

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

**TAKEDA PHARMACEUTICAL
COMPANY LIMITED, et al.,**

Plaintiffs,

v.

SUN PHARMA GLOBAL FZE, et al.,

Defendants.

Civil Action No. 14-4616 (MLC)

**MEMORANDUM OPINION
FILED UNDER TEMPORARY SEAL**

This matter comes before the Court upon Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Pharmaceuticals America, Inc.'s (collectively, "Takeda") letter motion seeking leave to amend their Infringement Contentions pursuant to L.Pat.R. 3.7. Defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Ltd. ("collectively, "Sun") oppose Takeda's motion. The Court has reviewed and considered all arguments set forth in favor of and in opposition to Takeda's motion. The Court considers Takeda's motion without argument pursuant to L.Civ.R. 78.1(b). For the reasons stated below, Takeda's motion is DENIED.

I. Background

This is a patent infringement case involving United States Patent No. 6,328,994 (the "994 patent"), which involves lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg, which Takeda sells under the name Prevacid® SoluTab™. Takeda claims that Sun's generic version of Prevacid® SoluTab™, for which Sun filed an Abbreviated New Drug Application ("ANDA") with the FDA, infringes the '994 patent. (*See generally*, Pl. Amended Cmplt.; Docket Entry No. 42).





On October 21, 2014, the Court conducted the Initial Pretrial Conference in this matter and on October 24, 2014, the Court entered a Letter Order setting the schedule that would govern this litigation. (*See* Letter Order of 10/24/2014; Docket Entry No. 28). According to that schedule, Takeda was to serve its Infringement Contentions by December 19, 2014, which it did. After reviewing Takeda's Infringement Contentions, Sun requested that Takeda supplement same, arguing that Takeda's Infringement Contentions lacked the specificity required by L. Pat. R. 3.1(c) because:

Takeda has failed to identify specifically where the claimed "enteric coating agent" and "sustained-release agent" of claim 1 of the '994 patent are found within Sun's proposed lansoprazole products. Rather, Takeda asserts in its Infringement Contentions that Sun's proposed drug product [REDACTED]

(Letter from Caroline L. Marsili to Takashi Okuda of 1/30/2015; Lockner Decl. Ex. 7; Docket Entry No. 78-8). While Takeda believed its original Infringement Contentions were sufficient, it agreed to supplement them in order to avoid burdening the Court with the parties' dispute.

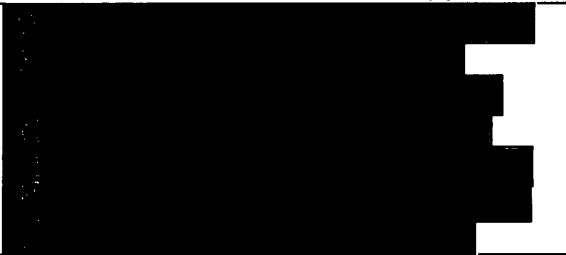
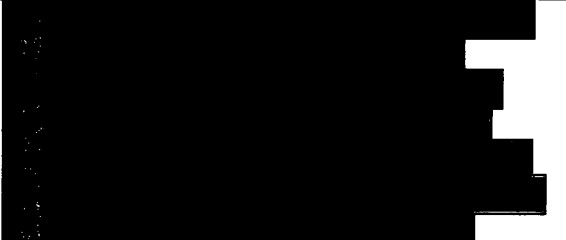
(Letter from Takashi Okuda to Caroline Marsili of 2/13/2015; Lockner Decl. Ex. 6 at Ex. 2; Docket Entry No. 78-7). As a result, on February 13, 2015, Takeda served its Supplemental Infringement Contentions. As part of its supplementation, Takeda changed its description of how Sun's generic lansoprazole delayed-release orally disintegrating tablets, 15 and 30 mg, satisfied certain of the limitations of Claim 1 and Claim 29 of the '994 patent:

Original Infringement Contentions

Claims of the '994 patent	Sun's Proposed Drug Products
Claim 1	
comprising a first component which is an enteric coating agent	
and a second component which is a sustained release agent,	
Claim 29	
comprising a first component which is an enteric coating agent	
and a second component which is a sustained release agent,	

(Lockner Decl. Ex. 5; Docket Entry No. 78-6).

Supplemental Infringement Contentions

Claim 1	
comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent,	
Claim 29	
Comprising a first component which is an enteric coating agent and a second component which is a sustained release agent,	

(Lockner Decl. Ex. 8; Docket Entry No. 78-9).

On February 3, 2015, the Court set June 22, 2015 as the fact discovery deadline. (See Minute Entry of 2/3/2015). That deadline was later extended until September 22, 2015 when

fact discovery officially closed. (See Letter Order of 6/2/2015; Docket Entry No. 58). The *Markman* schedule was revised via the Court’s Letter Order entered on April 13, 2015. (Docket Entry No. 50). According to that schedule, *Markman* briefing closed on June 29, 2015.

At the *Markman* hearing there was only one issue before the Court: how to construe the following claim language:

Claim Language	Takeda’s Proposed Construction	Sun’s Proposed Construction
“an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent”	The “enteric coating layer” may be constructed by plural (e.g., 2 or 3) layers and includes a first component that is an “enteric coating agent” which can be a methacrylate copolymer and a second component that is a “sustained-release agent” which can be a methacrylate copolymer.	“an enteric coating layer comprising two discrete components (i.e., not chemically the same) in an admixture, namely a first component which is an enteric coating agent and a second component which is a sustained-release agent. Eudragit L30D-55 is not a sustained-release agent.”

The District Court conducted the *Markman* hearing on December 2, 2015 and construed the disputed claim language as follows:

An enteric coating layer comprising two discrete components (i.e., not chemically the same), namely a first component which is an enteric coating agent and a second component which is a sustained-release agent.

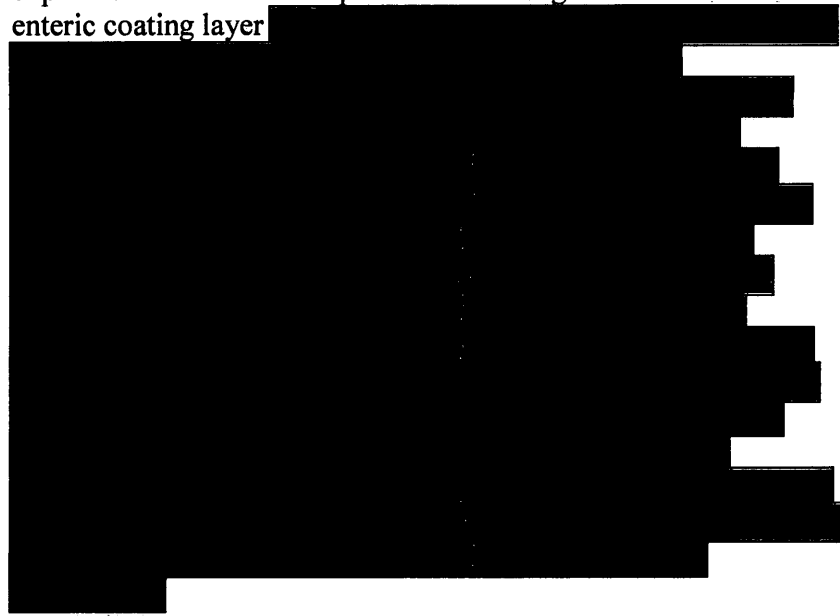
(Order of 12/4/2015; Docket Entry No. 75).

One week later, Sun wrote to Takeda seeking a stipulated judgment that its generic product did not infringe any claim of the ‘994 patent under the *Markman* Order entered in this case. (See Letter from Samuel T. Lockner to Counsel for Takeda of 12/9/2015; Lockner Decl. Ex. 12; Docket Entry No. 78-13). Takeda responded on December 23, 2015, indicating that it would not agree to a stipulated judgement and intended to seek leave to amend its Infringement Contentions in accordance with L.Pat.R. 3.7 (Email from Arlene Chow to Samuel Lockner of

12/23/2015; Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 1/20/2016, Ex. C; *see also* Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 12/23/2015; Docket Entry No. 77).

Following the Court's preferences, on December 23, 2015, Takeda also informally wrote the Court to advise of its intention to seek leave to amend its Infringement Contentions. (Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 12/23/2015; Docket Entry No. 77). The Court directed Takeda to provide a status update by January 8, 2016. Takeda complied and also produced a copy of its proposed Second Supplemental Infringement Contentions on that date. (Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 1/8/2016; Docket Entry No. 78-29). Takeda seeks to amend its Infringement Contentions to:

explain that Sun's ANDA products contain granules with an enteric coating layer



(Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 1/20/2016 at 4). After reviewing Takeda's letter, the Court directed the parties to provide additional briefing on the issue. The parties complied and Takeda's request to amend its Infringement Contentions is now ripe for the Court's consideration.

