IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. 2:15-cv-1455-WCB
	§	
TEVA PHARMACEUTICALS USA, INC., et al.,	§	
	§	
	§	
Defendants.		

MEMORANDUM OPINION AND ORDER

Before the Court is the motion of defendant Teva Pharmaceuticals USA, Inc., ("Teva") to amend its answer and counterclaims to raise the issues of inequitable conduct and unclean hands. Dkt. No. 189. The motion was briefed by the parties and argued during a telephonic hearing conducted on January 11, 2017. The Court DENIES the motion.

BACKGROUND

This case was filed on August 15, 2015. Dkt. No. 1. Teva filed its original answer and counterclaims on October 26, 2015. Dkt. No. 40. Teva did not at that time assert the defenses of inequitable conduct and unclean hands, nor did it assert a counterclaim for a declaratory judgment of inequitable conduct.

On February 18, 2016, the plaintiff, Allergan, Inc., filed an amended complaint adding a newly issued patent. Dkt. No. 96. Teva filed an amended answer and counterclaims in response to the amended complaint on March 11, 2016. Dkt. No. 99. Again, however, Teva did not add the defenses of inequitable conduct and unclean hands, or a counterclaim for a declaratory judgment of inequitable conduct.

The deadline for amending pleadings set forth in the Docket Control Order, Dkt. No. 76, was June 9, 2016. Teva did not file an amended answer and counterclaim by that date seeking to add defenses of inequitable conduct and unclean hands, or a counterclaim of inequitable conduct. Four months after that deadline, on October 21, 2016, Teva filed the present motion seeking leave to amend its answer and counterclaims to add the defense of unclean hands and the defense and counterclaim of inequitable conduct. Dkt. No. 189. Defendants Akorn, Inc.; Mylan Pharmaceuticals, Inc.; Mylan, Inc.; Innopharma, Inc.; and Famy Care Limited have joined Teva's motion. Dkt. Nos. 224, 229, 232, and 234. Allergan opposes that motion on the ground that the motion is untimely and that no adequate justification has been given for the amendment. Dkt. No. 194.

Teva's assertions of inequitable conduct and unclean hands are predicated on what it describes as its recent discovery of "strong evidence that Allergan defrauded the U.S. Patent and Trademark Office in order to obtain allowance of the patents in suit." Teva's Motion for Leave to Amend Answer and Counterclaims ("Teva's Motion to Amend"), Dkt. No. 189, at 1. In late 2013, the inventors filed a set of continuation applications that claimed, inter alia, the ophthalmic emulsion at issue in this case. The examiner rejected four of the applications as obvious over U.S. Patent No. 5,474,979 to Ding.

In response to the examiner's rejection of the applications' claims as obvious in light of Ding, the inventors submitted argument and declarations purporting to show that the claimed ophthalmic emulsion produced surprising and unexpected results. The two declarations on which the inventors relied in claiming that their ophthalmic emulsion had surprising and unexpected results were a declaration by Dr. Rhett M. Schiffman dated October 11, 2013

("Schiffman Declaration"), Dkt. No. 195-3, and a declaration by Dr. Mayssa Attar, dated October 14, 2013, Dkt. No. 195-2.

According to Teva, "the data and statements used to demonstrate unexpected results were, in fact, plagiarized from an article that had appeared in a well-known medical journal *over a decade earlier*, and those data and statements from the article were themselves derived from Allergan's own clinical trial data." Teva's Motion to Amend at 1 (emphasis in original). The article from which Teva claims Allergan plagiarized data is Sall et al., Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease, 107 Ophthalmology 631 (April 2000) ("Sall Article"), Dkt. No. 195-1. According to Teva, because the data and statements relied on by the inventors were taken from that 13-year-old article, the results Allergan presented to the PTO "were not 'unexpected' at all—and Allergan knew it." Teva's Motion to Amend at 1.

Following Allergan's submission of the declarations and the arguments of the prosecuting attorney based on those declarations, the examiner found that the inventors had overcome the obviousness rejection. The examiner then issued a notice of allowance for the claims of the four applications that had previously been rejected. Those applications issued as U.S. Patent Nos. 8,629,111; 8,633,162; 8,642,556; and 8,648,048. The examiner later issued a notice of allowance for a fifth application, which issued as U.S. Patent No. 8,685,930. Two years later, the PTO issued the last of the six related patents in suit, U.S. Patent No. 9,248,191. Teva argues that the misleading declarations and argument regarding unexpected results were plainly material to patentability, because it was those declarations and arguments that caused the examiner to withdraw the rejection and allow the six patents at issue in this case.

Allergan responds that the inventors and the prosecution counsel did not engage in deceptive conduct in dealing with the PTO. Allergan explains that the data set forth in the Schiffman Declaration were derived from Allergan's Phase 3 Study for Restasis, which was conducted in the late 1990s. The Sall Article was also based on that Phase 3 Study. Therefore, according to Allergan, it is not surprising that both the Schiffman Declaration and the Sall Article contained the same data and used some of the same Figures.

Allergan argues that there is no evidence that it attempted to deceive the examiner by concealing the relationship between the Sall Article and the Schiffman Declaration. The Sall Article was cited in the common specification of the six patents in suit and produced for the examiner during prosecution. In fact, the Sall Article was incorporated by reference in each of the patents and is cited in the "Background of the Invention" as "Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease. *CsA Phase 3 Study Group*." See, e.g., U.S. Patent No. 8,629,111, col. 1, ll. 48-52 (emphasis added).. Moreover, Allergan argues, a simple comparison of the data in the Schiffman Declaration and the Sall Article makes clear that Schiffman and Sall both report the same data, and that four of the figures attached as exhibits to the Schiffman Declaration are essentially identical to the four figures found in the Sall Article. Compare Sall Article, Dkt. No. 195-1, at 635-36, Figures 1-4, with Schiffman Declaration, Dkt. No. 195-3, Exhibit D, Figures 1-4. Accordingly, it would have been apparent to the examiner that the data came from the same source.

Allergan argues that documents in the case record show that Teva was aware of the similarities between the Sall Article and the Schiffman Declaration—and that both were based on the Allergan Phase 3 Study for Restasis—at least as early as a year ago. Nonetheless, Teva

waited until well after the deadline for amending the pleadings to move to amend its answer and counterclaims. Allergan argues that Teva's motion should be denied in light of that unjustified delay.

DISCUSSION

Under Rule 15(a)(1), Fed. R. Civ. P., a party may amend a pleading once as a matter of course more than 21 days after service of the original pleading or a responsive pleading or a motion under Fed. R. Civ. P. 12(b), (e) or (f). After that, a party may amend a pleading only with the opposing party's consent or leave of court. Fed. R. Civ. P. 15(a)(2). Leave of court is to be freely granted "when justice so requires." Fed. R. Civ. P. 15(a)(2).

Once a scheduling order has been entered in the case and a deadline has been set for filing amended pleadings, the decision whether to permit a post-deadline amendment is governed by Fed. R. Civ. P. 16(b). See Squyres v. Heico Cos., L.L.C., 782 F.3d 224, 237 (5th Cir. 2015); EEOC v. Serv. Temps Inc., 679 F.3d 323, 333-34 (5th Cir. 2012); S&W Enters., LLC v. Southtrust Bank of Ala, N.A., 315 F.3d 533, 535 (5th Cir. 2003); L.G. Motorsports, Inc. v. NGMCO, Inc., No. 4:11-cv-112, 2013 WL 2543398, at *6 (E.D. Tex. June 6, 2013). Under Rule 16(b)(4), Fed. R. Civ. P., a motion to modify the scheduling order by permitting the filing of an amended pleading after the deadline in the scheduling order may be granted "only for good cause and with the judge's consent."

