

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC.,  
PENINSULA PHARMACEUTICALS,  
INC., and SHIONOGI & CO. LTD.,

Plaintiffs,

v.

SANDOZ, INC.,

Defendant.

Civil Action No. 11-7247 (FLW)

**ORDER**

Presently before the Court is a motion by Defendant Sandoz, Inc. (“Sandoz”) for leave to supplement its Invalidity Contentions [Docket Entry No. 78]. Plaintiffs Janssen Pharmaceuticals, Inc. (“Janssen”), Peninsula Pharmaceuticals, Inc. (“Peninsula”), and Shionogi & Co. Ltd. (“Shionogi”)(collectively “Plaintiffs”) filed a patent infringement action on December 13, 2011, asserting that Sandoz infringed U.S. Patent No. 5,317,016 (the “’016 Patent”) by the filing of Abbreviated New Drug Application (“ANDA”) No. 203440, seeking to sell a generic version of the antibiotic doripenem prior to the expiration of the ‘016 Patent. In this motion, Sandoz seeks leave to supplement its Invalidity Contentions with respect to asserted claims 1-5 and 9-15 of the ‘016 Patent. Plaintiffs oppose this motion [Docket Entry No. 85]. The Court considers the motion on the papers, without oral argument, pursuant to Rule 78. For the reasons set forth below, Sandoz’s motion is **GRANTED**.

## I. BACKGROUND AND PROCEDURAL HISTORY

On May 16, 2012, the Court issued a Scheduling Order setting forth relevant deadlines. [Docket Entry No. 27.] In accordance with the Scheduling Order, on May 18, 2012, Plaintiffs served their Disclosure of Asserted Claims identifying claims 1-5 and 9-15 of the '016 Patent. *Id.* On July 20, 2012, Sandoz served its Invalidity Contentions. *Id.* On July 23, 2012, Plaintiffs discovered that they had inadvertently omitted claim 16 from their Disclosure of Asserted Claims, and advised Sandoz of the omission two days later. [Docket Entry No. 56 at 2]. The parties attempted to negotiate the possibility of adding claim 16 until mid-August, but could not reach an agreement. On September 21, 2012, Plaintiffs filed a Motion to Amend their Disclosure of Asserted Claims to add claim 16 of the '016 Patent, arguing that claim 16 had been inadvertently omitted. *Id.* In support of that motion, Plaintiffs contended that Sandoz would not suffer any prejudice because, in relevant part, the case was still in its early stages, the proposed amendment did not raise any new theories and would not change the substance of Sandoz's defenses. [Docket Entry No. 46 at 6-7]. Sandoz opposed Plaintiffs' motion arguing, in relevant part, that it would need to hire another expert and re-evaluate its non-infringement and invalidity positions with regard to claim 16. [Docket Entry No. 47 at 2, 9].

On October 25, 2012, the undersigned granted Plaintiffs' motion to amend, finding good cause to permit the amendment and, further, that the addition of the claim would not unfairly prejudice Sandoz. [Docket Entry 56 at 7-12]. Subsequently, on December 4, 2012, the Court entered a new Scheduling Order accounting for the addition of claim 16 of the '016 Patent. [Docket Entry No. 63]. The new Scheduling Order provided, in relevant part, that Sandoz was to serve Invalidity and Non-infringement Contentions by February 6, 2013, and Plaintiffs were to

respond by March 25, 2013. *Id.* The parties later agreed to extend the schedule by several weeks; on January 2, 2013, the undersigned entered an amended Scheduling Order requiring Sandoz to serve its Invalidity and Non-infringement Contentions for claim 16 by February 19, 2013, with Plaintiffs' responses due by April 5, 2013. [Docket Entry No. 64].

Sandoz's amended Invalidity Contentions include prior art that Sandoz previously disclosed in its initial Invalidity Contentions for claims 1-5 and 9-15, as well as additional prior art of which Sandoz alleges it only became aware following the addition of claim 16. On February 19, 2013, Sandoz filed the instant motion for leave to supplement its initial Invalidity Contentions for claim 1-5 and 9-15 to include this newly discovered prior art. [Docket Entry No. 78]. Plaintiffs filed opposition on March 4, 2013. [Docket Entry No. 85]. Sandoz filed a reply on March 22, 2013. [Docket Entry No. 91]. In early May, 2013, the parties submitted additional letters advising the Court that Plaintiffs had filed a Response to Sandoz's Invalidity Contentions for claim 16. [Docket Entry Nos. 97 & 98].

## II. LEGAL STANDARD

The Local Patent Rules govern the litigation process for patent infringement cases in the District of New Jersey. *See* L. Pat. R. 1.2. The 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).<sup>1</sup> Indeed, the Rules are "designed specifically to require parties to crystallize their

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<sup>1</sup>The District of New Jersey originally developed its Local Patent Rules based on those adopted by the Eastern District of Texas and the Northern District of California. While some changes have been made to the Rules, the original purpose and substance of the Rules remain

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. C95-1987 (FMS), 1998 WL 775115, at \*2 (N.D. Cal. Nov. 5, 1998).

Local Patent Rule 3.7 governs the “[a]mendment of any contentions, disclosures, or other documents required to be filed or exchanged.” Leave to amend may be granted “by order of the Court upon a timely application and showing of good cause.” *Id.* Rule 3.7 only permits amendment “absent undue prejudice to an adverse party.” *Id.* Accordingly, Rule 3.7 expressly permits a party to seek leave to amend its contentions, but the party seeking leave must make a particularized showing. The Rule includes a non-exhaustive list of circumstances in which, absent undue prejudice to the non-moving party, a court may permit amendment, including, for example, where material information was discovered that was not and could not have been found earlier despite a diligent search. Thus, Rule 3.7 does not amount to “a straitjacket into which litigants are locked from the moment their contentions are served,” but instead, provides for “a modest degree of flexibility, at least near the outset.” *TFH Publications, Inc. v. Doskocil Manufacturing Co., Inc.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010). As a result, pursuant to Rule 3.7, a court may permit a party to amend provided that the following three elements are established: (1) the moving party makes a timely application to the court; (2) there is good cause for the amendment; and (3) there is no undue prejudice to the adverse party. *Jazz Pharms, Inc., v. Roxane Laboratories, Inc.*, No. 10-6108, 2012 WL 3133943, at \* 2 (D.N.J. July 30, 2012).

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closely aligned. Thus, the Court finds it appropriate to look at those districts for additional guidance.

### III. DISCUSSION

#### A. Parties' Arguments

##### 1. Sandoz's Arguments in Support of the Amendment

In the instant matter, Sandoz argues that it should be permitted to supplement its initial Invalidation Contentions regarding claims 1-5 and 9-15 to include recently discovered prior art. First, Sandoz contends that the instant motion is timely. Sandoz discovered the relevant prior art while preparing its Invalidation Contentions for claim 16 of the '016 patent – the claim that Plaintiffs sought to belatedly add to this case – and Sandoz filed the motion for leave to amend on February 19, 2013, the same day that it filed its Invalidation Contentions for claim 16. Sandoz's Br. at 7-8.

Next, Sandoz argues that good cause exists to amend. Specifically, Sandoz notes that after the Court permitted Plaintiffs to add claim 16 in October 2012, Sandoz engaged a new expert – Dr. Mark Domagala – to conduct an invalidity analysis on claim 16, and, as part of that analysis, Dr. Domagala discovered additional prior art. Sandoz's Br. at 8. In addition, Dr. Domagala provided new insights on certain prior art references upon which Sandoz had relied in its initial Invalidation Contentions for claims 1-5 and 9-15. *Id.* Sandoz contends that these references are not only relevant to claim 16, but are also relevant to the invalidity of claims 1-5 and 9-15. *Id.* Moreover, Sandoz contends that in addition to engaging a new expert, Sandoz's counsel internally conducted an additional prior art search for claim 16 of the '016 patent and that, despite a diligent prior search, the recent search uncovered new prior art references that are relevant to the invalidity of claim 16 as well as the invalidity of claims 1-5 and 9-15. Sandoz's Br. at 8-9.

Finally, Sandoz argues that Plaintiffs would not suffer any prejudice if it is permitted to amend its Invalidity Contentions. Sandoz notes that it is timely serving its Invalidity and Non-infringement Contentions for claim 16 and, as set forth in the Scheduling Order, Plaintiffs have an opportunity to respond to these contentions by April 5, 2013. In that regard, Sandoz notes that because the prior art and much of the invalidity analysis for claim 16 is the same as for claims 1-5 and 9-15, Plaintiffs' responses to the proposed supplemental Invalidity Contentions will not be "overly burdensome." Sandoz's Br. at 9. In addition, Sandoz contends that Plaintiffs will not be prejudiced by having to respond to the supplemental Invalidity Contentions for claims 1-5 and 9-15 since Plaintiffs will need to address this new prior art and invalidity analysis regardless, with respect to claim 16. *Id.* at 9-10. Finally, Sandoz argues that the schedule favors amendment; specifically, Sandoz notes that *Markman* briefs are not due until July 18, 2013, that fact discovery does not close until November 25, 2013 and that expert discovery does not close until March 10, 2014 – nearly ten months from now. *Id.* at 10. Thus, Sandoz argues that Plaintiffs will not suffer any prejudice if it is permitted leave to amend.

## 2. Plaintiffs' Arguments Against the Amendment

In response, Plaintiffs initially argue that Sandoz was not diligent in seeking leave to amend its Invalidity Contentions for claims 1-5 and 9-15. Specifically, Plaintiffs suggest that Sandoz "knew of several of the references for at least seven months when it submitted its Invalidity Contentions" and "[f]or the remaining references, Sandoz never identifies when it discovered the" new prior art or why it waited until February to seek leave to supplement. Pls' Br. at 12.

Next, Plaintiffs contend that Sandoz has not demonstrated that good cause exists to permit amendment. Plaintiffs suggest that Sandoz is using the addition of claim 16 as a pretext to supplement its original Invalidity Contentions. In that regard, Plaintiffs contend that the only new element added by claim 16, that was not required in claims 1 and 12, is “bringing bacterium into contact with the claimed antibiotic,” Pls’ Br. at 13, and argue that Sandoz is not using the new prior art to show that this additional limitation was obvious. Pls’ Br. at 6-7, 9. Further, Plaintiffs argue that because the validity of claim 16 with respect to obviousness is “entirely dependent on the validity of the compounds covered by claim 1 of the ’016 patent,” there was no need for Sandoz to perform an additional prior art search. Pls’ Br. at 13 (quoting Sandoz’s Claim 16 Inv. Cont. at 7).

In addition, Plaintiffs argue that three of Sandoz’s new references are not newly discovered. Specifically, Plaintiffs argue that Sungawa 1991 was discussed in Sandoz’s initial Invalidity Contentions, that Thornber was produced in July 2012 as a document upon which Sandoz intended to rely, and, finally, that Sandoz used Murata ‘543 as a primary reference in its initial obviousness arguments. Pls’ Br. at 5, 14. Thus, Plaintiffs argue that good cause does not exist to permit “new contentions involving previously known art.” Pl’s Br. at 14. Further, with regard to the remaining two references – Burger and Korolkovas – Plaintiffs contend that Sandoz has not established why it should not have discovered these publicly available medicinal chemistry references earlier. Pls’ Br. at 15.

Next, Plaintiffs reject Sandoz’s claim that it discovered the new prior art because of new searches related to claim 16. Plaintiffs argue that at the time Sandoz was performing its initial prior art searches, Sandoz had no reason to believe that Plaintiffs would not assert claim 16 since

it was only on May 18, 2012, when Janssen served its Disclosure of Asserted Claims, that Sandoz could have questioned whether claim 16 was in the case. Pls' Br. at 16. Moreover, Plaintiffs argue that Sandoz's suggestion that it only discovered the new prior art because of a search performed with the guidance of the inventors' development materials, such reasoning is contrary to the Local Patent Rules. Specifically, Plaintiffs note that the Local Patent Rules provide for the disclosure of invalidity contentions before the patent owner is required to turn over the inventors' development materials. Pls' Br. at 16 (citing L. Pat. R. 3.6(d), (g)-(i)).

Plaintiffs also argue that good cause to amend does not exist because the references are not "material prior art." Pls' Br. at 17. Specifically, Plaintiffs suggest that the Burger and Korolkovas references are duplicative of Thornber; thus, they are not material as required by Local Patent Rule 3.7.

Finally, Plaintiffs argue that it will be prejudiced if Sandoz is allowed to supplement its invalidity contentions. Specifically, Plaintiffs suggest that by way of this motion, Sandoz is only seeking to correct the "flaws and deficiencies" that Plaintiffs pointed out in their responses to Sandoz's initial Invalidity Contentions. Pls' Br. at 17.

B. Analysis

1. Timeliness

On October 25, 2012, the Court permitted Plaintiffs to amend their Disclosure of Asserted Claims to add claim 16. As a result, the Court entered a new Scheduling Order, requiring Sandoz to serve Invalidity and Non-infringement Contentions regarding claim 16 by February 19, 2013. In accordance with the schedule, Sandoz states that it searched for and

engaged an additional expert who provided Sandoz with new prior art relating to claim 16. In addition, Sandoz conducted an additional in-house search for prior art relevant to claim 16. Thus, on February 19, 2013, the same date on which Sandoz served its Invalidity and Non-infringement Contentions regarding claim 16, Sandoz also filed the instant motion for leave to supplement its Invalidity Contentions for claims 1-5 and 9-15. The Court finds Sandoz's motion to be timely.

Although Sandoz has not specifically identified when it first discovered that the new prior art was relevant to claim 16 as well as claims 1-5 and 9-15, the Court notes that in a period of three months: (1) Sandoz engaged a new expert; (2) the new expert performed a prior art search and invalidity analysis; and (3) based on this search and analysis, Sandoz prepared Invalidity Contentions for claim 16, as well as supplemental Invalidity Contentions for claims 1-5 and 9-15. Courts have found similar time frames to be timely for purposes of amendment. *See, e.g., TFH Publications*, 705 F. Supp. 2d at 367 (permitting plaintiff to amend contentions two months after service of initial contentions); *Zilog, Inc. v. Quicklogic Corp.*, No. CO3-03725, 2006 WL 563057, at \* 1-2 (N.D. Cal. March 6, 2006) (permitting amendment where no more than three months passed between initial disclosure and motion to amend); *but see Jazz Pharmaceuticals*, 2012 WL 3133943 (denying leave to amend five months after discovering omission); *Nautilus Neurosciences, Inc. v. Wockhardt USA LLC*, No. 11-1997, Docket Entry No. 98 at 6, n.3 (D.N.J. Jan. 23, 2013)(denying leave where amendment was sought 14 months after original contentions were exchanged, but before the Markman hearing had occurred); *Atmel Corp. v. Info. Storage Devices, Inc.*, No. C 95-1987 FMS, 1998 WL 775115, at \*1-2 (N.D. Cal. Nov. 5, 1998) (denying plaintiff's motion for leave to amend where amendment was requested

more than a year after preliminary infringement contentions were served).

Finally, Plaintiffs were aware of the forthcoming invalidity analysis concerning claim 16, since it was warranted by Plaintiffs' own belated addition of claim 16 to the case. In that regard, Plaintiffs have received notice of the supplemental Invalidity Contentions early in this case, months before claim construction briefs are due and almost a year prior to the close of expert discovery. For all these reasons, the Court finds that Sandoz has satisfied the timeliness prong.

2. Good Cause

Next, the Court must consider whether good cause exists to permit the amendment. Rule 3.7 provides a non-exhaustive list of circumstances that may constitute good cause, including where there has been "recent discovery of material prior art despite earlier diligent search." L. Pat. R. 3.7 (b). In order to illustrate good cause, there must be a showing of diligence by the moving party. *O2 Micro Intern. Ltd. v. Monolithic Power Systems, Inc.*, 467 F.3d 1355, 1367 (Fed. Cir. 2006). Specifically, a good cause showing "requires diligence throughout the discovery process and that the moving party not only must act promptly upon discovery of new [information], but also must establish that it was diligent in its search." *West v. Jewelry Innovations, Inc.*, Civ. No. 07-1812, 2008 WL 4532558, at \*2 (N.D. Cal., Oct. 8, 2001). Thus, in addition to considering whether the application to amend is timely, the court must also consider whether the moving party was "diligent in discovering the basis for the proposed amendment."

Sandoz discovered the new prior art references while analyzing its Invalidity Contentions for the newly added claim 16. Indeed, Sandoz contends that despite diligent prior searches, both Sandoz and its new expert found additional new prior art pursuant to the search related to claim

16 and that this prior art is relevant both to claim 16 and to claims 1-5 and 9-15. That Sandoz and its expert performed new prior art searches should not surprise Plaintiffs, who belatedly added claim 16 and agreed to permit Sandoz the time to hire a new expert to analyze claim 16 and serve Invalidity Contentions.

The language of Local Patent Rule 3.7 provides for good cause to amend based on “recent discovery of material prior art despite earlier diligent search.” L. Pat. R. 3.7(b). Here, Sandoz’s initial Invalidity Contentions comprised 66 pages of legal and factual arguments concerning invalidity for obviousness and were supported with a nearly 200 page claim chart. Sandoz Rep. Br. at 8; Pls’ Br., Declaration of Scott B. Howard (“Howard Dec.”) ¶¶ 6, 7 [Docket Entry No. 85-1]. Further, as Sandoz points out, Plaintiffs themselves recognized that “Sandoz spent considerable time and effort in identifying prior art and setting forth its contentions.” Pls. Br. at 4. Thus, although Plaintiffs suggest that Sandoz could have found the references earlier, this does not negate Sandoz’s earlier diligent search, or Sandoz’s entitlement to perform an additional prior art search regarding claim 16.

For all these reasons, the Court finds that Sandoz has demonstrated good cause to amend its Invalidity contentions.

### 3. Prejudice

Finally, the Court must consider whether Plaintiffs will be prejudiced if Sandoz is allowed to supplement its Invalidity Contentions with regard to claims 1-5 and 9-15. In that regard, the Court notes that this is not a case where amendment would impede resolution of the case. Indeed, the current schedule contemplates that opening claim construction briefs are due on

July 18, 2013, that fact discovery will remain open until November 25, 2013, and that expert discovery will not close until March 10, 2014. In light of this schedule, Plaintiffs do not, and cannot, argue that the amendment would require any additional time to be added to the schedule.

Plaintiffs' main argument with regard to prejudice appears to be that Sandoz's attempt to supplement its Invalidity Contentions is a "do-over[]" to correct flaws and weaknesses pointed out by the opposing party." Pls' Br. at 17. Sandoz's discovery of new prior art arose, however, as a direct result of Plaintiffs' own omission regarding claim 16. Further, as Sandoz correctly points out, Plaintiffs "ignore the fact that they are already required to develop responsive contentions to Sandoz's Invalidity Contentions for Claim 16, which incorporate substantially the same invalidity analysis and rely on the same prior art as Sandoz's proposed Supplemental Invalidity Contentions for claim 1 and other asserted claims." Sandoz's Rep. Br. at 15. In light of the significant time left in the schedule, and that Plaintiffs have, in fact, served responsive contentions for claim 16, *see* Docket Entry Nos. 97 & 98, the Court finds that no prejudice will result if Sandoz is permitted to amend.

#### **IV. CONCLUSION**

For the reasons set forth above, and for good cause shown,

**IT IS** on this 22nd day of **May, 2013**,

**ORDERED** that Sandoz's Motion for Leave to Supplement its Invalidity Contentions is **GRANTED**; and it is further

**ORDERED** that Sandoz shall file its Supplemental Invalidity Contentions within 5 days of the date of this Order; and it is further

**ORDERED** that Plaintiffs shall respond to Sandoz's Supplemental Invalidity Contentions within 20 days of their receipt.

A handwritten signature in black ink, appearing to read "Lois H. Goodman", written over a horizontal line.

**LOIS H. GOODMAN**  
**United States Magistrate Judge**