NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEPOMED, INC., **Plaintiff,** **v.** **PURDUE PHARMA L.P., et al.,** **Defendants.**	**Civil Action No. 13-571 (MLC)** **MEMORANDUM OPINION FILED UNDER TEMPORARY SEAL**

BONGIOVANNI, United States Magistrate Judge

This matter comes before the Court upon Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P.'s (collectively, "Purdue") motion to amend their Invalidity Contentions pursuant to L.Pat.R. 3.3 and 3.4. (Docket Entry No. 129). Through its motion, Purdue seeks to amend its Invalidity Contentions served on September 3, 2013 in order to assert indefiniteness of the claim term "substantially all of said drug." Purdue also asks the Court to confirm that certain of the defenses it raised under 35 U.S.C. §§ 102 and 103 remain in this case after the Patent Trial and Appeal Board's ("PTAB") decision in the *inter partes* review ("IPR") proceedings it initiated.[1] Plaintiff Depomed, Inc. ("Depomed") opposes Purdue's motion to amend its Invalidity Contentions. Depomed also cross moves to strike certain invalidity theories raised by Purdue under 35 U.S.C. §§ 102 and 103. (Docket Entry No. 152). The Court has fully reviewed all arguments raised in support of and opposition to Purdue's

[1] Purdue filed three petitions requesting IPR (*See* IPR2014-00377, Paper 1; IPR2014-00378, Paper 1; and IPR2014-00379, Paper 1). IPR2014-00377 requested IPR of claims 1, 8-15, 43, 45 and 46 of the '280 patent. IPR2014-00378 requested IPR of claims 1, 8-15, 61 and 62 of the '475 patent. IPR2014-00379 requested IPR of claims 43, 54, 55, 57, 58 and 66 of the '475 patent.

motion to amend and Depomed's cross motion to strike. The Court considers the aforementioned motions without argument pursuant to L.Civ.R. 78.1(b). For the reasons set forth more fully below, Purdue's motion to Amend its Invalidity Contentions is GRANTED and Depomed's cross motion to strike is DENIED.

I. Background and Procedural History

The Court and the parties are very familiar with the facts underlying this matter as well as the issues presented in Purdue's motion to amend its Invalidity Contentions and Depomed's cross motion to strike. As such, the Court neither restates the facts of this case nor repeats the arguments made in support of and in opposition to both motions at length.

This is a patent infringement action involving United States Patent Nos. 6,340,475 (the "'475 patent"), 6,635,280 (the "'280 patent"), 6,723,340 (the "'340 patent") and 8,329,215 (the "'215 patent). While all four patents are currently asserted in the Amended Complaint (*see* Am. Compl. ¶ 1; Docket Entry No. 49), pending before the Court is also Depomed's motion to amend its Amended Complaint. (*See* Docket Entry No. 142). While that motion is not addressed herein, the Court notes that part of Depomed's motion involves its request to withdraw its assertions of patent infringement for the '340 and '215 patents. (Depomed Br. in Supp. of Motion to Amend at 1; Docket Entry No. 141-1). Purdue does not oppose that portion of Depomed's motion to amend its Amended Complaint. As a result, when the Court refers to the patents-in-suit herein, the Court refers only to the '475 and '280 patents.

The patents-in-suit are both entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode." (Am. Compl. ¶¶ 13 & 14). Further, both relate to "formulations for drugs that benefit from a prolonged time of controlled release in the stomach and upper gastrointestinal (GI) tract, and from an enhanced opportunity of absorption in the

stomach and upper GI tract rather than the lower portions of the GI tract." (Ex. 1 to Am. Compl, '475 patent at 1; Ex. 2 to Am. Compl., '280 patent at 1; Docket Entry No. 49-1). Depomed claims that Purdue's commercial manufacture, use, offer to sell, and or sale of OxyContin® in the United States, or importation of OxyContin® into the United States during the terms of the '475 and '280 patents have infringed and infringe one or more claims of said patents under 35 U.S.C. § 271(a). (Am. Compl. ¶¶ 19 & 25).

As part of its defense in this matter, Purdue has attacked the validity of the patents-in-suit. Indeed, Purdue served its Invalidity Contentions pursuant to L.Pat.R. 3.3 and 3.4 on September 3, 2013. In same, Purdue asserted that various claims of the patents-in-suit were invalid because they were anticipated by prior art, they would have been obvious to a person of skill in the art, they claimed a well-known, natural phenomenon not eligible for patent protection, certain claim terms were indefinite, certain claims were not enabled under 35 U.S.C. § 112(a), the asserted claims lacked an appropriate written description under 35 U.S.C. § 112(a) and that the asserted claims were invalid because under 35 U.S.C. § 102(g), the claimed oral dosage forms and methods asserted in the claims of the '475 and '280 patent were made in this country "by another inventor who had not abandoned, suppressed, or concealed [them]." (*See generally*, Purdue's Invalidity Contentions; Docket Entry No. 130).