The party seeking to modify the scheduling order has the burden to show good cause. Squyres, l782 F.3d at 237; Self v. Quinn's Rental Servs. (USA), LLC, Civil Action No. H-15-1569, 2016 WL 6835093, at *1 (S.D. Tex. Nov. 21, 2016). The Fifth Circuit has held that Rule 16 gives trial courts "broad discretion to preserve the integrity and purpose of the pretrial order" in making the "good cause" determination. Geiserman v. MacDonald, 893 F.2d 787, 790 (5th

Cir. 1990) (quoting Hodges v. United States, 597 F.2d 1014, 1018 (5th Cir. 1979)).[1] The Fifth Circuit, moreover, has directed that in deciding whether to permit amendments to the pleadings after the deadline for such amendments, district courts should consider "(1) the explanation for the party's failure to [timely move for leave to amend]; (2) the importance of the [amendment]; (3) potential prejudice in allowing the [amendment]; and (4) the availability of a continuance to cure such prejudice." United States ex rel. Bias v. Tangipahoa Parish Sch. Bd., 816 F.3d 315, 328 (5th Cir. 2016) (quoting S&W Enters., 315 F.3d at 536 (alterations in original)); Filgueira v. U.S. Bank Nat'l Ass'n, 734 F.3d 420, 422 (5th Cir. 2013); Ciena Corp. v. Nortel Networks, Inc., 233 F.R.D. 493, 494 (E.D. Tex. 2006). The Court will consider each of those factors in exercising its discretion whether to grant the motion to amend.

1. Teva's Explanation for Its Untimely Motion to Amend

The most important factor bearing on the "good cause" inquiry under Rule 16(b)(4) is whether the party seeking to modify the scheduling order can show that it has been diligent in pressing its claims but despite its diligence could not reasonably have met the scheduling deadline. See Wachovia Bank, Nat'l Ass'n v. Schlegel, Civil Action No. 3:09-cv-1322, 2010 WL 2671316, at *2 (N.D. Tex. June 30, 2010). The Wright and Miller treatise notes that "many more motions seeking modification of scheduling orders are denied than are granted," and that "the good-cause standard will not be satisfied if the court concludes that the party seeking relief (or that party's attorney) has not acted diligently in compliance with the schedule." 6A Charles

[1] Although this case is subject to the appellate jurisdiction of the Federal Circuit, the issue of whether to grant an untimely motion to amend the complaint is a procedural question not specific to patent law or bearing on substantive patent law issues, so the law of the regional circuit—in this case the Fifth Circuit—applies to this issue. See Creative Compounds, LLC v. Starmark Labs., 651 F.3d 1303, 1309 (Fed. Cir. 2011); Ultimax Cement Mfg. Corp. v. CDTS Cement Mfg. Corp., 587 F.3d 1339, 1354 (Fed. Cir. 2009); Optivus Tech., Inc. v. Ion Beam Applications S.A., 469 F.3d 978, 985 (Fed. Cir. 2006); Kalman v. Berlyn, 914 F.2d 1473, 1480 (Fed. Cir. 1990).

Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice & Procedure § 1522.2, at 322 (3d ed. 2010) (citing numerous cases); see also, e.g., Cub USA Servs., LLC v. Jetta Operating Co., Civil Action No. 3:14-cv-2508-D, 2016 WL 1028128, at *2 (S.D. Tex. Mar. 15, 2016) ("the court usually denies motions to amend the scheduling order when the moving party fails to demonstrate that, despite its diligence, it could not have reasonably met the scheduling deadline").

Teva's explanation for its untimely amendment is insufficient to justify its belated filing. Although Teva contends that it did not have critical information about Allergan's allegedly fraudulent conduct until recently, the evidence does not support that contention.

As Allergan points out, Teva was aware of the facts underlying its motion at least four months before the deadline to amend its pleadings. Allergan points to the following evidence of Teva's knowledge:

In its invalidity contentions, dated January 29, 2016, Teva noted that

> the same clinical trial presented by the Schiffman Declaration and the purported "unexpected" results were reported in Sall, which was published more than three years before the earliest priority date of the '556 patent. A comparison of Figures 1-4 of the Schiffman Declaration Exhibit D with Sall's Figures 1-4 demonstrates that Sall reported the same data presented in the Schiffman Declaration. The near identity of Sall's Figures and the Exhibit D Figures demonstrates that both Sall and the Schiffman Declaration set forth results from the same Phase 3 clinical trial.

