

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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JAZZ PHARMACEUTICALS, INC.	:	
	:	Civil Action: 10-6108 (ES)
Plaintiff,	:	
	:	<u>OPINION</u>
v.	:	
	:	
ROXANE LABORATORIES, INC.	:	
	:	
Defendant.	:	
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SALAS, DISTRICT JUDGE

I. Introduction

Pending before this Court is an appeal of Magistrate Judge Cathy Waldor’s July 30, 2012 Order (the “July 30th Order”) denying Defendant’s motion for leave to amend its Local Patent Rule 3.7 Initial Invalidity and Non-Infringement Contentions. (D.E. No. 143, Defendant’s Brief in Support of its Appeal (“Def. Br.”)). The Court has considered the submissions made in support of and in opposition to the instant motion, and decides the motion without oral argument, pursuant to Federal Rule of Civil Procedure 78. For the reasons that follow, the Court affirms the July 30th Order.

II. Background

As Magistrate Judge Waldor detailed the relevant facts in her Opinion (D.E. No. 136, Opinion (“Op.”)), the Court provides background here in summary fashion.

Defendant Roxane Laboratories, Inc. (“Defendant” or “Roxane”) appeals Magistrate Judge Waldor’s Opinion denying Defendant’s motion for leave to supplement its invalidity contentions, alleging that the Opinion and July 30th Order are based on clear

error and are contrary to law. (D.E. No. 143-1, (Def. Br.) at 2). Specifically, Defendant Roxane argues that Judge Waldor committed clear error in finding that (a) Roxane did not have good cause for supplementing its invalidity contentions; (b) Roxane did not make a timely application to the Court; and (c) Jazz would be unduly prejudiced by Roxane's supplementation. (*Id.*). Further, Roxane alleges that Judge Waldor erred in finding that Roxane's proposed materials were not prior art. (*Id.*). Finally, Roxane contends that Judge Waldor misapplied the law in applying the Local Patent Rules of this District. (*Id.* at 15-16).

In opposition, Plaintiff Jazz Pharmaceuticals, Inc. ("Plaintiff" or "Jazz") argues that Judge Waldor did not err in finding that (a) Roxane was not diligent in seeking to amend its invalidity contentions; (b) Roxane could not show good cause to permit the amendment; (c) Roxane's request to amend was untimely; (d) allowing an amendment would be prejudicial to Jazz; and (e) Roxane failed to provide sufficient evidence that the disputed materials qualify as prior art. (D.E. No. 146, Plaintiff's Reply Brief in Opposition of Appeal) ("Pl. Rep. Br.") at 1).

III. Legal Standard

A United States Magistrate Judge may hear and determine any [non-dispositive] pretrial matter pending before the Court pursuant to 28 U.S.C. § 636(b)(1)(A). The district court will only reverse a magistrate judge's decision on these matters if it is "clearly erroneous or contrary to law." 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A). Therefore, "this Court will review a magistrate judge's findings of fact for clear error." *Lithuanian Commerce Corp., v. Sara Lee Hosiery*, 177 F.R.D. 205, 213 (D.N.J. 1997) (citing *Lo Bosco v. Kure Eng'g Ltd.*, 891 F. Supp. 1035, 1037

(D.N.J. 1995)).

Under this standard, a finding is clearly erroneous when "although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Anderson v. Bessemer City*, 470 U.S. 564, 573 (1985) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948)). The district court will not reverse the magistrate judge's determination, even in circumstances where the court might have decided the matter differently. *Bowen v. Parking Auth. of City of Camden*, No. 00-5765, 2002 WL 1754493, at *3 (D.N.J. July 30, 2002). "A district judge's simple disagreement with the magistrate judge's findings is insufficient to meet the clearly erroneous standard of review." *Andrews v. Goodyear Tire & Rubber Co.*, 191 F.R.D. 59, 68 (D.N.J. 2000).

