

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION

ROXANE LABORATORIES, INC.,

Plaintiff,

vs.

Civil Action 2:12-cv-312  
Judge Watson  
Magistrate Judge King

ABBOTT LABORATORIES,

Defendant.

OPINION AND ORDER

This matter is before the Court on *Plaintiff's Motion to Modify the Joint Claim Construction Statement* ("Plaintiff's Motion"), Doc. No. 77, on defendants' response, *Defendants' Opposition to Plaintiff's Motion to Modify the Joint Claim Construction Statement* ("Defendants' Response"), Doc. No. 85, and on plaintiff's reply, *Roxane's Reply in Support of its Motion to Modify the Joint Claim Construction Statement* ("Plaintiff's Reply"), Doc. No. 86. For the reasons that follow, *Plaintiff's Motion* is **GRANTED**.

**I. Background**

This is a patent infringement action in which plaintiff Roxane Laboratories, Inc., seeks a declaration of noninfringement of patents currently held by defendant AbbVie Inc., relating to the drug Norvir®. *Amended Complaint*, Doc. No. 56, ¶¶ 1, 11-15. The Court set December 19, 2012 as the date by which the parties were to file a joint claim construction statement. *Preliminary Pretrial Order*, Doc. No. 29, p. 3. The parties met that deadline. *Joint Claim Construction and*

*Prehearing Statement*, Doc. No. 65. The parties were to have completed claim construction discovery by February 4, 2013; opening claim construction briefs were due by February 19, 2013 and responsive claim construction briefs were due by March 21, 2013. *Preliminary Pretrial Order*, p. 3.

The *Joint Claim Construction Statement* identifies two disputed claim terms: "substantially pure" and "amorphous ritonavir." *Appendix B to Joint Claim Construction Statement*, Doc. No. 66. Plaintiff proposes that "amorphous ritonavir" be construed as "the physical form of ritonavir characterized by lack of defined crystal structure and three-dimensional long-range structure." *Id.* at p. 14. Defendants propose that the term be construed as "the solid physical form of ritonavir characterized by lack of crystal structure." *Id.*

After the *Joint Claim Construction Statement* was filed, the parties attempted, through a series of letters, to further narrow the claim construction disputes. On January 3, 2013, defendants suggested that the phrases lack of "defined crystal structure" and "three-dimensional long-range structure" were synonymous. *Plaintiff's Motion*, Exhibit A. Plaintiff rejected that suggestion on January 9, 2013, *Plaintiff's Motion*, Exhibit B, and, on February 13, 2013, proposed the following alternative construction: "the solid physical form of ritonavir (i.e., the form of ritonavir having a glass transition as shown in Figure 10 of the '359 patent) that is also characterized by the lack of crystal structure (i.e., as shown in Figure 3 of the '359 patent)." *Plaintiff's Motion*, Exhibit C. Defendants rejected that proposal on February 15, 2013, and suggested

that the parties proceed with claim construction briefing using the definitions provided in the *Joint Claim Construction Statement*. *Plaintiff's Motion*, Exhibit D. Plaintiff declined that suggestion and informed defendants that it intended "to present its compromise construction of 'amorphous ritonavir' to the Court in its claim construction briefing so as to narrow the remaining issues in dispute." *Plaintiff's Motion*, Exhibit E. Defendants again requested that plaintiff abide by the definitions provided in the *Joint Claim Construction Statement*. *Plaintiff's Motion*, Exhibit F. plaintiff refused. *Plaintiff's Motion*, Exhibit G. After the Court conferred with counsel for all parties on February 19, 2013, the Court directed plaintiff to file a motion to modify the joint claim construction statement. *Amended Order*, Doc. No. 74. The Court also suspended the dates for filing opening claim construction briefs and responsive claim construction briefs pending resolution of that issue. *Id.*

Plaintiff's motion to amend the *Joint Claim Construction Statement* is intended "to clarify its original construction." *Plaintiff's Motion*, pp. 5-6. Specifically, plaintiff seeks to amend its construction of "amorphous ritonavir" to be "the solid physical form of ritonavir (*i.e.*, the form of ritonavir having a glass transition as shown in Figure 10 of the '359 patent) that is also characterized by the lack of crystal structure (*i.e.*, as shown in Figure 3 of the '359 patent)". See *id.* at pp. 5-6, Exhibit C.