II. Analysis

A. Standard of Review

This District's Local Patent Rules govern Takeda's motion to amend its Infringement Contentions. "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.*, Civ. No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (quoting *Computer Acceleration Corp. v. Microsoft Corp.*, 503 F.Supp.2d 819, 822 (E.D. Tex. 2007) (internal quotation marks and citation omitted). Indeed, they "'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.'" *Id.* (quoting *Atmel Corp. v. Info. Storage Devices, Inc.*, No. C 95-1987 (FMS), 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)). As such, unlike proposed amendments of the pleadings, which are liberally granted pursuant to FED.R.CIV.P. 15, amendments to invalidity contentions are governed by the more conservative standard set forth in L.Pat.R. 3.7. *See Id.* (noting that "the philosophy behind amending claim charts is decidedly conservative and designed to prevent the 'shifting sands' approach to claim construction." (internal quotation marks and citation omitted)). Thus, while L.Pat.R. 3.7 certainly "is not a straitjacket into which litigants are locked from the moment their contentions are served," the "modest degree of flexibility" that it provides to amend "at least near the outset[,] must be viewed in the context of the Local Patent Rules' overarching goal of having the parties establish their contentions early on. *Comcast Cable Communs. Corp., LLC v. Finisar Corp.*, No. C 06-04206 WHA, 2007 U.S. Dist. LEXIS, at *5 (N.D. Cal. March 2, 2007).

As just noted, Local Patent Rule 3.7 governs amendments of infringement contentions. Pursuant to L.Pat.R. 3.7, "[a]mendment of any contentions . . . may be made only by order of the

Court upon a timely application and showing of good cause.” L.Pat.R. 3.7 sets forth a “[n]on-exhaustive” list of “examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause[.]” one of which is “a claim construction by the Court different from that proposed by the party seeking amendment[.]” L.Pat.R. 3.7(b) (Emphasis added). Under L.Pat.R. 3.7, good cause “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.” *Acer, Inc. v. Tech. Prob. Ltd.*, Case No. 5:08-cv-00877 JF/HRL, Case No. 5:08-cv-00882 JF/HRL, Case No. 5:08-cv-05398 JF/HRL, 2010 U.S. Dist. LEXIS at *3 (N.D. Cal. Sept. 10, 2010) (citing *O2 Micro Intl’l Ltd. v. Monolithic Power Sys., Inc.* 467 F.3d 1355, 1366-68 (Fed. Cir. 2006)). Importantly, absent a showing of diligence, the Court does not reach prejudice. *See Warner Chilcott Co., LLC v. Lupin Ltd.*, Civil Action No. 11-7228 (JAP), 2013 U.S. Dist. LEXIS 116988, at *5 (D.N.J. Aug. 19, 2013) (citing *Apple v. Samsung*, Case No.: 11-CV-01846-LHK, 2012 U.S. Dist. LEXIS 83115, at *13 (N.D. Cal. Mar. 27, 2012) (collecting cases)).

The party seeking to amend its contentions bears the burden of establishing diligence. *O2 Micro.*, 467 F.3d at 1366. Further, in determining good cause and diligence, the Court may consider other facts such as:

- (1) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings.

Warner Chilcott, Civil Action No. 11-7228 (JAP), 2013 U.S. Dist. LEXIS 116988, at *5-6 (citing *Oy Ajat, Ltd. v. Vatech Am., Inc.*, Civil Action No. 10-4875 (PGS), 2012 WL 1067900, at *20-21 (D.N.J. Mar. 29, 2012) (collecting cases)).

Importantly, while “a claim construction by the Court different from that proposed by the party seeking amendment” may support a finding of good cause under L.Pat.R. 3.7, “courts in this district have made clear that ‘a *Markman* ruling is not a ‘free pass’ to grant motions to amend contentions. The moving party still has to show that it acted diligently to determine that the amendment was necessary.” *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, Civil Action No. 10-6108 (ES)(MAH), 2015 WL 3822210, *2 (D.N.J. June 19, 2015) (quoting *Horizon Pharma AG v. Watson Labs., Inc.—FL*, No. 13-5124, D.E. No. 138 at 14 (D.N.J. Feb. 24, 2015)). Certainly, L.Pat.R. 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. Such a leap ‘would destroy the effectiveness of the local rules in balancing the discovery rights and responsibilities of the parties.’” *Prometheus Labs. Inc. v. Roxane Labs., Inc.*, Case Nos. 11-1241, 11-230, Transcript of Recorded Opinion, at 14 (D.N.J. Aug. 6, 2012) (D.E. 174 in 11-1241) (quoting *Finisar Corp. v. DirecTV Group Inc.*, 424 F.Supp. 2d 896, 900-01 (E.D. Tex. 2006)). Instead, L.Pat.R. 3.7 “is intended to allow a party to respond to an unexpected claim construction by the court.” *Id.* (quoting *Finisar*, 242 F.Supp. 2d at 901).

B. Diligence

Here, the Court finds that Takeda has not carried its burden of establishing that it acted diligently in seeking to amend its invalidity contentions. As such, the Court finds that good cause does not exist to permit the proposed amendment under L.Pat.R. 3.7. While the District Court did not adopt Takeda’s proposed claim construction and while Takeda is correct, the District Court also did not adopt Sun’s construction, the Court finds the construction adopted, which represents in large part Sun’s proposed construction, to be far from unexpected.

Takeda relies heavily on the fact that the District Court adopted a claim construction that “was different from that proposed by both parties” in arguing that its diligence should be measured from the date of said claim construction and not any time sooner. (Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 1/20/2016 at 3). Indeed, Takeda in its reply argues that Sun’s proposed claim construction (embracing three proposed noninfringement limitations) and the claim construction entered by the Court are fundamentally different.” (Letter from John E. Flaherty to Hon. Tonianne J. Bongiovanni of 2/10/2016 at 4).

Below is the District Court’s construction shown as an overlay on Sun’s proposed construction. The rejected portions of Sun’s construction appear in a lighter font:

an enteric coating layer comprising two discrete components (i.e., not chemically the same) in an admixture, namely a first component which is an enteric coating agent and a second component which is a sustained-release agent. Eudragit L30D-55 is not a sustained-release agent

The constructions are different, but hardly fundamentally so, especially when examined in the context of Takeda’s request to amend.

Takeda, itself, appears to recognize as much. Indeed, Takeda in its reply states that “Sun ignores that Takeda’s amended infringement contentions are in response to a noninfringement limitation (i.e., “not chemically the same”) that *Sun* proposed.” (*Id.* at 7). In other words, Takeda acknowledges that its basis for Takeda’s amendment request is the noninfringement limitation proposed by Sun in March 2015, included in Sun’s proposed construction during the *Markman* process and adopted by the District Court on December 2, 2015. At the end of the day, it is Sun’s proposal, which the District Court adopted, triggering Takeda’s request to amend. Takeda was on notice that the District Court could potentially adopt Sun’s proposed construction and the District Court’s construction is exactly the type for which Takeda can reasonably be held

accountable. *See Prometheus*, Case Nos. 11-1241, 11-230, Transcript of Recorded Opinion, at 14 (quoting *Convolve Inc. v. Compaq Computer Corp.*, Civ. No. 5141, 2006 WL 2527773 at *4 (S.D.N.Y. Aug. 13, 2006) (finding that “parties who are on notice of the opposing party’s claim construction and do not prepare for the fact that the court may adopt it, can be held accountable.”))

As the *Prometheus* Court found, L.Pat.R. 3.7:

attempts to provide a means to amend contentions to address an unexpected construction. To interpret the rule otherwise, would mean that a party could wait until after the construction to take action, even though they were fully equipped to act sooner. This would be inconsistent with the rule’s purpose, which is to solidify all known positions. If a party knows of the adverse party’s construction, it will undoubtedly take steps to defeat the construction and to ameliorate the impact of the construction if adopted. Thus, if a party presents a claim construction that if adopted would result in new invalidity or infringement positions by an opposing party, the opposing party has a duty to act diligently on such information and make an application to amend. It would not be acting diligently if it sat back, waited to see if the construction was adopted, then sought to embrace another defense it was aware it would adopt if its claim construction were rejected and the adversary’s was adopted.

Id. at 15-16.

As a result, the Court is unpersuaded by Takeda’s argument that it was diligent because it made its request to amend its Infringement Contention a mere month (which included the Christmas and New Year’s holidays) after the District Court rendered its *Markman* ruling. Instead, Takeda was fully equipped to act sooner. It certainly could have sought to amend its Infringement Contentions in March 2015 or shortly thereafter when Sun proposed its “not chemically the same” noninfringement limitation. Takeda did not do so and its failure is its own.

Further, the Court finds diligence to be lacking especially given the fact that here there was only one claim term in dispute. Unlike in other cases like *Celgene Corp. v. Natco Pharma*

Ltd., Civil Action No. 10-5197 (SDW), 2014 WL 6471600, * 3 (Nov. 18, 2014), where the number of disputed patents, claims and claim terms may make it unreasonable for a party to address every possible adverse claim construction ruling, Takeda certainly could have and should have done so here. Not only is there only one patent in dispute in this litigation but, as just stated, there was only one claim term in need of construction. As a result, the Court finds that Takeda has failed to carry its burden of establishing that it acted diligently in seeking to amend its Infringement Contentions.

C. Prejudice

Because the Court has determined that Takeda was not diligent in moving to amend its infringement contentions, the Court does not reach the issue of prejudice. The Court does, however, note that given the fact that fact discovery has closed, a *Markman* decision has been reached and the 30-month stay is set to expire on December 3, 2016, the Court is hard-pressed to see how Sun would not be prejudiced by Takeda's proposed amendment despite the fact that a trial date has not yet been set.

III. Conclusion

For the reasons stated above, Takeda's request to amend its Infringement Contentions is DENIED. An appropriate Order follows.

Dated: March 4, 2016

s/Tonianne J. Bongiovanni
HONORABLE TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE