

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
TYLER DIVISION**

<b>POZEN INC.</b>	§	
	§	
<b>Plaintiff,</b>	§	
	§	
<b>v.</b>	§	<b>CIVIL ACTION No. 6:08cv437-LED-JDL</b>
	§	
<b>PAR PHARMACEUTICAL, INC.,</b>	§	<b>CONSOLIDATED with</b>
<b>ALPHAPHARM PTY LTD,</b>	§	<b>CIVIL ACTION No. 6:09cv003 and</b>
<b>TEVA PHARMACEUTICALS</b>	§	<b>CIVIL ACTION No. 6:09cv182</b>
<b>USA INC.,</b>	§	
<b>DR. REDDY’S LABORATORIES, INC.</b>	§	
	§	
<b>Defendants.</b>	§	

**MEMORANDUM OPINION AND ORDER**

Before the Court are two related Motions. Defendants Par, Alphapharm Pty Ltd., and Dr. Reddy’s Labs, Inc. (collectively, “Defendants”) have filed a Motion for Leave to Amend Their Invalidity Contentions (Doc. No. 198) (“Motion to Amend”). Pozen has filed a Response to the Motion (Doc. No. 205) (“Response to Motion to Amend”) and Defendants support their Motion with a Reply (Doc. No. 212) (“Reply”). Pozen then filed a Motion to Strike Defendants’ Invalidity Contentions (Doc. No. 218) (“Motion to Strike”) and Defendants filed a Response (Doc. No. 223) (“Response to Motion to Strike”). A hearing on both Motions was held on May 25, 2010. Having considered the parties’ arguments, (1) the Motion to Amend is **GRANTED in part** and **DENIED in part**, and (2) the Motion to Strike is **GRANTED** to the extent discussed herein.

**BACKGROUND**

Pozen filed three separate lawsuits alleging infringement of asserted claims in U.S. Patent Nos. 6,060,499; 6,586,458, and 7,332,183 (collectively, “the patents-in-suit”). These cases were

consolidated into a single action in February 2009 (Doc. No. 30). In the instant action, Pozen manufactures and sells a pharmaceutical, Treximet, that treats migraine headaches. Treximet is covered under the patents-in-suit for the pharmaceutical formulations and methods it uses to treat migraines in patients. The drug received FDA approval on April 15, 2008. Shortly thereafter, Alphapharm and the other Defendants filed Abbreviated New Drug Applications (“ANDA”) for approval to sell a generic bioequivalent version of Treximet.<sup>1</sup> Shortly thereafter, Pozen filed suit accusing Defendants, generic drug manufacturers, of infringing its patents.

Defendants are seeking leave to amend their Invalidity Contentions. The parties agree that the Original Invalidity Contentions were served on May 13, 2009.<sup>2</sup> Through the discovery process, including efforts to work with invalidity experts to identify additional prior art references, Defendants learned of prior art that they were not aware of at the time the Original Invalidity Contentions were served. MOTION TO AMEND at 4–5.

Defendants specifically seek to amend the Invalidity Contentions to include patient records obtained from a third party. On August 6, 2009, Defendant Par subpoenaed non-party Henry Ford Health System (“HFHS”) for documents relating to Defendants’ invalidity theories. Defendants allege that the HFHS patient records have the potential to invalidate the patents-in-suit under 35 U.S.C. § 102(a) or (b) because the combination of sumatriptan and a non-steroidal anti-inflammatory

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<sup>1</sup> The Hatch-Waxman Act, 21 U.S.C. § 355, requires companies to obtain approval from the Food and Drug Administration (“FDA”) before selling or marketing pharmaceutical products in the United States. A branded-drug company, such as Pozen, must then identify prospective generic competitors who are recorded in the FDA “Orange Book.” See 21 U.S.C. § 355(j)(7)(A). Companies interested in manufacturing and selling a generic bioequivalent of the pioneer drug must file an Abbreviated New Drug Application with the FDA, which provides an expedient method of obtaining FDA approval to bring generic drugs to market. See generally *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp.2d 937, 940 (N.D. Ill. 2003); *In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp.2d 121, 124 (E.D.N.Y. 2003).

<sup>2</sup> Par and Alphapharm filed their Original Invalidity Contentions on May 13, 2009. Dr. Reddy’s filed its Invalidity Contentions in October 2009, soon after being added to the case. MOTION TO AMEND at 4, n.5.

drug (“NSAID”) to treat migraine headaches was publicly known or used before the critical dates for the patents-in-suit. *Id.* at 4–5. Henry Ford Health Systems produced the subpoenaed records to Par on November 20, 2009 and Defendants then disclosed these references to Pozen in December 2009. Defendants also disclosed relevant invalidity experts such as Dr. Anthony Palmeiri II, Dr. Nabih M. Ramadan, and Dr. Judith Goldberg throughout December 2009, January 2010, and March 2010 respectively. RESPONSE TO MOTION TO AMEND at 8, n.1. Once invalidity experts were disclosed, Defendants worked with them, especially medical expert Dr. Ramadan, to assess the HFHS records.

Based on expert input, Defendants decided to seek leave to rely upon the prior art references discussed herein that support their positions as to anticipation and/or public knowledge and public use. MOTION TO AMEND at 4–6. The Court entered its Provisional Claim Construction Order (Doc. No. 189) on March 26, 2010. Defendants subsequently filed their Motion to Amend their Invalidity Contentions, stating that they did not move until April 16, 2010 in order to give Dr. Ramadan a chance to opine on the implications of the HFHS. Arguing that the proposed Amended Invalidity Contentions contradict the intended purpose of Patent Rule 3-6(a)(2) and lack good cause, Pozen filed its Motion to Strike the Amended Invalidity Contentions on May 18, 2010.

### **LEGAL STANDARD**

Patent Rule 3-6(b) provides that a party may amend its Invalidity Contentions (“ICs”) by order of the court upon a showing of good cause. When determining whether a party has shown good cause to amend its ICs under P.R. 3-6(b), a court must consider the following factors: (1) the reason for the delay and whether the party has been diligent; (2) the importance of what the court is excluding and the availability of lesser sanctions; (3) the danger of unfair prejudice; and (4) the

availability of a continuance and the potential impact of a delay on judicial proceedings. *Cummins-Allison Corp. v. SBM Co., Ltd.*, No. 9:07-cv-196, 2009 WL 763926 at \*2 (E.D. Tex. Mar. 19, 2009).

The purpose of the Patent Rules is to “further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases, not to create supposed loopholes through which parties may practice litigation by ambush.” *IXYS Corp. v. Advanced Power Tech., Inc.*, No. C 02-03942, 2004 WL 1368860, at \*3 (N.D. Cal. June 16, 2004); *see also STMicroelectronics, Inc. v. Motorola, Inc.*, 307 F. Supp.2d 845, 849 (E.D. Tex. 2004). A party cannot wait until shortly before trial to prepare its case. *See Finisar v. DirecTV Group, Inc.*, 424 F. Supp.2d 896, 901 (E.D. Tex. 2006). Moreover, the right to amend is subject to the court’s duty to avoid unfairly prejudicing a party “through eleventh-hour alterations.” *IXYS Corp.*, 2004 WL 1368860, 2004 WL 1368860, at \*1.

Nonetheless, courts in this district recognize that “it is likely that...amended [infringement contentions] will impact [a defendant’s] claim construction positions and invalidity contentions.” *MacLean-Fogg Co. v. Eaton Corp.*, No. 2:07-CV-472, 2008 WL 4601476, at \*2 (E.D. Tex. Oct. 6, 2008). This recognition is understandable because “[s]pecific [infringement] theories create a specific trajectory for the case.” *Connectel, LLC v. Cisco Sys., Inc.*, 391 F. Supp. 2d 526, 527 (E.D. Tex. 2005). For example, Patent Rule 3-6(a)(1) provides a deadline so that, after the Court issues its Claim Construction Ruling, a plaintiff may modify its ICs in response to the Claim Construction Ruling, without seeking leave of Court. Patent Rule 3-6(a)(2)(A) provides a deadline so that if a plaintiff modifies its Infringement Contentions pursuant to Rule 3-6(a)(1), the defendant may modify its ICs in response to the plaintiff’s amended infringement theories, without seeking leave of Court.

## ANALYSIS

### **I. Patent Rule 3-6(a)(2)**

Defendants filed the instant Motion to Amend ICs on April 16, 2010 and Pozen filed its Response on May 3, 2010. Shortly thereafter, Defendants filed a Notice (Doc. No. 210) (“Notice of Mootness”) indicating that the Motion to Amend ICs was rendered moot by the Amended Infringement Contentions Pozen served on April 26, 2010. In the Notice, Defendants interpret Patent Rule 3-6(a)(2) to provide Defendants an automatic opportunity to amend their ICs, without leave of the Court, in the event that a plaintiff serves Amended Infringement Contentions after the Court issues its Claim Construction Ruling. NOTICE OF MOOTNESS; RESPONSE TO MOTION TO STRIKE at 3–5 (arguing that since Pozen served its Amended Infringement Contentions under P.R. 3-6(a)(1), Defendants should be permitted to serve Amended Invalidity Contentions under P.R. 3-6(a)(2)(A) without a showing of good faith or good cause that Defendants’ amendments related to changes made by Pozen).

Pozen contests Defendants’ interpretation of P.R. 3-6 in a Response to the Notice of Mootness (Doc. No. 213) (“Response to Notice of Mootness”). Specifically, Pozen argues that the clear purpose of P.R. 3-6(a)(2) is to permit amendments to Invalidity Contentions under two specific circumstances, and not to provide Defendants “unbridled license to inject new prior art and invalidity positions at late stages in the case.” RESPONSE TO NOTICE OF MOOTNESS at 2. Pozen maintains that the amendments it made to its Infringement Contentions on April 26, 2010 were responsive to the Court’s Claim Construction Ruling and were limited to theories of infringement under the doctrine of equivalents (“DOE”) as to the ‘183 patent. *Id.* at 3. Therefore, Pozen argues that Defendants’ Motion to Amend ICs is not moot because the Defendants’ proposed Amended ICs are not in

response to Pozen's amended DOE theories, and Defendants seek to interject, without justification, new invalidity theories at the eleventh hour. *Id.*

The Court disagrees with Defendants. To allow *carte blanche* amendment of Invalidity Contentions simply because a plaintiff amended its contentions pursuant to the Claim Construction Order would eviscerate the purpose and function of the Patent Rules. *See Cummins-Allison Corp.*, 2009 WL 763926, at \*1 (discussing that the purpose of the Local Rules, generally, is to “further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases, not to create supposed loopholes through which parties may practice litigation by ambush”); *Finisar*, 424 F. Supp.2d at 901 (citation omitted) (noting that the goals of the Local Patent Rules include providing adequate notice and information to all parties and ensuring full, timely discovery). Assuming a plaintiff has complied with P.R. 3-6(a)(1), a defendant's amendments pursuant to P.R. 3-6(a)(2)(A) must respond to plaintiff's amendments.

In response to the Pozen Motion to Strike, Defendants cite Judge Ward's ruling in *Franks Casing Crew & Rental Tools, Inc. v. Tesco Corp* to support the proposition that when a plaintiff serves Amended Infringement Contentions, a defendant may introduce previously unasserted invalidity theories, without leave, pursuant to P.R. 3-6(a)(2)(A). RESPONSE TO MOTION TO STRIKE at 4 (citing *Franks Casing Crew & Rental Tools, Inc. v. Tesco Corp.*, No. 2:07-cv-15, slip op. at 2 (E.D. Tex. Feb. 20, 2009) (Doc. No. 178) (unpublished)). A review of the Motion to Strike the Invalidity Contentions in *Frank's Casing*, however, presents a distinguishable set of circumstances. Notably, Judge Ward's Order did not discuss the extent to which each party sought to amend infringement and then invalidity contentions following the Claim Construction Ruling. The Order simply ruled that leave was not required for Tesco to serve its Invalidity Contentions in light of the

arguments presented. The briefing in that case makes clear, however, that Tesco was amending its Invalidity Contentions after Plaintiff Frank's Casing Crew & Rental asserted *seven new patent claims* after the Court issued its Claim Construction Ruling. FRANK'S CASING RESPONSE at 1–2 (2:07-cv-15, Doc. No. 158). Tesco was then allowed to amend its Invalidity Contentions, without leave, upon successfully arguing that the amendments (1) directly responded to plaintiff's seven newly asserted claims, (2) related to Tesco's original invalidity theories, (3) were responsive to the Court's Claim Construction Ruling, and (4) were served in accordance with the time requirements of the Local Patent Rules. *Id.* at 2.

Here, Pozen amended its Infringement Contentions in response to the Claim Construction Ruling and these limited DOE amendments did not open the door for Defendants to assert, without limitation, new ICs and prior art references that were not tailored to the altered infringement positions. In the Notice of Mootness, Defendants do not contend that the new ICs are responsive to Pozen's amended infringement positions and/or the Court's Claim Construction Order. Accordingly, Defendants are required to demonstrate good cause for the relief sought in the Motion for Amend. *See* P.R. 3-6(b).

## **II. The Good Cause Standard**

In seeking leave to amend their ICs, Defendants' Motion categorizes the proposed "new" prior art references into two categories: the HFHS records secured through a third party pursuant to a subpoena, and "Recently Identified Prior Art" that Defendants identified through working with their experts. MOTION TO AMEND at 1. Pozen's Response also addresses the HFHS records, but further breaks down the Defendants' "Recently Identified Prior Art" category into two subsets of references. For ease of reference, the following analysis will adopt Pozen's categorization of the

disputed prior art references: (A) “the HFHS records,”<sup>3</sup> (B) “Recently Discovered Prior Art References,”<sup>4</sup> and (C) “Additional Appendix References.”<sup>5</sup>

#### **A. The Henry Ford Health Systems Records**

##### *Diligence*

After first receiving the HFHS records on November 20, 2009, Defendants now move to include these third party patient files because they contend the references are critical to their efforts to invalidate the patents-in-suit. Defendants primary explanation for the five month delay between first receiving the records and seeking leave to amend is premised on their purported need to retain an expert to assess the references and determine their relevance and import to invalidity. MOTION TO AMEND at 5.

As a whole, the Court finds Defendants’ showing of diligence to be weak. Recognizing that a litigant may take a reasonable amount of time to “digest and marshal [the] evidence, develop a new theory, and then chronicle the complete theory in the contentions,” five months amounts to excessive delay in filing the instant Motion by virtue of waiting on expert input. *Realtime Data, LLC v. Packeteer, Inc.*, No. 6:08-cv-144, 2009 WL 2590101, at \*4 (E.D. Tex. Aug. 18, 2009) (Love, M.J.).

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<sup>3</sup> In Defendants’ Amended Invalidation Contentions (Doc. No. 198–4) (“Am. ICs”), these prior art references are identified in Section E, “Prior Art Public Knowledge and/or Use.” *See* AM. ICs at 10.

<sup>4</sup> In Defendants’ Amended Invalidation Contentions, these prior art references are identified in Sections B and C, “Prior Art Publications” and “Prior Art Patents.” *See* AM. ICs at 6–9. Defendants further list these references in the attachment listed as Exhibit C in support of the Motion to Amend (Doc. No. 198–3) and Defendants also discussed specific references at the May 25, 2010 hearing (mentioning by name references such as Catarci, Parma, Saadah, WO 98/06392, Ansel 1990, Ansel 1995, Capone, Fiese, Ravin, Sances, Zanchin, and the Physicians’ Desk Reference (Midrin (1994), Imitrex Inj.(1994), Cafergot (1994), and Aleve (1995))).

<sup>5</sup> In Defendants’ Amended Invalidation Contentions, these prior art references are identified in Section VI, “Additional Prior Art.” *See* AM. ICs at 37–41. Pozen further pointed out that these reference were not listed in Defendants’ Exhibit C, and made a supplemental list of Additional Appendix References in Exhibit H in support the Pozen Resonse (Doc. No. 205–9).

Expert witnesses were not retained until after the HFHS records had been subpoenaed, and even then, depositions and opinion testimony of these experts was not compiled until Defendants had been in possession of the HFHS records for several months. As will be discussed in more detail in the following section, an invalidity expert may have an evidentiary role in aiding the parties to assess prior art, but Defendants' extensive reliance on expert analysis in providing notice of its invalidity positions resulted in a lack of diligence in notifying Plaintiff of an intent to rely on these records.

*Potential Prejudice*

Although inclusion of the HFHS records may interject some prejudice at this stage of the litigation, the advance notice of the subpoenaed documents lessens any prejudice by allowing Pozen an opportunity to adequately defend against these references at trial. The parties do not dispute that Pozen was served a copy of the HFHS records on December 17, 2009, thus affording Pozen's experts ample time to review these references and submit rebuttal arguments to Defendants' invalidity theories.<sup>6</sup> MOTION TO AMEND at 2, 6–7; RESPONSE TO MOTION TO AMEND at 4. Furthermore, Pozen does not dispute the characterization of the HFHS records as “four highly similar, brief, and straightforward references.” REPLY at 6.

Considering the HFHS records apart from the other references Defendants are seeking to add, the Court is further persuaded these references are not unduly prejudicial because they supplement an invalidity theory that Pozen was already on notice of. The Original Invalidity Contentions established § 102 and/or § 103 defenses claiming that the combination of sumatriptan and an NSAID was used to treat migraines prior to the critical date of the first Pozen patent. As such, these

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<sup>6</sup> It is noted that Defendants did not produce an inadvertently omitted HFHS record until late April 2010. RESPONSE TO MOTION TO AMEND at 5. However, given Defendants' representation that all these patient records are similar in nature, it is unlikely that this single reference introduces significant surprise.

particular references serve to supplement and clarify anticipation and obviousness theories that were already established earlier in the case. Therefore, because these patient records are limited in number and Pozen's experts have had sufficient time to review the prior art in light of established invalidity theories, this factor weighs in favor of showing good cause.

Pozen asserts that the HFHS records are improper because it perceives Defendants to be making "eleventh-hour alterations" that prevent Plaintiff from conducting adequate discovery on the circumstances surrounding the records. RESPONSE TO MOTION TO AMEND at 12–13. In order to properly respond to the Amended ICs, Pozen suggests that it would need, at a minimum, the depositions of third party witnesses from the Henry Ford Health Institute, as well as the third party fact deposition of Dr. Ramadan and the employment records of the treating physicians identified in the patient records. See MOTION TO AMEND at 12. Therefore, having explored the requested discovery further at the hearing, and in an effort to provide Pozen a chance to fully respond to the invalidity positions advanced by the HFHS records, the Court **GRANTS** Pozen leave to conduct limited discovery on specific topics set forth at the conclusion of this Order. Upon collecting this additional discovery, the Court is satisfied that Pozen will be in a position to adequately respond to the Amended ICs and any prejudice will be cured.

#### *Importance*

Defendants' overall showing as to this factor persuades the Court that the HFHS records play an important role in Defendants' invalidity theories. As presented, the HFHS records are patient records that disclose the administered combination of sumatriptan and naproxen sodium to treat migraines before the critical date of the first Pozen patent application. MOTION TO AMEND at 6. Applying this theory under § 102 and/or § 103, the records could potentially invalidate the '499 and

‘458 patents. The importance of these records and the low prejudice overcomes a weak showing of diligence. As a whole the factors weigh in favor of a showing of good cause. Accordingly, Defendants’ Motion to Amend ICs is **GRANTED** as to the HFHS records and the Motion to Strike is **DENIED** as to these same references.

**B. Recently Discovered Prior Art References**

*Diligence*

In addition to the HFHS records, Defendants move to include a category of primary and secondary prior art references that they “recently identified” through honing their invalidity theories with their experts. Defendants contend that they have satisfied the good cause standard for the Recently Discovered Prior Art References because they were unaware of these references at the time the Original ICs were disclosed in May 2009 and many of the current invalidity theories and corresponding references were identified once Defendants’ experts began preparing their reports and the theories were “solidly formed.” MOTION TO AMEND at 5 (stating that Defendants moved to amend once it was decided that Defendants’ experts would rely on these new references). Defendants generally assume that diligence was demonstrated because the importance of these references only became apparent upon review by its expert. Therefore, although the references could have been identified at an earlier stage of the case, Defendants presume the references are “recently identified” as a result of the expert’s decision to rely upon them in the expert report. MOTION TO AMEND at 5–6.

In response Pozen argues that the purpose of Local Rule 3-3 is to place Plaintiff on notice of potentially invalidating art that will be asserted at trial, arguing that Defendants’ reliance upon its expert is not an adequate showing of diligence when seeking to add references that could have been asserted much earlier in the case. RESPONSE TO MOTION TO AMEND at 6–8 (citing *Cummins-Allison*

*Corp. v. SBM Co., Ltd.*, No. 9:07-cv-196, 2009 WL 763926, at \*4 (E.D. Tex. Mar. 19, 2009)). Pozen suggests that Defendants have no legitimate reason for seeking to amend at this late date since the good cause standard will only attribute diligence to a party who demonstrates that it was unable to meet the earlier deadline for disclosure. *Id.* (citing *ST Microelectronics*, 307 F. Supp.2d at 850). Since these references could have been identified without the involvement of Defendants' expert, Pozen argues that Defendants' delay in investigating the prior art is a delay of its own making. RESPONSE TO MOTION TO AMEND at 7–9.

At the hearing, in discussing the purported showing of diligence, the Court specifically asked Defendants to address why the Recently Discovered Prior Art References were not identified much earlier in the case and why it took Defendants until April 2010 to seek leave to add the new references.<sup>7</sup> Counsel for Defendants stated that only in working with the invalidity expert were they able to identify and focus on the references that are the subject of this Motion. The Court expressed concern that Defendants have an obligation to disclose relevant prior art references as soon as possible<sup>8</sup> and that Defendants are improperly conflating disclosure under the Patent Rules with the preparation of expert reports.

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<sup>7</sup> Based on a timeline discussed at the hearing, it appears undisputed that Defendants retained relevant experts in December 2009 and January 2010 but did not move to amend ICs until expert reports were due. Additionally, it is undisputed that Defendants have been doing invalidity analysis on the patents-in-suit since before this lawsuit was filed.

<sup>8</sup> Defendants argue that they should not have to move to amend their ICs at the time they “learned of” the new prior art references because it “would result in Defendants moving for leave to amend on more than twenty different occasions.” While the Court agrees that twenty such motions would be inefficient, the purpose of P.R. 3-3 requires such a motion at the time it becomes apparent that a defendant is in possession of potentially invalidating prior art. *See Realtime Data, LLC v. Packeteer et al.*, No. 6:08-cv-144, 2009 WL 4782062, at \*2 (E.D. Tex. Dec. 8, 2009) (citing *Cummins-Allison Corp.*, 2009 WL 763926, at \*4)). In short, litigants should be cognizant that they may have to move to amend ICs on more than one occasion.

Defendants reliance upon its expert in seeking to excuse the delay in disclosing the Recently Discovered Prior Art is impermissible in light of the well-established goals of Patent Rule 3-3. *Realtime Data, LLC v. Packeteer et al.*, No. 6:08-cv-144, 2009 WL 4782062, at \*2 (E.D. Tex. Dec. 8, 2009) (Love, M.J.) (hereinafter “Realtime”) (citing *Cummins-Allison Corp.*, 2009 WL 763926, at \*4); *Finisar Corp. v. DirectTV Group, Inc.*, 424 F. Supp.2d at 901). Defendants argue that their delay was the result of discovery efforts and “working with [their] experts,” but have not identified what prevented them from either disclosing these references much earlier in the litigation and/or engaging expert witnesses at a point that would have ensured earlier disclosure.<sup>9</sup> Instead, Defendants’ diligence arguments conflate the notice function of Invalidity Contentions with the evidentiary function of expert reports.<sup>10</sup> In short, the Court sees no reason why Defendants could not have disclosed these references as a matter of pleading in their contentions while then presenting some, if not all, of these references in their expert reports. *IXYS Corp. v. Advanced PowerTech, Inc.*, No. C 02-03942, 2004 WL 1368860, at \*3 (N.D. Cal. June 16, 2004); *see also Realtime*, 2009 WL 4782062, at \*2 (citing *Cummins-Allison Corp.*, 2009 WL 763926, at \*4). The path pursued by Defendants, however— using expert reports to “confirm legal theories” and *then* seek leave to amend— renders the requirements of P.R. 3-3 essentially meaningless because notice is unduly

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<sup>9</sup> Defendants appear to argue that they needed experts to provide notice as to their potential reliance on invalidity theories, however, the relevant theory underlying the “recently identified” references does not seem any different from the one already being asserted. Thus, it would seem that the theory could have been fully formed and charted prior to expert involvement in the case. Alternatively, if expert involvement was truly the basis for identification, Defendants should have involved such experts with sufficient time to provide Pozen with adequate notice.

<sup>10</sup> This is not the first case in which the Court has observed parties’ seeking to import the notice function of Invalidity and Infringement Contentions into the evidentiary stage of preparing expert reports. Given the distinct role of Invalidity and Infringement Contentions to clarify the scope of the case, it is difficult to accept the representation that there is a corollary between the notice disclosures made under the Patent Rules and the evidentiary disclosures made in expert reports.

delayed until late in the discovery process under the guise of seeking expert advice to understand prior art. See *Cummins-Allison Corp.*, 2009 WL 763926, at \*1; *O2 Micro Int'l Ltd. v. Mololoithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006) (“The rules seek to balance the right to develop new information in discovery with the need for certainty as to legal theories.”). As such, Defendants’ diligence arguments are unavailing and do not weigh in favor of showing good cause to amend.

*Potential Prejudice and Importance of the Amendments*

Given Defendants’ weak showing as to diligence, good cause requires a heightened showing of importance and low prejudice to Pozen, neither of which is clearly established for these references. Defendants argue that Pozen has not experienced any unfair prejudice because Pozen’s expert(s) have already considered the references that are the subject of this Motion and retain an opportunity to rebut the invalidity theories advanced in Defendants’ expert reports. MOTION TO AMEND at 6–7. While Pozen does not dispute that its expert has had an opportunity to submit a report rebutting Defendants’ invalidity theories, it contends that the overall process was prejudicial because its rebuttal positions were developed under time constraints that did not allow Pozen to fully assess the Recently Discovered Prior Art References. Thus, the Court finds some prejudice to exist because since May 2009 Pozen relied upon Defendants’ Original ICs, which Defendants now seek to drastically narrow and supplement with prior art disclosed at the close of discovery. Particularly concerning is that Pozen sought confirmation of Defendants’ invalidity theories through 30(b)(6) depositions and interrogatories, but Defendants never advised that they were asserting the prior art discussed herein until the exchange of expert reports. As a result, Pozen was prejudiced because

deadlines in this case prevented it from fully engaging in discovery and then developing its rebuttal positions in the same manner that it would have if there had been proper notice.

The factual considerations underlying these references appears distinguishable from those surrounding the HFHS records. Whereas when seeking to add the HFHS records, Defendants could point to a discrete number of documents and identify how this prior art fits together with previously asserted theories, the Recently Discovered Prior Art References lack such a clear characterization. As argued by Pozen, the total number of Recently Discovered Prior Art References introduces greater prejudice than the HFHS records and while the HFHS records were provided in December 2009, there is evidence that the last of the Recently Discovered Prior Art References were not disclosed until as recently as April 2010.<sup>11</sup>

Lastly, Defendants' discussion as to the importance of the Recently Discovered Prior Art References is not as persuasive as that presented for the HFHS records. Defendants generally allude that the references are important because they were identified by its experts, but when further questioned at the hearing, Defendants did not make a particularized showing of importance as to each of the presented references. For example, in the Reply brief, Defendants respond only to timing and complexity arguments related to the HFHS records, without any further explanation as to how the more "recently identified" references fit with established invalidity theories. Overall, Defendants

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<sup>11</sup> In a timeline that appears undisputed, Pozen states that Par produced nine additional references on April 2, 2010 and forty references on April 16, 2010. RESPONSE TO MOTION TO AMEND at 4–5. Although the actual manner of disclosure as to particular references was not addressed in any further detail, the Court's initial impression is that the nine references disclosed on April 2<sup>nd</sup> fall into the "Recently Discovered Prior Art" category and the forty references disclosed on April 16<sup>th</sup> fall into the "Additional Appendix References" category. The overall lack of precision in indicating which particular references were disclosed on what date, however, only supports the Court's conclusion that the timing and manner of disclosure is prejudicial.

do not successfully demonstrate the importance of individual references in the context of each theory.

*Lack of Good Cause Warrants that the Recently Discovered Prior Art References be Stricken*

Having considered the factors comprising a showing of good cause under P.R. 3-6(b), the Court finds that Defendants have failed to show either diligence or a reasonable explanation for the delayed filing of the Motion to Amend ICs. Further, while the amendments may be important in a general sense, Defendants have not shown with specificity how each of these references fits into their invalidity theories and the prejudice Pozen would suffer weighs against allowing the references. Thus, Defendants have failed to show good cause as to these references and the Court **DENIES** the Motion as to the Recently Discovered Prior Art References. Accordingly, the Motion to Strike is **DENIED** as to these same references.

**C. Additional Appendix References**

For the same reasons identified in the previous section, the Court finds that Defendants have not shown good cause to add the Additional Appendix References as potentially invalidating prior art. Additionally, in support of the Motion to Amend the ICs, Defendants attached the relevant claim charts for the HFHS records, as well as the “recently identified” primary prior art references such as Catarci, Parma, Saadah, and WO 98/06392. *See* MOTION, EXHS. B–I. No such charts were disclosed for the Additional Appendix References and there is no indication that Defendants have prepared such charts. Instead, in disclosing these references in the Amended ICs, Defendants “reserve the right to rely on these references in any way to prove the invalidity of the asserted claims of the patents-in-suit in a manner consistent with the Federal Rules of Civil Procedure and the Court’s Rules.” AM. ICs at 37.

Where there is no explanation as to how particular references anticipate or render the asserted claims obvious, a defendant will not be permitted to “reserve the right” to assert largely undisclosed invalidity theories. *See Realtime*, 2009 WL 4782062, at \*2–\*3. A defendant must submit charts for any asserted prior art reference “providing notice as to how each claim element is met” and/or, when necessary, identify combinations of prior art that render a claim obvious. *Id.* at \*3 (citing P.R. 3-3(b) & (c)). Accordingly, Defendants have also failed to show good cause as to the Additional Appendix References due to their failure to comply with P.R. 3-3, and the Court **DENIES** the Motion to Amend ICs as it relates to these references. Accordingly, the Motion to Strike is **GRANTED** as to these same references.

Finally, while Defendants will not be allowed to assert the Additional Appendix References at summary judgment or trial for the purpose of invalidating the patents-in-suit, nothing prevents the experts from relying upon or otherwise citing these references in an expert report for background purposes or a discussion of the state of the art on or before the critical date for Pozen’s patents. Defendants represented at the hearing that its experts intended to cite these prior art references for such purposes and those citations are permissible so long as these prior art references are not relied upon in a §102 or § 103 invalidity analysis. Patent Rule 3-3 does not discuss or otherwise require that an expert’s assessment of the background technology be charted and disclosed in its invalidity contentions unless those the references are relied upon for the express purpose of invalidating the patents-in-suit.

### **CONCLUSION**

For all the foregoing reasons, Defendants’ Motion to Amend Their Invalidity Contentions is **GRANTED** as to the HFHS records but **DENIED** as to the Recently Discovered Prior Art

References and the Additional Appendix References. Similarly, the Motion to Strike Defendants' Invalidation Contentions is **GRANTED** as to all references discussed herein, except the HFHS records.

In allowing the HFHS records the Court finds that further limited discovery is warranted to allow Pozen an opportunity to adequately rebut the invalidity theories related to the HFHS records. Accordingly, if requested, the Court **ORDERS** the following additional discovery:

- Defendants are to make Dr. Ramadan available as a fact witness for four hours of deposition addressing invalidity theories that include the HFHS records by **June 28, 2010**.<sup>12</sup>
- Pozen is **GRANTED** leave to subpoena the employment records for the treating physicians and other personnel identified in the HFHS records.
- Should further discovery be requested following the aforementioned discovery, the parties are **ORDERED** to meet and confer and seek leave of the Court in the form of either a joint or opposed<sup>13</sup> motion setting forth the specific parameters of the requested discovery.

Upon collecting this additional discovery, Pozen is **GRANTED** leave to supplement its expert reports, if necessary, by **July 14, 2010**. Defendants are also afforded leave to amend their Amended Invalidation Contentions and expert reports to the extent discussed herein. Amended Invalidation Contentions adding only the HFHS records should be served and filed with the Court by **June 17, 2010**. Defendants' expert reports should also be appropriately amended to include the HFHS records and exclude the stricken prior art references by **June 17, 2010**.<sup>14</sup>

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<sup>12</sup> The parties are to meet and confer to agree upon a specific location, date, and time for such a deposition.

<sup>13</sup> Such a motion should clearly identify the type of discovery sought, what relevant information the additional discovery is believed to secure, and why the additional information is needed.

<sup>14</sup> References should be excluded for the purposes of invalidating the patents-in-suit. *See* Section II.C at 18, *supra*.

So ORDERED and SIGNED this 8th day of June, 2010.

  
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JOHN D. LOVE  
UNITED STATES MAGISTRATE JUDGE