Purdue now seeks leave to amend its Invalidity Contentions to assert the indefiniteness of another claim term: "substantially all of said drug." While Purdue did not assert this claim term in its original Invalidity Contentions, it contends that it is appropriate for the Court to permit it do so now in light of the Supreme Court's decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 189 L.Ed.2d 37 (2014). Purdue also seeks to confirm that the following defenses under 35 U.S.C. §§ 102 and 103 remain in this case:

- "**Defense 1**"[2]**:** Claims 11 and 12 of the patents-in-suit would have been obvious for the reasons set forth in Purdue's Invalidity Contentions;

- "**Defense 2**"**:** Claims 1, 8, 9, 13, 14, 45, and 46 of the '280 Patent and claims 1, 8, 9, 13, 14 and 61 of the '475 Patent are anticipated by S.K. Baveja *et al*., "Zero-order release hydrophilic matrix tablets of β-adrenergic blockers" *International Journal of Pharmaceutics*, 39 (1987) 39-45 ("Baveja");

- "**Defense 3**"**:** Claims 1, 8, 9, 13, 14, 45 and 46 of the '280 Patent and claims 1, 8, 9, 13, 14, 61 and 62 of the '475 Patent are anticipated by P. Colombo *et al*., "Drug release modulation by physical restrictions of matrix swelling" *International Journal of Pharmaceutics*, 63 (1990) 43-48 ("Colombo");

- "**Defense 4**"**:** Claim 43 of the '280 Patent and claims 43, 57 and 58 of the '475 Patent are anticipated by U.S. Patent No. 5,582,837 (the "'837 Patent");

- "**Defense 5**"**:** Claim 10 of each of the patents-in-suit is obvious over Colombo, C.J. Kim, "Drug release from compressed hydrophilic POLYOX-WSR tablets" *Journal of Pharmaceutical Sciences*, 84 (3) (1995) 303-306 ("Kim"), the '837 Patent, and U.S. Patent No. 4,871,548 (the "'548 Patent");

- "**Defense 6**"**:** Claims 43, 54, 55, 57, 58 and 66 of the '475 Patent are obvious over U.S. Patent No. 6,120,803 (the "'803 Patent"), Baveja, and Colombo; and

- "**Defense 7**"**:** Claims 1, 8, 9, 13, 14, 45 and 46 of the '280 Patent are obvious over Colombo, the '837 Patent, and the '548 Patent.

(Purdue Br. at 11; Dkt. 129-1).

Depomed opposes Purdue's request to amend its Invalidity Contentions to assert indefiniteness of the claim term "substantially all of said drug." In so doing, Depomed argues that Purdue has failed to establish good cause for the proposed amendment, contending that the decision in *Nautilus* did not change the relevant inquiry for indefiniteness; several District

[2] The Court will hereinafter refer to these defenses as by number, e.g. "Defense 1," in place of the full defense descriptive.

Courts, Purdue and the PTAB were able to construe the term of degree "substantially" utilized in the patents-in-suit; and Purdue has failed to demonstrate that it was diligent in raising this proposed amendment. (*See* Depomed Opp. Br. at 10-15; Docket Entry No. 152). Depomed also argues that it would be prejudiced by Purdue's proposed amendments, including its request to assert indefiniteness of the claim term "substantially all of said drug" and Purdue's attempt to asset Defenses 1-7 as well as its 35 U.S.C. § 102(g) defense in this case. (*Id*. at 20-23). In this regard, Depomed argues that through its request to confirm that certain defenses remain viable, Purdue is, in fact, attempting to amend its Invalidity Contentions to assert Defenses 2-7 and its § 102(g) defense as these defenses were not properly asserted in Purdue's original Invalidity Contentions. Depomed argues that Purdue's masked attempt to make such amendments should be denied. As a result, Depomed asks the Court to deny Purdue's motion to amend its Invalidity Contentions. Depomed also asks the Court to grant its cross motion to strike.

II. Analysis

A. Standard of Review

Local Patent Rule 3.7 governs amendments of invalidity contentions. Pursuant to L.Pat.R. 3.7, "Amendment of any contentions . . . may be made only by order of the Court upon a timely application and showing of good cause." L.Pat.R. 3.7 sets forth a "[n]on-exhaustive" list of "examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause." These circumstances include: "(a) a claim construction by the Court different from that proposed by the party seeking amendment; (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; (d) disclosure of an infringement contention by a Hatch-Waxman

Act party asserting infringement under L.Pat.R. 3.6(g) that requires response by the adverse party because it was not previously presented or reasonably anticipated; and (e) consent by the parties in interest to the amendment and a showing that it will not lead to an enlargement of time or impact other scheduled deadlines." L.Pat.R. 3.7. As explicitly noted in the Rule, this list is non-exhaustive and other circumstances may arise justifying the amendment of contentions.

The Local Patent Rules "exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases." *Computer Accelarations Corp. v. Microsoft Corp.*, 503 F.Supp.2d 819, 822 (E.D. Tex. 2007). Indeed, they "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Atmel Corp. v. Info. Storage Devices, Inc.*, No. C 95-1987 (FMS), 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998). As such, unlike proposed amendments of the pleadings, which are liberally granted pursuant to Rule 15, amendments to invalidity contentions are governed by a more conservative standard. *See Id.* (noting that "the philosophy behind amending claim charts is decidedly conservative and designed to prevent the 'shifting sands' approach to claim construction.") Thus, while L.Pat.R. 3.7 certainly "is not a straitjacket into which litigants are locked from the moment their contentions are served," the "modest degree of flexibility" that it provides must be viewed in the context of the Local Patent Rules' overarching goal of having the parties establish their contentions early on. *Comcast Cable Communs. Corp. v. Finisar Corp.*, No. C 06-04206 WHA, 2007 WL 716131, at *2 (N.D. Cal. March 2, 2007).

B. Indefiniteness of the Claim Term "Substantially All of Said Drug"

Purude seeks to amend its invalidity contentions to assert indefiniteness of the claim term "substantially all of said drug." Purdue argues that there is good cause to permit this amendment now in light of the Supreme Court's decision in *Nautilus*. According to 35 U.S.C. § 112, ¶ 2, a patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention." Prior to the Supreme Court's decision in *Nautilus*, a patent claim would pass "the § 112, ¶ 2 threshold so long as the claim [wa]s 'amenable to construction,' and the claim, as construed, [wa]s not 'insolubly ambiguous.'" *Nautilus*, 134 S.Ct. at 2124 (quoting 715 F.3d 891, 898-99 (2013)). In *Nautilus*, however, the Supreme Court determined that this standard did not satisfy the Patent act's definiteness requirement. Instead, the Supreme Court held that "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id*. The Supreme Court determined that "[t]he definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable." *Id*. at 2129. In so doing, the Supreme Court noted that "[i]t cannot be sufficient that a court can ascribe *some* meaning to a patent's claims; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters *post hoc*." *Id*. at 2130.

While Depomed suggests that *Nautilus* did not change the relevant inquiry for indefiniteness, the Court disagrees. Even cases relied upon by Depomed acknowledge that *Nautilus* changed the standard for indefiniteness. For example, in *In re Maxim Integrated Products, Inc.*, Master Docket Misc. No. 12-244, MDL NO. 2354, 2014 WL 3696137, *1 (W.D.

Pa. July 23, 2014), the court noted that "[i]n *Nautilus*, the Supreme Court replaced the tests previously established and applied by the Court of Appeals for the Federal Circuit to determine whether a patent claim is invalid for indefiniteness, i.e., the 'insoluble ambiguity' and 'amendable to construction' tests, with a 'reasonable certainty' test." Indeed, the court noted that the Supreme Court's decision in *Nautilus* "rejected" the tests previously used by the Federal Circuit in determining indefiniteness and replaced them with the "'reasonable certainty' test[,]" thereby "overrul[ing]" the earlier indefiniteness standard. *Id*. at 3-4. As a result, the Court finds that the Supreme Court's decision in *Nautilus* may provide Purdue with good cause to amend its invalidity contentions unless additional considerations convince the Court otherwise.

One such consideration raised by Depomed is the fact that many courts, including one in this District, have construed the claim term "substantially" recited in the patents-in-suit, as have Purdue and the PTAB. While *Nautilus* does stand for the proposition that terms of degree, such as "substantially all" are "inherently indefinite[,]" it is not enough post-*Nautilus* that a court be able "to identify *some standard* for measuring the scope of the phrase." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014) (internal quotation marks and citation omitted). Instead, "[t]he claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art." *Id*. at 1371.

Here, all the cases relied upon by Depomed to show that courts have been able to construe the claim term "substantially" predate the *Nautilus* decision. (*See* Depomed Br. at 13 (citing *Depomed, Inc. v. Lupin Pharm., Inc.*, No. C-09-05587 PJG, Dkt. No. 107 at 15-16, 23 (N.D. al. May 17, 2011); *Depomed Inc. v. Ivax Corp.*, No. C-06-00100 CRB, Dkt. No. 76 at 6-8 (N.D. Cal. Dec. 20, 2006); *Depomed Inc. v. Actavis Elizabeth LLC*, 12-cv-1358 (JAP (TJB), Dkt. 252 at 18-19 (D.N.J. Jan. 28, 2014); and *Depomed, Inc. v. Sun Pharma Global FZE, et al.*, 11-

3553 (JAP) (D.N.J. Aug. 3, 2012). As a result, while Depomed contends that the intrinsic evidence available in these cases supported the courts' prior constructions of the term of degree "substantially," their value is somewhat diminished. More importantly, the one court from this District that, in fact, construed the claim term "substantially all of said drug" in the context of the same patents at issue in this case, noted the difficulty "with construing 'substantially all' based solely on the intrinsic evidence." *Depomed, Inc. v. Sun Pharma Global FZE*, Civil Action No. 11-3553 (JAP), 2012 WL 3201962, *11 (D.N.J. Aug. 3, 2012). While the Court does not suggest that the claim term "substantially all of said drug" will be found to be indefinite under the standard set forth in *Nautilus*, the Court is unpersuaded by Depomed's argument that cases assessing this term of degree in the past support the conclusion that Purdue should be foreclosed from amending its invalidity contentions to assert indefiniteness of this claim term now in light of *Nautilus*.

The Court also is unpersuaded that Purdue or the PTAB's ability to construe the term "substantially all of said drug" demonstrates that there is no good cause to allow Purdue to amend its invalidity contentions now to assert indefiniteness of this term. In reaching this conclusion, the Court notes that indefiniteness is generally not a ground that can be raised in an IPR proceeding (*see* 35 U.S.C. § 311(b) (stating that "[a] petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications")); though the Court also recognizes that indefiniteness has entered into IPR proceedings, at least in the context of IPRs involving means-plus-function claims, when the PTAB has determined in at least three instances that it was unable to construe a claim term and therefore could not even reach the asserted §§ 102 and 103 challenges. *See, e.g.*, IPR2013-

00036, IPR2014-01170 and IPR2014-01370 (terminating IPRs where PTAB found challenged claims to be indefinite).

The Court does not fault Purdue for failing to ask the PTAB to address whether or not the claim term "substantially all of said drug" was amendable to construction in the context of its IPR proceedings. First, as noted above, pursuant to 35 U.S.C. § 311(b), indefiniteness under § 112 is not a ground on which a petitioner may request IPR. Second, Purdue filed its IPRs over 5 months prior to the *Nautilus* decision being rendered at a time when a court in this District had already determined that this exact claim term, as used in the same patents as those at issue in this case, was amenable to construction and not indefinite. As such, at the time of filing, Purdue had no reason to believe that the PTAB, which reviews claims under the more expansive "broadest reasonable interpretation" standard, would find the term "substantially all of said drug" indefinite. Third, while Depomed takes issue with Purdue's failure to appeal the PTAB's construction of the claim term "substantially all of said drug" to the Federal Circuit even though the appeal occurred after the Supreme Court issued the *Nautilus* opinion, Depomed has failed to establish that this would have been an appropriate ground upon which to raise an appeal. Further, even if it were, Purdue's "failure" to do so would not necessarily be unreasonable in light of the more lenient "broadest reasonable interpretation" standard used by the PTAB. As a result, the Court finds that the ability of other courts, Purdue and the PTAB to construe the term "substantially all of said drug" does not demonstrate that good cause is lacking for Purdue's proposed amendment.

In addition, the Court finds that Purdue was diligent in seeking to amend its invalidity contentions to add indefiniteness of the claim term "substantially all of said drug." The Court notes that this matter was first stayed on February 10, 2014, when the Court stayed the matter so

that the parties could participate in mediation. (Order of Designation for Mediation of 2/10/2014 at 1, ¶ 5; Docket Entry No. 73). The Court continued the stay even after mediation proved unsuccessful, determining that the efficiencies of this case would best be served by continuing the stay until after both the PTAB and Federal Circuit ruled on Purdue's IPR's. (*See* Letter Order of 7/9/2014, Docket Entry No. 84 (continuing stay); Order of 7/25/2014, Docket Entry No. 90 (same); Letter Order of 5/7/2015, Docket Entry No. 94 (same); Letter Order of 7/22/2015, Docket Entry No. 104 (same); Letter Order of 9/28/2015, Docket Entry No. 108 (same). Thus, it was not until March 31, 2016 that the stay was lifted and this matter began being actively litigated again. (Order Lifting Stay of 3/31/2016; Docket Entry No. 117). As is clear from this timeline, the stay was in place on June 2, 2014 when *Nautilus* was decided.

Given the stay, which was imposed for efficiency purposes and to preserve judicial economy, Purdue was not in a position to move to amend its invalidity contentions when the *Nautilus* decision was rendered. In fact, had Purdue requested permission to move to amend its invalidity contentions at that time, said request would almost certainly have been summarily rejected as antithetical to the purpose of the stay. It certainly would have been inefficient for the Court to have litigated the propriety of Purdue's proposed indefiniteness defense when the issue may have become moot depending on the outcome of the IPR proceedings. As such the Court finds no lack of diligence in Purdue's failure to move to amend during the pendency of the stay.[3]

[3] The Court also finds no support for Depomed's argument that Purdue should have sought to amend its invalidity contentions when the Supreme Court granted *certiori* in *Nautilus* in January 2014. While *certiori* was granted prior to the Court's imposition of the mediation stay and prior to Purdue filing its IPR petitions, at that time, Purdue's indefiniteness argument concerning the claim term "substantially all of said drug" was still precluded by controlling case law. There is no basis on which to fault Purdue for failing to raise its indefiniteness argument based on the hypothetical outcome of a future decision.

Under these circumstances, the Court finds that Purdue has established good cause under L.Pat.R. 3.7 to permit it to amend its invalidity contentions to assert indefiniteness of the claim term "substantially all of said drug" at this juncture. The Court also finds that Depomed will not be unduly prejudiced by Purdue's amendment. Despite the age of this case, in light of the two year stay, this matter is still in its relative infancy. Further, given that the parties are already litigating this issue in the context of their claim construction briefing and related expert discovery, the Court finds that Depomed will not have to expend significant additional resources litigating this defense. As a result, Purdue shall be permitted to amend its invalidity contentions to assert indefiniteness of the claim term "substantially all of said drug."

C. Defenses 1-7 and Purdue's 35 U.S.C. §§ 102(b) and 102(g) Defenses

As set forth above, in addition to seeking to amend its Invalidity Contentions to assert indefiniteness of the claim term "substantially all of said drug," Purdue also seeks to confirm that Defenses 1-7 remain in this case. Conversely, Depomed asks the Court to strike these invalidity defenses, along with Purdue's §§ 102 (b) and 102(g) defenses because Purdue is statutorily estopped from raising the defenses now, failed to sufficiently disclose the defenses in its original Invalidity Contentions, or should be judicially estopped from pursuing the defenses now.

1. Statutory Estoppel

Depomed filed a cross motion to strike Purdue's invalidity defenses relating to the MS Contin® product (§ 102(b) on-sale bar defense), Purdue's § 102(g) defense and Defense 1 under a theory of statutory estoppel,[4] claiming that Purdue could have raised these defenses in its IPRs,

[4] Depomed does not contend that Purdue is statutorily estopped under 35 U.S.C. § 315(e)(2) from litigating Defenses 2-7 before this Court, nor could it. The PTAB declined to institute review on these grounds and, as the Federal Circuit noted in *Shaw Indus. Group, Inc. v. Automated Creel Sys.*, noninstituted grounds do not become part of the IPR. 817 F.3d 1293, 1300 (Fed. Cir. 2016). As a result, Purdue did not raise, nor could it have reasonably raised

but failed to do so. (Depomed Opp. Br. at 29-30). With respect to the MS Contin® product, Depomed argues that Purdue could have pursued its § 102(b) on-sale bar theory at the PTAB because it had sufficient documentation about the MS Contin® product to raise the theory. (*Id*. at 30-31). Similarly, with respect to the § 102(g) defense, Depomed argues that Purdue could have pursued this theory at the PTAB because it is based on the '963 patent and the '623 provisional application of James W. McGinity, two documents Depomed argues qualify as printed publications and which Purdue had in its possession months before it filed its IPRs. (*Id*. at 31). Finally, with respect to Defense 1, which involves obviousness theories regarding claims 11 and 12 of the patents-in-suit, Depomed argues that Purdue is overreaching and should be estopped from raising grounds that Purdue included in its Invalidity Contentions but opted not to include in its IPRs.[5] (*Id*. at 32).

The scope of IPR is limited to grounds "that could be raised under section 102 [anticipation] or 103 [obviousness] and only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b); *see also Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1316 (Fed. Cir. 2016) (finding that "[i]nter partes review cannot replace the district court in all instances, for example, when claims are challenged in district court as invalid based on the on-sale bar, for claiming patent-ineligible subject matter, or on grounds of indefiniteness.")

---

these grounds during the *inter partes* review as required by 35 U.S.C. § 315(e)(2). Instead, as discussed below, Depomed argues that Purdue should be precluded from pursuing Defenses 2-7 because it failed to adequately disclose same in its original Invalidity Contentions and based on principles of judicial estoppel.

[5] Depomed provides one example to support this argument, *i.e.*, that Purdue alleged patent claims 11 and 12 are invalid as obvious over Kim in view of the '453 Patent in its invalidity contentions. (*Id*.)

Section 315(e)(2) of Title 35 provides:

> [t]he petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

35 U.S.C. § 315(e)(2). Since the effective date of the American Invents Act (AIA), the Federal Circuit has only tangentially commented on the scope of the estoppel provisions of 35 U.S.C. § 315(e) in addressing other appealed issues. *See Synopsys*, 814 F.3d 1309; *Shaw*, 817 F.3d 1293; *HP Inc. v. MPHJ Tech. Invs.*, 817 F.3d 1399 (Fed. Cir. 2016).

In *Synopsys*, the Federal Circuit was asked whether the PTAB is required to address every patent claim raised in a petition for IPR in its final written decision. 814 F.3d at 1313-14. There, Synopsys, Inc. argued that the PTAB's practice of issuing final written decisions addressing some, but not all, of the patent claims in an IPR petition is inconsistent with the estoppel provisions because final written decisions that do not address all of the patent claims will have limited estoppel effect. *Id*. at 1316. The Federal Circuit disagreed, reasoning that:

> The validity of claims for which the Board did not institute inter partes review can still be litigated in district court. We see no inconsistency in this. Inter partes review cannot replace the district court in all instances, for example, when claims are challenged in district court as invalid based on the on-sale bar, for claiming patent-ineligible subject matter, or on grounds of indefiniteness. See 35 U.S.C. § 311(b) (limiting inter partes review to grounds "that could be raised under section 102 [anticipation] or 103 [obviousness] and

> only on the basis of prior art consisting of patents or printed publications").

Id.

The Federal Circuit also construed the estoppel provisions set forth in 35 U.S.C. § 315(e) in *Shaw*, finding that the provisions would not statutorily estop a party from litigating an invalidity ground in a later proceeding if that invalidity ground was raised in a prior petition for IPR, but not instituted. *Id*. at 1300. Shaw Industries Group, Inc. ("Shaw") petitioned for a writ of mandamus instructing the United States Patent and Trademark Office ("USPTO") to reevaluate its decision to decline institution of an IPR on a ground that the USPTO deemed redundant of other instituted grounds. *Id*. at 1299. Shaw argued that mandamus review was warranted because it may be estopped from arguing the declined ground(s) in later proceedings given the estoppel rules. *Id*. The USPTO submitted a brief as an intervenor and argued that Shaw's interpretation of 35 U.S.C. § 315(e) was incorrect and that the estoppel provisions only apply to invalidity grounds that were raised or reasonably could have been raised *during* that *inter partes* review. *See Id*. at 1300. The Federal Circuit agreed with the USPTO's interpretation and explained that estoppel did not apply to an invalidity ground that was not instituted because that invalidity ground never became part of the *inter partes* review, and as a result Shaw did not raise, nor could it have reasonably raised that invalidity ground *during* the *inter partes* review, as required by the text of 35 U.S.C. § 315(e). *Id.*

Further, the Federal Circuit discussed the estoppel provisions of 35 U.S.C. § 315(e) in *HP v. MPHJ Tech.*, 817 F.3d 1399. In that case, HP Inc. ("HP") appealed the PTAB's refusal to institute an *inter partes* review on what it said was a redundant invalidity ground. *Id*. at 1344. HP expressed concern that it would be estopped from raising invalidity grounds declined as redundant in future proceedings. *Id*. at 1347. The Federal Circuit, however, citing *Shaw*, explained that the

estoppel provisions of § 315(e) do not apply because "noninstituted grounds do not become a part of the IPR. Accordingly, the noninstituted grounds were not raised and, as review was denied, could not be raised in the IPR." *Id.*

Thus, while the Federal Circuit has not directly addressed the scope of estoppel, its comments in the aforementioned cases are helpful and are consistent with the plain meaning of the estoppel provisions of 35 U.S.C. § 315(e). As a result, the Court finds that if a claim of a patent is not instituted in an IPR, and there is no final written decision as to that claim, the estoppel provisions of 35 U.S.C. § 315(e) do not apply. *See Synopsys*, 814 F.3d at 1316. Similarly, if an invalidity ground is raised in a petition for IPR, but the PTAB declines to institute an IPR as to that invalidity ground, the estoppel provisions of 35 U.S.C. § 315(e) do not apply to said invalidity ground because it was not raised nor could it have reasonably been raised *during* that IPR. *Shaw*, 817 F.3d at 1300. Under this standard, the Court finds that Purdue is not estopped from pursuing its § 102(b) on-sale bar defense, § 102(g) defense or Defense 1.

As noted above, the scope of *inter partes* review is limited to invalidity grounds "that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b). "Inter partes review cannot replace the district court in all instances, for example, when claims are challenged in district court as invalid based on the on-sale bar . . . ." *Synopsis*, 814 F.3d at 1316. Here, Purdue argues that its on-sale bar and 102(g) defenses are not based solely on patents or printed publications. Purdue further argues that the use of patents or printed publications to support its contentions that "the claimed invention was on sale prior to the filing of the patents-at-issue, or invented by another before that time" should not transform these defenses, *i.e.*, the on sale bar and § 102(g) defenses, "into a statutory ground for relief in an IPR." (Purdue Reply at 14; Docket Entry No. 156). The Court agrees with Purdue and notes that

Depomed has cited no binding case law supporting its contrary position. Further, under the circumstances of this case when this is coupled with the fact that Purdue's MS Contin® product, itself, exhibits features claimed in the patents-in-suit, characteristics that represent Purdue's highly confidential information and which were not disclosed in any patents or printed publications, and where the majority of documents cited by Purdue in support of the on-sale bar defense likewise contain Purdue's highly confidential information and were never publicly disclosed, the Court finds that the estoppel provisions of 35 U.S.C. § 315(e)(2) do not apply to Purdue's on-sale bar or § 102(g) defenses.

Turning to Defense 1, the Court notes that Purdue raised the following invalidity grounds in its IPR petitions:

- Claims 11 and 12 of the '280 patent would have been obvious over Baveja in view of the '453 patent, and further in view of the '837 patent, and further in view of the '548patent. (IPR2014-00377, Paper 1 at 13).
- Claims 11 and 12 of the of the '280 patent would have been obvious over Colombo in view of the '453 patent, and further in view of the '837 patent, and further in view of the '548 patent. (*Id*.)
- Claims 11 and 12 of the '475 patent would have been obvious over Baveja in view of the '453 patent, and further in view of the '837 patent, and further in view of the '548 patent. (IPR2014-00378, Paper 1 at 9.)
- Claims 11 and 12 of the '475 patent would have been obvious over Colombo in view of the '453 patent, and further in view of the '837 patent, and further in view of the '548 patent. (*Id*.)

The Court notes that the PTAB declined to institute IPR as to all of these invalidity grounds. (IPR2014-00377, Paper 11 at 22-25; IPR2014-00378, Ppaer 10 at 20-22, 24). As a result, claims 11 and 12 of the patents-in-suit were not subject to an IPR proceeding or a final written decision and Purdue is not statutorily estopped from challenging their validity before this Court. *Synopsys*, 814 F.3d at 1316 (noting that "[t]he validity of claims for which the Board did not institute inter partes review can still be litigated in district court.")

