained how any ANDA amendments or supplementations would change its products so as to bring them outside the covenant. AZ Opp. Br 13.

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<sup>6</sup> Apotex also contends that Astrazeneca's covenant does not cover other dosing strengths, such as if Apotex were to seek approval for a 1.0 mg dosage. Apotex has not indicated, however, that it plans to even make such a dosage, thus calling into question whether a substantial dispute exists here or whether such a controversy is merely hypothetical. However, this point is moot, since the Court finds the covenant inadequate on other grounds.

"Whether a covenant not 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) (finding Article III case or controversy where covenant not to sue did not bar future infringement actions if accused infringer again offered for sale the allegedly infringing articles). In Revolution Eyewear, the Federal Circuit applied the Supreme Court's test in MedImmune as set forth in SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372 (Fed. Cir. 2007), holding:

[W]here a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where the party contends that it has the right to engage in the accused activity without a license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights.

Revolution Eyewear, 556 F.3d at 1297 (quotations omitted). The Court "explained that declaratory judgment jurisdiction is met when the patentee 'puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do.'" Id. at 1298 (quoting SanDisk, 480 F.3d at 1381).

Here, Apotex has represented that its ANDA has already been amended since the filing date of March 30, 2009, and since the covenant only provides protection to Apotex's ANDA "as it existed on March 30, 2009," AZ Ex. B, it is clear that Apotex's current

ANDA falls outside the scope of this covenant. Thus, Apotex is in precisely the position described in Revolution Eyewear: it must either pursue arguably illegal behavior in launching its product or abandon its plan to launch, even though Apotex claims a right to do so (on the grounds that the kit claims are invalid).

AstraZeneca points to Medeva Pharma Suisse, A.G. v. Par Pharm., Inc., 774 F. Supp. 2d 691, 698-99 (D.N.J. 2011), where the district judge found that a covenant not to sue on a particular patent deprived the defendant of standing to seek a declaratory judgment on that patent. Medeva is readily distinguishable. First, the parties there did not dispute the adequacy of the covenant. Id. at 699. Second and most importantly, the Medeva covenant identified the protected products as of the date of the covenant, unlike here, where the covenant identifies the protected products as of the filing date of Apotex's ANDA, which according to Apotex has already changed. Id. at 698-99.

Additionally, Apotex expresses legitimate concern that this covenant is "unreliable" because it conflicts with AstraZeneca's exclusive licensing agreement with Teva. That agreement provides that AstraZeneca will not "grant to any Third Party a covenant not to sue with respect to the infringement of AstraZeneca Patents . . . ." AZ Ex. C at 6, § 2.1; Ap. Br. 12. AstraZeneca

responds that (1) Teva does not have "all" rights to bring suit under the '609 and '099 patents, and (2) if Teva brought suit against Apotex, AstraZeneca would be an indispensable party and must be joined, but the covenant not to sue would prevent AstraZeneca from joining the action. AZ Opp. Br. 14 (emphasis in original). Notably, however, AstraZeneca has not addressed the possibility that Teva may sue both the defendants and AstraZeneca. Thus, AstraZeneca, a necessary party, would join the action but would not itself sue the defendants (thereby avoiding violation of the covenant). 7 Wright & Miller, Fed. Prac. & Proc. § 1614 n.31 (3d ed. 2013) (a patent owner who refuses to join as a party but is subject to service of process, may be joined as a defendant).

Based on the above analysis, AstraZeneca has failed to show that it could not reasonably be expected to resume its enforcement efforts against Apotex. Moreover, even if the burden fell on Apotex to establish standing, the Court would still conclude that a case or controversy remains because the covenant does not cover Apotex's current ANDA. Accordingly, Apotex's counterclaims survived AstraZeneca's issuance of the covenant not to sue. Under these circumstances, reconsideration is clearly necessary to correct a clear error of law and to prevent manifest injustice. Max's Seafood Café v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999).

The next question the Court must decide is whether Apotex has proved its counterclaims and established that the kit claims are invalid. Putting aside whether the Federal Circuit's decision at the preliminary injunction stage binds this Court's decision under the law-of-the-case doctrine, see generally Am. Civil Liberties Union v. Mukasey, 534 F.3d 181, 187 (3d Cir. 2008), cert. den'd, 555 U.S. 1137 (2009) ("[W]hen a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case."), the Court sees no reason to alter its prior opinion anyway. The counterclaims present a legal issue, so there was no need for further development of the factual record beyond the record from the preliminary injunction hearing. Since the budesonide drug suspension was known in the prior art, the issue raised by the kit claims was whether the accompanying label, which indicated a regimen of not more than once per day, was entitled to patentable weight. AstraZeneca, 633 F.3d at 1063. Both the Federal Circuit and AstraZeneca characterized this as a legal issue. AstraZeneca, 633 F.3d at 1064 ("[W]hether the asserted claims . . . are invalid for failure to claim statutory subject matter under 35 U.S.C. § 101 is a question of law which we review without deference."); AZ Appellate Br., Ap. Ex. A, Dkt. Ent. 812-1 ("Did the District Court incorrectly resolve the legal issue of whether AstraZeneca's kit claims were invalid as improperly

incorporating 'printed matter' when the District Court relied on In re Ngai, 367 F.3d 1336 (Fed. Cir. 2004) (per curiam) . . . ."). Before issuing its preliminary injunction opinion, this Court ordered supplemental briefing on this issue. The Court further notes that the record from this preliminary injunction hearing is part of the trial record. Fed. R. Civ. P. 65(a)(2) ("Even when consolidation [of the preliminary injunction hearing with the trial on the merits] is not ordered, evidence that is received on the motion [for preliminary injunction] and that would be admissible at trial becomes part of the trial record and need not be repeated at trial.").

AstraZeneca avers that had it known the kit claims were still in the case, it would have taken affirmative steps to adduce evidence at trial to demonstrate their validity. AZ Opp. Br. 16. Since this was a legal issue, however, it is unclear what type of evidence AstraZeneca would have presented. AstraZeneca is silent on this point. In any event, Apotex repeatedly raised this issue before trial, in the Joint Final Pretrial Order and at a pre-trial conference with the Court. Pre-trial Conf. Tr. 14, Dkt. Ent. 644; Joint Final Pretrial Order, Dkt. Ent. 700 at 14. On both occasions, Apotex argued that AstraZeneca's covenants did not moot its counterclaims, which remained in the case. AstraZeneca even addressed the issue in its statement of the case in the Joint Final Pretrial Order.

Dkt. Ent. 700 at 9. The Court thus finds that AstraZeneca was on notice that the counterclaims were still at issue in this litigation.

For the reasons set forth in this Court's preliminary injunction decision and the Federal Circuit's opinion affirming that decision, the Court again finds, as a matter of law, that the kit claims are invalid. AstraZeneca, 623 F. Supp. 2d at 588-91; AstraZeneca, 633 F.3d at 1063-65. The Court therefore enters judgment in favor of Apotex on its counterclaims pertaining to the kit claims.<sup>7</sup>

## **2. Method Claims**

Apotex also moves for reconsideration of the Court's ruling on method claims 6, 11, 18, and 21-23 of the '603 patent (the "method claims"). Throughout the litigation, AstraZeneca maintained that Apotex infringed these claims. Apotex counterclaimed that the method claims were invalid. AstraZeneca included the method claims in its infringement contentions in the Joint Final Pretrial Order. Dkt. Ent. 700 at 5. At trial, AstraZeneca chose to abandon these claims and did not present any evidence to support them. In its Bench Opinion, the Court noted in a footnote that AstraZeneca had conceded the method claims.

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<sup>7</sup> Thus, the Court need not reach Apotex's alternative argument that AstraZeneca's purported removal of jurisdiction over Apotex's counterclaims occurred after the preliminary injunction decisions had already firmly determined the invalidity of the kit claims. Ap. Br. 5.



AstraZeneca LP v. Breath Ltd., Civ. No. 08-1512, 2013 WL 1385224, \*4, n.11 (D.N.J. Apr. 3, 2013) (entered under temporary seal on April 1, 2013). The Court therefore dismissed these claims with prejudice. Id.

Apotex now argues that the Court should enter judgment as opposed to dismissal on the method claims, as the Court did when it granted the defendants' motion for judgment on partial findings under Rule 52(c) as to certain other claims, which AstraZeneca had abandoned at trial. Id. at n.6 (citing Dkt. Ent. 610). Apotex also asks the Court to rule on its counterclaims of invalidity.

As to the first issue, although the Court did not use the word "judgment", it certainly viewed this "dismissal with prejudice" as a final judgment on the method claims, just like its ruling on the other claims AstraZeneca had abandoned at trial. Like those other claims, AstraZeneca included the method claims in the Joint Final Pretrial Order. Dkt. Ent. 700 at 5. The final pretrial order "controls the course of the action unless the court modifies it," Fed. R. Civ. P. 16(d); it effectively supersedes the pleadings and defines the issues for trial.<sup>8</sup> DiNenno v. Lucky Fin Water Sports, LLC, 837 F. Supp. 2d 419, 423 & n.8 (D.N.J. 2011) (citing Basista v. Weir, 340 F.2d

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<sup>8</sup> Generally, prior to the entry of a final pretrial order, "[a] plaintiff who wishes to drop some claims but not others should do so by amending his complaint pursuant to Rule 15." 9 Wright &

74, 85 (3d Cir. 1965)) (collecting cases); see also Mechmetals Corp. v. Telex Computer Prods., Inc., 709 F.2d 1287, 1294 (9th Cir. 1983) (party's attempt to withdraw claims at trial required modification of pretrial order).

Since AstraZeneca never sought to withdraw the method claims from the Joint Final Pretrial Order, these claims proceeded to trial, where AstraZeneca chose to abandon them. In fact, the Court notes that AstraZeneca did not move for reconsideration of the Court's Opinion dismissing these claims with prejudice.

The Court understands Apotex's desire for clarity on this issue, given the many years of vigorous litigation on these claims. To clarify, the Court's Order dismissing the method claims with prejudice effectively represents a final judgment of non-infringement in favor of all of the defendants.

As for Apotex's second argument, the Court must determine whether it should enter judgment on Apotex's counterclaims of invalidity as to the method claims.

The first issue to resolve is whether Apotex had standing to assert these counterclaims at trial. Since the Court has found that AstraZeneca did not withdraw its infringement claims, Apotex's counterclaims of invalidity presented a live case or controversy. Fort James Corp. v. Solo Cup. Co., 412 F.3d 1340, 1348 (Fed. Cir. 2005), cert. den'd, 547 U.S. 1069 (2006) (citing

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Miller, supra, § 2362.

Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 95 (1993)) (“[A] case or controversy adequate to support jurisdiction of a declaratory judgment counterclaim necessarily exists if a party has actually been charged with infringement of a patent.”).

Next, the Court must consider whether the judgment of non-infringement divested the Court of subject matter jurisdiction over Apotex’s invalidity counterclaims. MedImmune, 549 U.S. at 127 (finding that there must be “a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment”); Cardinal Chem., 508 U.S. at 95-96 (holding that appellate affirmance of a non-infringement judgment did not moot trial court’s invalidity judgment but stressing that in the trial court, “of course, a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy”). Federal Circuit jurisprudence, albeit pre-MedImmune, suggests that the Court retains jurisdiction over these invalidity counterclaims. Fort James, 412 F.3d at 1348 (holding that covenant did not moot counterclaim for unenforceability where jury had already returned verdict of non-infringement, because “a counterclaim questioning the validity or enforceability of a patent raises issues beyond the initial claim for infringement that are not disposed of by a decision of non-infringement”). Nevertheless, the judgment of non-infringement

here does seem to extinguish any threat of future enforcement or litigation, and the Court thus questions whether a live case or controversy truly exists concerning these invalidity counterclaims.

The Court need not decide this issue, however, since it declines to exercise jurisdiction over the counterclaims. Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1371 (Fed. Cir. 2004) (“A district court judge faced with an invalidity counterclaim challenging a patent that it concludes was not infringed may either hear the claim or dismiss it without prejudice, subject to review only for abuse of discretion.”) (citations omitted); Cardinal Chem., 508 U.S. at 95 n.17 (“[T]he Declaratory Judgment Act affords the district court some discretion in determining whether or not to exercise that jurisdiction, even when it has been established.”); Wells-Gardner Elec. Corp. v. C. Ceronix, Inc., Civ. No. 10-2536, 2011 WL 1467182, \*3 (N.D. Ill. Apr. 14, 2011) (collecting cases). Here, the non-infringement judgment firmly and clearly resolves the case, and Apotex has not shown how a judgment of invalidity would provide any additional benefit. These counterclaims are therefore dismissed without prejudice.

For these reasons, the Court grants in part and denies in part Apotex’s motion for reconsideration with respect to the method claims.

### **3. Counterclaims of Invalidity of the '834 Patent<sup>9</sup>**

Sandoz has advised the Court that its April 1st Order may not be considered a final judgment because it did not resolve the counterclaims of invalidity for the '834 patent. In the April 1 Opinion, the Court determined that these counterclaims were moot in light of the Court's finding of non-infringement. The Court now clarifies that it declines to exercise jurisdiction over these counterclaims. The Court's non-infringement finding resolves the case. The Court need not expend additional judicial resources in this already extensively litigated case on counterclaims that may, effectively, become moot by the Federal Circuit's decision. The Court therefore dismisses these counterclaims without prejudice.

### **4. Clarification of Order to Identify Specific Claims at Issue**

AstraZeneca asks the Court to clarify its April 1st Order of Judgment to specify the asserted claims at issue in this litigation rather than simply the relevant patents. While the Opinion accompanying that Order specifies the asserted claims, the Court will grant AstraZeneca's request and amend the Order of Judgment to formally specify the asserted claims.

### **CONCLUSION**

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<sup>9</sup> U.S. Patent No. 7,524,834.

For the reasons set forth above, the Court GRANTS AstraZeneca's motion and GRANTS IN PART and DENIES IN PART Apotex's motion. The Court also addresses Sandoz's concerns by dismissing without prejudice the defendants' counterclaims of invalidity of the '834 patent. An Order consistent with this Opinion will issue herewith.

s/Renée Marie Bumb  
RENÉE MARIE BUMB  
United States District Judge