

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

SANDOZ, INC.,

Defendant.

Civil Action No. 12-3289 (PGS)(LHG)

**ORDER DENYING DEFENDANT'S
MOTION FOR LEAVE TO AMEND
INVALIDITY CONTENTIONS AND
GRANTING PLAINTIFF'S MOTION TO
STRIKE CERTAIN PORTIONS OF
SANDOZ'S EXPERT REPORT**

This matter comes before the Court on a Motion for Leave to Amend Invalidity Contentions (the "Motion") by Defendant Sandoz, Inc. ("Defendant" or "Sandoz") submitted to the Court on October 17, 2013 ("Def.'s Ltr. in Supp."). [Docket Entry No. 131]. Plaintiff Merck Sharpe & Dohme Corp. ("Plaintiff" or "Merck") opposed the Motion on October 24, 2013 ("Pl.'s ltr. in Opp'n"). [Docket Entry No. 133]. Sandoz replied on October 29, 2013 ("Def.'s Ltr. in Reply"). [Docket Entry No. 134]. The Court has considered the moving, responding, and reply papers without oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth below, Defendant's Motion is DENIED. In addition, Plaintiff's pending request to strike portions of Defendant's expert report, filed on September 13, 2013 [Docket Entry No. 118], is hereby GRANTED.

I. BACKGROUND

The facts assume the parties' familiarity with the case and are therefore limited to those pertinent to this Motion:

Merck sued Sandoz for infringement of U.S. Patent No. 5,691,336 ("the '336 Patent") based upon Defendant's April 23, 2012 Paragraph IV notice letter and associated submission of

an Abbreviated New Drug Application (“ANDA”) seeking to market and sell a generic version of Plaintiff’s antiemetic product fosaprepitant.¹

The Court conducted an Initial Pretrial Scheduling Conference on October 2, 2012. [Docket Entry No. 16]. Pursuant to the Court’s October 4, 2012 Pretrial Scheduling Order [Docket Entry No. 26], Sandoz provided Plaintiff with its Preliminary Invalidity Contentions on October 16, 2012. Merck served Defendant with its Response to Invalidity Contentions on November 30, 2012. Fact discovery closed on June 28, 2013. [Docket Entry No. 26]. The Court later granted a limited extension of the deadlines for expert reports, pursuant to which initial expert reports were to be served on August 7, 2013, rebuttal expert reports were due on September 20, 2013, and reply expert reports were to be served on October 25, 2013. [Docket Entry No. 116]. Expert discovery was scheduled to close on November 22, 2013, and dispositive motions were originally due on December 27, 2013. [Docket Entry No. 26].

During the first week of January 2013, Sandoz retained Dr. David H. Sherman to serve as an expert in this matter. Pl.’s Ltr. in Opp’n. at 9, 13. In April 2013, Plaintiff moved to disqualify Dr. Sherman as an expert. Def.’s Ltr. in Reply at 3. The Court denied Plaintiff’s motion on May 21, 2013. [Docket Entry No. 97]. On August 7, 2013, Defendant served the expert report of Dr. Sherman (“the Sherman Report”), which included 16 prior art references not specified in Defendant’s October 16, 2012 Invalidity Contentions. Def.’s Ltr. in Supp. at 3. The parties met and conferred regarding the appropriateness of these references absent a motion to amend and were unable to reach a resolution. Pl.’s Ltr. in Opp’n. at 7, 14. On September 13, 2013, Merck brought a motion to strike Dr. Sherman’s expert report insofar as it includes

¹ This suit originally involved U.S. Patent No. 5,716,942 (“the ‘942 Patent”) as well. On May 14, 2013, pursuant to a Stipulation and Order signed by the Honorable Peter G. Sheridan, U.S.D.J., the ‘942 Patent was dismissed from the case. [Docket Entry No. 93].

references to previously undisclosed prior art. *Id.* at 7. Defendant responded on September 25, 2013, and on October 10, 2013, the Court heard argument on the motion to strike. *Id.* At the conclusion of argument, the Court permitted Defendant to seek leave to amend its Invalidity Contentions. [Docket Entry No. 130 at 44-45].

II. Legal Standard

In 2009, the District of New Jersey adopted the Local Patent Rules to assist in the conduct of patent cases. Local Patent Rule 3.3 governs the service of a party's infringement contentions and is very specific with regard to what must be included in the disclosure, mandating that it contain the following:

(a) The identity of each item of prior art that allegedly anticipates each asserted claim or renders it obvious. Each prior art patent shall be identified by its number, country of origin, and date of issue. Each prior art publication shall be identified by its title, date of publication, and where feasible, author and publisher. Prior art under 35 U.S.C. § 102(b) shall be identified by specifying the item offered for sale or publicly used or known, the date the offer or use took place or the information became known, and the identity of the person or entity which made the use or which made and received the offer, or the person or entity which made the information known or to whom it was made known. Prior art under 35 U.S.C. § 102(f) shall be identified by providing the name of the person(s) from whom and the circumstances under which the invention or any part of it was derived. Prior art under 35 U.S.C. § 102(g) shall be identified by providing the identities of the person(s) or entities involved in and the circumstances surrounding the making of the invention before the patent applicant(s);

(b) Whether each item of prior art anticipates each asserted claim or renders it obvious. If obviousness is alleged, an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness;

(c) Other than for design patents, a chart identifying where specifically in each alleged item of prior art each limitation of each asserted claim is found, including for each limitation that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in each item of prior art that performs the claimed function; and

(d) Any grounds of invalidity based on 35 U.S.C. § 101, indefiniteness under 35 U.S.C. § 112(2) or enablement or written description under 35 U.S.C. § 112(1) of any of the asserted claims.

Pursuant to Local Patent Rule 3.4, the disclosure must be accompanied by documents including “[a] copy or sample of the prior art identified pursuant to L. Pat. R. 3.3(a) which does not appear in the file history of the patent(s) at issue.” Local Patent Rule 3.6 sets the schedule for such disclosure in Hatch-Waxman cases, such as the one at issue. L. Pat. R. 3.6 (c)-(i).

Rule 3.7 governs amendments to contentions: “Amendment of any contentions, disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules may be made only by order of the Court upon a timely application and showing of good cause. . . . Non-exhaustive examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause include . . . (b) recent discovery of material prior art despite earlier diligent search”

While Rule 3.7 “is not a straightjacket into which litigants are locked from the moment their contentions are served [and t]here is a modest degree of flexibility . . . *near the outset*” of the matter, *Comcast Cable Comms. Corp., LLC., v. Finisar Corp.*, No. C 06-04206, 2007 WL 716131 (N.D.Cal. March 2, 2007)² (emphasis added), this standard is readily “[d]istinguishable from the liberal standard for amending the pleadings” in that it is “decidedly conservative.” *King Pharms., Inc. et al., v. Sandoz, Inc.*, No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010).

The Local Patent Rules were promulgated to “further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases.” *King Pharms., Inc. et al., v. Sandoz, Inc.*, No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (citing *Computer Accelerations Corp. v. Microsoft Corp.*, 503 F.Supp.2d 819 (E.D.Tex. 2007)). A second and equally important purpose of these rules is to “require parties to

² The Court’s decision is informed by districts with analogous local patent rules, such as the Northern District of California and the Eastern District of Texas.

crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed.” *Amtel Corp. v. Info. Storage Devices, Inc.*, No. C 95–1987, 1998 WL 775115, at *2 (N.D.Cal. Nov. 5, 1998). This is intended “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) (internal citations omitted). Accordingly, the Rules require the “ultra early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act.” *Sanofi-Aventis v. Barr Labs.*, 598 F. Supp. 2d 632, 637 (D.N.J. 2009).

On a motion to amend invalidity contentions, the court must scrutinize the submissions to evaluate whether good cause has been shown. *Novartis Pharms., Corp., et al., v. Wockhardt USA LLC, et al.*, No. 12-3967, 2013 WL 4732296, at *2 (D.N.J. Sep. 3, 2013). In doing so, the Court “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 at 1366-68). In considering whether good cause exists, courts consider such other factors as (1) the reason for the delay, including whether it was within the reasonable control of the part responsible for it; (2) the importance of what is to be disclosed; (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.*, No. 10–4875, 2012 WL 1067900, at *20-21 (D.N.J. Mar. 29, 2012) (compiling authority).

The burden to establish diligence rests with the movant. *O2 Micro*, 467 F.3d at 1366. This itself is a two-pronged requirement that the movant proceed with diligence “throughout discovery and in discovering the basis for the proposed amendment,” *Novartis*, 2013 WL 4732296, at *2, as well as “promptly moving to amend when new evidence is revealed in

discovery.” *O2 Micro*, 467 F.3d at 1363. The latter requirement is consistent with Local Patent Rule 3.7’s mandate that the motion be “timely.”

The Court will only consider prejudice to the non-moving party if the moving party has made the requisite showing of diligence. *AstraZeneca AB v. Dr. Reddy’s Laboratories Inc.*, No. 11-2317, 2013 WL 1145359, at *3 (D.N.J. Mar. 18, 2013) (internal authority omitted).

III. Parties’ Arguments

A. Defendant’s Argument

Sandoz seeks leave to amend its Invalidity Contentions to include 15 prior art references (“the New Prior Art”).³ Def.’s Ltr. in Supp. at 1. Sandoz argues that the good cause analysis is satisfied when the proposed amendments are based upon previously disclosed references. Def.’s Ltr. in Supp. at 4 (citing *Kilopass Tech., Inc. v. Sidense Corp.*, No. C 10-02066 SI, 2012 WL 1901198 (N.D.Cal. May 24, 2012)). Here, Defendant contends that four of the prior art publications are cited in the ‘336 Patent’s prior art and were therefore disclosed previously.⁴ Moreover, Sandoz says it expressly reserved its right to rely on this art in its Invalidity Contentions by referencing “prior art cited in the ‘336 Patent.” Def.’s Ltr. in Supp. at 4-5.

Defendant argues that a party acts with diligence when it attempts to amend invalidity contentions based on prior art or theories discovered during the preparation of an expert’s report. Def.’s Ltr. in Supp. at 4 (relying on *Chemfree Corp. v. J. Walter, Inc.*, No. 1:04-CV-3711-JTC, 2008 WL 4845129 (N.D. Ga. Aug. 27, 2008)). Prohibiting the amendment of invalidity

³Although the Sherman Report originally included 16 new prior art references, Defendant decided not to “seek[] leave to amend its contention as to the Magnevist reference,” leaving only 15 references at issue. Def.’s Ltr. in Supp. at 1, n. 1.

⁴These four references are: (1) WO 93/01169; (2) Edmonds-Alt, et al., *A Potent and Selective Non-Peptide Antagonist of the Neurokinin A (NK2) Receptor*, 50 LIFE SCI. PL101 (1992); (3) EPO 0,360,390; and (4) Varia, et al., *Phenytoin Prodrugs III: Water-Soluble Prodrugs for Oral and/or Parenteral Use*, 73(8) J. PHARM. SCI. 1068 (1984).

contentions based on references discovered during the preparation of an expert's report, Sandoz argues, would render expert discovery meaningless by limiting experts to reiterating previously disclosed information. Def.'s Ltr. in Reply at 2. Cast in this light, diligence should be measured from the time an expert discovers the relevant prior art. Tailoring this argument to the facts at hand, Defendant states that Dr. Sherman recognized the relevance of these references while analyzing Plaintiff's response to contentions in July 2013 and that Defendant proceeded with diligence when it disclosed them simultaneously with service of the Sherman Report on August 7, 2013. Def.'s Ltr. in Supp. at 4, 6. Defendant attributes any delay in finding these references to Merck's earlier motion to disqualify Dr. Sherman, which impeded Sandoz's ability to work with him. Def.'s Ltr. in Reply at 3.

Furthermore, Sandoz denies any fault with regard to the delay in bringing this motion. First, Defendant emphasizes that "the parties had a genuine dispute as to whether it was necessary for [Defendant] to amend its contentions" until the hearing held on October 10, 2013. Def.'s Ltr. in Supp. at 6. Defendant also faults Plaintiff's motion to strike for the gap in time between service of the Sherman Report and the submission of the present Motion. *Id.*

Defendant argues that adequate notice of its overall position regarding invalidity is more important than the timeliness of its Motion to Amend. Def.'s Ltr. in Supp. at 5 (relying on *V. Mane Filks S.A. v. Int'l Flavors and Fragrances, Inc.*, No. 06-2304, 2011 WL 1344193, at *8 n.10 (D.N.J. Apr. 8, 2011)). Because the New Prior Art is rebuttal to Plaintiff's Response to Sandoz's Invalidity Contentions and complementary to previously disclosed references, Sandoz claims that Merck has had adequate notice of its position. *Id.* Thus, Sandoz argues that, even if the Court finds the Motion untimely, the proposed amendment should be allowed.

Focusing on whether Merck would need to expend significant additional resources and whether authorizing the proposed amendments would significantly delay the resolution of the dispute, Defendant contends that Plaintiff will not suffer undue prejudice from the proposed amendment. *Id.* at 6 (citing *AS Am., Inc., v. Masco Corp. of Indiana*, No. 13-05, 2013 WL 4084237, at *3 (D.N.J. Aug. 13, 2013)). Sandoz argues that Plaintiff “has not shown that it has or would need to expend any ‘significant additional resources,’ or that it would need to undertake any new discovery, in light of [Defendant’s] proposed amendment.” *Id.* Sandoz suggests that the additional prior art references are minimal in that they often support a single assertion. *Id.*

Defendant further argues that the amount of time Plaintiff has had to review the Sherman Report mitigates any potential prejudice. *Id.* According to Defendant, any decision by Merck to place expert discovery in abeyance was made of Plaintiff’s own volition. Def.’s Ltr. in Reply at 6. Additionally, Defendant insists that Plaintiff would not have proceeded differently through discovery had the contentions been amended at an earlier date. *Id.* at 5.

B. Plaintiff’s Argument

First, Merck argues that Defendant’s vague reference to the prior art cited in the ‘336 Patent did not adequately notify Plaintiff of its intention to rely on the New Prior Art because the patent cites many prior art references, not just the ones currently at issue, and Plaintiff had no way of knowing which Sandoz was referencing. Pl.’s Ltr. in Opp’n at 10. Plaintiff asserts that Defendant’s later representations—through the detail in the narrative section of its Invalidity Contentions as well as in an October 31, 2012 e-mail to Plaintiff—countered any representation that Sandoz intended to rely on more than the charted prior art. *Id.* at 10.

Plaintiff dismisses Defendant’s contention that an amendment was unnecessary as incompatible with Local Patent Rule 3.7. Plaintiff further argues that Sandoz’s characterization

of these references as important is undercut by Defendant's portrayal of the references as merely "complementary." *Id.* at 13.

Merck contests Defendant's characterization of the timeframe relevant to diligence. Plaintiff argues that diligence is measured from the time when Defendant should have uncovered the information, not from the time an expert discovers the relevance of the references. *Id.* at 11. According to Plaintiff, this point in time is at the outset of litigation and no later than the service of invalidity contentions. *Id.* (citing Jerome B. Simandle, *Litigation in New Jersey Under the New Local Patent Rules*, N.J. LAW., June 2009, at 21; *Jazz Pharms., Inc., v. Roxanne Labs., Inc.*, No. 10-6108, 2012 U.S. Dist. LEXIS 107408, at * 19 (D.N.J. July 30, 2012)). In an attempt to further buttress this point, Plaintiff contends that analyzing diligence through the lens of the expert's date of discovery would shift the burden of diligence from the party onto its expert. *Id.* at 11-12. Plaintiff challenges Defendant's reliance on *Chemfree*, which Merck interprets to permit amendment when an expert discovers a technical defect in the patent at issue. *Id.* at 11, n. 9. Even if the Court focused its inquiry on Dr. Sherman's diligence, Merck contends that Sandoz's Motion should still be denied because it took Dr. Sherman half a year to discover the relevance of these prior art references. *Id.* at 12.

According to Merck, Sandoz's assertion of a diligent search is undermined by Sandoz's admission that four of the prior art references are cited in the '336 Patent. *Id.* at 9. Merck also disputes that Dr. Sherman discovered these references in July, 2013 when in fact he made use of these same references in a previous lawsuit. *Id.* at 10-11. As a result, Plaintiff contends that Sandoz's claim of diligence for these "references is either deliberately false or reckless," regardless of whether the Court looks to Sandoz's diligence or that of Dr. Sherman. *Id.* at 11.

Although Sandoz depicts the new references as rebuttal to Merck's November 30, 2012 response to Sandoz's Invalidity Contentions, Merck argues that a diligent party would have performed this reassessment upon receipt of Merck's Response to Invalidity Contentions. *Id.* at 12. Plaintiff claims that Defendant's decision to wait nearly ten months before proposing an amendment is simply inexcusable, especially given that during the parties' meet and confers preceding Plaintiff's motion to strike, Plaintiff put Defendant on notice that the proper course of conduct was to seek an order from the Court authorizing amendment. *Id.*

IV. ANALYSIS

At the outset, the Court addresses Sandoz's argument that an amendment is not needed. Sandoz engages in somewhat inconsistent reasoning, first contending that the New Prior Art is complementary to that previously disclosed and does not raise any new arguments. At the same time, however, Sandoz posits that without the amendment, it will be prejudiced in presenting its case at trial. The Local Patent Rules could not be clearer, however: pursuant to Rule 3.3, invalidity contentions must be detailed and specific in setting forth the prior art on which the party is relying, regardless of how that prior art is characterized.

Sandoz contends that it met its obligation with regard to four of the New Prior Art references by advising in the Invalidity Contentions that it intended to rely on all of the prior art referenced in the patent at issue. A general incorporation by reference of more than 50 prior art references cited in the '336 Patent simply does not meet the high standard set by Rule 3.3. "In order to incorporate by reference, 'the host document must identify *with particularity* what specific material it incorporates *and clearly indicate* where the material is found in the various documents.'" *Astrazeneca AB v. Hanmi USA, Inc.*, No. 11-760, 2012 WL 6203602, at *7 (D.N.J. Dec. 12, 2012) (quoting *Zenon Env'tl., Inc. v. United States Filter Corp.*, 506 F.3d 1370, 1378

(Fed. Cir. 2007)) (emphasis added). It is a question of law whether a document has been properly incorporated by reference. *Id.* “In making that determination, ‘the standard of one reasonably skilled in the art should be used to determine whether the host document describes the material to be incorporated by reference with sufficient particularity.’” *Id.* (quoting *Zenon*, 506 F.3d at 1378-79). Based on the record, Sandoz has not met its burden of showing that one reasonably skilled in the art would understand the incorporation to reference the four specific prior art publications at issue.

Moreover, “[i]f the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery and trial preparation.” *O2 Micro*, 467 F.3 at 1366. Even if Defendant were unfamiliar with the appropriate procedure under the Local Rules, Merck has advised that it told Sandoz in no uncertain terms that it believed an amendment was called for. Pl.’s Ltr. in Opp’n at 14.

At the October 10 hearing, the undersigned made clear that the proper way to proceed was by a motion for leave to amend the Invalidity Contentions. The reason for this can be found in the Local Patent Rules. The Rules clearly contemplate a situation in which discovery or further investigation by a party, including by the party expert, may lead to the need to expand the invalidity contentions. Specifically, Rule 3.7 sets forth the mechanism for such an amendment. By choosing not to seek leave to amend but to instead insert the New Prior Art in its expert report, Sandoz essentially put the burden on Merck to show why it should not be allowed, rather than bearing the burden itself under Rule 3.7 to show why the amendment should be allowed. This the Court could not allow. Accordingly, Sandoz was given the opportunity to move to amend its Invalidity Contentions.

Having determined that a motion for leave to amend is the proper way to proceed, the issue now before the Court is whether the amendment should be allowed. In deciding this issue, the Court is guided by the Local Patent Rules, as well as the case law interpreting those rules.

The cornerstone of a motion to amend invalidity contentions is good cause. L. Pat. R. 3.7. The key and primary consideration in determining the existence of good cause is the diligence of the moving party. *Novartis Pharms.*, 2013 WL 4732296, at *2. If the moving party has not shown its diligence in finding the new information or seeking leave to amend, the court does not even reach the issue of whether the proposed amendment would prejudice the non-moving party. *AstraZeneca AB*, 2013 WL 1145359, at *3.

Sandoz argues it has been diligent, tying the diligence to its expert's investigation, rather than its own. This Court finds it is the obligation of the party, not the expert, to act with diligence. To find otherwise would turn Local Patent Rule 3.7 on its ear. It is therefore Sandoz's burden to show that it was diligent from the outset and that despite its diligence, it did not discover the New Prior Art until Dr. Sherman made his investigation in July 2013. Sandoz simply has not met this burden.

In its papers and at the October 10 hearing, Sandoz argued that its delay was appropriate because the New Prior Art is in rebuttal to Merck's Response to Invalidity Contentions. Nonetheless, although Sandoz received Merck's Response in November 2012, the disclosure of the New Prior Art was not made until August 2013. Sandoz says its expert only discovered the majority of these references in July. Other than accounting for the time during which Merck sought to preclude Sandoz's reliance on Dr. Sherman as an expert in this case, Sandoz does not explain what it was doing between November 2012 and July 2013 to develop a rebuttal to

Merck's Response, and why it could not have uncovered the New Prior Art earlier. *O2 Micro, supra*, 467 F.3d at 1367.

Defendant's reliance on *Chemfree*, 2008 WL 4845129, to support its argument that a party may amend contentions based on prior art discovered during the preparation of an expert report, is misplaced. The defendants in *Chemfree* sought to amend their invalidity contentions to include three distinct types of information: (1) a new defense theory highlighting "scientific deficiencies in the 'patents-in-suit' first recognized by" the defendants' expert; (2) further explanation of prior art references included in a previous version of the invalidity contentions; and (3) prior art references the defendants cited for the first time. *Id.* at *4-5. Although the court granted the defendants leave to include the new theory and the previously charted prior art, it denied their motion with regard to the newly cited prior art. *Id.* at *5. The *Chemfree* defendants sought to justify their late amendment based on a decision to await expert confirmation as to the propriety of their assertions; the court nonetheless found the delay inexcusable. *Id.*

The Court does not find *Kilopass*, 2012 WL 1901198, relied upon by Sandoz to support the statement that "[c]ourts have also found good cause to allow parties to amend invalidity contentions when the amendments are based upon previously disclosed references," Def.'s Ltr. in Supp. at 4, to be persuasive here. In *Kilopass*, the court granted the defendant leave to amend its claim chart to reflect new invalidity theories "based on previously disclosed *and* charted prior art references," which the court found did "not 'substantially depart' from the original contentions." 2012 WL 1901198, at *3 (emphasis added). In reaching this decision, the court relied on two cases that denied leave to amend when prior art was previously uncharted or inadequately specified. *Kilopass*, 2012 WL 1901198, at *2-3 (citing *Chemfree*, 2008 WL

4845129, and *Oracle America, Inc. v. Google, Inc.*, 2011 WL 3443835 (N.D.Cal. Aug. 8, 2011)).

Because these four references Sandoz seeks to add were both uncharted and inadequately specified prior to the Motion at hand, the *Kilopass* decision does not support a finding of diligence.

Finally, Sandoz errs in arguing that adequate notice can mitigate a party's burden to proceed with diligence. Courts consider the existence and adequacy of notice in determining whether the non-moving party would be prejudiced by the proposed amendment. *See Braintree Labs., Inc. v. Novel Labs., Inc.*, No. 11-1341, 2013 U.S. Dist. LEXIS 7698, at *50 (D.N.J. Jan. 18, 2013) ("As Novel was on notice of Braintree's theory, Novel's assertion that Braintree's conduct will prejudice Novel is baseless."). The language relied upon by Sandoz, found in *V. Manes*, 2011 WL 1344193, is in a footnote, referencing a Southern District of New York case in which the proposed amendments related to two affidavits from an expert disclosed at the time of the *Markman* hearing, years before the motion to amend and much earlier than in the present case. *See V. Manes*, *8 n.10 (citing *Convolve, Inc. v. Compaq Computer Corp.*, No. 00-5141, 2007 U.S. Dist. LEXIS 15747, 2007 WL 700904, at *12-13 (S.D.N.Y. Mar. 7, 2007)).

In short, this Court finds that Sandoz has not met its burden of showing that it was diligent in seeking to discover the New Prior Art that it now wants to reference at this late date. Because Sandoz did not act diligently, the Court need not address whether Merck would be prejudiced by the proposed amendment.

Finally, in light of the prior determination that the introduction of the New Prior Art should be made in the first instance by amendment, rather than through an expert report, the Court grants Merck's motion to strike those portions of Dr. Sherman's report that rely on or reference the New Prior Art. *See Chemfree*, 2008 WL 4845129, at * 8; *Monolithic Power*

Systems, Inc., v. O2 Micro Int'l LTD, No. C 08-04567, 2009 U.S. Dist. LEXIS 101035, at *9-10 (N.D.Cal. Oct. 16, 2009).

V. CONCLUSION

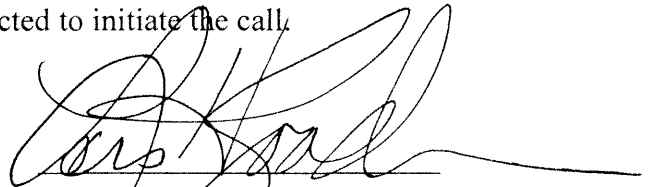
For the foregoing reasons, and for good cause shown,

IT IS on this 6th day of **January, 2014**,

ORDERED that Defendant's Motion for Leave to Amend Invalidation Contentions is hereby DENIED; and it is further

ORDERED that Plaintiff's Motion to Strike Certain Portions of Sandoz's Expert Report is GRANTED; and it is further

ORDERED that the Court will conduct a status conference on **January 14, 2014, at 11:30 a.m.**, via telephone. Counsel for Plaintiff is instructed to initiate the call.



LOIS H. GOODMAN
United States Magistrate Judge