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On May 23, 2013, Defendant Teva appealed the Magistrate Judge's Opinion and Order denying its motion to amend its non-infringement contentions, alleging that (1) the Magistrate Judge erred in finding that Teva was not diligent in seeking to amend its contentions; (2) there would be no prejudice to Plaintiffs should Teva be allowed to amend; and (3) the interests of justice favor amendment. Teva's Brief in Support of its Rule 72 Appeal ("Def. Br.") at 1-2.

In opposition, the Janssen Plaintiffs, although they neither opposed nor consented to Teva's motion for leave to amend its non-infringement contentions, argue that the Magistrate Judge's Order is neither clearly erroneous nor contrary to law.¹ Janssen Plaintiffs' Brief in Opposition to Teva's Rule 72 Appeal ("Janssen Pls. Br.") at 3. More specifically, they argue that Teva offers no explanation for its failure to realize the basis for its proposed amendment with respect to the '946 patent prior to August 7, 2012. *Id.* at 8-9. Instead, Janssen argues, Teva fixates on what it alleges was the Magistrate Judge's error in finding that "Teva, by its own admission, first recognized its darunavir hydrate argument in early April of 2012, nearly six months before filing the instant motion." *Id.* at 9-10; May 9, 2013 Order at 9. Further, Janssen highlights that Teva is attempting to draw a "fallacious distinction" between the bases for its proposed defenses to the '946 and '506 patents. Janssen Pls. Br. at 10-11. Finally, Janssen concludes that the Order was in line with the recent rulings in *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, Civ. No. 10-6108, 2013 WL 785067 (D.N.J. Feb. 28, 2013), and *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355 (Fed. Cir. 2006). Janssen Pls. Br. at 11-12.

¹ This Court notes that there is no requirement that a party opposing a Rule 72 appeal must have also opposed the original motion before the magistrate judge. Local Civil Rule 72.1(c)(1) permits "[a]ny party opposing the appeal" to file a responsive brief. As the Janssen Plaintiffs argue, this appeal also seeks different relief from the underlying motion. Janssen Pls. Br. at 16. Previously, Teva sought leave to amend its non-infringement contentions, but now seeks the reversal of the Magistrate Judge's Order. *Id.* It follows that this Court will read and consider Janssen's opposition to Teva's appeal.

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The Government Plaintiffs contend that Teva fails to substantiate its objections as to the '506 patent, and simply attempt to sweep them into the '946 patent. Government Plaintiffs' Brief in Opposition to Teva's Rule 72 Appeal ("Gov. Pls. Br.") at 1. The Government adds Teva had ample opportunity to set forth its non-infringement arguments since January 2011, and had full knowledge of the nature of its own active ingredient. *Id.* at 2.

STANDARD OF REVIEW

A magistrate judge may hear and determine any non-dispositive pretrial matter pending before the district 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."² 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72. 1(c)(1)(A). "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)). *See also Jazz Pharms., Inc.*, 2013 WL 785067, at *1.

A finding is considered "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." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948). A decision is considered contrary to the law if the magistrate judge has "misinterpreted or misapplied applicable law." *Doe v. Hartford Life Acc. Ins. Co.*, 237 F.R.D. 545, 548 (D.N.J. 2006).

² The Court rejects Teva's argument that the Magistrate Judge's decision should be reviewed *de novo*. This is not a dispositive matter such as a motion for summary judgment or a motion to dismiss, but a discovery dispute. Courts within this District have treated motions to amend non-infringement contentions as non-dispositive matters to be reviewed under a "clearly erroneous or contrary to law standard." *See, e.g., Jazz Pharms., Inc.*, 2013 WL 785067, at *1. *See also* Gov. Pls. Br. at 7-8 (arguing that the Magistrate Judge's Opinion and Order in no way eliminates all of Teva's defenses to the '506 patent infringement claim).

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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*, Civ. 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).

"Decisions 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)).

DISCUSSION

Under 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." Unlike the liberal standard for amending pleadings, "the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the 'shifting sands' approach to claim construction." *King Pharms., Inc. v. Sandoz, Inc.*, Civ. No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (citing *Atmel Corp. v. Info. Storage Devices, Inc.*, Civ. No. 95-1987, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)). Because this action arises under the Hatch-Waxman Act, it is even more imperative that the parties establish their contentions early. *See Jazz Pharms., Inc.*, 2013 WL 785067, at *4 ("This District requires 'ultra early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act.'") (quoting *Sanofi-Aventis v. Barr Labs., Inc.*, 598 F. Supp. 2d 632, 637 (D.N.J. 2009)) (emphasis in original).

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With regard to 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 1366-67. The moving party has the burden of demonstrating its diligence, *id.* at 1366, and must show that it was both diligent throughout discovery and in “discovering the basis for the proposed amendment.” *West v. Jewelry Innovations, Inc.*, Civ. No. 07-1812, 2008 WL 4532558, at *2 (N.D. Cal. Oct. 8, 2008).

Defendant Teva argues that the Magistrate Judge incorrectly calculated the time between Teva’s discovery of its non-infringement defense for the ‘946 patent and the filing of its motion to amend, and it was diligent in seeking to amend its contentions. Def. Br. at 2-3. Teva argues that it became aware of its defense in August 2012 when drafting its non-infringement contentions for the related U.S. Patent No. RE42,889. *Id.* at 2. Two months later, Teva sought Janssen’s consent to amend its contentions. *Id.*

This Court affirms the Magistrate Judge’s finding that Teva did not act with the requisite diligence. The party “seeking to amend its contentions bears the burden of establishing diligence.” *West*, 2008 WL 4532558, at *1; *see also Jazz Pharms., Inc.*, 2013 WL 785067, at *3. The Magistrate Judge found that Teva failed to meet this burden, and this Court finds no error in the Magistrate Judge’s determination that Teva first recognized its darunavir hydrate argument in April 2012, if not earlier.

As the Janssen Plaintiffs point out, the evidence supporting the Magistrate Judge’s determination that Teva acknowledged that it first recognized its darunavir hydrate argument in April 2012 comes from Teva’s original moving papers. Teva’s Mot. for Leave to Amend Non-Infringement Contentions (“Teva Mot. Br.”) at 4-5 (describing Teva’s recognition during the exchange of claim construction disclosures that “administration of Teva USA’s ANDA products

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would not infringe the asserted claims of the '506 patent because Teva USA's ANDA products do not contain darunavir, but rather they contain a solvate [darunavir hydrate] that is substantially different from darunavir."); *see also* Janssen Pls. Br. at 10-11. The parties exchanged lists of claim terms to be construed on or about April 3, 2012, and exchanged preliminary claim constructions on or about April 24, 2012. ECF No. 144 (Magistrate Judge Arleo's Discovery Stipulation and Order).

Teva argues that the Magistrate Judge conflated, without explanation, the timing on the discovery of the defenses of the '506 and '946 patents. Def. Br. at 7. This Court finds that the Magistrate Judge did not err in his treatment of the two patents' defenses. Teva admits in its original motion to amend that both its proposed amendments share the same premise – that Teva's products do not contain darunavir but a solvate (darunavir hydrate) that is allegedly substantially different from darunavir. *Compare* Teva Mot. Br. at 3 (proposed defense to the '946 patent is that Teva's "ANDA products do not contain darunavir, but rather that they contain a solvate that is substantially different from darunavir") *with* Teva Mot. Br. at 5 (proposed defense to the '506 patent is that Teva's "ANDA products do not contain darunavir, but rather they contain a solvate that is substantially different from darunavir"). *See also* Janssen Pls. Br. at 10-11. It follows, logically, that if Teva was aware of the defense to one patent, it was on notice that the defense might apply to others. Even if Teva did not grasp, as it claims, that it might assert this non-infringement position with respect to the '946 patent before August 7, 2012, Teva does not explain its failure to discover the basis for such a position sooner. Janssen Pls. Br. at 9.

Moreover, as the Government Plaintiffs note, Teva has had numerous opportunities to amend since as early as January 2011 to set forth its non-infringement contentions with regard to the '506 patent. Gov. Pls. Br. at 10-13. As example, the Paragraph IV Certification Notice that

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Teva served in January 2011 described its product as “Darunavir Hydrate Tablets.” *Id.* at 13; May 9, 2013 Order at 12. In his Opinion, the Magistrate Judge reiterated the Government’s observation that “it is apparent that Teva recognized that its products contained darunavir hydrate at the time it served its Paragraph IV certification on January 31, 201[1].”³ May 9, 2013 Order at 12. This Court adds that an independent review of the record reveals the Magistrate Judge even gave Teva the benefit of the doubt by dating the discovery to April 2012, and not earlier.

This Court also finds that the Magistrate Judge’s decision is not contrary to law. Simply because Teva is able to cite a few decisions granting leave to amend contentions in the face of comparable delays by the parties seeking amendment does not render the Magistrate Judge’s Order clearly erroneous. *See Jazz Pharms., Inc.*, 2013 WL 785067, at *4 (“In short, mere disagreement with the judicial finding of a Magistrate Judge does not meet the ‘clear error’ standard required for reversal.”); *Andrews v. Goodyear Tire & Rubber Co.*, 191 F.R.D. 59, 68 (D.N.J. 2000); *Walzer v. Muriel Siebert & Co., Inc.*, Civ. No. 04-5672, 2010 WL 4366197, at *9 (D.N.J. Oct. 28, 2010); *Toth v. Alice Pearl, Inc.*, 158 F.R.D. 47, 50 (D.N.J. 1994).

Finally, the Court need not reach the issue of prejudice since it does not find that the Magistrate Judge clearly erred in finding that Teva was not diligent. *See Jazz Pharms., Inc.*, 2013 WL 785067, at *5 (citing *CBS Interactive, Inc. v. Etilize, Inc.*, 257 F.R.D. 195, 201 (N.D. Cal. 2009)). Similarly, the interests of justice would not be served by granting the motion to amend and prejudicing the non-moving parties. Fact discovery is closed, and expert reports are due. *See CBS Interactive, Inc.*, 257 F.R.D. at 203. *See also Abbott Diabetes Care Inc. v. Roche Diagnostics Corp.*, Civ. No. 05-3117, 2007 WL 2221029, at *2 (N.D. Cal. July 30, 2007).

³ The Magistrate Judge’s Opinion states January 31, 2012, not 2011, which is a typographical error.

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CONCLUSION

This Court concludes that the Magistrate Judge's Order is not clearly erroneous, unsupported by any evidence, or contrary to law. The May 9, 2013 Order is affirmed.

June 18, 2013

/s/ William H. Walls
United States Senior District Judge