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September 06, 2016

The Honorable Chief Judge Leonard P. Stark
United States District Court, District of Delaware
J. Caleb Boggs Federal Building
844 North King Street, Unit 26, Room 6124
Wilmington, Delaware 19801-3556

VIA ELECTRONIC MAIL

Re: *Meda Pharmaceuticals Inc., et al. v. Teva Pharmaceuticals USA, Inc.,*
Civil Action No. 15-cv-785-LPS

Dear Chief Judge Stark:

We, along with Sterne, Kessler, Goldstein & Fox PLLC, represent Plaintiffs Meda Pharmaceuticals and Cipla Ltd. ("Plaintiffs") in the above-captioned action. We write seeking leave to file a motion to amend Plaintiffs' complaint to include the newly issued Certificate of Correction of U.S. Patent No. 9,259,428 ("'428 patent").

On February 29, 2016, Plaintiffs filed an amended complaint asserting the '428 patent against Teva. The '428 patent, as issued, contained inadvertent typographical errors by the U.S. Patent and Trademark Office ("PTO") that appeared on the title page, in the specification, and in the claims. On March 3, 2016, Plaintiffs applied to the PTO for correction of these inadvertent errors. On May 3, 2016, the PTO issued Plaintiffs' requested Certificate of Correction for the '428 Patent. Plaintiffs now simply seek to ensure an accurate record by incorporating the corrected '428 patent into this action.

Teva continues to withhold its consent to Plaintiffs' motion to amend despite Plaintiffs' repeated attempts to informally resolve this dispute with Teva, including multiple meet-and-confers between lead and local counsel, all to no avail. Teva challenges the applicability of Plaintiffs' corrected '428 patent to this action and asserts that the inadvertent (and now corrected) errors in the claims of the '428 patent render those claims indefinite. As a consequence of Teva's position, Plaintiffs now seek leave to file a Second Amended Complaint.

Teva is incorrect on both counts. The Federal Circuit and decisions from this district have determined that certificates of correction apply to causes of action for future acts of infringement. For example, in *E.I. du Pont de Nemours & Co. v. MacDermid Printing*, the

Federal Circuit held that, in the context of a motion for preliminary injunction, a certificate of correction applied to that proceeding because prospective infringing conduct was at issue. 525 F.3d 1353, 1362 (Fed. Cir. 2008).

Here, because this action arises under 35 U.S.C. § 271(e)(2), and Teva's ANDA remains pending at FDA, only prospective infringement is at issue. Indeed, Judge Sleet found that, in the context of an infringement action under 35 U.S.C. § 271(e)(2), "for purposes of determining when a certificate of correction applies, the date on which the infringing conduct will occur, rather than the date a complaint is filed, dictates." *Pfizer Inc. v. Teva Pharmaceuticals U.S.A, Inc.,* 882 F. Supp. 2d 643, 699 (D. Del. 2012). In doing so, Judge Sleet correctly recognized that in cases arising under § 271(e)(2)(A)—like this case—the filing of an ANDA is "merely a vehicle to create case or controversy jurisdiction" and thus the infringement inquiry is properly focused on prospective, future infringement upon FDA approval. *Id*. at 697 (*quoting Bayer AG v. Elan Pharm. Research Corp*., 212 F.3d 1241, 1249 (Fed. Cir. 2000)). Here, like in *Pfizer*, 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.

During the parties' meet-and-confers to resolve this issue, Teva relied on two cases that it believes govern the applicability of certificates of correction to ongoing litigations arising under § 271(e)(2)(A), namely *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000) and *Nautilus Neurosciences, Inc. v. Wockhardt USA LLC*, No. CIV.A. 11-1997-ES, 2013 WL 775750 (D.N.J. Feb. 27, 2013).

Teva's authority is easily distinguished. Teva asserts that the Federal Circuit's holding in *Southwest Software, Inc. v. Harlequin Inc.* holds that a certificate of correction is not effective for purposes of an action that arose before the correction issued. Teva however, ignores the salient fact that here, as a practical matter, Teva is engaged in future torts not cut off by Plaintiffs' date of filing this action. For this reason, the Federal Circuit's more recent *du Pont* case, cited by Judge Sleet in the *Pfizer* decision, is more pertinent to this analysis. In *du Pont*, the Federal Circuit addressed a similar argument and rejected the defendant's attempt to challenge a certificate of correction's applicability to future acts of infringement, finding defendant's argument to be a "misreading of *Southwest Software*." 525 F.3d at 1362. The underlying concern in *Southwest Software* was that until a certificate of correction issues, "a claim would appear invalid to the public, and reasonable competitors would be justified in conducting their affairs accordingly." 226 F.3d at 1295. Thus, the Federal Circuit noted in *Southwest Software* that it would be "an illogical result to allow the patent holder…to sue an alleged infringer for activities that occurred before the issuance of the certificate." *Id*. But in this case and in *E.I. du Pont Nemours*, the infringing conduct is actually "future conduct (i.e., prospective infringement occurring after the issuance of the certificate of correction)" and thus does not render the "illogical result" that the court was wary of in *Southwest Software*. *Id*. at 1364.

Further, the court in *Pfizer* held that because "infringement under § 271(e) is hypothetical and, therefore, cannot occur prior to the filing of a complaint, a certificate of correction can be applied where the defendants' ANDA products will prospectively infringe the patents-in-suit." 882 F. Supp. at 699.

Teva also relies on *Nautilis v. Wockhardt*, but that case is also inapposite. In *Nautilis*, the patentee had only applied to the Patent Office for the certificate of correction, unlike here and in *Pfizer* where the Patent Office has already issued the certificate of correction.

Resolving the applicability of the '428 patent's Certificate of Correction has the additional salutary effect of rendering moot one of the currently disputed claim construction issues. As identified in the parties' Joint Claim Construction Chart (D.I. 47), Teva asserts that the Court should construe as indefinite the claim term "from 0.001% (weight/weight) % (weight/weight) of azelastine hydrochloride," as it appears in claims 28, 29, and 30 of the '428 patent. Teva's indefiniteness theory rests solely on the fact that this claim term contains a typographical error—one that is now corrected in the Certificate of Correction.

For all of the stated reasons, Plaintiffs respectfully ask the Court for leave to amend the record to add the properly issued certificate of correction to the '428 patent. Plaintiffs' Second Amended Complaint is attached hereto as Exhibit 1 with accompanying exhibits. A redlined version of the pleading is attached as Exhibit 2.

Respectfully,

/s/ *Andrew C. Mayo*

Andrew C. Mayo (#5207)

AMC/nml
Attachments

cc: All counsel of record (via electronic mail w/attachment)