NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AUXILIUM PHARMACEUTICALS, INC., ET AL.,	:	
Plaintiffs,	:	**Civil Action No. 12-3084 (JLL)**
v.	:	
WATSON LABORATORIES, INC. (NV), ET AL.,	:	**OPINION (FILED UNDER SEAL)**
Defendants.	:	

I. INTRODUCTION

This matter comes before the Court by way of Defendant Watson Laboratories, Inc.'s ("Watson" or "Defendant") application to amend its invalidity contentions (ECF No. 50) pursuant to Local Patent Rule 3.7. Plaintiffs Auxilium Pharmaceuticals, Inc. and FCB I LLC (collectively "Auxilium" or "Plaintiffs") oppose Watson's request. The Court heard oral argument on May 22, 2013. Hearing Tr., ECF No. 89.

Auxilium has brought an action for patent infringement against Watson pursuant to 35 U.S.C. § 271. The Local Patent Civil Rules of this district require a patent defendant to file invalidity contentions that set forth the basis for any assertion that the plaintiff's patent is invalid. Watson filed those contentions on October 29, 2012, and now seeks to amend them. Watson claims that during the early stages of fact discovery, Auxilium produced confidential documents that led to the discovery of additional prior art, which forms the basis for a number of new

defenses based on that prior art. Further, Watson claims it "discovered" certain claim limitations were indefinite as it prepared for claim construction. Thus, Watson seeks to amend its contentions to add prior art references and to add a claim for indefiniteness. For the reasons below, the Court will grant Defendant's application in part and deny it in part.

II. BACKGROUND

Plaintiffs have a number of patents allegedly related to Auxilium's Testim testosterone gel product.[1] Compl. ¶ 31. Watson filed an Amended New Drug Application ("ANDA") with the Food and Drug Administration to manufacture a generic version of Testim. Id. at ¶ 33. On April 12, 2012, Watson sent Plaintiffs a notice letter pursuant to 21 U.S.C. § 355. Pl. Opp., ECF No. 56, at 2. That notice letter set out Watson's positions as to why its generic product did not infringe Plaintiffs' patents, and why those patents were invalid. On May 23, 2012, Auxilium filed suit alleging patent infringement.

The Local Patent Rules require any party "opposing an assertion of patent infringement" must serve invalidity contentions on the patent holder. L. Pat. R. 3.3. Those contentions must set forth the prior art that a defendant alleges anticipates a patent under 35 U.S.C. § 102 or renders it obvious under 35 U.S.C. § 103, as well as an accompanying chart identifying where each claim limitation is found in the prior art. See L. Pat. R. 3.3(a), (b). In addition, the rule requires the defendant to state "any grounds of invalidity based on . . . indefiniteness under 35 U.S.C. § 112(2)." L. Pat. R. 3.3(d).

Watson filed its invalidity contentions on October 29, 2012. It now seeks to amend those

[1] The patents at issue are: U.S. Patent Nos. 7,320,968; 7,608,605; 7,608,606; 7,608,607; 7,608,608; 7,608,609; 7,608,610; 7,935,690; 8,063,029; and 8,178,518 ("patents-in-suit").

contentions for two reasons. First, it wants to add additional prior art references. Based on these new references, Watson seeks to argue that the patents-in-suit are invalid because they are obvious under 35 U.S.C. § 103, because there was an earlier public use and prior sale, and because the patentees failed to name a coinventor. Watson contends that as it reviewed Auxilium's production of confidential, internal documents, it learned of a product that embodied limitations of the patents-in-suit. This discovery, Watson maintains, allowed it to more fully understand publicly available documents and develop additional invalidity theories. Def. Appl., ECF No. 50, at 3. Auxilium claims that if Watson had been diligent, it could have gleaned all necessary information solely from the publicly available documents before filing its invalidity contentions. Pl. Opp., ECF No. 56, at 1.

Second, Watson seeks to add an indefiniteness contention. Watson claims it learned of the basis for the indefiniteness contention as it reviewed the patents-in-suit during the claim-construction process. Def. Appl. at 1. Auxilium argues that Watson should have done this analysis well in advance of filing its invalidity contentions. Pl. Opp. at 6.

III. DISCUSSION

The District of New Jersey promulgated the Local Patent Rules in 2009 for the administration of "all civil actions . . . which allege infringement of a patent." L. Pat. R. 1.2. Those rules require early disclosure of the patentee's infringement contentions and the alleged infringer's invalidity contentions. Sanofi-Aventis v. Barr Labs., Inc., 598 F. Supp. 2d 632, 637 (D.N.J. 2009) (describing the disclosure requirements as "*ultra* early" (emphasis in original)). The purpose of such early disclosure, at least in part, is "to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate

their cases." King Pharm., Inc. v. Sandoz Inc., Civ. No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (quoting Computer Accelerations Corp. v. Microsoft Corp., 503 F. Supp. 2d 819, 822 (E.D. Tex 2007)) (internal quotation marks omitted). 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." King Pharm., 2010 WL 2015258, at *4 (citing Atmel Corp. v. Info. Storage Devices, Inc., Civ. No. 95-1987, 1998 U.S. Dist. LEXIS 17564, at *2 (N.D. Cal. Nov.5, 1998)) (internal quotation marks omitted). The courts of this district have distinguished this stricter standard from that of the liberal standard to amend a pleading. Astrazeneca AB v. Dr. Reddy's Labs., Inc., No. 11-2317, 2013 U.S. Dist. LEXIS 36779, at *6-9 (D.N.J. Mar. 18, 2013). Nevertheless, Rule 3.7 "is not a straitjacket into which litigants are locked from the moment their contentions are served . . . [a] modest degree of flexibility [exists], at least near the outset." Id. at *8-9. 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." Id. (internal quotations omitted).

Rule 3.7 allows for amendment of contentions "only by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7. Good cause "considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted." Dr. Reddy's Labs., 2013 U.S. Dist. LEXIS 36779, at *8 (citing O2 Micro Int'l, Ltd. v. Monolithic Power Sys., 467 F.3d 1355 (Fed. Cir. 2006)). Therefore, with respect to each of the two proposed amendments, the Court must inquire first whether Watson was diligent, and if so, whether Auxilium would suffer unfair prejudice. In determining whether good cause exists, courts have also considered factors such as

(1) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings. See Oy Ajat, Ltd. v. Vatech Am., Inc., 2012 U.S. Dist. LEXIS 43443, at *20-21 (D.N.J. Mar. 29, 2012); see also L. Pat. R. 3.7 ("Non-exhaustive examples of circumstances that may support a finding of good cause include . . . (b) recent discovery of material prior art despite earlier diligent search; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention").

A. Prior Art References

Watson contends that after it served its invalidity contentions, Plaintiffs produced documents that allowed Watson to uncover additional prior art. In particular, Watson learned that Auxilium had acquired a product referenced as CPE-215. Def. App., ECF No. 50, at 3. Watson claims that it learned from Auxilium's internal and confidential documents that the CPE-215 technology was "actually a reference to the same permeation enhancer set forth in the asserted claims." Id. Watson claims that this discovery allowed it to fully appreciate other, publicly available documents. Watson claims that once it could analyze these public documents through a better-informed lens, it developed additional invalidity arguments based on the public and private documents. Watson refers to the other, publicly available documents as the "Bentley Pharmaceutical Disclosures." See Watson Proposed Amended Invalidity Contentions, ECF No. 50-1, at 9, (attached as Exh. 1 to Def. App.). These other documents include: (1) the CPE-215 Trademark Application; (2) a May 31, 2000 License Agreement; (3) a June 6, 2000 Press

Release; (4) a December 18, 2000 Press Release; (5) a March 20, 2001 Press Release; (6) the Annual Report for 2000; (7) a S-3 Registration Statement; (8) the Annual Report for 2001; and (9) Amendment No. 2 to the 2001 Annual Report. Id.; Pl. Opp., ECF No. 56, at 1-2. [redacted]

[redacted]

Proposed Amended Invalidity Contentions (attached as Exhibit to Def. Appl., ECF No. 50-1) at 9; Def. Reply, ECF No. 58, at 3-4.

[redacted]

[redacted][2] Instead, Auxilium argues that because Watson's new prior art arguments are based "in large part" on the publicly available Bentley Pharmaceutical Disclosures, Watson cannot establish diligence to amend those contentions. Pl. Opp., ECF No. 56, at 1 ("Watson's belated invalidity theories are based almost entirely on the following [publicly available documents]"); id. at 2 ("[T]he vast majority of information on which [Watson] bases its late-

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[2] Auxilium does address [redacted] in an unauthorized sur-reply (ECF No. 61) and Watson responds in an unauthorized sur-sur-reply (ECF No. 62). Both parties failed to follow Local Civil Rule 7.1(d)(6), which states: "No sur-replies are permitted without permission of the Judge or Magistrate Judge to whom the case is assigned." The Court issued an Order that no more papers were to be filed in this matter absent good cause (ECF No. 63). It is within the Court's discretion whether to consider or strike improperly filed briefs, although courts within this district routinely strike such papers. See Baier v. Princeton Office Park, 2011 U.S. Dist. LEXIS 123268, at *16 (D.N.J. Oct. 24, 2011)In re Ford Motor Co. E-350 Van Prods. Liab. Litig., No. 03-4558, 2010 U.S. Dist. LEXIS 68241 (D.N.J. July 9, 2010); Hailstalk v. Antique Auto Classic Car Storage, LLC, No. 07-5195, 2008 U.S. Dist. LEXIS 68016, at *8 (D.N.J. Sept. 9, 2008). However, the Court need not reach this issue to resolve Watson's application. The unauthorized supplemental papers raise no new material arguments. Auxilium contends that Watson did not articulate until its reply that its prior art amendment is based, in part, on the [redacted] Auxilium argues this belated argument is further evidence of Watson's "shifting sands" approach to this litigation. But Watson's initial application asserted that Watson's prior art amendment is based, in part, on [redacted] and its review of the proposed amended invalidity contentions, as discussed above. See, e.g., ECF 50 at 3. Thus, Auxilium's argument is unavailing.

proposed contentions is publicly available."); id. at 3 ("[Watson's new theories] were based in large part on publicly available documents.").

There does not seem to be any dispute that the Bentley Pharmaceutical Disclosures were publicly available before Watson served its contentions. If the entirety of Watson's diligence showing was based on these documents, the Court would be reluctant to allow an amendment. But there is more. Watson explains, and Auxilium does not directly dispute, that Watson more fully appreciated and understood the Bentley Disclosures after it learned the specifics of CPE-215 through [redacted] Auxilium quotes from Watson's proposed amended contentions to argue that Watson's amendment is based on the Bentley Pharmaceutical Disclosures. While Watson discusses the Bentley Pharmaceutical Disclosures at some length in its proposed contentions, it also states that the claims of the patents-in-suit are obvious in light of "the Bentley Pharmaceutical Disclosures . . . and in further view of the [redacted] Proposed Amended Invalidity Contentions, ECF No. 50-1, at 10; see also id. at 17-18. [redacted] are internal Auxilium documents that Auxilium produced after Watson filed its disclosures.[3] Def. Reply, ECF No. 58, at 3-4. They are also cited extensively in Watson's amended invalidity charts. See, e.g., Proposed Amended Invalidity Contentions, at 49-55 (invalidity chart for U.S. Patent No. 7,320,968). The Bentley Pharmaceutical Disclosures are not cited in the charts. At oral argument, Watson advanced this distinction in support of its motion. Hearing Tr., ECF No. 89,

[3] Watson attached the [redacted] to its reply. ECF No. 58-1, Exhs. 3-4. The Court notes that they are marked as "Highly Confidential-Outside Counsel Eyes Only." Assuming the parties abided by their protective order, this established that these documents were not publicly available before production. Further, no party suggests that they were publicly available.

at 10-11.

At oral argument, Auxilium also asserted that even if the [redacted] were unavailable, that Watson relies on [redacted] only for some of its new contentions. Hearing Tr., ECF No. 89, at 47. Watson, on the other hand, argues that aside from indefiniteness, all other new contentions—that the CPE-215 helps render the patents-in-suit obvious, that the [redacted] constituted a public prior use and prior sale of the invention, and that the patent is invalid for failing to name a coinventor, in particular the inventor of CPE-215—are based on understanding CPE-215 in light of the [redacted]

Watson appears correct. Other than indefiniteness, all other new contentions are based upon its new understanding of CPE-215. Each of these theories–obviousness, prior use and sale, and failure to name a coinventor–appear to be premised on discovering that CPE-215 is supposedly an invention embodying some of the limitations of the claims at issue. Watson's new obviousness argument is premised on first learning that "the CPE-215 described in the publicly available documents is the exact same permeation enhancer recited in the patents-in-suit as 'oxacyclohexadecan-2-one'" through the [redacted] Def. Reply, ECF No. 58, at 5. Watson also argues that when Bentley purchased CPE-215 it was a prior sale and that earlier clinical studies using CPE-215 were prior public uses.[4] Id. at 3-4. Finally, Watson

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[4] Specifically, Watson argues that the [redacted] revealed that plaintiffs represented to the PTO that "we are the first entity to come up with the claimed combination of testosterone and a specific permeation enhancer. Here on this page, it's entitled CPE-215. In the patent, it's actually referred to as oxacyclohexadecane-2-one; that's its chemical name." Hearing Tr., ECF No. 89, at 10:16 to 10:21. But Watson maintains from its review of the [redacted] Id. at 11:1 to 11:10. Conrex subsequently sold the technology to Bentley in a 1999 Asset Purchase Agreement. Def. Reply, ECF No. 58, at 1.
(continued...)

argues that [redacted] Conrex should have been listed as a co-inventor. Id. None of these arguments could have been developed without first understanding the nature of CPE-215.[5] Watson cites extensively to the [redacted] throughout its argument and throughout its invalidity contentions for each of its prior art-based contentions, and relied heavily on them at oral argument.

Auxilium points out that the face of the patent specifically lists publications regarding CPE-215 and the sale of CPE-215 to Auxilium. Hearing Tr., ECF No. 58, at 28-29. There appears to be no dispute that those documents were publicly available. Watson maintains, however, that it could not fully appreciate their significance without the internal, confidential documents that Auxilium produced. After oral argument, the Court ordered Defendant to produce a copy of the file history for U.S. Patent No. 7,320,968. May 23, 2013 Order, ECF No. 85. The Court has reviewed the file history in its entirety and the only reference to the CPE-215 documents is in an Initial Disclosure Statement that the applicants filed with the examiner. August 16, 2005, Supplemental Information Disclosure Statement, ECF No. 86-4 at 68. The

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[4](...continued)
According to Watson, Bentley then claimed the technology as its own. Hearing Tr., ECF No. 89, at 11:1 to 11:10. On that basis, Watson asserts a prior sale of the invention and potential public use. Id. at 11:11 to 11:17. That basis also forms Watson's improper inventorship claim, because Watson maintains that the PTO application disclosed only Robert Gyurik as the inventor, and did not disclose [redacted] Id. at 11:17 to 11:23.

[5] At oral argument, Auxilium stressed what it perceives as the flaws in Watson's contentions, including whether the CPE-215 actually embodied claimed elements of the patents-in-suit and whether it was public such that it could be considered prior art. Hearing Tr., ECF No. 58, 31-33. These arguments may be well-founded and ultimately prove correct, but they go to the merits of the contentions themselves, which is beyond the question for the Court at this juncture. The only question for the Court is whether Defendant should be given an opportunity to try and prove its contentions.

public documents that were submitted do not provide any detail about CPE-215, such as is found in the [redacted] Rather, they discuss CPE-215 generically:

> Our permeation enhancement technology consists of a series of related chemical compounds that enhance the absorption of a wide variety of products across various biological membranes. Our primary compound and the foundation for our drug delivery platform technology is CPE-215 (cyclopentadecanolide).
>
> CPE-215 when combined with certain drugs, has been shown to significantly enhance the amount and asorption of those drugs through various biological membranes. By controlling the amount of CPE-215 that is combined with certain drugs, we have the ability to affect the quantity and rate at which the drug is absorbed through biological membranes.

Bentley Pharmaceutical S-3 SEC Form, ECF No. 86-5 at 13. Importantly, these documents refer to CPE-215 "cyclopentadecanolide"–which is different than oxacyclohexadecan-2-one, the compound discussed in the patent, and, according to Watson, the same as CPE-215. Auxilium has not argued that these are equivalent. Nor did the patent examiner discuss CPE-215, and nothing else in the file history appears to provide more fulsome detail. Therefore, although the '968 patent lists documents discussing CPE-215, it does not provide nearly the same detail or insight into the compound as the [redacted] and could not provide a basis for Watson's contentions.

The Court finds that Watson's request to add prior art references is based, at least in part, on the recent discovery of facts that were not otherwise available to Watson when it initially filed its invalidity contentions. Auxilium implicitly acknowledges this fact by stating that Watson's application is based "in large part" on publicly available documents. By logical extension, some part of Watson's application is necessarily based on non-publicly available documents. Courts in this district have found that a party could amend contentions even when something was missed

"through simple inadvertence and oversight." See Int'l Dev., LLC v. Richmond, No. 09-2495, 2010 U.S. Dist. LEXIS 106616, at *7-9 (D.N.J. Oct. 4, 2010); TFH Publs., Inc. v. Doskocil Mfg. Co., 705 F. Supp. 2d 361, 367 (D.N.J. 2010). This is especially so when the matter is in an early stage. See Int't Dev., 2010 U.S. Dist. LEXIS 106616, at * 8 ("Therefore, while the Local Patent Rules strive to have a party establish their contentions early on, it is important to recognize that preliminary infringement contentions are still preliminary.") (internal quotations omitted). Certainly Watson was more diligent in searching for prior art than a party who missed something through simple inadvertence. And Watson was diligent in moving to amend the contentions after it discovered the prior art. Soon after Watson reviewed the documents, it attempted to meet and confer with Auxilium regarding its proposed amendments. When those efforts were unsuccessful, Watson filed its application to amend. See Exh. 10 to Def. Appl., ECF No. 50-10.

Indeed, Local Rule 3.7 appears to contemplate amendment in this situation. The rule sets out a non-exhaustive list of circumstances that may, absent undue prejudice, support an amendment. The second example provided is the "recent discovery of material prior art despite earlier diligent search." L. Pat. R. 3.7.[6] Here, the record suggests that it would be unreasonable to expect Watson to have fully discovered this prior art before Auxilium produced the [redacted] despite any diligent prior art search. Based on the above, the Court finds that Watson was diligent in discovering the new prior art.

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[6] In its opposition, Auxilium points out that amendment is usually only allowed when there has been "the ***recent discovery of new facts***." Pl. Opp. at 4 (emphasis in original). This appears to be correct. But Auxilium makes this statement in the context of arguing that Watson should have discovered the prior art exclusively from the publicly available Bentley Disclosures. Because the Court has found that Watson did discover new facts—in particular the [redacted]—Auxilium's point ultimately bolsters Watson's position.

In terms of prejudice or delay, this matter case is in a relatively nascent stage, particularly considering the comparatively long litigation life-span for a typical Hatch Waxman patent infringement action. Courts in this district are more lenient in allowing amendments when the case is in its early proceedings. In Int'l Dev, the Court noted that although the parties had filed briefs on claim construction, the Court had not yet scheduled a hearing. Int't Dev., 2010 U.S. Dist. LEXIS 106616, at * 9. In TFH, fact discovery was ongoing but the parties had not yet briefed claim construction. TFH Publs., 705 F. Supp. 2d at 366; see also Oy Ajat, Ltd. v. Vatech Am., Inc., 2012 U.S. Dist. LEXIS 43443, at *68-69 (D.N.J. Mar. 29, 2012) ("Fact discovery has yet to be completed and, although Markman briefs have been submitted, no hearing has been scheduled such that any additional discovery and/or revisions to Markman briefs may proceed when the stay is lifted."). In AstraZeneca AB v. Hanmi USA, Inc., the court found there was no significant delay when the modifications "would in no way prevent this matter from being tried" on schedule. AstraZeneca AB v. Hanmi USA, Inc., No. 11-760, 2011 U.S. Dist. LEXIS 130980, at *22-24 (D.N.J. Nov. 14, 2011).

These cases represent a reasonable approach to handling amendments to contentions where the amendment neither is necessitated by a party's dereliction nor poses significant delay. In this case, the Court entered the Scheduling Order on November 13, 2013. See Initial Scheduling Order, ECF No. 36. Fact discovery is ongoing, expert discovery has not yet begun, the parties have not submitted claim-construction briefs, the Court has not yet set a claim-construction hearing, and no trial has been set. Plaintiffs will have ample time to explore and probe Watson's additional references. And if Plaintiffs require additional time for discovery because of this amendment, they may seek it from the Court. Therefore, allowing Watson to

amend its contentions based on the newly discovered prior art will not cause any significant delay or prejudice to Plaintiff.

A review of the good-cause factors further supports allowing Watson to add its recently discovered prior art to its contentions.

1. Reason for the delay

As discussed above, the reason for the delay was based, in part, on Watson not having access to confidential documents, particularly the [redacted] until Auxilium produced them. Although Watson had access to other, publicly available documents, the Court cannot conclude with any certainty that Watson should have completely understand their relevance to this case until before comprehending the nature of the CPE-215 product from Auxilium's internal documents. Watson was not responsible for this delay and worked diligently to amend once it discovered the existence of the additional prior art.

2. The importance of what is to be excluded

No party disputes that the additional prior art references are important to this matter and that the issue of patent invalidity, in general, is critical in any patent infringement action. If a patent is invalid, then it would preclude a finding of liability for patent infringement. Thus, Watson would be allowed to manufacture and sell its generic product.

3. *The danger of unfair prejudice*

To not allow Watson to amend its contentions would undoubtedly prejudice Watson. And considering that Watson did not have previous access to the necessary information, that prejudice would be fundamentally unfair. As discussed above, the Court does not find that this amendment will cause significant delay. This matter is in a relatively early stage. Moreover,

although Auxilium will have to spend resources defending the validity of the patents-in-suit against prior art references, this is largely an expense it would have had to incur without the proposed amendment. For example, in AstraZeneca AB v. Hanmi USA, Inc., the court found no undue prejudice when a party "had to invest significant resources in evaluating" the amended claims because it had to spend these resources in evaluating the original claims as well. Thus, the amendment did not pose a "significant additional expense." AstraZeneca AB v. Hanmi USA, Inc., 2011 U.S. Dist. LEXIS 130980, at *22. A review of the proposed amended invalidity charts shows that much of Watson's arguments remain the same with or without the proposed amendments.

4. The potential impact of a delay on this proceeding

As Watson points out, fact discovery is on-going, the parties have not exchanged claim construction briefs, expert discovery has not begun, and no trial date has been set. As discussed above, courts in this district are more likely to allow a party to amend when a matter, such as this one, is in its early stages. See TFH Publs., Inc. v. Doskocil Mfg. Co., 705 F. Supp. 2d 361, 367 (D.N.J. 2010). To allow Watson to amend would cause no significant delay.

Accordingly, the good-cause factors weigh in favor of finding of good cause to allow the amendments. For the above reasons, the Court finds that Watson may amend its invalidity contentions and charts to include the additional prior art references and arguments based on those references.

B. Indefiniteness Contention

Unlike Watson's first proposed amendment, the second is relatively straightforward. Watson seeks to add a contention that the patents-in-suit are invalid for being indefinite. A

patent is indefinite if it is "'not amenable to construction' or 'insolubly ambiguous.'" Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005) (quoting Novo Indus., L.P. v. Micro Molds Corp., 350 F.3d 1348, 1353 (Fed. Cir. 2003); Honeywell Int'l, Inc. v. Int'l Trade Comm'n, 341 F.3d 1332, 1338 (Fed. Cir. 2003); Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001)). The idea behind indefiniteness is simple: A patent is supposed to demarcate to a person of skill in the art the bounds between what is claimed and what is not. United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942). ("The statutory requirement of particularity and distinctness in claims is met only when [the claims] clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise."). If a person of requisite skill is unable to make that determination, then the patent is invalid. Of particular importance for this analysis is that a court looks to the disclosure of the patent, and the intrinsic evidence, to decide indefiniteness. "We rather look at the ***disclosure*** of the patent and determine if one of skill in the art would have understood that ***disclosure*** to encompass [the required structure]." ePlus, Inc. v. Lawson Software, Inc., 700 F.3d 509, 519 (Fed. Cir. 2012) (emphasis in original). The patent disclosure is publicly available.

All of the patents-in-suit include a claim limitation "viscosity measurement." Watson seeks to amend its invalidity contentions to argue that "viscosity measurement" is indefinite because, it argues, it is not amenable to construction.[7] Watson has been reviewing these patents-

[7] The parties also argue whether Watson should be allowed to make an indefiniteness argument as part of its claim construction brief irrespective of what is contained in its invalidity contentions. The Federal Circuit has recently explained that "indefiniteness is a question of law and in effect part of claim construction." ePlus, Inc. v. Lawson Software, Inc., 700 F.3d 509, 517 (continued...)

in-suit for some time—at the very least, since April 2012, when it had to detail its invalidity arguments as part of its notice letter to Auxilium. Watson claims that it developed its indefiniteness position only recently as it prepared its claim-construction positions. That may be the case, but that is not sufficient to establish diligence or good cause. Watson should have considered whether any claims were indefinite before filing its contentions. Local Patent Rule 3.3(d) mandates that a party provide "[a]ny grounds of invalidity based on . . . indefiniteness under 53 U.S.C. § 112(1) . . . ." L Pat. R. 3.3(d). The disclosure for the patents-in-suit, namely the specification and the file history, has been available since January 22, 2008, when the application for the first patent-in-suit was published. None of the information needed to reach the conclusion that a limitation is indefinite was either in the exclusive control of Auxilium or obscure. Watson points to nothing beyond the patents themselves. Watson could have reviewed the disclosure and considered indefiniteness at least as early as April 2012 for its notice letter.

At oral argument, Watson argued that it did not envision this as an "indefiniteness case" but rather one about prior art. Hearing Tr., ECF No. 89, at 17-19. That does not relieve Watson of its obligations under the local rules. To allow Watson to add this position now would directly contravene the policy behind those rules. The stated purpose is to require litigants to develop positions early to provide notice and give structure to the contours of the action. Watson had ample opportunity to review the patent and develop any indefiniteness theory before serving its invalidity contentions. See Nautilus Neurosciences, Inc. v. Wockhardt USA, LLC, No. 11-1997, ECF No. 98, at *12-14 (D.N.J. Jan. 23, 2013) (denying a request to amend invalidity contentions

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[7](...continued)
(Fed. Cir. 2012). Nevertheless, the issue of what arguments Watson can or cannot make at claim construction is not before the Court today and it need not decide that issue.

with an indefiniteness argument because defendants had failed to act diligently in reviewing the patent disclosure). Even if Watson did not believe this case would involve indefiniteness, it had an obligation to examine the possibility of such a defense before now.

Watson cannot show good cause and satisfy Local Patent Rule 3.7 to amend its invalidity contentions to include an indefiniteness argument. Because Watson cannot establish good cause, there is no need to address whether Auxilium would be unfairly prejudiced by this amendment.

IV. CONCLUSION

For the reasons stated above, the Court grants in part and denies in part Defendant's application to amend its invalidity contentions. Watson is allowed to amend its invalidity contentions to add prior art references and to contend, based on those references, that the patents-in-suit are obvious, and are invalid due to a prior public use and prior sale, and because the patentees failed to name a coinventor. However, Watson's application to amend its invalidity contentions to include indefiniteness is denied. An Order consistent with this opinion will issue.[8]

June 6, 2013

s/ Michael A. Hammer
UNITED STATES MAGISTRATE JUDGE

[8] This Opinion will be filed under seal to give the parties an opportunity to move to seal pursuant to Local Civil Rule 5.3 should any part of the Opinion contain confidential or highly sensitive materials.