Importantly, "[d]ecisions enforcing local rules in patent cases will be affirmed unless clearly unreasonable, arbitrary, or fanciful; based on erroneous conclusions of law; clearly erroneous; or unsupported by any evidence." *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366-67 (Fed. Cir. 2006) (citing *Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761, 774 (Fed. Cir. 2002)).

IV. Analysis

Pursuant to Local Patent Rule 3.7, leave to amend infringement contentions may be granted "by order of the Court upon a timely application and showing of good cause." The Local Patent Rules "exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases." *TFH Publications, Inc. v. Doscocil Mfg. Co., Inc.*, 705 F. Supp. 2d 361, 365 (D.N.J. 2010) (citing *Computer Acceleration Corp. v. Microsoft Corp.*, 503 F.Supp.2d 819, 822 (E.D.

Tex. 2007) (internal quotations omitted)). “The rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.” *King Pharmaceuticals, Inc. v. Sandoz Inc.*, No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (quoting *Atmel Corp. v. Info. Storage Devices, Inc.*, No. 95-1987, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)).

Distinguishable from the liberal standard for amending the pleadings, “the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the ‘shifting sands’ approach to claim construction.” *King*, 2010 WL 2015258 at *4. However, Rule 3.7 “is not a straitjacket into which litigants are locked from the moment their contentions are served,” but instead, “a modest degree of flexibility [exists], at least near the outset.” (*Id.*) (quoting *Comcast Cable Comm. Corp. v. Finisar Corp.*, 2007 WL 716131, at *2 (N.D. Cal. March 2, 2007)). While “preliminary infringement contentions are still preliminary,” it is important to recognize that the Local Patent Rules strive to have the parties establish their contentions early on. (*Id.*) (citing *General Atomics v. Axis–Shield ASA*, 2006 WL 2329464, at *2 (N.D. Cal. Aug. 9, 2006)).

a. Good Cause

Exploring the “good cause” requirement, the Federal Circuit has stated that parties must “proceed with diligence in amending when new information comes to light in the course of discovery.” *O2 Micro*, 467 F.3d at 1366-68. Thus, to illustrate good cause, the moving party must demonstrate its diligence. (*Id.* at 1366).

Defendant argues it was diligent in its search for relevant prior art and thus satisfied the good cause requirement. (D.E. No. 143-1, (Def. Br.) at 8-9). Defendant argues that Judge Waldor erred in finding it was not diligent because its initial prior art

search did not include a search for FDA materials. (*Id.* at 10). Defendant argues that such FDA materials would not ordinarily be uncovered in a simple prior art search. (*Id.*). In opposition, Plaintiff argues that Defendant’s counsel admitted that it could have looked earlier through the FDA records. (D.E. No. 146 (Pl. Rep. Br.) at 7).

The Court affirms Judge Waldor’s finding that Defendant did not act with the requisite diligence because the party “seeking to amend its contentions bears the burden of establishing diligence.” *West v. Jewelry Innovations, Inc.*, No. 07-1812, 2008 WL 4532558, at *1 (N.D. Cal. Oct. 8, 2008) (citing *O2 Micro*, 467 F.3d at 1366-67)). Judge Waldor found that Defendant failed to meet such a burden, and this Court finds no error in Judge Waldor’s finding.

Moreover, not only must the party prove that it was diligent throughout the course of discovery, but also that it was diligent in its search for relevant prior art. *See West*, 2008 WL 4532558, at *2. Thus, “a party’s diligence in amending its preliminary invalidity contentions upon finding new prior art is only one factor to consider; the Court also must address whether the party was diligent in discovering the basis for the proposed amendment.” (*Id.*). On appeal, Defendant merely restates reasons why it purportedly took five months to seek leave to amend. Judge Waldor found none of Defendant’s reasons availing, and this Court finds that Judge Waldor did not err in making such a finding.

Defendant argues that Judge Waldor “got wrong” the fact that the alleged “[p]rior art that is the subject of [Roxane’s] Motion are referenced on the face of the patents-in-suit” because four of the six prior art references with which Roxane seeks to supplement “were *not* listed on the face of the distribution patents.” (D.E. No. 143-1 (Def. Br.) at 9)

(emphasis in original). Plaintiff disagrees and highlights the fact that “Roxane does not and cannot dispute that two of the six disputed references . . . **are listed** on the face of the patents-in-suit.” (D.E. No. 146 (Pl. Rep. Br.) at 9) (emphasis in original). Defendant also “concedes the indisputable fact that the Advisory Committee meeting—from which Roxane derives the remaining disputed materials—**was referenced in the Advisory Committee Transcript that is cited on the face of the patents in the ‘730 patent family** . . . [as well as] in all four prosecution histories.” (*Id.*) (emphasis in original). Plaintiff further highlights that “[t]o date, [Defendant] has yet to offer any reason for why it did not originally review the FDA website, despite its awareness of the citations on the face of the patents in the ‘730 patent family” and Defendant “just chose not to search for them for more than a year after becoming aware of the citations to the Advisory Committee Transcript.” (*Id.* at 10).

Defendant is unable to make the requisite showing that Judge Waldor committed an error warranting reversal because even if the four additional documents were not referenced on the face of the patents-in-suit, this does not affect the Court’s finding that Defendant was not diligent in its initial search. Defendant’s entire diligence argument appears to be premised on contentions that were either considered and rejected by Judge Waldor, or arguments that could have been presented prior to that ruling. This Court is accordingly not persuaded by Defendant’s argument.

b. Timeliness

Defendant alleges that Judge Waldor erred in finding the Defendant did not timely seek leave to amend its invalidity contentions. (D.E. No. 143-1 (Def. Br.) at 8). As justification for any alleged untimeliness, Defendant argues that, before properly seeking

leave to supplement, it needed to confirm that the prior art-at-issue was not cumulative of the art already discussed in its initial contentions, as well as to confirm that the prior art was not publicly available as of December 2001. (*Id.* at 11-12). Plaintiff agrees with Judge Waldor’s determination that a five-month delay did not constitute “diligence” and in further support, highlights a Federal Circuit decision which stated that an even shorter period of three months showed a lack of diligence.¹ (D.E. No. 146 (Pl. Rep. Br.) at 13).

This District requires “*ultra* early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act.” *Sanofi-Aventis v. Barr Labs., Inc.*, 598 F. Supp. 2d 632, 637 (D.N.J. 2009) (emphasis in original). As Judge Waldor observed, the Federal Circuit has emphasized the importance of the “timely application” element by recognizing that “if the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery in trial preparation.” *O2 Micro*, 467 F.3d at 1366.

Although Defendant disagrees with Judge Waldor’s finding, it provides no legal support to refute such a finding. Defendant argues that it needed the time due to the unconventional investigation it had to undertake to ascertain the date of public disclosure of the FDA materials. (D.E. No. 143-1 (Def. Br.) at 12). Defendant argues that “[b]ecause it was not evident from the documents themselves that they were publicly available in 2001, Roxane had to . . . [turn] to the Wayback Machine after exhausting other methods of ascertaining the date of public disclosure” of the FDA materials. (*Id.*). Defendant also blames Plaintiff for the delay in seeking leave because but for Plaintiff’s

¹ *O2 Micro*, 467 F.3d at 1367 (“O2 Micro waited almost three months . . . to serve its proposed amended contentions and two more weeks to formally move to amend.”).

delay in responding to Defendant's request to submit a joint letter to the Court, Defendant could have "cut[] down the time between discovery of the materials to the time of application to approximately four months."² (*Id.*). Defendant could have informed the Court of any delay on the part of Plaintiff, at the time of the delay, but failed to do so.

In short, mere disagreement with the judicial finding of a Magistrate Judge does not meet the "clear error" standard required for reversal. *See Walzer v. Muriel Siebert & Co., Inc.*, No. 04-5672, 2010 WL 4366197, at *9 (D.N.J. Oct. 28, 2010). Judge Waldor's finding of untimeliness is not clearly erroneous, nor contrary to law, as it is in line with Federal Circuit precedent. *See O2 Micro*, 467 F.3d at 1367. As such, Judge Waldor's finding of untimeliness is affirmed.

c. Undue Prejudice

Only if the moving party is able to show diligence may the court consider the prejudice to the non-moving party. *See CBS Interactive, Inc.*, 257 F.R.D. at 201; *see also Acer, Inc. v. Technology Properties Ltd.*, 2010 WL 3618687, at *3 (N.D.Cal. Sept. 10, 2010) ("[The moving party] must demonstrate good cause, an inquiry that considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted . . . If [the moving party] was not diligent, the inquiry should end.").

Defendant argues that Judge Waldor clearly erred in finding that Defendant's proposed supplementation would unduly prejudice Plaintiff. (D.E. No. 143-1 (Def. Br.)

² Court again notes that the Federal Circuit in *O2 Micro* found a shorter three-month delay to constitute a lack of diligence, making Defendant's present argument unavailing. *See also Genentech, Inc. v. Trustees of the Univ. of Penn.*, No. 10-02037, 2011 WL 4965638, at *2 (N.D. Cal. Sept. 16, 2011) (District Judge affirmed Magistrate Judge who found that a four-month delay showed a lack of diligence).

at 2). Defendant provides a timeline of the case but cites to no legal authority in support of its “clearly erroneous” argument. Notwithstanding Defendant’s argument, this Court need not address this issue on appeal because it does not find that Judge Waldor clearly erred in finding that Roxane was not diligent in discovering the disputed materials, a requisite showing for reversal of the Order. As such, Judge Waldor’s Order need not be reversed on these separate grounds.

V. Prior Art

Defendant argues that Judge Waldor committed an error of law in holding that the prior art materials at issue were not in fact prior art under § 102(b). (D.E. No. 143-1 (Def. Br.) at 13). Defendant argues that Judge Waldor “failed to recognize that a reference constitutes § 102(b) prior art so long as the reference is accessible to a person of ordinary skill in the art, regardless of whether he or she would have searched for it or found it.” (*Id.*). In response, Plaintiff disagrees with Defendant’s reading of its cited caselaw, and argues that “for something to qualify as prior art, it must be accessible to a person practicing ‘reasonable diligence.’” (D.E. No. 146 (Pl. Rep. Br.) at 15).

This Court need not address this issue on appeal because it does not find that Judge Waldor erred in finding that Roxane was not diligent in discovering the disputed materials, a requisite showing for reversal of the Order. As such, Judge Waldor’s Order need not be reversed on these separate grounds.

VI. Application of Local Patent Rules

Finally, Defendant argues that Judge Waldor erred in applying the Local Patent Rules of this District because they are “contrary, not only to the more liberal contention practice in other jurisdictions, but also the patent act.” (D.E. No. 143-1 (Def. Br.) at 15).

This Court is to utilize and enforce its designated local rules for patent cases. *Elan Pharma Int'l Ltd. v. Lupin Ltd.*, No. 09-1008, 2010 WL 1372316, at *3 (D.N.J. Mar. 31, 2010) (“[Local patent rules] apply to all civil actions filed in, or transferred to, this Court which allege infringement of a patent in a complaint . . . Local [Civil Rules] shall also apply to such actions, except to the extent that they are inconsistent with these Local Patent Rules.”). Thus, this Court finds that Judge Waldor did not err in applying the Local Patent Rules of this District.

VII. Conclusion

The Court concludes that Judge Waldor’s Order is neither clearly erroneous, nor contrary to law. Thus, Judge Waldor’s Order is affirmed.

s/Esther Salas
Esther Salas, U.S.D.J.