

NOT FOR PUBLICATION

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

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CELGENE CORPORATION,	:	
	:	Civil Action No. 10-5197 (SDW)(SCM)
Plaintiff,	:	
	:	
v.	:	<b>OPINION</b>
	:	
NATCO PHARMA LIMITED,	:	July 9, 2015
ARROW INTERNATIONAL LIMITED,	:	
And WATSON LABORATORIES, INC.	:	
Defendants.	:	
	:	
_____	:	

**WIGENTON**, District Judge.

Before this Court is Plaintiff Celgene Corporation’s (“Celgene”) Partial Appeal of Magistrate Judge Madeline Cox Arleo’s<sup>1</sup> (“Judge Arleo”) November 18, 2014 Opinion and Order granting, in part, Defendants’ (Natco Pharma Limited, Arrow International Limited, and Watson Laboratories, Inc.) (collectively, “Natco”) Motion to Amend their Invalidity Contentions against U.S. Patent No. 7,465,800 (the “800 patent”) pursuant to 35 U.S.C. § 112 (“§112 defenses”). Jurisdiction in this Court is proper pursuant to 28 U.S.C. § 1332. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b). For the reasons set forth herein, this Court will **AFFIRM** Judge Arleo’s November 18, 2014 Opinion and Order.

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<sup>1</sup> As of December 2014, Judge Arleo was appointed and elevated to the position of United States District Judge. Notwithstanding, all action taken by Judge Arleo in this matter occurred in her previous capacity as a United States Magistrate Judge.

## BACKGROUND

This litigation arose when Defendants Natco filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration. Natco sought to market a generic version of the drug lenalidomide, which Plaintiff Celgene markets under the brand name Revlimid. Celgene alleged that Natco’s proposed generic drug infringed eighteen (18) patents, including the ’800 patent.

On June 8, 2011, and again on October 18, 2013, Celgene offered in a Joint Claim Construction and Prehearing Statement a proposed claim construction for the ’800 patent disputed claim term “hemihydrate.” After holding a Markman hearing (“Markman”), on May 14, 2014, this Court adopted Celgene’s construction of the term “hemihydrate.” See Markman Opinion, Dkt. No. 312, at 6-7. Celgene defined “hemihydrate” as “[a] hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate.” See Judge Arleo’s Opinion, Dkt. No. 366, at 2. By contrast, Natco defined “hemihydrate” as “a solid crystalline form of lenalidomide containing one water molecule for every two molecules of 3-(4-amino-1-oxo-1,3 dihydroisoindol-2-yl)- piperidine-2,6-dione, formally associated with one another within the unit cell in the solid crystalline structure, and which crystal form is specifically identified in the ’800 patent as the Form B polymorphic form, and demonstrated in TGA, Karl Fischer analysis, powder X-ray diffraction patterns, IR spectra, and/or DSC analysis, as distinguishable from other polymorphs, such as the anhydrous form[.]” Id. at 2-3.

On June 19, 2014, twenty-three days after the Markman opinion was issued, Defendants filed a Motion to Amend their Invalidity Contentions against the ’800 patent, arguing that the ’800 patent “is invalid for indefiniteness, lack of enablement, and lack of written description.” Judge Arleo’s Opinion, at 3. On November 18, 2014, Judge Arleo granted Defendants Natco’s motion

as to the '800 patent. Id. at 7. In reaching her conclusion, Judge Arleo said that “Local Patent Rule 3.7 allows for amendment of contentions ‘only by order of the Court upon a timely application and showing of good cause’” and that “Local Patent Rule 3.7 provides: ‘Non-exhaustive examples of circumstances that may support a finding of good cause include (a) a claim construction by the Court different from that proposed by the party seeking amendment.’” Id. at 4-5.

Judge Arleo then concluded that the plain language of Local Patent Rule 3.7 permitted a finding of good cause to allow Defendants to amend their Invalidity Contentions, especially in light of this Court’s rejection of Defendants’ proposed claim construction. Judge Arleo’s Opinion, at 6. Judge Arleo also deemed Defendants’ motion to amend timely, as it was filed only twenty-three days after this Court issued its Markman opinion. Id. Judge Arleo distinguished Prometheus Labs., Inc. v. Roxane Labs., Inc., No. 11-1241 (D.N.J. Aug. 6, 2012) on the grounds that “[t]here . . . the court concluded that the moving party was fully capable of moving to amend prior to an adverse Markman ruling . . . . In this case, however, the number of disputed patents, claims, and claim terms, is so great that the Court cannot conclude that Defendants should have moved to amend on June 8, 2011 to address every possible adverse claim construction ruling.” Id. Finally, Judge Arleo concluded that Celgene would not suffer undue prejudice as a result of Defendants’ amendment because permitting the amendment would neither “require Celgene to expend significant additional resources [nor] significantly delay the resolution of this case.” Id. at 6-7.

## **LEGAL STANDARD**

A United States Magistrate Judge may hear non-dispositive motions under 28 U.S.C. § 636(b)(1)(A) and Federal Rule of Civil Procedure 72(a). A party may then appeal a magistrate judge’s order within fourteen days of being served with a copy of the order. § 636(b)(1); Fed. R.

Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A). Subsequently, “[t]he district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law.” Fed. R. Civ. P. 72(a); see also § 636(b)(1)(A); L. Civ. R. 72.1(c)(1)(A); O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1366–67 (Fed. Cir. 2006) (“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.”); Janssen Prods., L.P. v. Lupin Ltd., Civ. No. 10-5954, 2013 WL 3086378, at \*1 (D.N.J. June 18, 2013) (applying both the clearly erroneous and the contrary to law standards to, and affirming, a magistrate judge’s opinion and order denying the defendants’ motion for leave to amend its non-infringement contentions under Local Patent Rule 3.7); Jazz Pharm., Inc. v. Roxane Labs., Inc., Civ. No. 10-6108, 2013 WL 785067, at \*1 (D.N.J. Feb. 28, 2013) (applying both the clearly erroneous and the contrary to law standards to, and affirming, a magistrate judge’s opinion and order denying the defendants’ motion for leave to amend its invalidity and non-infringement contentions under Local Patent Rule 3.7).

The clearly erroneous standard of review applies to a magistrate judge’s findings of fact. Lithuanian Commerce Corp. v. Sara Lee Hosiery, 177 F.R.D. 205, 213 (D.N.J. 1997) (citing Lo Bosco v. Kure Engineering Ltd., 891 F.Supp. 1035, 1037 (D.N.J. 1995)). A finding of fact 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 Third Circuit has interpreted this “to mean that the appellate court must accept the factual determination of the fact finder unless that determination ‘either (1) is completely devoid of minimum evidentiary support displaying some hue of credibility, or (2) bears

no rational relationship to the supportive evidentiary data.” Haines v. Ligget Group Inc., 975 F.2d 81, 92 (3d Cir. 1992) (quoting Krasnov v. Dinan, 465 F.2d 1298, 1302 (3d Cir. 1972)). Therefore, a district judge will not reverse a magistrate judge’s decision even if the district judge would 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). In other words, “[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). Finally, under the clearly erroneous standard, “a district court may not consider any evidence which was not presented to the magistrate judge.” Lithuanian, 177 F.R.D. at 213 (citing Haines, 975 F.2d at 92).

In contrast to the clearly erroneous standard of review, the contrary to law, or de novo, standard of review applies to a district judge’s review of a magistrate judge’s legal conclusions. Id. at 214; see also Haines, 975 F.2d at 91 (“[T]he phrase ‘contrary to law’ indicates plenary review as to matters of law.”). “A ruling is ‘contrary to law’ when the magistrate judge has misinterpreted or misapplied the applicable law.” Pharmaceutical Sales & Consulting Corp. v. J.W.S. Delavau Co., Inc., 106 F.Supp.2d 761, 764 (D.N.J. 2000).

## **DISCUSSION**

Under Local Patent Rule 3.7, parties may amend contentions “only by order of the Court upon a timely application and showing of good cause.” L. Pat. R. 3.7. An example of a circumstance “that may, absent undue prejudice to the adverse party, support a finding of good cause include[s]: (a) a claim construction by the Court different from that proposed by the party seeking amendment.” Id. Therefore, amendment is permitted only when (1) there is a timely application, (2) there is a showing of good cause, and (3) the adverse party does not suffer undue

prejudice. AstraZeneca AB v. Hanmi, USA, Inc., No. 11-760, 2013 WL 264609, at \*1 (Jan. 23, 2013).

As stated above, Defendants filed a Motion to Amend their Invalidity Contentions against the '800 patent twenty-three days after the issuance of this Court's Markman opinion in which Plaintiff's construction of the term "hemihydrate" was adopted. While Rule 3.7 does not define "timely application," Rule 3.3 allows parties to file their Invalidity Contentions within forty-five days of receiving a Disclosure of Asserted Claims and Infringement Contentions. Therefore, Judge Arleo correctly found that Defendants' motion was timely. Cf. O2 Micro Int'l Ltd., 467 F.3d at 1367 (federal circuit ruling upholding a district court's decision that the appellant failed to amend its contentions diligently since appellant waited for more than three months to move to amend). Moreover, great deference is due to a magistrate's decision in discretionary matters. Kresefky v. Panasonic Commc'ns & Sys. Co., 169 F.R.D. 54, 64 (D.N.J. 1996) ("Where, as here, the magistrate has ruled on a non-dispositive matter . . . his or her ruling is entitled to great deference and is reversible only for abuse of discretion.").

Second, Judge Arleo determined that Defendants' motion to amend comports with the good cause requirement of Rule 3.7 which specifically allows for amendment when "a claim construction by the Court differ[s] from that proposed by the party seeking amendment." L. Pat. R. 3.7. Judge Arleo rejected Celgene's argument that this phrase should be interpreted as "a claim construction by the Court different from that proposed by either party." See Judge Arleo's Opinion, at 5-6. In doing so, Judge Arleo remarked that "[i]f the Local Patent Rules were intended to limit amendment to instances where the Court adopts a claim construction different from either of those proposed by the parties, the Rules would reflect that language." Id. at 6. This Court finds no error

in Judge Arleo's reasoning. Put differently, Judge Arleo did not misapply or misinterpret Rule 3.7.

The plain language of Rule 3.7 is limited only by its permissiveness. If “a claim construction by the Court different from that proposed by the party seeking amendment . . . *may* . . . support . . . a finding of good cause,” then such adverse construction may also, in some circumstances, *not* support a finding of good cause. *Id.* (emphasis added); Prometheus Labs., Inc., No. 11-1241 (D.N.J. Aug. 6, 2012) (“[Rule 3.7] does not mean that anytime a court adopts a claim construction different from what a party proposed that that party may automatically amend its invalidity contentions.”). Presumably, then, Rule 3.7's permissiveness must be balanced with the broader purposes of the Local Patent Rules.

“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.’” King Pharm., Inc. v. Sandoz Inc., No. 08-5974, 2010 WL 2015258, at \*4 (D.N.J. May 20, 2010) (quoting Computer Accelerations Corp. v. Microsoft Corp., 503 F. Supp. 2d 819, 822 (E.D.Tex. 2007)). The Local Patent 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.” Atmel Corp. v. Info. Storage Devices, Inc., No. 95-1987, 1998 WL 775115, at \*2 (N.D. Cal. Nov. 5, 1998). “Unlike the liberal policy for amending pleadings, the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the ‘shifting sands’ approach to claim construction.” *Id.* To that end, Rule 3.7 requires a showing of diligence by the party seeking to amend its pleadings. See O2 Micro Int'l Ltd., 467 F.3d at 1366. Rule 3.7, however, “is not a straitjacket into which litigants are locked from the moment their contentions are served. There is a modest degree of flexibility, at least near the outset.” Comcast Cable Commc'ns. Corp. v. Finisar

Corp., No. 06-04206, 2007 WL716131, at \*2 (N.D. Cal. March 2, 2007). Here, as Judge Arleo found, given the volume of disputed patents, claims, and claim terms, it was not unreasonable that Defendants delayed moving to amend until after this Court issued its Markman opinion.

Finally, Judge Arleo determined that Plaintiff would not suffer undue prejudice if Defendants were allowed to amend their contentions. In doing so, Judge Arleo considered “whether permitting the proposed amendments would: (1) require Celgene to expend significant additional resources, or (2) significantly delay the resolution of this case.” Judge Arleo’s Opinion, at 7 (citing TFH Publ’ns, Inc. v. Doskocil Mfg. Co., 705 F. Supp. 2d 361, 366 (D.N.J. 2010)). Judge Arleo concluded that:

. . . Celgene would not suffer adverse prejudice if amendment is permitted. First, because expert reports have not been exchanged, Celgene will simply be able to address these arguments in their initial reports. Second, if Celgene believes additional fact discovery is necessary, Celgene may request that fact discovery be reopened for the limited purpose of conducting discovery on Defendants’ new invalidity contentions. Third, a trial date has not been set. Fourth, additional expenses in amending responses to invalidity contentions does not constitute undue prejudice.

Id. at 7 (footnote and citations omitted). Clearly, Judge Arleo cited more than enough facts to support her conclusion that Plaintiff would not suffer undue prejudice if Defendants’ motion to amend were granted. Therefore, this Court will affirm Judge Arleo’s findings and conclusions.

## CONCLUSION

For the reasons set forth above, Judge Arleo’s November 18, 2014 Opinion and Order granting, in part, Defendants’ Motion to Amend their Invalidity Contentions against U.S. Patent No. 7,465,800 pursuant to 35 U.S.C. § 112 is **AFFIRMED**.



*s/ Susan D. Wigenton*  
**SUSAN D. WIGENTON**  
**UNITED STATES DISTRICT JUDGE**

Orig: Clerk  
cc: Parties  
Madeline Cox Arleo, U.S.D.J.  
Steven C. Mannion, U.S.M.J.