Defendants' Preliminary Joint Invalidity Contentions, Dkt. No. 196-1, at 51. See also id. at 137 ("[T]he [Schiffman] data appear to be taken directly from the prior art Sall publication, because the data provided show the exact same numerical results arranged in the exact same way as the data in Sall Figures 1-4."). Teva made the same representations in its Abbreviated New Drug Application notice sent to Allergan on February 24, 2016. Dkt. No. 194-1, at 35.

In light of those representations, there is no force to Teva's statement in its motion that it only "recently discovered that the data in Dr. Schiffman's declaration was plagiarized from [the Sall Article] and that [the Sall Article] in turn sourced those data from Allergan's own clinical trials conducted in the late 1990s." Dkt. No. 189, at 6. In its reply brief, Teva argues that it knew in early 2016 of the Schiffman Declaration and Sall Article, and it therefore had a basis to contend that Sall anticipated the patents' claims and that the results in the Schiffman Declaration "were not in fact unexpected." Teva's Reply in Support of Motion for Leave to Amend Answer and Counterclaim, Dkt. No. 201, at 2. However, Teva claims that what it did not know in early 2016 was that Allergan's New Drug Application ("NDA") for Restasis, when compared to the Sall Article and Schiffman Declaration, revealed that Dr. Schiffman "copied the figures" from the Sall Article "and then nonetheless represented that those results were unexpected in view of the prior art." Id. Teva contends that it was this comparison to "the underlying data from Allergan's NDA (which was produced during discovery) . . . that gave Teva the basis for its inequitable conduct claims." Id.

Teva's attempt to show diligence by tying its knowledge to its examination of the NDA does not work. For one thing, Teva admits that, independent of the NDA, it "recognized in early 2016 that (1) Allergan overcame the PTO's obviousness rejections using Dr. Schiffman's declaration and (2) that Sall contained conclusions very similar to those found in the declaration." Id. Teva's preliminary invalidity contentions, recited above, establish that it also knew in early 2016 that the data in the Schiffman Declaration, like the data in the Sall Article, were drawn from the same Allergan Phase 3 Study and that several of the figures in the Schiffman Declaration were almost identical to corresponding figures in the Sall Article. Teva therefore did not need the information in Allergan's NDA to allege that Dr. Schiffman "copied

the figures" from the Sall Article, or at least the figures were based on data from the same source.

While acknowledging that in early 2016, it was aware that the data in the Sall Article and in the Schiffman Declaration came from the same source, Teva contends that it did not know at that time that Dr. Schiffman "plagiarized" several of the figures used in his declaration from the Sall article. But it remains unclear to the Court why it matters whether Dr. Schiffman took his data from the Sall article or from the Allergan Phase 3 Study from which the Sall Article also derived its data. In either case, it is clear that some, but not all, of the information relied on by Dr. Schiffman in his declaration was disclosed in the Sall Article. That information was in the prior art, and thus has the same effect on the issue of patentability whether Dr. Schiffman took the information directly from the Sall Article or not.

The Court is also skeptical of Teva's claim that it was improper for Dr. Schiffman's to "plagiarize" the figures from the Sall Article without revealing the source of those figures to the PTO. Dr. Schiffman was listed in the Sall Article as a member of the Cyclosporin A Phase 3 Study Group, and the Study Group was listed among the co-authors of the Sall Article. See Dkt. No. 195-1, at 631, 638. Accordingly, it hardly seems accurate to charge Dr. Schiffman with plagiarizing data from an article he is credited with co-authoring.

Moreover, even if Teva's statements in January and February 2016 had not already made clear that Teva recognized the relationship between the Phase 3 Study, the Sall Article, and the Schiffman Declaration, that relationship was obvious on its face, and was not hidden from the examiner. In fact, like Poe's purloined letter, the evidence that Teva claims to have extracted through great effort from a complex tangle of prosecution history was actually sitting in plain view all along.

As noted, the Sall Article was incorporated by reference in each of the applications and was cited with the title "Two Multicenter, Randomized Studies . . . CsA Phase 3 Study Group," so it was hardly concealed from the examiner. The article made clear that the Cyclosporin A Phase 3 Study on which the article reported was sponsored by Allergan, and as noted, Dr. Schiffman was involved in its authorship. The Schiffman Declaration, moreover, made clear that it was based on Allergan's Phase 2 and Phase 3 Studies for Restasis. Thus, the links between the Phase 3 Study, the Sall Article, and the Schiffman Declaration were obvious.

As for the figures in the Schiffman Declaration, the near identity between Figures 1-4 of the Sall Article (which were the only four figures in the Article), Dkt. No. 195-1, at 635-36, and Figures 1-4 of Exhibit D of the Schiffman Declaration, Dkt. No. 195-3, Exh. D, at 21-22, is immediately apparent upon even the most cursory examination of the two documents. Even without the evidence that Teva had already made those connections, a reasonably diligent examination of the important materials in the case would have made that connection evident.

In sum, given what Teva knew or should have known by February 2016, the Court concludes that Teva did not act with reasonable diligence when it failed to amend its answer and counterclaims to add the defenses of inequitable conduct and unclean hands and the counterclaim of inequitable conduct by the June 2016 deadline for amending the pleadings. The materials in Teva's possession before that time should have prompted it to explore its theories of inequitable conduct and unclean hands long before October 2016. See Millennium Partners, L.P. v. Colmar Storage, LLC, 494 F.3d 1293, 1298-99 (11th Cir. 2007) (defendant failed to demonstrate good cause for seeking to raise a defense after the district court's scheduling order deadline when the evidence showed that the defendant, "with some investigation," could have discovered the defense. "The fact that [the defendant] failed to conduct such investigation does not equate to

'good cause' for leave to amend under Rule 16 . . . ."); Carrier Corp. v. Goodman Global, Inc., 49 F. Supp. 3d 430, 433 (D. Del. 2014); Perfect Pearl Co. v. Majestic Pearl & Stone, Inc., 889 F. Supp. 2d 453, 458-59 (S.D.N.Y. 2012); Transamerica Life Ins. Co. v. Lincoln Nat'l Life Ins. Co., 590 F. Supp. 2d 1093, 1101-03 (N.D. Iowa 2008). As Judge Hittner observed in Ruiz v. University of Texas M.D. Anderson Cancer Center, 291 F.R.D. 170, 172 (S.D. Tex. 2013), district courts within the Fifth Circuit have repeatedly held that if a party was "previously aware of the factual underpinnings of the claim she seeks to assert beyond the time allowed by a scheduling order, leave to amend is improper." See also, e.g., Info-Power Int'l, Inc. v. Coldwater Tech., Inc., No. 3:07-CV-0937-P, 2008 WL 5552245, at *3 (N.D. Tex. Dec. 31, 2008) ("[T]he court may deny the motion [for leave to amend] if the movant knows or should have known of the facts upon which the proposed amendment is based but fails to include them in the original [answer]."); Am. Tourmaline Fields v. Int'l Paper Co., No. 3:96-CV-3363-D, 1998 WL 874825, at *1 (N.D. Tex. Dec. 7, 1998) (same).

Accordingly, the Court concludes that the "due diligence" factor cuts strongly against granting the motion to amend.

2. The Importance of the Amendment

Teva argues that allowing it to amend its answer and counterclaims is of critical importance because the claim and defenses of inequitable conduct and unclean hands, if successful, would dispose of much if not all of the case. Of course, it is frequently true that success on the defenses of inequitable conduct or unclean hands would end a patent infringement action. But that is not to say that an amendment raising such defenses or counterclaims must invariably be regarded as important. What is called for in assessing the importance of the amendment is not just the theoretical effect of success on the claims being asserted, but a

pragmatic judgment as to the likelihood that the newly asserted claims or defenses will succeed. See Filgueira, 734 F.3d at 423 ("Filgueira fails to show the importance of his amendment" because "it would not have changed the outcome of the court's ruling" on the motion to dismiss.); Sw. Bell Tel. Co. v. City of El Paso, 346 F.3d 541, 547 (5th Cir. 2003) (treating "likely failure of the proposed counterclaims on the merits" as a factor weighing against allowing untimely amendment); see also Bombardier Aerospace Corp. v. United States, 831 F.3d 268, 284 (5th Cir. 2016) (futility of amendment supports decision to deny motion to amend); Tangipahoa Parish Sch. Bd., 816 F.3d at 328 (same); Nourison Rug Corp. v. Parvisian, 535 F.3d 295, 299 (4th Cir. 2008) (same).

Although the Court recognizes that Teva has not completed its discovery on the inequitable conduct and unclean hands issues, the outlines of Teva's theory are nonetheless clear. Based on the evidentiary materials and arguments presented by the parties, the Court is able to conclude that the counterclaim and defenses of inequitable conduct and unclean hands would be unlikely to succeed.[2] For that reason, the Court regards the amendment as not being of sufficient importance to justify overlooking Teva's failure to meet the filing deadline.

Teva's argument is that Dr. Schiffman and the prosecuting attorney who submitted the Schiffman Declaration (and Dr. Attar's similar declaration) to the examiner intentionally deceived the PTO and persuaded the examiner to issue five of the patents in suit as a result of the

[2] If the issues in question were for a jury to determine, this Court would be less willing to venture a judgment at this stage as to the likelihood of Teva prevailing on its counterclaim and defenses. But this case will be heard by the Court without a jury, and in any event the issues of inequitable conduct and unclean hands are equitable issues for the Court to decide. For that reason, the Court is less diffident about predicting how those issues will be resolved, at least based on the showing that has been made at this point.

falsehoods contained in the declarations.[3] In particular, Teva argues that the misrepresentation in the Schiffman Declaration was that the particular cyclosporin formulation described in the patent applications produced results that were unexpected in light of the prior art. Schiffman Declaration ¶¶ 14-20. Teva contends that because the data set forth in the Schiffman Declaration were drawn from the Sall Article, which was itself prior art, the results that Dr. Schiffman highlighted, based on data from the Sall Article, could not have been "unexpected" in light of the prior art. Accordingly, Teva argues, the patents in suit were improperly obtained as a result of inequitable conduct, and that conduct in turn gives rise to a defense of unclean hands.[4]

There are two problems with Teva's inequitable conduct argument. First, Teva argues that the results reported by Dr. Schiffman could not have been "surprising" or "unexpected," because they were based on data set out in the Sall Article, which was more than a decade old at the time of Dr. Schiffman's declaration. The unexpected or surprising nature of a particular invention, however, is judged as of the time of the invention, which in this case would be the priority date of the patents, or September 15, 2003. See Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc., 752 F.3d 967, 977 (Fed. Cir. 2014).

Second, and more importantly, Teva suggests that the unexpected results described in the Schiffman Declaration were disclosed in the prior art Sall Article. But Dr. Schiffman explained

[3] Teva argues that the issuance of the sixth patent in suit, U.S. Patent No. 9,248,191, was the result of the earlier, successful efforts to persuade the examiner that the inventors' formulation had been found to produce surprising and unexpected results.

[4] Teva makes clear that its unclean hands argument is based entirely on its allegations of inequitable conduct. As the Federal Circuit explained in Therasense, Inc. v. Becton Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011), the doctrine of inequitable conduct grew out of the doctrine of unclean hands, but "came to embrace a broader scope of misconduct" than the doctrine of unclean hands, which "included only egregious affirmative acts of misconduct intended to deceive both the PTO and the courts." Id. at 1287. Because conduct that is insufficient to constitute inequitable conduct necessarily falls short of giving rise to a claim of unclean hands, this Court need only address Teva's inequitable conduct claim.

that the unexpected results discovered as a result of the Phase 3 Study for Restasis were the surprisingly good results obtained from the specific combination of 0.05% by weight of cyclosporin A with 1.25% by weight of castor oil. Schiffman Declaration at ¶¶ 14-20. The Sall Article did not disclose the weight percentage of the castor oil in that formulation, so the fact that Dr. Schiffman drew his data from the Phase 3 Study and may have obtained several of his figures from the Sall Article does not necessarily establish that the Sall Article anticipates (or renders obvious) the formulation that is recited in many of the claims of the patents in suit.

In sum, based on the showing made by Teva, the Court is not persuaded that the inequitable conduct and unclean hands argument that Teva raises in the second amended complaint is likely to be meritorious.

3. The Potential Prejudice to the Plaintiff from Allowing the Amendment

In arguing that it would be prejudiced by an order permitting Teva to amend its answer and counterclaims, Allergan relies mainly on the fact that the addition of those defenses and counterclaim would inject a new layer of complexity into an already complex case at a time when the discovery deadlines are approaching. The Court agrees.

Although the time for discovery has not expired, the deadline for fact discovery is February 2, 2017, a little more than a month from the date that briefing was completed on the motion to amend. Introducing the new and discrete issues of inequitable conduct and unclean hands would complicate discovery. The inquiry into issues such as specific intent to deceive would presumably require discovery of a different nature from the ongoing discovery regarding the issues already in the case. Moreover, because discovery relating to the issue of inequitable conduct could well involve inquiries into the activities of the prosecuting attorney, the expense and time required to conduct the additional discovery could be increased by issues of privilege.

The additional discovery costs imposed on the responding party are entitled to consideration in determining the issue of prejudice. See Squyres, 782 F.3d at 238-39; Marlowe Patent Holdings LLC v. Dice Elecs., LLC, 293 F.R.D. 688, 695 (D.N.J. 2013); Anderson v. La. ex rel. La. Dep't of Pub. Safety & Corrections, Civil Action No. 09-75, 2010 WL 2545817, at *3 (M.D. La. May 24, 2010). In addition, the introduction of the new legal theories raised by inequitable conduct and unclean hands would be likely to make the preparation and disposition of pretrial motions more cumbersome and time-consuming.

In light of the procedural posture of this case, where fact discovery has not closed and dispositive motions have not yet been filed, the Court recognizes that this factor is not entitled to dispositive weight. However, on balance this factor favors Allergan and cuts moderately in favor of denial of the motion to amend.

4. The Availability of a Continuance

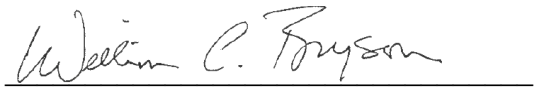
Finally, the question of the availability of a continuance has little pertinence here. Because the trial of this case is not scheduled to begin until August 2017, it is not likely that the issues raised in Teva's proposed amended answer and counterclaims would require a continuance even if Teva's motion were granted. Nonetheless, there is a related interest in proceeding expeditiously in this Hatch-Waxman Act case that cuts against adding new issues at this relatively late point in the proceedings. It is in the interest of the parties and the public that the issues in this case, as in many Hatch-Waxman Act cases, be resolved as promptly as possible. While expediting judicial proceedings is always an important consideration, it is even more so in the Hatch-Waxman Act context. Therefore, given the strong interest in not granting a continuance, the possible availability of a continuance does not cut in favor of granting the

motion to amend, and the desirability of a prompt resolution of this case cuts slightly in favor of denying the motion to amend.

Upon analysis of the factors that govern the decision whether to grant a motion to amend a pleading after the deadline in the scheduling order, the Court finds that each of the factors cuts against a finding that Teva has shown "good cause" to modify the scheduling order. Fed. R. Civ. P. 16(b)(4). Accordingly, the Court DENIES Teva's motion for leave to amend its answer and counterclaims.

IT IS SO ORDERED.

SIGNED this 12th day of January, 2017.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE