

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

HELSINN HEALTHCARE S.A. and	:	
ROCHE PALO ALTO LLC,	:	Civil Action No. 11-3962 (MLC)
	:	(consolidated)
Plaintiffs,	:	
	:	
v.	:	
	:	
DR. REDDY’S LABORATORIES	:	OPINION AND ORDER
LTD, et al.,	:	
	:	
Defendants.	:	
_____	:	

This matter comes before the Court on separate Motions to Amend Invalidation Contentions by Defendants Sandoz Inc. (“Sandoz”), Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, “Teva”), and Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, “DRL”) (collectively, “Defendants”) [dkt. nos. 119, 120, 124]. Plaintiffs Helsinn Healthcare S.A. (“Helsinn”) and Roche Palo Alto LLC (“Roche”) (collectively, “Plaintiffs”) opposed the Motions [dkt. no. 130]. The Court has considered the Parties’ submissions pursuant to FED. R. CIV. P. 78 and, for the reasons set forth below, Defendants’ Motions are **GRANTED**, in part, and **DENIED**, in part.

I. BACKGROUND

Plaintiffs sued Defendants for infringement of two patents relating to liquid formulations of palonosetron on July 8, 2011. Plaintiffs filed suit on a third patent on September 23, 2011. Collectively, the patents relate to Plaintiffs’ Aloxi ® product (“Aloxi” or “the accused product”).

The facts relevant to the instant Motions are as follows. Pursuant to the Court's December 2, 2011 Scheduling Order [dkt. no. 75]¹, Defendants served their initial Invalidity Contentions on December 1, 2011. Prior to serving its initial Invalidity Contentions or conducting any discovery, Sandoz also provided Plaintiffs with notice of an on-sale bar defense relating to a transaction with a company called Oread Laboratories, Inc. ("Oread") that appeared in the public prosecution history for the patents-in-suit. After receiving that notice, Plaintiffs and Sandoz engaged in settlement discussions, which continued through Summer 2012.

The Parties completed claim construction briefing and U.S. District Judge Mary L. Cooper conducted a Markman hearing on September 7, 2012. Judge Cooper has reserved claim construction rulings until trial. See dkt. nos. 103, 104.

Between January 2012 and November 2012, the Parties exchanged a substantial number of documents to meet the discovery deadlines in this case. In September 2012, it became clear that the settlement discussions between Plaintiffs and Sandoz would not resolve the matter. Therefore, pursuant to a stipulation between Plaintiffs and Sandoz, the Court permitted Sandoz to (a) amend its contentions to assert the "on-sale" defense; and (b) conduct discovery relating to those newly added defenses. See dkt. no. 102 (September 12, 2012 Stipulation and Order) (the "September 12 Order").

Pursuant to the Court's September 12 Order, Sandoz served its First Amended Invalidity Contentions on September 25, 2012. Sandoz alleged, based on documents submitted by the patentees during prosecution of the patents-in-suit, that the claimed invention was "ready for patenting" by March 24, 1999, and that Helsinn appeared to have purchased a substantial

¹ The December 2, 2011 Scheduling Order memorialized dates by which Defendants were required to serve their Invalidity Contentions based on the Parties' previously approved Joint Discovery Plan.

quantity of palonosetron from a third party supplier, Oread, under circumstances that constituted a commercial sale or offer for sale. Sandoz's Br. at 4 (citing First Amended Invalidity Contentions).

On December 27, 2012, the Court granted pro hac vice motions admitting counsel from the law firm of Morrison & Foerster, who thereafter became co-lead counsel for Sandoz, along with Cozen O'Connor and Hill Wallack LLP. On January 7, 2013, Hui Liu, Esq., of Morrison & Foerster began reviewing Plaintiffs' document production. One of Ms. Liu's primary objectives was to identify Plaintiffs' internal documents that related to Sandoz's on-sale bar defense. Through her review, Ms. Liu identified a number of Plaintiffs' internal documents that provided additional and stronger support for Sandoz's on-sale bar defense. In addition, according to Sandoz, in December 2012, Plaintiffs substantially changed the identities of the named inventors in this action indicating a potentially invalidating defect in their inventorship claims. Sandoz claims this fact, coupled with its review of certain of Plaintiffs' documents, support its new inventorship defense.

On January 16, 2013, Sandoz notified Plaintiffs of its intention to move to amend its invalidity contentions based on counsel's review of Plaintiffs' document production. The Court held a status conference with the Parties on January 17, 2013. At that time, DRL and Teva also informed the Court of their intention to move to amend their Invalidity Contentions.² The Defendants unsuccessfully attempted to obtain Plaintiffs' consent to amend their Invalidity Contentions. Thereafter, pursuant to a briefing schedule set by the Court, Defendants filed the instant Motions on February 15, 2013.

² It is unclear when either DRL or Teva first notified Plaintiffs of their respective intentions to move to amend their Invalidity Contentions.

II. LEGAL STANDARD

The District's 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." Computer Accelerations Corp. v. Microsoft Corp., 503 F.Supp.2d 819, 822 (E.D.Tex. 2007). The rules are designed specifically to "require parties to crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed." Atmel Corp. v. Info. Storage Devices, Inc., 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998). This is "to 'prevent the 'shifting sands' approach to claim construction.'" O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1364 (Fed. Cir. 2006) (citing Atmel, 1998 WL 775115, at *2). As distinguished from the liberal standard for amending pleadings, "the philosophy behind amending claim charts is decidedly conservative." Atmel, 1998 WL 775115, at *2. However, Rule 3.7 "is not a straitjacket into which litigants are locked from the moment their contentions are served"; instead, "a modest degree of flexibility [exists], at least near the outset." Comcast Cable Communs. Corp. v. Finisar Corp., 2007 WL716131, at *2 (N.D. Cal. March 2, 2007).

Pursuant to L. Pat. R. 3.7, leave to amend invalidity contentions may be granted "only by order of the Court upon a timely application and showing of good cause." Rule 3.7 provides a nonexhaustive list of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause:

- (a) a claim construction by the Court different from that proposed by the party seeking amendment;
- (b) recent discovery of material prior art despite earlier diligent search;
- (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention;
- (d) disclosure of an infringement contention by a Hatch- Waxman Act party asserting infringement under L. Pat. R. 3.6(g) that requires response by the adverse party because it was not previously presented or reasonably anticipated;
- and (e) consent by the parties in interest to the amendment and a

showing that it will not lead to an enlargement of time or impact
other scheduled deadlines

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., 2010 WL 3618687, at *3 (N.D. Cal. Sept. 10, 2010) (citing O2 Micro, 467 F.3d 1355, 1355). Importantly, however, the Court may only consider prejudice to the non-moving party if the moving party is able to demonstrate diligence. Apple v. Samsung, 2012 U.S. Dist. LEXIS 83115, at *13 (N.D. Cal. Mar. 27, 2012) (collecting cases).

Courts have understood diligence to require a “showing that the party seeking leave to amend acted . . . promptly [in] moving to amend when new evidence is revealed in discovery.” O2 Micro, 467 F. 3d 1355, 1363, 1366 (collecting cases). This requirement is consistent with L. Pat. Rule 3.7’s requirement that the Motion be “timely.” As with good cause in general, the burden “is on the movant to establish diligence rather than on the opposing party to establish lack of diligence.” O2 Micro, 467 F. 3d 1355, 1366.

In determining whether good cause exists, courts have also considered such other factors 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. See Oy Ajat, Ltd. v. Vatech Am., Inc., 2012 WL 1067900, at *20-21 (D.N.J. Mar. 29, 2012) (collecting cases).

III. DISCUSSION

A. Sandoz's Motion

Sandoz seeks leave to supplement its on-sale bar defense and to add a new inventorship defense. First, Sandoz has identified three instances which it claims show that the claimed invention was on sale more than one year prior to the "Critical Date."³ Specifically, Sandoz identifies three agreements to manufacture or deliver the claimed invention: (1) Plaintiffs' 1998 dealings with Oreal; (2) Plaintiffs' 2000 dealings with SP Pharmaceuticals ("SP"); and (3) Plaintiffs' 2000 dealings with MGI Pharma, Inc. ("MGI").

Sandoz argues its application is timely and is supported by good cause, for (at least) the following reasons: (1) Sandoz advised Plaintiffs of its proposed amendments within two months of the completion of document production, and provided Plaintiffs with a copy two weeks before the first deposition in the case; (2) the proposed amendments represent only further development of the on-sale bar defense disclosed by Sandoz over one year ago; and (3) the subject matter of the proposed amendments is extremely important. Sandoz's Br. at 14.

In opposition, Plaintiffs argue that Sandoz was not diligent in moving to amend. Specifically, Plaintiffs claim Sandoz's proposed Amended Invalidity Contentions are based on long-available information and present new legal and factual theories not previously disclosed.

1. Diligence & Timeliness

In this case, Sandoz has made a threshold showing that it was diligent in moving to amend its Invalidity Contentions following discovery of new information. Sandoz cites ten documents in support of its proposed amendments. Eight of those documents were produced in

³ In this case, as the parent application for all three patents-in-suit was filed on January 30, 2003, the Critical Date is January 30, 2002.

June 2012 and two more documents were produced in November 2012. Cert. of H. Liu at ¶ 7.

Plaintiffs claim that they produced documents as early as May 2012 which should have alerted Sandoz to the defenses it now seeks to raise. Pl.'s Opp. at 5 (referring to document included in Sandoz's initial Invalidity Contentions, the "Stacher Reference"). Plaintiffs also point out that at least eight of the documents Sandoz now relies on were produced as early as June 2012. Id. at 8-9. Plaintiffs, however, do not dispute that their document production was not complete until November 2012. Indeed, it appears that more than half of Plaintiffs' production occurred at that time, including at least two documents which Sandoz claims are critical to its proposed amended Invalidity Contentions. See Decl. of H. Liu at ¶ 7 (Ex.'s A-J). That pieces of the puzzle might have been revealed at earlier times does not mean that a complete picture was likewise available. It is reasonable to conclude, therefore, that Sandoz was not able to formulate a "comprehensive story of Plaintiffs' commercial activities in violation of the on-sale bar," Sandoz's Br. at 5, until Plaintiffs had completed their document production.⁴

Sandoz also maintains its delay in moving to amend is justified by ongoing settlement discussions as well as its own document production. See Sandoz Reply at 2. These arguments are not, in and of themselves, independently compelling. To be sure, a party should not be able to avoid its responsibilities in one respect (i.e., diligence in moving to amend) simply because it has concurrent discovery obligations or ongoing settlement discussions. However, when viewed in context, they suggest Sandoz was conscientiously pursuing its obligations in this case and further counsel against a finding of neglect or lack of diligence.

Sandoz was also diligent in moving to amend following discovery of new evidence to support its inventorship defense. Sandoz's inventorship defense is based on papers Plaintiffs

⁴ This is not to say that Sandoz acted as expeditiously as possible. Still, when viewed on balance, the Court believes Sandoz's proposed amendments should be permitted.

filed with the U.S. Patent and Trademark Office in December 2012 seeking to remove Enrico and Riccardo Braglia as inventors from each of the patents-in-suit. Based on Plaintiffs' actions in removing these inventors, Sandoz began researching the potential new inventorship defense. On November 14, 2012, Plaintiffs produced a May 1995 "Formulation Book for Intravenous Dosage Forms" (the "Formulation Book") prepared by Dr. Roger Fu from nonparty Syntex. This book, according to Sandoz, demonstrates that the invention may have been conceived at Syntex.

Plaintiffs argue that Sandoz was not diligent with respect to its inventorship defense because the Formulations Book was previously produced. However, although excerpts of the Formulations Book were, in fact, produced, the entire book was not produced until November 2012. And, more importantly, Plaintiffs did not seek to remove the previously named inventors until December 2012—just one month before Sandoz filed its Motion to Amend. Thus, when viewed in context, it appears Sandoz did diligently move to amend after it learned of the possible defense.

Finally, Plaintiffs' reliance on this Court's decision in King Pharmaceuticals, Inc. v. Sandoz Inc., 2010 WL 2015258 (D.N.J. May 20, 2010), is misplaced. King involved Sandoz's attempt to amend its Invalidity Contentions nearly eight months after serving its initial Invalidity Contentions. Id. at 1. In that case, Sandoz based its motion to amend on documents which had been available to it for 18 months prior to filing its motion. Id. This Court denied Sandoz's motion because "waiting 18 months to appreciate the materiality" of the publications which gave rise to the motion to amend did not demonstrate diligence in moving to amend. Id. at *4. This Court also denied Sandoz's motion because the proposed amendments in that case would "delay discovery, lengthen the life of this case and ultimately prejudice Plaintiffs." Id. at *5.

In this case, although Sandoz served its initial Invalidity Contentions in December 2011, its First Amended Invalidity Contentions were not served until November 2012. In contrast to King, Sandoz here took only two months to seek leave to amend its First Amended Invalidity Contentions. In addition, Sandoz claims that it was not until document production was complete in November 2012 that it fully appreciated the materiality of documents they claim support their Motion. Accepting this as true, it took Sandoz only two months from that time to move to amend.⁵ Furthermore, as discussed below, the Court here does not have similar concerns regarding prejudice and delay.

2. Prejudice

In deciding whether Plaintiffs' proposed amendments would unfairly prejudice Plaintiffs, the Court considers whether permitting the proposed amendments would (1) require Plaintiffs to expend significant additional resources; or (2) significantly delay the resolution of the dispute. TFH Publications, Inc. v. Doscocil Mfg. Co., Inc., 705 F. Supp. 2d 361, 366 (D.N.J. 2010); see also O2 Micro, 467 F.3d at, 1366-68.

Here, Plaintiffs will suffer no prejudice if Sandoz is granted leave to amend. Fact discovery closed on May 15, 2013 and will likely not need to be reopened because of the new Invalidity Contentions.⁶ Although depositions are ongoing, the Parties have agreed to conditionally allow questions regarding the proposed amendments. Expert discovery is also ongoing. The deadline for dispositive motions is not until August 16, 2013, and a trial date has

⁵ Plaintiffs place great emphasis on a document relied on by Sandoz in its December 2011 Invalidity Contentions, the "Stacher Reference". See, e.g., Pl.'s Opp. at 5. Plaintiffs claim the Stacher Reference evidences Plaintiffs' agreement with MGI. Id. at 5-6. Plaintiffs, however, fail to adequately support their position that a single paragraph in this document should have led Sandoz to conclude that Plaintiffs had reached an agreement with MGI prior to the Critical Date.

⁶ To the extent the Parties need to conduct additional discovery regarding Sandoz's new inventorship defense, the Court believes such discovery will be minimal. Thus, there would be no significant prejudice to Plaintiffs in this regard.

not yet been set. By all accounts, the litigation is progressing according to schedule. Allowing the proposed Amended Invalidity Contentions, therefore, will not cause Plaintiffs to incur additional expenses or significantly delay resolution of this matter.

Moreover, in contrast to Plaintiffs, Sandoz may be significantly prejudiced if it is not permitted to proceed with its proposed new defenses. Plaintiffs do little to contradict Sandoz's position that the evidence is potentially fatal to Plaintiffs' case (and patent). As a result, preventing Sandoz from presenting all of its defenses would not facilitate resolution on the merits. See Acco Brands, Inc. v. PC Guardian Anti-Theft Prods., Inc., 2008 U.S. Dist. LEXIS 88142 (N.D. Cal. May 22, 2008) (granting motion to amend invalidity contentions and discussing court's preference to decide cases on the merits); see also Dole v. Arco Chem. Co., 921 F.2d 484, 487 (3d Cir. 1990) (discussing strong policy for deciding claims on the merits as opposed to technicalities). This notion is especially true where, as here, any risk of unfair surprise or delay is mitigated by the fact that Plaintiffs' own documents (and actions) form the bases of the proposed Amended Invalidity Contentions. Contra CoreLogic Info. Solutions, Inc. v. Fiserv, Inc., 2012 WL 4051823, at *3 (E.D. Tex. Sept. 13, 2012) (denying motion to amend invalidity contentions where movant "fail[ed] to appreciate the importance of enforcing the disclosure and discovery rules to ensure that outcomes are based upon the merits, and not unduly influenced by surprise and delay."). Accordingly, Sandoz's Motion is **GRANTED**.

B. Teva's Motion

Teva also seeks leave to amend its Invalidity Contentions to include on-sale bar defenses that are substantially identical to Sandoz's. Teva's proffered bases for granting leave to amend are likewise substantially the same as Sandoz's. As a result, the discussion above is incorporated by reference, and Teva's Motion is **GRANTED**.

C. DRL's Motion

DRL seeks leave to amend its Invalidity Contentions as to the obviousness of the patents-in-suit by adding certain pieces of prior art; namely, three Helsinn press releases totaling six pages. According to DRL, these “newly-discovered prior art press releases strengthen DRL’s existing contention that the patents-in-suit are invalid for obviousness.” DRL’s Br. at 1.

Plaintiffs once again point out that the press releases cited by DRL were produced first in May 2012 and later in June 2012. Pl.’s Opp. at. 23. For substantially the same reasons discussed with respect to Sandoz above, the Court concludes that DRL was diligent in moving to amend; that is, DRL did not have a complete picture of Plaintiffs’ actions until document production was complete.

Furthermore, Plaintiffs have not demonstrated any tangible prejudice which would result if the press releases are permitted. In fact, Plaintiffs even argue that the press releases “are simply not material because, among other reasons, they are at best cumulative of other documents that [DRL] already cites.” *Id.* at 25. DRL, moreover, has stated that the press releases do not add a new defense, but rather add to its existing obviousness defense. The Court, therefore, concludes that the press releases would not cause additional expense or delay. Accordingly, DRL’s Motion in this regard is **GRANTED**.

In addition to the press releases, DRL also asks the Court to grant it leave to amend its Invalidity Contentions to “incorporate by reference” any amendments permitted as to Sandoz and/or Teva. DRL’s Br. at 1. DRL’s request, without more, does not obviate DRL’s need to comply with Local Patent Rule 3.7. *Cf. Johnson v. Manhattan Ry. Co.*, 289 U.S. 479, 496-97 (1933) (“[C]onsolidation is permitted as a matter of convenience and economy in administration, but does not merge the suits into a single cause, or change the rights of the parties, or make those

who are parties in one suit parties in another.”). Accordingly, DRL’s Motion is this regard is **DENIED**.

IV. CONCLUSION & ORDER

The Court has considered the papers submitted pursuant to FED. R. CIV. P. 78 and, for the reasons set forth above,

IT IS on this 2nd day of July, 2013,

ORDERED that Sandoz’s Motion to Amend its Invalidity Contentions is **GRANTED**; and it is further

ORDERED that Teva’s Motion to Amend its Invalidity Contentions is **GRANTED**; and it is further

ORDERED that DRL’s Motion to Amend its Invalidity Contentions is **GRANTED**, in part, and **DENIED**, in part; and it is further

ORDERED that Defendants shall serve their Amended Invalidity Contentions within seven (7) days from the date of this Order; and it is further

ORDERED that a telephone status conference, to be initiated by counsel for Plaintiffs, has been scheduled in this matter for **July 10, 2013** at **10:00 AM**.

/s/ Douglas E. Arpert

DOUGLAS E. ARPERT
UNITED STATES MAGISTRATE JUDGE