**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| MEDA PHARMACEUTICALS INC. and CIPLA LTD., | : | |
| Plaintiffs, | : | |
| v. | : | C.A. No. 15-785-LPS |
| TEVA PHARMACEUTICALS USA, INC., | : | |
| Defendant. | : | |

**MEMORANDUM ORDER**

At Wilmington this 14th day of November, 2016, having reviewed the parties' letter briefs (D.I. 62, 65, 68) and other filings related to Plaintiffs Meda Pharmaceuticals, Inc. and Cipla Ltd.'s ("Plaintiffs") Motion for Leave to File a Second Amended Complaint (D.I. 61) ("Motion"), **IT IS HEREBY ORDERED** that the Motion is **DENIED** for the reasons below.

1. Plaintiffs seek leave to file a Second Amended Complaint to introduce a Certificate of Correction ("CoC") for U.S. Patent No. 9,259,428 ("'428 patent") into this case. (D.I. 62 at 1) Defendant Teva Pharmaceuticals USA, Inc. ("Defendant") opposes Plaintiffs' Motion. (D.I. 65 at 1)

2. On March 3, 2016, Plaintiffs "applied to the PTO for correction" of "inadvertent typographical errors" in the '428 patent. (D.I. 62 at 1) "On May 3, 2016, the PTO issued Plaintiffs' requested Certificate of Correction for the '428 patent." (*Id.*) Plaintiffs explain that thereafter, but starting no early than July 1, they engaged in "a lengthy negotiation process" with Defendant, to obtain Defendant's consent for introduction of the CoC into this case. (D.I. 68 at

1) However, Defendant did not consent to assertion of the CoC. (D.I. 68 at 1-2) On August 5, the parties filed a joint claim construction chart (D.I. 47) and on September 2 they served opening claim construction briefs (D.I. 53, 56). Only on September 6 did Plaintiffs move for leave to assert the CoC. (D.I. 61) The parties completed briefing on Plaintiffs' Motion on September 16. (D.I. 62, 65, 68)

3. The Scheduling Order in this case set February 26, 2016 as the deadline for amendment of pleadings. (*See* D.I. 16 ¶ 2) As Plaintiffs sought leave to amend well after that date, they must satisfy Federal Rule of Civil Procedure 16(b)(4), which provides that "[a] schedule may be modified only for good cause and with the judge's consent." *See also WebXchange Inc. v. Dell Inc.*, 2010 WL 256547, at *2 (D. Del. Jan. 20, 2010) (citing *E. Minerals & Chemicals Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000)) ("After a pleading deadline has passed, the Third Circuit requires a showing of good cause in order to amend.")). Good cause is present when the schedule cannot be met despite the moving party's diligence. *See Leader Techs., Inc. v. Facebook, Inc.*, 2010 WL 2545959, at *3 (D. Del. June 24, 2010); *see also S. Track & Pump, Inc. v. Terex Corp.*, 722 F. Supp. 2d 509, 521 (D. Del. 2010) ("In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party.") (internal citation omitted).

4. Defendant argues that Plaintiffs have not shown good cause or diligence to support permitting them to file their Second Amended Complaint. (D.I. 65 at 5) Plaintiffs respond that good cause is shown by their attempt to negotiate with Defendant to convince

Defendant to consent to Plaintiffs injecting the CoC into this case. (D.I. 68 at 1-2)[1] The Court agrees with Defendant.

5. Plaintiffs cite an email chain as evidence of "negotiations" between Plaintiffs and Defendant regarding Plaintiffs' Motion. (*See* D.I. 68 Ex. 2) However, the vast majority of Plaintiffs' cited email chain does not relate to Plaintiffs' Motion; moreover, it is unclear why multiple months of negotiations would be necessary to determine whether Defendant would support Plaintiffs' Motion. (*See id.*) Even when the email chain discusses Plaintiffs' Motion, it evidences Defendant's consistent opposition to Plaintiffs' request. (*See, e.g.*, *id.* at 1) Plaintiffs' alleged "negotiations" are not strong evidence of diligence, especially as they coincided with waiting more than four months to seek to amend their pleading.

6. Plaintiffs could have moved to amend the Scheduling Order as earlier as March, when they requested the CoC. Alternatively, Plaintiffs could have moved in May, when the CoC issued from the PTO. Importantly, a filing in May would have predated the parties' preparation and submission of extensive claim construction briefing and analysis, including Defendant's indefiniteness analysis of at least one claim that appears to have been materially altered by the CoC. (*See* D.I. 65 at 2 n.1) (noting that, before Plaintiffs filed their Motion, Defendant disclosed indefiniteness arguments regarding claim 28 of '428 patent, arguments that would be affected by introduction of CoC into this case) Instead of moving to amend at these earlier dates, Plaintiffs waited until ***after*** the parties had submitted their opening claim construction briefs to seek leave to amend. Plaintiffs' decision had the consequence of requiring Defendant to engage in a

[1]Inexplicably, in their opening letter brief in support of the Motion, Plaintiffs fail to cite Rule 16 or the burden that rests squarely on Plaintiffs to demonstrate good cause and diligence. (*See* D.I. 62)

significant amount of litigation under the assumption that the parties were litigating the ***uncorrected*** version of the '428 patent. (*See* D.I. 65 at 5) (discussing litigation that took place before Plaintiffs filed their Motion) It was Plaintiffs, not Defendant, who were in control of when to move for leave to amend their complaint or to amend the Scheduling Order. By waiting so long to do so, with seemingly no justification for delay other than an unfounded hope (so far as the record reveals) that Defendant might eventually agree to Plaintiff's request, all while the parties expended substantial efforts litigating the case based on the assumption that Plaintiffs' request would ***not*** be granted (i.e., in the belief that the Court would have to resolve claim construction disputes relating to the uncorrected version of the patent), Plaintiffs have failed to show the good cause required for the Court to grant their Motion. *See generally St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co.*, 2012 WL 1015993, at *6 (D. Del. Mar. 26, 2012) ("A strategic mistake does not equate to a showing of good cause under Rule 16.")

7. The Court has considered Plaintiffs' arguments that the amendment should be permitted because this case involves an Abbreviated New Drug Application ("ANDA"), and is brought pursuant to 35 U.S.C. § 271(e)(2), so all infringement is prospective. (*See* D.I. 62 at 2) Plaintiffs contend that "applying the Certificate of Correction at this point in the proceeding is not improper or unfair to Teva since any actual infringement will only occur after the Certificate of Correction issued." (*Id.*) Yet, because Plaintiffs must satisfy Rule 16, and application of Rule 16 turns on Plaintiffs' diligence, the Court's finding that Plaintiffs have failed to show they acted with diligence is decisive, even assuming Plaintiffs are correct that the CoC should "apply" prospectively and even if Plaintiffs are correct about the relative lack of prejudice to Defendant.

Accordingly, Plaintiffs' Motion (D.I. 61) is **DENIED**.[2]

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

[2]As the Court has denied Plaintiffs' Motion based on Plaintiffs' failure to meet its burden under Rule 16, the Court does not reach Defendant's arguments under Federal Rule of Civil Procedure 15. (*See generally* D.I. 65 at 1-5) Nor does the Court need to reach any conclusion about Plaintiffs' arguments addressing Rule 15.