NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al., **Plaintiffs,** **v.** **PERRIGO COMPANY PLC, et al.,** **Defendants.**	**Civil Action No. 15-1057 (MLC)** **MEMORANDUM OPINION**

This matter comes before the Court upon Defendants Perrigo Company PLC, Perrigo Company and L. Perrigo Company's (collectively "Perrigo") motion seeking leave to amend their Answer, Defenses and Counterclaims in order to add declaratory judgment claims of non-infringement and invalidity as to U.S. Patent No. 6,428,810 (the "'810 patent"). [Docket Entry No. 41]. Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP and Zeneca Inc. (collectively "AstraZeneca") oppose Perrigo's motion. The Court has fully reviewed and considered all arguments made in support of, and in opposition to, Perrigo's motion. The Court considers Perrigo's motion without oral argument pursuant to L.Civ.R. 78.1(b). For the reasons set forth more fully below, Perrigo's motion is GRANTED.

I. Background and Procedural History

This case arises under the Hatch-Waxman Act and involves Perrigo's Abbreviated New Drug Application ("ANDA") No. 207193 seeking approval from the U.S. Food and Drug Administration ("FDA") to market a generic version of AstraZeneca's NEXIUM 24HR® product ("Perrigo's ANDA product" or "Perrigo's generic product"). In response to Perrigo's

ANDA, AstraZeneca filed the instant litigation claiming that Perrigo infringed two of the eight patents listed for NEXIUM 24HR® in the FDA's Orange Book: U.S. Patent No. 6,369,085 (the "'085 patent") and U.S. Patent No. 7,411,070 (the "'070 patent"). AstraZeneca did not assert any claims against Perrigo on the other patents listed in the Orange Book, including the '810 patent even though Perrigo notified AstraZeneca of its Paragraph IV certification that the '810 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Perrigo's ANDA product.

Perrigo filed an Answer in response to AstraZeneca's Complaint on April 1, 2015. (Docket Entry No. 8). As part of its Answer, Perrigo asserted Defenses and Counterclaims against AstraZeneca. However, Perrigo did not assert any Counterclaims against AstraZeneca based on the '810 patent.

On April 10, 2015, the Court set a schedule in this matter, which it coordinated with two additional cases: *AstraZeneca AB, et al. v. Actavis Laboratories FL, Inc., et al*., Civil Action No. 14-7263 (MLC) (the "Actavis matter") and *AstraZeneca AB, et al. v. Andrx Labs, LLC, et al.*, Civil Action No. 14-8030 (MLC) (the "Andrx matter"). (*See* Letter Order of 4/10/2015; Docket Entry No. 18). According to the schedule set by the Court, the deadline for any party to move to amend the pleadings or add parties was September 4, 2015.

Approximately a month and a half after Perrigo filed its Answer, Defenses and Counterclaims, Perrigo, on May 22, 2015, forwarded AstraZeneca a proposed covenant not to sue on the '810 patent, which, as already noted, was listed in the FDA's Orange Book for AstraZeneca's NEXIUM 24HR® product. In prior litigation, AstraZeneca had conceded that another generic company's product did not infringe the '810 patent. *See Dr. Reddy's Laboratories, Ltd., et al. v. AstraZeneca AB, et al.*, Civil Action No. 08-2496 (JAP), Docket

Entry No. 42, ¶ 30). AstraZeneca did not immediately respond to Perrigo's proposed covenant not to sue. Under the circumstances, Perrigo believed that AstraZeneca was "actively considering that approach as a means to resolve the status of Perrigo's ANDA product with respect to the '810 patent." (Perrigo Br. at 4; Docket Entry No. 41).

Having not heard from AstraZeneca and with the deadline for motions to amend looming, on August 24, 2015, Perrigo contacted AstraZeneca to determine whether it would grant Perrigo a covenant not to sue on the '810 patent. (*See* Email from Kenneth Spina to Einar Stole of 8/24/2015; Docket Entry No. 41-6). The parties apparently discussed this issue via telephone on August 26, 2015 at which time AstraZeneca informed Perrigo that it would not grant Perrigo a covenant not to sue on the '810 patent. (*See Id*.) In light of the failure to reach an agreement on the covenant not to sue, Perrigo informed AstraZeneca that it would seek leave to amend its pleading in order to add declaratory judgment claims with respect to the '810 patent and sought to confirm whether AstraZeneca would consent to or oppose such a motion. (*See* Email from David Airan to Einar Stole of 8/28/2015; Docket Entry No. 41-6). On September 1, 2015, AstraZeneca informed Perrigo that it would oppose any attempt by Perrigo to add declaratory judgment counterclaims regarding the '810 patent. Perrigo filed its motion to amend on September 4, 2015 (Docket Entry No. 41) and AstraZeneca, as expected, filed an opposition brief on September 21, 2015. (Docket Entry No. 42). Perrigo replied to same on September 28, 2015. (Docket Entry No. 43).

As already noted, Perrigo seeks to amend its Answer, Defenses and Counterclaims in order to add declaratory judgment claims of non-infringement and invalidity as to the '810 patent. Perrigo argues that these declaratory judgment claims are necessary to assure certainty with respect to the '810 patent. Perrigo argues that under *Teva Pharms. USA, Inc. v. Novartis*

Pharms. Corp., 482 F.3d 1330, 1342-45 (Fed. Cir. 2007), its proposed declaratory judgment counterclaims represent a justiciable controversy, and therefore are not futile. Further, Perrigo contends that it did not unduly delay in seeking to assert its proposed declaratory judgment counterclaims, noting that it moved to do so within the time period set in the Court's scheduling order and within just over a week after learning that AstraZeneca would not agree to a covenant not to sue.

In addition, Perrigo argues that AstraZeneca would not be unfairly prejudiced by its proposed declaratory judgment counterclaims. In this regard, Perrigo claims that the parties and the Court should be able to resolve Perrigo's proposed declaratory judgment counterclaims without extensive discovery or prolonged proceedings. Perrigo argues that AstraZeneca has already tacitly conceded that Perrigo's ANDA product does not infringe the '810 patent when AstraZeneca elected not to bring suit on same. Therefore, Perrigo claims any prejudice to AstraZeneca based on changes to the schedule, discovery burdens, etc. are only theoretical and, consequently, should be afforded no weight. Perrigo further claims that it would be far more burdensome to the Court and the parties for Perrigo's declaratory judgment claims regarding the '810 patent to be heard in a separate action. Given the overlapping subject matter, Perrigo argues it would be far more efficient for all fact and expert discovery, the *Markman* proceeding and a trial relating to AstraZeneca's patents to be handled in one, single action. Perrigo also notes that regardless of whether the '810 action is addressed in this matter or a separate action, it must be addressed. If AstraZeneca charges Perrigo with infringement of the '810 patent, then discovery regarding this patent and a *Markman* hearing will occur. Perrigo argues that there is no reason why it would be more efficient or economic for same to happen in a separately filed case. Perrigo further notes that at the time it moved to amend to assert declaratory judgment

claims based on the ‘810 patent this matter was in its early stages: (1) fact discovery was still in its relative infancy, not set to close until April 17, 2016 and with no depositions having taken place; (2) no expert reports had been exchanged; and (3) no *Markman* briefs had yet to been exchanged. Under these circumstances, Perrigo argues that its motion to amend should be granted under the liberal standards set forth in FED.R.CIV.P. (“Rule”) 15(a)(2).

In contrast, AstraZeneca argues that Perrigo’s motion should be denied. In this respect, AstraZeneca claims that Perrigo unduly delayed in seeking to assert its proposed declaratory judgment counterclaims under the ‘810 patent. AstraZeneca notes that Perrigo could have, but didn’t, assert its proposed declaratory judgment counterclaims in its original Answer. AstraZeneca further notes that Perrigo could have filed its motion to amend at any point between when it filed its original Answer and September 4, 2014, the deadline for filing motions seeking leave to amend and the day Perrigo chose to file its motion. AstraZeneca claims that the delay was solely Perrigo’s fault because while “Perrigo asked AstraZeneca for a covenant not to sue for the ‘810 patent, on May 22, 2015, Perrigo only raised the issue of amending its answer for the first time on August 28, 2015.” (Pl. Opp. Br. at ; Docket Entry No. 42 (citation omitted)).

In addition, AstraZeneca argues that both it and the Court would be unfairly burdened by the addition of Perrigo’s proposed declaratory judgment counterclaims. As such, AstraZeneca urges that Perrigo’s proposed new claims be denied on prejudice grounds. In this regard, AstraZeneca argues that the addition of Perrigo’s proposed declaratory judgment claims will require the Court to conduct two *Markman* proceedings. Indeed, AstraZeneca notes that opening claim construction briefs are scheduled to be filed only 3 days before the return date for Perrigo’s motion to amend. In addition, AstraZeneca claims that if Perrigo is allowed to amend its Answer, Defenses and Counterclaims to assert the proposed declaratory judgment claims, then

that will prompt new discovery requests to be propounded, which will delay the resolution of AstraZeneca's currently pending infringement claims. AstraZeneca notes that this matter has been consolidated for discovery purposes with two other lawsuits and that allowing Perrigo to pursue its proposed declaratory judgment claims here will also undoubtedly cause the resolution of those matters to be delayed as well. As such, AstraZeneca argues that Perrigo should not be permitted to complicate these cases by now asserting claims relating to the '810 patent. Doing so, AstraZeneca argues, "would be akin to beginning an entirely different case anew." (*Id*. at 6). As a result, AstraZeneca claims that the Court should appropriately deny Perrigo's motion based on the significant complexity and costs associated with same, as well as the delay it would cause in resolving AstraZeneca's claims.

II. Analysis

A. Standard of Review

Pursuant to Rule 15(a)(2), leave to amend the pleadings is generally granted freely. *See Foman v. Davis,* 371 U.S. 178, 182 (1962); *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000). Nevertheless, the Court may deny a motion to amend where there is "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment." *Id*. However, where there is an absence of undue delay, bad faith, prejudice or futility, a motion for leave to amend a pleading should be liberally granted. *Long v. Wilson,* 393 F.3d 390, 400 (3d Cir. 2004).

In deciding whether to grant leave to amend, "prejudice to the non-moving party is the touchstone for the denial of the amendment." *Bechtel v. Robinson,* 886 F.2d 644, 652 (3d Cir. 1989) (quoting *Cornell & Co., Inc. v. Occupational Health and Safety Review Comm'n,* 573 F.2d

820, 823 (3d Cir. 1978)). To establish prejudice, the non-moving party must make a showing that allowing the amended pleading would (1) require the non-moving party to expend significant additional resources to conduct discovery and prepare for trial, (2) significantly delay the resolution of the dispute, or (3) prevent a party from bringing a timely action in another jurisdiction. *See Long*, 393 F.3d at 400. Delay alone, however, does not justify denying a motion to amend. *See Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001). Rather, it is only where delay becomes "'undue,' placing an unwarranted burden on the court, or . . . 'prejudicial,' placing an unfair burden on the opposing party" that denial of a motion to amend is appropriate. *Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir. 1984).

Further, a proposed amendment is appropriately denied where it is futile. An amendment is futile if it "is frivolous or advances a claim or defense that is legally insufficient on its face." *Harrison Beverage Co. v. Dribeck Imp., Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990) (internal quotation marks and citations omitted). To determine if an amendment is "insufficient on its face," the Court utilizes the motion to dismiss standard under Rule 12(b)(6) (*see Alvin*, 227 F.3d at 121) and considers only the pleading, exhibits attached to the pleading, matters of public record, and undisputedly authentic documents if the party's claims are based upon same. *See Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

To determine if a complaint would survive a motion to dismiss under Rule 12(b)(6), the Court must accept as true all the facts alleged in the pleading, draw all reasonable inferences in favor of the plaintiff, and determine if "under any reasonable reading of the complaint, the plaintiff may be entitled to relief[.]" *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008 "[D]ismissal is appropriate only if, accepting all of the facts alleged in the [pleading] as true, the p[arty] has failed to plead 'enough facts to state a claim to relief that is plausible on its face[.]'"

Duran v. Equifirst Corp., Civil Action No. 2:09-cv-03856, 2010 WL 918444, *2 (D.N.J. March 12, 2010) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). Put simply, the alleged facts must be sufficient to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009).

Discussion

Here, AstraZeneca does not raise futility as a grounds for denying Perrigo's motion, but, instead, focuses solely on Perrigo's alleged undue delay and the prejudice the Court and AstraZeneca would face if Perrigo was allowed to assert its proposed declaratory judgment counterclaims. Absent an argument to the contrary from AstraZeneca, the Court, like Perrigo, finds that the proposed declaratory judgment counterclaims present a justiciable controversy. As a result, the Court focuses its analysis on whether Perrigo's motion is the product of undue delay or would result in undue prejudice to AstraZeneca or the Court. As described below, the Court finds that neither undue delay nor undue prejudice is present here.

First, the Court finds that Perrigo did not unduly delay in seeking to amend its Answer, Defenses and Counterclaims to assert declaratory judgment claims of non-infringement and invalidity as to the '810 patent. As Perrigo notes and AstraZeneca concedes, Perrigo filed its motion to amend within the deadline set by the Court in its scheduling order, albeit on the last permissible date: September 4, 2015. (Letter Order of 4/10/2015). The Court would find it difficult to hold that a motion filed within the deadline set by the Court and known to the parties was the product of undue delay.

More importantly, however, the Court finds AstraZeneca to be equally responsible for the delay as Perrigo. On May 22, 2015, Perrigo forwarded AstraZeneca a proposed covenant not to

sue on the ‘810 patent. Perrigo’s decision to do so should have put AstraZeneca on notice that Perrigo was seeking to obtain patent certainty with respect to the ‘810 patent. AstraZeneca did not immediately respond to Perrigo’s proposal and the Court finds that it was reasonable for Perrigo to have assumed that was because AstraZeneca was seriously considering same, particularly in light of AstraZeneca’s decision not to pursue claims on the ‘810 patent in a prior litigation. While Perrigo did not specifically raise its intent to seek to amend its Answer, Defenses and Counterclaims to include declaratory judgment claims of non-infringement and invalidity as to the ‘810 patent until August 28, 2015, after AstraZeneca informed Perrigo that it would not agree to the covenant not to sue, the Court is nonplussed by Perrigo’s failure to do so. Indeed, the Court finds that that is an obvious result emanating from AstraZeneca’s rejection of the covenant not to sue, certainly one AstraZeneca should have contemplated. Perrigo had no reason to pursue an amendment when it appeared reasonably possible that AstraZeneca would agree not to sue on the ‘810 patent. As a result, the Court finds that Perrigo did not unduly delay in pursuing its motion to amend.

Second, the Court finds that AstraZeneca will not be unfairly prejudiced if Perrigo is permitted to pursue its proposed declaratory judgment claims in this litigation. In this regard, it is still unclear if AstraZeneca intends to charge Perrigo with infringement of the ‘810 patent. While AstraZeneca certainly intimated as much through its rejection of the covenant not to sue and in its opposition to Perrigo’s motion to amend, AstraZeneca specifically chose not to include claims based on the ‘810 patent in this litigation even though it was listed for NEXIUM 24HR® in the FDA’s Orange Book and even though Perrigo notified AstraZeneca of its Paragraph IV certification that the ‘810 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Perrigo’s ANDA product. Without a definitive

statement from AstraZeneca that it is going to pursue infringement claims against Perrigo as to the '810 patent, there still remains a legitimate question concerning whether Perrigo's assertion of its proposed declaratory judgment claims will have any negative impact on the schedule set in this case, the Court or AstraZeneca.

However, even assuming that there will be, the Court finds that the impact will not unduly burden AstraZeneca or the Court. While the *Markman* briefing in this matter is now underway, that was not true when Perrigo's motion was filed. Further, even considering the fact that the *Markman* briefing is now well underway in this matter, that, in and of itself, does not convince the Court that it would be unduly burdensome to permit Perrigo's amendments. In this regard, it may still be feasible to coordinate any *Markman* briefing regarding the '810 patent with that already filed. Further even if it isn't, the prospect of having two *Markman* hearings in this case, while not ideal, is not so burdensome as to convince the Court that Perrigo's proposed amendments would be prejudicial. Indeed, denying Perrigo's motion would not eliminate the Court's need to conduct a second *Markman* hearing to address the '810 patent. It would just cause that hearing to be conducted in a separately filed matter. Given the overlapping issues involved with the '810 patent and the patents currently in suit, the Court finds the prospect of a separately filed action to be more burdensome than conducting additional proceedings here. This is particularly true in light of the fact that discovery in this matter is still in the early stages and is not set to close until April 17, 2016.

Further, while the Court agrees that the resolution of this matter, and potentially the other two with which it is consolidated for discovery purposes, may be delayed by the addition of Perrigo's declaratory judgment claims, should AstraZeeca pursue infringement claims against Perrigo on the '810 patent, the Court sees no reason to believe that any such delay will be

significant. As already stated, the schedule in this matter remains in its early stages. The parties should be able to bring discovery on the '810 patent up to speed relatively quickly. Further, as also already noted, AstraZeneca is in part responsible for any delay caused by the addition of Perrigo's declaratory judgment claims. AstraZeneca did not promptly reject Perrigo's proposed covenant not to sue. Had it, Perrigo's motion, though timely when filed, may have been made months earlier. Under these circumstances, the Court finds that Perrigo has satisfied the liberal standards set forth in Rule 15(a)(2). As a result, Perrigo shall be permitted to amend its Answer, Defenses and Counterclaims to assert declaratory judgment claims of non-infringement and invalidity as to the '810 patent.

III. Conclusion

For the reasons set forth above, Perrigo's motion to amend is GRANTED. An appropriate Order follows.

Dated: December 8, 2015

s/ Tonianne J. Bongiovanni
HONORABLE TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE