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

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