IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC. and MAYNE PHARMA INTERNATIONAL PTY LTD.,	)	
Plaintiffs/ Counterclaim Defendants,	)	
v.	)	Civil Action No. 13-2002-GMS
FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC.,	)	
Defendants/ Counterclaim Plaintiffs.	)	

ORDER

WHEREAS, on December 5, 2013, the plaintiffs Teva Pharmaceuticals USA, Inc. and Mayne Pharma International Pty Ltd. (collectively "Plaintiffs") filed a complaint against defendant Forest Laboratories, Inc. ("Forest Labs") for infringing Plaintiffs' United States Patent No. 6,194,000 ("the '000 patent"). (D.I. 1);

WHEREAS, on April 4, 2014, Forest Labs filed its answer to the initial complaint. (D.I. 9);

WHEREAS, October 29, 2015, Plaintiffs filed their First Amended Complaint adding Forest Pharmaceuticals, Inc. ("Forest Pharma") as a party. (D.I. 99);

WHEREAS, on November 18, 2015, Forest Labs and Forest Pharma (collectively "Defendants") filed an answer to the amended complaint. (D.I. 108);

WHEREAS, presently before the court is Plaintiffs' Motion to Dismiss Defendants' Counterclaim for Invalidity and Motion to Strike Defendants' Fourth and Fifth Affirmative Defenses. (D.I. 115);

WHEREAS, the court having considered the motion, the parties' positions as set forth in their papers, as well as the applicable law;

IT IS HEREBY ORDERED THAT:

Plaintiffs' Motion to Dismiss Defendants' Counterclaim for Invalidity and to Strike Defendants' Fourth and Fifth Affirmative Defenses (D.I. 115) is GRANTED WITH PREJUDICE.[1]

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[1] Teva Pharmaceuticals USA, Inc. and Mayne Pharma International Pty Ltd. (collectively "Plaintiffs") argue that the court should dismiss the counterclaims and new affirmative defenses for invalidity because defendants Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. ("Forest Labs," "Forest Pharma" or collectively "Defendants") failed to obtain leave from the court before significantly amending its answer. (D.I. 116.) According to the Plaintiffs, allowing these counterclaims and affirmative defenses nearly two years into the litigation and after fact discovery has closed would cause prejudice and substantially delay the adjudication of this case. (*Id.* at 13.) Moreover, the Plaintiffs contend that the Defendants have not shown good cause to introduce new invalidity arguments at this late stage. (*Id.* at 12-13.) Specifically, the Defendants have not presented any new facts that might support their new invalidity contentions. In addition, Plaintiffs argue that their amended complaint should be interpreted as a supplemental pleading, governed by Federal Rule of Civil Procedure 15(d). (*Id.* at 10-11.) *See* Fed. R. Civ. P. 15(d).

The Defendants respond that because the Plaintiffs chose to expand the scope of litigation by adding Forest Pharma to the case more than six months after the deadline to join parties and amend the pleadings, Plaintiffs cannot complain when Forest Pharma asserts defenses in response to the new allegations against it. (D.I. 120 at 1.) Additionally, or perhaps in the alternative, the Defendants argue that the November 2015 answer and counterclaims could not have been brought earlier because they depend upon deposition testimony. (*Id.* at 11-12.) As a result, the Defendants claim that they have been diligent in advancing the contentions as the discovery has unveiled them, and leave to amend should be granted. (*Id.*) The Defendants also claim that their affirmative defense of invalidity under § 102 is proper given the nature of Plaintiffs' contentions since this court issued its July 7, 2015 claim construction order. (*Id.* at 9.) The Defendants assert that they now wish to argue that any attempt by the Plaintiffs to read out two of the recently construed claim terms would render the claims invalid under § 102. (*Id.*)

The court must first consider whether the Defendants' Answer and Counterclaims to the First Amended Complaint is correctly characterized as a response to an amended pleading or as a response to a supplemental pleading. *See Sirona Dental Sys., Inc. v. Dental Imaging Techs. Corp.,* No. CIV.A. 10-288-GMS, 2012 WL 3929949, at *2 (D. Del. Sept. 10, 2012). The Plaintiffs would have the court interpret its Amended Complaint as a supplemental pleading. (D.I. 116 at 10-11.) The Third Circuit has found an "amended complaint" to be a "supplemental pleading," where it "refer[red] to events that occurred after the original pleading was filed" rather than to "matters that occurred before the filing of the original pleading but were overlooked at the time." *Owens-Illinois, Inc. v. Lake Shore Land Co.*, 610 F.2d 1185, 1187 (3d Cir. 1979). In *Owens-Illinois*, the plaintiffs sought a declaratory judgment that a valid option agreement for the purchase of certain real property existed between the parties. *Id.* When it became clear that the matter would not be resolved before the option purchase date passed, Owens-Illinois requested and was granted leave to file an amended complaint, adding a request for specific performance. *Id.* The Third Circuit interpreted this as a supplemental pleading. Similarly, in *Sirona*, the plaintiff amended its complaint to add a new defendant after it learned of a series of mergers that occurred after the initial complaint was filed, which lead the court to conclude that Rule 15(d) applied. *Sirona Dental Sys. Inc.*, No. CIV.A. 10-288-GMS, 2012 WL 3929949, at *4. In contrast, in the present case, there was no new event that led to the amendment. Rather, the Plaintiffs simply did not have the knowledge of the subsidiary status of Forest Pharma until late into the litigation because, according to the Plaintiffs, Forest Labs did not state that Forest Pharma was an importer until August 31, 2015. (D.I. 123 at 7.)

Thus, it is apparent that this dispute must be analyzed through the lens of Federal Rule of Civil Procedure 15(a)(3). Fed. R. Civ. P. 15(a)(3). Specifically, the parties contest whether an answer in response to an amended pleading requires leave from the court if it addresses issues outside of the scope of the amended complaint. The

Dated: June 16 2016

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Plaintiffs contend that any additions to the Defendants' answer should have been tailored to address only the changes made in the Amended Complaint. (D.I. 116 at 9.) The Defendants respond that when the Plaintiffs added a new party, the Defendants were permitted to amend the complaint as a matter of course under Rule 15(a). (D.I. 120 at 6.)

The court declines to endorse an interpretation of Rule 15(a)(3) that would "throw the door open to entirely new claims and defenses each time a ministerial amendment was made to a pleading." *Sirona Dental Sys., Inc.*, No. CIV.A. 10-288-GMS, 2012 WL 3929949, at *2 n.3. *See, e.g., Elite Entm't, Inc. v. Khela Bros. Entm't*, 227 F.R.D. 444, 446 (E.D. Va. 2005) ("[T]he moderate, and most sensible, view is that an amended response may be filed without leave only when the amended complaint changes the theory or scope of the case, and then, the breadth of the changes in the amended response must reflect the breadth of the changes in the amended complaint.") Inherent in the Defendants' argument is the assumption that adding a new defendant changed the theory of recovery or expanded the scope and nature of the case. (D.I. 120 at 1.) In this case, the court does not agree. Forest fails to explain why adding Forest Pharma—a wholly owned subsidiary of Forest Labs—expanded the scope of its defenses or claims. (D.I. 123 at 3.) Indeed, the two defendants brought the new claims jointly, and none of the new claims uniquely apply to the new defendant. (*Id.* at 3-4.) The court is not persuaded that adding Forest Pharma as a new defendant expanded the scope of this case. Moreover, one can only assume that Forest Lab was aware of the potential that Forest Pharma would be added to the suit and therefore of the potential for the complaint to be amended in a way that it would be required to defend.

Finally, the court finds that the Defendants' answer to the amended complaint, viewed as an amended pleading, fails to comport with the requirements of Rule 16(b)(4). Federal Rule 16(b)(4) requires good cause to amend a pleading if it does not comply with a deadline set forth in a scheduling order. Fed. R. Civ. P. 16(b)(4) ("A schedule may be modified only for good cause and with the judge's consent."). The court's scheduling order cut off pleading amendments on April 16, 2015. (D.I. 20.) With Forest Labs' consent, Plaintiffs obtained leave from the court to amend their complaint. (D.I. 94.) The Defendants did not obtain leave from the court prior to filing its answer and thereby failed to satisfy the consent requirement. *Sirona Dental Sys., Inc.*, No. CIV.A. 10-288-GMS, 2012 WL 3929949, at *5 (D. Del. Sept. 10, 2012). The Defendants contend that Forest Pharma has shown all the diligence possible for a party because it had just been brought into the action on October 29, 2015 by amendment. (D.I. 120 at 11.) As previously discussed, the court does not buy this argument because it does not see the potential counterclaims and defenses of Forest Pharm as distinct from Forest Labs. Nor does the court find the Defendants' arguments regarding a change in theory as a result of deposition testimony and claim construction sufficient to excuse the procedural shortcomings.

In conclusion, this case is simply too close to trial to add completely new issues without prejudicing Plaintiffs and unduly delaying the litigation. Forest Labs had an opportunity to assert its Section 101 and 102 defenses and counterclaims in its initial answer to Plaintiffs' complaint. Because Plaintiffs' First Amended Complaint made no substantive changes other than adding Forest Pharma as a defendant, Defendants' answer is rightly construed as an amended answer, for which Rule 15(a)(3) requires leave and Rule 16(b)(4) requires good cause. Because the counterclaims are dismissed as untimely, the court need not address whether they are plausibly pleaded.