

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

<b>KING PHARMACEUTICALS, INC.,</b>	:	<b>Civil Action No. 08-5974 (GEB)</b>
<b>et al.,</b>	:	
	:	
<b>Plaintiffs,</b>	:	
	:	
<b>v.</b>	:	
	:	
<b>SANDOZ INC.,</b>	:	<b>MEMORANDUM OPINION</b>
	:	<b>AND ORDER</b>
<b>Defendant.</b>	:	
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**ARPERT, U.S.M.J.**

**I. INTRODUCTION**

This matter comes before the Court on a Motion by Defendant Sandoz Inc. (“Sandoz”) for Leave to Amend its Local Patent Rule 3.7 Invalidity Contentions [dkt. entry no. 60]. Plaintiffs King Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc. (collectively “King”) and Pharmaceutical IP Holding, Inc.’s (“Pharma IP”) (with King, collectively “Plaintiffs”) has opposed the Motion and Sandoz has filed a reply. The Court has reviewed the papers submitted and heard oral argument on May 10, 2010. For the reasons stated herein, Sandoz’s Motion is denied.

**II. BACKGROUND AND PROCEDURAL HISTORY**

This is a patent infringement case wherein Plaintiffs are asserting infringement of U.S. Patent No. 7,122,566 (“the ‘566 patent”), entitled “Metaxalone Products, Method of Manufacture, and Method of Use”, based on Sandoz’s application for FDA approval to market a generic metaxalone product.

On April 27, 2009, the Court issued a Scheduling Order setting a May 22, 2009 deadline

for Sandoz to serve its Invalidity Contentions. Accordingly, on May 22, 2009, Sandoz served its Invalidity Contentions, citing 30 pieces of prior art. Sandoz contends that it was not until January 2010 that it first recognized the materiality of an additional prior art reference, Beebe, *A Clinical and Pharmacologic Review of Skeletal Conditions*, 12 American Journal of Therapeutics, 151-171 (2005) (the “Beebe” article). On January 26, 2010, Sandoz provided Plaintiffs with a copy of the Beebe article and requested Plaintiffs’ consent to amend its Invalidity Contentions to include the Beebe article. On February 3, 2010, Plaintiffs advised Sandoz that they objected to Sandoz’s attempted revision of its Invalidity Contentions. As a result, on March 12, 2010 Sandoz filed the instant Motion for Leave to Amend its Invalidity Contentions to identify the Beebe article as additional prior art and add an explanation of how it applies to the claims of the ‘566 patent.

**A. Sandoz’s Arguments in Support of the Motion to Amend**

Sandoz argues that it should be permitted to amend its Invalidity Contentions because (1) the Beebe article was only recently identified as material prior art and (2) there will be no undue prejudice to Plaintiffs at this stage of the litigation.

Sandoz contends that the significance of the Beebe article was not realized until late January 2010 despite the fact that the Beebe article was identified in two searches performed in 2008. The search results provided the title of the article and an abstract of its contents which did not include any reference to a cytochrome p450 isozyme. (*See generally* Sandoz’s Br. at 4-5.) Sandoz also contends that the Beebe article was not found in Sandoz’s metaxalone-related files nor identified in the file history of the ‘566 patent. *Id.* Sandoz maintains that the Beebe article is relevant and material because “[n]o prior art known to Sandoz, other than Beebe, discloses that

metaxalone is a substrate of any cytochrome p450 isozyme.” *Id.* at 6. Specifically, Sandoz explains that such disclosure is

relevant and material to each claim of the ‘566 patent because each claim has an ‘informing’ step that requires informing a patient or medical care worker that metaxalone affects the activity of a cytochrome p450 isozyme, and the ‘566 patent makes clear that metaxalone affects the activity of cytochrome p450 when it is a substrate of that isozyme.

*Id.* Therefore, Sandoz argues, because the Beebe article “discloses that metaxalone affects the activity of certain cytochrome p450 isozymes, Beebe is material to the claims of the ‘566 patent.”

*Id.*

Next, Sandoz argues that there will be no prejudice to Plaintiffs by its proposed amendment because “fact discovery is ongoing, expert discovery has not yet begun, and no depositions have been scheduled.” *Id.* at 7. Consequently, Sandoz contends, “Plaintiffs will have a full and fair opportunity to take discovery with respect to the Beebe reference.” *Id.* at 11. Sandoz further argues that “the Beebe reference does not add any new defense to [P]laintiffs’ claim of infringement; Sandoz previously asserted that all claims of the ‘566 patent were invalid in view of prior art, and only seeks to add Beebe as further evidence of invalidity.” *Id.*

Ultimately, Sandoz contends that allowing its proposed amended Invalidity Contentions at this stage in the litigation will promote the fair resolution of this case without prejudicing Plaintiffs.

**B. Plaintiffs’ Arguments Opposing the Motion to Amend**

Plaintiffs oppose Sandoz’s Motion arguing generally that Sandoz’s delay in amending the Invalidity Contentions is undue and that Plaintiffs will suffer significant prejudice if Sandoz is granted the relief sought. Sandoz acknowledges that the two 2008 searches identified only 80 publications by title and abstract including the Beebe article, “[b]ut Sandoz did not deem the

Beebe publication to be among the ‘most relevant and non-cumulative’ of the references . . . [and, therefore,] did not even obtain a full-text copy of the Beebe publications for review.” (Pls.’ Opp’n Br. at 2.) Therefore, Plaintiffs argue, “Sandoz’s application is untimely [because] [i]t comes ten months after the deadline for serving invalidity contentions. Leaving aside the fact that Sandoz has been aware of the Beebe publication during this entire case, Sandoz asserts that it re-discovered the Beebe publication on January 26, 2010.” *Id.* at 4-5 (citing Sandoz’s Br. at 4).

Against this backdrop, Plaintiffs argue that “[t]hese facts belie Sandoz’s claim of diligence” and, furthermore, “Sandoz’s failure to appreciate the alleged materiality of Beebe over the last couple of years is the result of either carelessness, inadvertence or ineptitude.” *Id.* at 6. Plaintiffs observe that Courts have found the requisite diligence to be “lacking where the movant failed to appreciate the potential materiality of certain prior art for several months after becoming aware of that prior art.” *Id.* (citing *CBS Interactive, Inc. v. Etilize, Inc.*, 257 F.R.D. 195, 203 (N.D. Cal. 2009) (“denying leave to amend invalidity contentions and declining to ‘speculate as to whether [the movant’s] motivations for this late-stage motion are attributable to gamesmanship or mere ineptitude’ since proof of diligence is lacking in either circumstance”). Therefore, Plaintiffs maintain, because Sandoz cannot establish that it was diligent with respect to its discovery of the Beebe article in the first place, it cannot carry its burden of establishing good cause for the relief it seeks. *Id.* at 7.

Next, Plaintiffs argue that the Beebe article is not “material” despite Sandoz’s contention that it is the only prior art that discloses that metaxalone is a substrate of any cytochrome p450 isozyme. Plaintiffs assert that it is not material because “Sandoz has alleged that several references disclose that metaxalone is a cytochrome p450 substrate . . . [and] Beebe is never the

only reference Sandoz cites as disclosing any particular claim element.” *Id.* at 8.

Moreover, Plaintiffs argue that they will be prejudiced if Sandoz is permitted to amend its Infringement Contentions at this stage in the litigation. Specifically, Plaintiffs assert that they have planned their litigation strategy based on Sandoz’s original invalidity contentions claim construction briefing has been completed and the Court has ruled on the majority of the disputed claim terms, and the Court has expressed its intent to expedite trial in this case. *Id.* at 8-9. Plaintiffs further assert that “[f]orcing Plaintiffs to change course at this stage will require additional discovery and lengthen the timeline for this case, while seriously undermining Plaintiffs’ trial preparation.” *Id.* at 9.

**C. Sandoz’s Reply**

In reply, Sandoz argues that “[t]he cases relied upon by [P]laintiffs with respect to the timeliness of this [M]otion are easily distinguished.” (Sandoz’s Reply at 2.) Sandoz explains that in the instant matter:

1) there is no fact discovery or expert cut-off date; 2) no depositions have been taken; 3) [P]laintiffs’ initial disclosures did not identify the Beebe reference; 4) Sandoz has not waited three months to seek to amend its invalidity contentions; and 5) Sandoz prepared and filed the instant motion within a reasonable time after learning of Beebe’s materiality.

*Id.* at 3. Sandoz also explains that it does not assert any new theories of invalidity in its proposed amended Invalidity Contentions and further contends that it “did not belatedly retain an expert to search for prior art related to the ‘566 patent – the Beebe reference was identified by CPLP based on a prior art search performed in connection with a different matter.” *Id.* at 3-4.

Sandoz cites *Tessera, Inc. v. Advanced Micro Devices, Inc.*, 2007 U.S. Dist. LEXIS 35957, \*6 (N.D. Cal. April 30, 2007) in which case “defendants were aware of two references

prior to filing their invalidity contentions because they were among the approximately 300 references cited during the prosecution of the five patents, but the materiality of those two references only became apparent after defendants' invalidity contentions were filed." *Id.* at 6. Sandoz contends that it is in a position akin to the defendants who were found to be diligent in seeking to amend their invalidity contentions more than eight months after serving their original contentions in the *Tessera* case because "Sandoz too has shown that it was unaware of the materiality of Beebe at the time it filed its original invalidity contentions and that Beebe's materiality was only recently discovery." *Id.* Sandoz explains, "[t]his is not a case where Sandoz was hiding the Beebe reference; this is a situation where the materiality of the Beebe reference did not come to Sandoz's attention until January 2010, and Sandoz then promptly disclosed it to [P]laintiffs." *Id.* at 9.

Next, Sandoz argues that despite Plaintiffs' contentions to the contrary, "Beebe is the only cited prior art that expressly discloses that metaxalone was actually tested and shown to be a substrate of CYPs 1A2, 2D6, 2E1 and 3/4A, i.e., the specific isozymes identified in the claims of the '566 patent." *Id.* at 10. Lastly, Sandoz argues that "[P]laintiffs never explain why they would not have a full and fair opportunity to take discovery with respect to the Beebe reference, or how they will be unduly prejudiced" *Id.* Sandoz asserts that "Plaintiffs offer no reason why the addition of Beebe to Sandoz's invalidity contentions will lengthen the timeline for this case . . . [nor have they] identified any discovery that they will require as a result of the invalidity contentions being amended by the addition of Beebe and, in any event, plaintiffs contend Beebe is not 'material.'" *Id.* at 11.

### III. DISCUSSION

Pursuant to Local Patent Rule 3.7, leave to amend invalidity contentions may be granted “by order of the Court upon a timely application and showing of good cause.”<sup>1</sup> 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.” *Computer Accelerations Corp. v. Microsoft Corp.*, 503 F.Supp.2d 819, 822 (E.D.Tex. 2007). “The 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.*, 1998 WL 775115, at \*2 (N.D. Cal. Nov. 5, 1998). Distinguishable from the liberal standard for amending the pleadings, “the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the ‘shifting sands’ approach to claim construction.” *Id.* However, Rule 3.7 “is not a straitjacket into which litigants are locked from the moment their contentions are served,” but 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). Therefore, while “preliminary infringement contentions are still preliminary” it is important to recognize that the Local Patent Rules strive to have the parties establish their contentions early on. *General Atomics v. Axis-Shield ASA*, 2006 WL 2329464, at \*2 (N.D.Cal. Aug. 9, 2006).

In determining whether Sandoz’s Motion was the byproduct of undue delay, the Court

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<sup>1</sup> The Court notes that the District of New Jersey developed its Local Patent Rules taking guidance from the Local Patent Rules of the Eastern District of Texas and the Northern District of California. The Court recognizes that the issues raised in the instant Motion have not been widely analyzed in this District and, therefore, finds it appropriate to consider decisions from these districts.

examines Sandoz's reasons for not sooner seeking leave to amend. Sandoz claims that it could not have sought to amend its Invalidity Contentions sooner because it was unaware of the contents of the Beebe article until January 2010. Sandoz further claims that it diligently attempted to identify potentially relevant non-patent publications in July 2008 when it commissioned outside counsel to perform prior art searches. Sandoz argues that its Motion is timely in light of its prompt action upon recognizing the materiality of the Beebe article and Plaintiffs' objection to the proposed revision of its Invalidity Contentions to include it. The Court does not find Sandoz's arguments persuasive particularly with respect to Sandoz's rationale for not fully reviewing the substance of the Beebe article until January 2010 despite the fact that a July 2008 search identified the Beebe reference by title and abstract. Waiting approximately 18 months to appreciate the materiality of the publication, the Court also finds that Sandoz could have been more diligent in its efforts to obtain the full text of the Beebe article. However, while not compelling, reasons have been proffered and, therefore, the Court must consider whether Plaintiffs would be unfairly prejudiced by Sandoz's proposed amendments.

In this regard, the Court must consider whether permitting the proposed amendments would significantly delay the resolution of the dispute. Notwithstanding Sandoz's statements to the contrary, this case is no longer in its early stages, which is evidenced by the fact that claim construction briefing has been completed and the Court has ruled on the disputed claim terms, the July 1, 2010 Final Pretrial Conference and the July 6, 2010 Trial dates set by the Court. The Court's intent for this case to proceed on this schedule is clear and, therefore, any amendment to Sandoz's contentions would inevitably delay the July 6, 2010 date established for trial. *See CBS Interactive, Inc. v. Etalize, Inc.*, 257 F.R.D. 195, 203 (N.D. Cal. 2009) (“[T]he court finds that

[the movant's] right to amend in good faith is far outweighed by its (and the court's) countervailing duty to avoid prejudicing [the non-movant] through eleventh-hour alterations"). Furthermore, the Court acknowledges Plaintiffs' contention that their litigation strategy is based upon Sandoz's originally served Invalidity Contentions and if Sandoz is permitted to amend its contentions it will delay discovery, lengthen the life of this case and ultimately prejudice Plaintiffs. Finally, the Court finds that prompt and efficient administration of justice weighs in favor of denying Sandoz's Motion, especially given the current stage of this case being that it is poised for trial. *See In re Fine Paper Antitrust Litigation*, 685 F.2d 810, 817 (3d Cir.1982) ("matters of docket control [including the scheduling of trial] and conduct of discovery are committed to the sound discretion of the district court.") (citations omitted).

#### **IV. CONCLUSION AND ORDER**

The Court having considered the papers submitted and for the reasons set forth above,

**IT IS** on this 19<sup>th</sup> day of May, 2010

**ORDERED** that Sandoz's Motion to Amend its Invalidity Contentions [dkt. entry no. 60] is **DENIED**.

*s/ Douglas E. Arpert* \_\_\_\_\_

**DOUGLAS E. ARPert**

**UNITED STATES MAGISTRATE JUDGE**