Defendants oppose any such modification, arguing that plaintiff has failed to show good cause to modify the scheduling order and that defendants would be prejudiced by the proposed amendment.

Specifically, defendants argue that the proposed amendment "add[s] new, unwarranted claim limitations" based on evidence that "has been available through the public record," and it deprives defendants of the opportunity to "develop the evidence and arguments necessary for the claim construction briefing." *Defendants' Response*, pp. 2-3, 6-7. Defendants also argue that the grant of the requested modification would deprive them "of the opportunity to consider and present expert testimony on the new construction." *Id.* at p. 6. Alternatively, defendants ask, should the modification be permitted, that they be granted at least sixty (60) days to conduct additional discovery, including expert discovery, prior to the filing of opening claim construction briefs. *Id.* at pp. 6-7.

## **II. Discussion**

Plaintiff first argues that it has the unqualified right to amend the *Joint Claim Construction Statement*. *Plaintiff's Motion*, p. 3 ("[Plaintiff] is not aware of any requirement that a party seek leave of the Court to amend its proposed constructions. . . . The absence of a provision requiring [] leave to propose a modified construction for purposes of compromise creates a presumption that there is no such requirement."). Alternatively, plaintiff cites to Pat.L.R. 103.7, "Amendment to Contentions," for the proposition that amendment is permissible if there is "no undue prejudice to the parties and the party seeking amendment acts in good faith." *Id.* at p. 4.

In the case presently before the Court, the parties filed a Rule 26(f) report, Doc. No. 25, the Court held a preliminary pretrial conference at which all parties were represented, and the Court issued

a Rule 16 scheduling order that, *inter alia*, set a date for the filing of a joint claim construction statement. *Preliminary Pretrial Order*, Doc. No. 29, p. 3. The Local Patent Rules do not usurp either the Federal Rules of Civil Procedure or the local rules of this Court that are not inconsistent with the Local Patent Rules. See Pat.L.R. 101.2 ("The Local Civil Rules of this Court shall also apply to these actions, except to the extent that they are inconsistent with these Local Patent Rules."); *RFR Indus., Inc. v. Century Steps, Inc.*, 477 F.3d 1348, 1351 (Fed. Cir. 2007) (citing *Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 857-58 (Fed. Cir. 1991) ("[O]ur practice has been to defer to regional circuit law when the precise issue involves an interpretation of the Federal Rules of Civil Procedure or the local rules of the district court."); *Connective Tissue Imagineering, LLC v. Mitts*, C 07-00058 WHA, 2007 WL 2348741 (N.D. Cal. Aug. 14, 2007) (applying Rule 16(b) to a motion for leave to amend the joint claim construction statement). The date for filing a joint claim construction statement was established in a Rule 16 scheduling order; a motion for leave to amend a joint claim construction statement must therefore comply with Fed. R. Civ. P. 16.

Rule 16(b) of the Federal Rules of Civil Procedure requires the Court, in each civil action not exempt from that rule, to issue a scheduling order. Fed. R. Civ. P. 16(b). "A schedule may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4). "'The primary measure of Rule 16's 'good cause' standard is the moving party's diligence in attempting to meet the case management order's requirements.'" *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 625

(6th Cir. 2002) (quoting *Bradford v. DANA Corp.*, 249 F.3d 807, 809 (8th Cir. 2001)). "A district court should also consider possible prejudice to the party opposing the modification." *Andretti v. Borla Performance Indus., Inc.*, 426 F.3d 824, 830 (6th Cir. 2005) (citing *Inge*, 281 F.3d at 625). The focus is, however, "primarily upon the diligence of the movant; the absence of prejudice to the opposing party is not equivalent to a showing of good cause." *Ortiz v. Karnes*, 2:06-cv-562, 2010 WL 2991501, at \*1 (S.D. Ohio July 26, 2010) (citing *Tschantz v. McCann*, 160 F.R.D. 568, 571 (N.D. Ind. 1995)). Whether to modify a pretrial schedule pursuant to Rule 16(b) falls within the district court's discretion. *Leary v. Daeschner*, 349 F.3d 888, 909 (6th Cir. 2003).

Plaintiff argues, for the first time in its reply brief, that it established good cause to modify the scheduling order because "it immediately sought to amend its construction of 'amorphous ritonavir' as soon as the dispute between the parties crystallized." *Plaintiff's Reply*, p. 1. See also *id.* at p. 2 ("[Plaintiff notified defendants] of its intention to pursue its compromise construction on the same day that it became aware of the dispute."). Plaintiff also argues that it "could not have brought up this dispute any earlier" because the parties were not aware "that the dispute existed" or that "further construction" was necessary until the parties met and conferred after the *Joint Claim Construction Statement* had been filed. *Id.* at p. 2.

The issue presently before the Court is not whether the parties disputed plaintiff's current proposed construction prior to the deadline for filing a joint claim construction statement; had there

been no dispute, the term would certainly have been included in the appendix of "Agreed Terms" attached to the *Joint Claim Construction Statement*. See *Joint Claim Construction Statement*, p. 6. Yet, plaintiff has provided no explanation whatsoever why it did not present its new construction earlier.

Plaintiff argues that "the very need for [] further construction was not evident until after the parties engaged in their meet and confer in January and February 2013." *Plaintiff's Reply*, p. 2 n.2. Plaintiff does not, however, explain why "further construction" was necessary and why it was not evident that further construction was necessary until one day prior to the deadline for filing opening claim construction briefs. The Figures in United States Patent No. 7,148,359 referred to in plaintiff's new construction, see *Plaintiff's Motion*, pp. 5-6, Exhibit C, were available to plaintiff prior to the filing of the *Joint Claim Construction Statement* and prior to the parties' exchange of proposed claim terms and phrases for construction. See *Plaintiff's Reply*, p. 6. In fact, plaintiff cited to these Figures as intrinsic evidence in support of its construction in the *Joint Claim Construction Statement*. See *Appendix B to Joint Claim Construction Statement*, p. 14. Given plaintiff's prior knowledge of the information upon which it now relies, the Court sees no reason, and plaintiff has provided no explanation, why plaintiff's new construction could not have been asserted in the *Joint Claim Construction Statement*.

Under the circumstances, plaintiff has failed to show good cause for modifying the scheduling order to permit an amendment to the *Joint*

*Claim Construction Statement.* Nevertheless, because claim construction is a question of law to be determined by the Court, see *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996), and because plaintiff's amended construction might assist the Court in making that determination, the Court will permit plaintiff to file an amended *Joint Claim Construction Statement* to amend its construction of the term "amorphous ritonavir." In so deciding, the Court also concludes that any prejudice otherwise accruing to defendants can be ameliorated. The parties have not yet filed opening claim construction briefs, a claim construction hearing has not yet been scheduled, and defendants will be permitted to pursue discovery and to prepare expert testimony on the new construction. Finally, plaintiff does not object to the withdrawal by defendants of their original three interrogatories directed to plaintiff's original construction of term "amorphous ritonavir." See *Plaintiff's Reply*, p. 6 n.4.

*Plaintiff's Motion to Modify the Joint Claim Construction Statement*, Doc. No. 77, is therefore **GRANTED**. Plaintiff is **ORDERED** to file an amended joint claim construction statement no later than March 25, 2013. The amended statement may modify only plaintiff's construction of the term "amorphous ritonavir."

The *Preliminary Pretrial Order*, Doc. No. 29, is amended as follows:

**CLAIM CONSTRUCTION PROCEEDINGS:**

All claim construction discovery must be completed no later than May 31, 2013. Opening claim construction briefs, see Pat.L.R. 105.4(b), must be filed by June 15, 2013; responsive claim



construction briefs, *see id.*, must be filed no later than July 15, 2013. The matter will be available for a claim construction hearing, to be held by Judge Watson, in July or August 2013.

**DISCOVERY AND EXPERTS:**

All fact discovery must be completed within 45 days after the Court's ruling on claim construction, but in no event later than August 30, 2013.

The reports of primary experts on issues on which each party bears the burden of proof must be produced within 45 days after the Court's ruling on claim construction, but in no event later than August 30, 2013. The reports of primary experts on issues on which the opposing party bears the burden of proof must be produced within 45 days thereafter. The reports of rebuttal experts must be produced within 30 days thereafter. The reports shall conform to the requirements of Fed. R. Civ. P. 26(a)(2)(B) or (C), as appropriate.

Depositions of experts must commence within 14 days after the production of rebuttal expert reports and must be completed within 60 days of the commencement of the deposition period.

If any date herein falls on a weekend or holiday, the next business date will control.

March 28, 2013

*s/Norah McCann King*  
Norah M<sup>c</sup>Cann King  
United States Magistrate Judge