UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

SHIRE DEVELOPMENT, LLC, SHIRE PHARMACEUTICAL DEVELOPMENT, INC., COSMO TECHNOLOGIES LIMITED and NOGRA PHARMA LIMITED,

Plaintiffs,

v.

Case No: 8:12-cv-1190-T-36AEP

MYLAN PHARMACEUTICALS, INC. and MYLAN, INC.,

Defendants.

<u>ORDER</u>

This cause comes before the Court upon the Expedited Motion for Supplemental Briefing and Adjournment of Expert Discovery Deadlines, filed by Plaintiffs Shire Development, LLC, Shire Pharmaceutical Development, Inc., Cosmo Technologies Limited, and Nogra Pharma Limited (collectively, "Shire") (Doc. 221). Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan") responded in opposition to the Motion (Doc. 228). The Court, having considered the parties' submissions and being fully advised in the premises, will now GRANT-IN-PART and DENY-IN-PART the Motion.

I. BACKGROUND

This dispute is but one of many lawsuits brought by Shire alleging the infringement of United States Patent No. 6,773,720 (the "#720 Patent"). Prior to bringing suit against Mylan, Shire filed suit against, *inter alia*, Watson Pharmaceuticals, Inc. ("Watson") in the Southern District of Florida. *See Shire Development LLC v. Watson Pharmaceuticals, Inc.*, Case No. 12-cv-60862 (S.D. Fla.). The parties in that case engaged in the claim construction process in late 2012, and

the district court issued a claim construction order in January 2013. *See Shire Development LLC v. Watson Pharmaceuticals*, Case No. 12-cv-60862, 2013 WL 174843 (S.D. Fla. Jan. 17, 2013) ("*Watson I*"). In its order, the district court construed eight terms, including "inner lipophilic matrix" and "outer hydrophilic matrix." *See id.* at *4-5. Dissatisfied with the outcome of that order, Watson appealed it to the Federal Circuit, which reversed the district court's construction of those two terms in an order dated March 2014. *See Shire Development, LLC v. Watson Pharmaceuticals, Inc.*, 746 F.3d 1326, 1334 (Fed. Cir. 2014) ("*Watson II*"). Shire thereafter filed a petition for certiorari to the Supreme Court.

While Shire's petition for certiorari in *Watson* was pending, the parties engaged in claim construction proceedings in this case before this Court. The parties filed their opening claim construction briefs in October 2014, Docs. 175, 178, and their responses to those briefs in November 2014, Docs. 192, 194. The Court held a *Markman* hearing in December 2014. Doc. 208. As in *Watson*, the construction of the terms "inner lipophilic matrix" and "outer hydrophilic matrix" is in dispute. *See, e.g.*, Docs. 175 and 178.

In January 2015, the Supreme Court issued its opinion in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015). The dispute before the Supreme Court in *Teva* arose over whether a claim was indefinite under 35 U.S.C. § 112(b). *See id.* at 832. After considering conflicting expert evidence, the district court concluded that the claim was sufficiently definite and held that the patent was therefore valid. *See id.* Upon appeal, the Federal Circuit reviewed *de novo* all aspects of the district court's claim construction, including the district court's determination of subsidiary facts, and reversed, finding the claim indefinite and the patent invalid. *See id.* at 833. Subsequently, the Supreme Court granted Teva's petition for certiorari, and vacated the Federal Circuit's opinion. *See id.* at 843. In so doing, it began by noting that Federal Rule of Civil Procedure 52(a)(6) requires an appeals court to accept a district court's factual findings "unless clearly erroneous." *See id.* at 836-37. It then noted that there were no convincing grounds for creating an exception to that rule in the claim construction context. *See id.* at 837. It concluded, therefore, that a district court's factual findings preceding the function of construction must, like all other factual determinations, be reviewed not *de novo*, but rather for clear error. *See id.* at 838. The Supreme Court, however, was careful to specify that, in the context of claim construction, clear error review applies only to the district court's findings as to extrinsic evidence—and that "when the district court reviews only evidence intrinsic to the patent . . . the judge's determination will amount solely to a determination of law, and the Court of Appeals will review that construction *de novo*." *Id.* at 841.

Shortly after the Supreme Court issued *Teva*, it granted Shire's petition for certiorari in *Watson*, vacated *Watson II*, and remanded the case for further consideration in light of *Teva*. *See Shire Development, LLC v. Watson Pharmaceuticals, Inc.*, Case No. 14-206, 2015 WL 303221 (Jan. 26, 2015). Shire now argues that, in light of the Supreme Court's decision to vacate *Watson II*, it should be afforded leave to submit supplemental briefing on the terms "inner lipophilic matrix" and "outer hydrophilic matrix." Shire also requests that the Court adjust the case schedule for expert reports and discovery to follow the resolution of claim construction.

II. DISCUSSION

District courts enjoy broad discretion in deciding how best to manage the cases before them. *See Chudasama v. Mazda Motor Corp.*, 123 F.3d 1353, 1366 (11th Cir. 1997). Here, Shire is essentially seeking another round of claim construction briefing, as well as a stay of the case

until the Court resolves all of the claim construction issues in this case, including those raised in the supplemental briefing. The Court declines to grant Shire's request, because supplemental briefing would not be necessary or even helpful. Importantly, *Teva* was explicit that the clear error standard of review applies only to subsidiary findings of fact, and that findings of law, based on intrinsic evidence, are still to be reviewed *de novo*. After a careful review of *Watson I* and *Watson II*, the Court agrees with Mylan that, in *Watson*, both the district court and the Federal Circuit construed the terms "inner lipophilic matrix" and "outer hydrophilic matrix" solely on the basis of intrinsic evidence. *See Watson I* at *4-5 (in construing "inner lipophilic matrix" and "outer hydrophilic matrix," relying only on the prosecution history, claims, specification, and plain meaning of the terms); *Watson II* at 1331-33 (in reversing the district court's construction of "inner lipophilic matrix" and "outer hydrophilic matrix," reviewing only "the intrinsic evidence as a whole," including the language of the claims, specification, prosecution history, structure of the claim, ordinary meaning of the claim terms, and patent's description of the invention). The Federal Circuit's opinion regarding these two terms is therefore unlikely to change in light of *Teva*.

Although the Court finds additional claim construction briefing on these terms to be unnecessary, the Court agrees with Shire that, because the Court has yet to issue an order on the terms already briefed and argued and expert discovery deadlines are fast approaching, an adjustment to the case schedule is warranted. Granting a brief and definite extension of the discovery and case deadlines to provide the parties with the benefit of the Court's claim construction order would preserve the parties' resources and simplify the issues, and would not unduly prejudice Mylan. *See Alps South, LLC v. The Ohio Willow Wood Co.*, Case No. 09-cv-386, 2010 WL 2465176, at *1 (M.D. Fla. June 16, 2010) ("In determining whether to grant a stay, courts generally examine three factors: (1) whether a stay will unduly prejudice or tactically

disadvantage the non-moving party; (2) whether a stay will simplify the issues and streamline the trial; and (3) whether a stay will reduce the burden of litigation on the parties and on the court.") (quotation marks and citations omitted).

Accordingly, it is hereby **ORDERED**:

- Shire's Expedited Motion for Supplemental Briefing and Adjournment of Expert Discovery Deadlines (Doc. 221) is GRANTED-IN-PART and DENIED-IN-PART.
- 2. The Court will issue by separate order a Fifth Amended Case Management and Scheduling Order that will extend all deadlines.
- 3. The Motion is otherwise **DENIED**.

DONE AND ORDERED in Tampa, Florida on February 24, 2015.

Charlene Edwards Honeywell

United States District Judge

Copies to: Counsel of Record and Unrepresented Parties, if any