2. Sufficiency of Disclosures in Original Invalidity Contentions

Depomed argues that Purdue failed to meet the disclosure requirements of the Local Patent Rules for the invalidity contentions it asserts under 35 U.S.C. § 103, § 102(b), and § 102(g). In this regard, contrary to L.Pat.R. 3.3, Depomed argues that Purdue failed to

> identify ***all*** of its invalidity theories, including each prior art refrence it intended to rely upon in the litigation, including, *inter alia*, "an explanation of why the prior art reference renders the asserted claim obvious," "identification of any combinations of prior art showing obviousness," and the identifies of the persons and circumstances surrounding any challenges brought under 35 U.S.C. §§ 102 (b)(f)(g).

(Depomed Opp. Br. at 24). Instead, in seeking to confirm that certain defenses are still viable, Depomed argues that Purdue is inappropriately utilizing a shifting-sands approach to its invalidity contentions and is seeking to in effect amend its contentions to correct the deficiencies in same or to add combinations.

For example, with respect to Defenses 5, 6 and 7, Depomed argues that the obviousness combinations outlined in same were not disclosed in Purdue's invalidity contentions as required by L.Pat.R. 3.3(b).[6] In this regard, Depomed claims that tables included in Purdue's invalidity

[6] Depomed also notes that the PTAB determined that the combinations outlined in said defenses did not merit IPR review.

contentions, which list dozens of prior art references, do not comply with the requirements of the Local Patent Rules because "[t]hey do not provide any information regarding how the references would be combined or how a person of ordinary skill in the art would be motivated to do so." (*Id*. at 26). Additionally, Depomed argues that the entirety of Purdue's invalidity contentions, "which span 359 pages and contain hundreds of prior art references, did not and could not have put Depomed on notice of the specific obviousness theories it now advances." (*Id*. at 26-27). As a result, Depomed contends that the combinations outlined in Defenses 5, 6 and 7 should be stricken.

Similarly, Depomed claims that the anticipation theories outlined in Defenses 2, 3 and 4 should be stricken because Purdue's invalidity contentions did not sufficiently disclose same. In this regard, Depomed contends that all that Purdue disclosed was that "[i]n 1984, more than one year prior to the alleged invention, Purdue Pharma L.P. first offered the prescription medication MS Contin® controlled-release morphine sulphate tablets for sale in the United States." (*Id*. at 27 (internal quotation marks and citation omitted). Depomed argues that this disclosure is "woefully deficient" under the Local Patent Rules because:

> Purdue failed to identify the specific item offered for sale or publicly used or known, the date the offer or use took place or the information became known, 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.

(*Id*. at 27-28 (citing L.Pat.R. 3.3)). Therefore, Depomed argues that these anticipation defenses should be stricken.

In addition, Depomed argues that Purdue failed to properly disclose the sale of MS Contin® it seeks to rely on for its invalidity claims. Depomed further argues that it would be prejudiced if Purdue is allowed to pursue this theory now because it would need discovery into

the basic facts related to the purported circumstances of the offer of sale, facts Depomed argues should have been disclosed when Purdue served its invalidity contentions so that Depomed could have properly assessed the merits of Purdue's claims. Depomed argues that the sale of MS Contin® Purdue now relies upon "would have impacted Depomed's decision regarding which claims to assert against Purdue and potentially have raised claim construction issues." (*Id*. at 28). As a result, Depomed argues that Purdue's § 102(b) claims relating to MS Contin® should be stricken.

Likewise, Depomend claims that Purdue's § 102(g) contention, *i.e.*, that Depomed's "claimed oral dosage forms and methods were made in this country 'by another inventor who had not abandoned, suppressed, or concealed [them],'" is deficient. (*Id.* at 29 (internal quotation marks and citation omitted)). In this regard, Depomed argues that under L.Pat.R. 3.3, Purdue was required to "have identified the identities of the person(s) or entities involved in and the circumstances surrounding the making of the invention before the patent applicant(s)." (*Id*. at 29). Depomed claims that Purdue's failure to do so in its contentions is fatal to Purdue's current assertion that it is seeking to pursue this defense. Further, Depomed argues that it would be prejudiced if Purdue was allowed to pursue this defense at this juncture because Purdue "failed to provide fundamental information regarding this claim" and, as such, Depomed "has been prevented from seeking appropriate discovery into" same. (*Id*.) Consequently, Depomed argues that this contention should also be stricken.

Unlike Depomed, the Court does not find that Purdue is seeking to amend its Invalidity Contentions to raise previously undisclosed defenses. Instead, the Court finds that the disputed defenses were disclosed in Purdue's original Invalidity Contentions, but that Depomed is seeking to strike same, arguing that Purdue's disclosures are insufficient under the Local Patent Rules.

As such, it is not Purdue's burden to establish good cause to amend its Invalidity Contentions under L.Pat.R. 3.7, but Depomed's burden to establish that the disputed Invalidity Contentions are deficient under L.Pat.R. 3.3. The Court finds that Depomed has not carried its burden.

With respect to Defenses 2-7, the Court has reviewed the sections of Purdue's Invalidity Contentions outlined in the table found on page 17 of Purdue's brief and finds that these defenses are adequately disclosed. Indeed, as claimed by Purdue, Defense 2 is adequately disclosed in pages 22-26, 33-35 and 80-84 of Purdue's Invalidity Contentions (Docket Entry No. 130); Defense 3 is adequately disclosed in pages 22, 26-35 and 80-84 of Purdue's Invalidity Contentions (*Id.*); Defense 4 is adequately disclosed in pages 36-41, 46 and 84-85 of Purdue's Invalidity Contentions (*Id.*); Defense 5 is adequately disclosed in pages 56-60, 63-65, 67 and 92-94 of Purdue's Invalidity Contentions (*Id.*); Defense 6 is adequately disclosed in pages 68 and 73-75 of Purdue's Invalidity Contentions (*Id.*); and Defense 7 is adequately disclosed in pages 63-68, 92-94 and 96 of Purdue's Invalidity Contentions. (*Id.*) As a result, there is no basis on which to strike any of these defenses.

Similarly, the Court finds that Purdue adequately disclosed its on-sale bar defense under § 102(b) as well as its §102(g) defense in its Invalidity Contentions. With respect to the on-sale bar defense, the Court notes that L.Pat.R. 3.3(a) states:

> 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.

In its Invalidity Contentions, Purdue discloses that the item offered for sale was MS Contin®, the date of the offer was 1984, and the entity which made the use/offer was Purdue. (Ex. A, Purdue's Invalidity Contentions at 46); Docket Entry No. 130). Purdue then includes a rather

extensive discussion of how this sale of MS Contin® in the United States in 1984 anticipates the claims of the patents-in-suit. (*Id*. at 46-51, 85-91). The Court finds this disclosure to be sufficient under L.Pat.R. 3.3(a), and that, consequently, Purdue's on-sale bar defense shall not be stricken.

Likewise, with respect to § 102(g), L.Pat.R. 3.3(a) states, "[p]rior 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)[.]" In its Invalidity Contentions, Purdue identifies the names of the inventors who made the invention before the patent applicants: James W. McGinity and Feng Zhang, as well as the publications that detail the circumstances surrounding the making of the invention: U.S. Patent No. 6,488,963 and U.S. Provisional Patent Application 60/020,623. (Ex. A, Purdue's Invalidity Contentions at 21). Purdue then includes a more detailed discussion of its § 102 (g) and the support for it later in its Invalidity Contentions. (*Id*. at 187-89). Again, Purdue's disclosures regarding its § 102(g) defense are sufficient under the Local Patent Rules and the Court shall not strike same.

3. Judicial Estoppel

Depomed argues that Purdue should be judicially estopped from litigating its invalidity positions based on the representations it made to this Court when requesting that this matter be stayed pending the PTAB's decisions on its IPRs. In the Third Circuit, judicial estoppel is only appropriate when three threshold requirements are met:

> [F]irst, the party in question must have adopted irreconcilably inconsistent positions; second, the party must have adopted these positions in "bad faith"; and third, there must be a showing that judicial estoppel is tailored to address the harm and that no lesser sanction would be sufficient.

Chao v. Roy's Constr., Inc., 517 F.3d 190, 185, 186 n.5 (3d Cir. 2008) (citing *Krystal Cadillac-Oldsmobile GMC Truck, Inc. v. Gen. Motors, Corp.*, 337 F.3d 314, 319-20 (3d Cir. 2033)).

The Court finds that Depomed has not established that these requirements have been met here. In this regard, the Court finds that Purdue's position regarding estoppel has remained consistent. Both in requesting the stay pending the PTAB's decisions on the IPRs and now, Purdue has maintained that under 35 U.S.C. § 315(e) it is estopped from raising any arguments that it "raised or reasonably could have raised" during the IPRs. In *Synopsys* and *Shaw*, the Federal Circuit shed light on the scope of estoppel, holding that a party is not estopped from raising §§ 102 and 103 defenses that were not instituted for trial at the PTAB. In other words, where the PTAB chooses not to consider the merits of a defense raised in an IPR, that defense remains viable in litigation. For this reason, the Court has already determined that Purdue is not statutorily estopped from raising any of the contested §§ 102 and 103 defenses. While the Court appreciates Depomed's frustration at having to litigate certain issues that were presented to the PTAB, particularly defenses on which the PTAB declined to institute review based on Purdue's failure to establish a likelihood of success or because the asserted prior art combinations were redundant in light of other reviewed combinations, the Court cannot ignore the fact that the Federal Circuit has determined that it is appropriate to do so.

Nor, under the circumstances of this case, can the Court find that Purdue adopted its position in bad faith. From the beginning, Purdue has argued that staying these proceedings pending the PTAB would preserve judicial economy by streamlining the invalidity issues to be tried in this matter. While the Court and Depomed may have preferred a greater simplification of issues, the IPR proceedings did reduce the number of prior art references and defenses that Purdue can now raise. While other defenses remain viable for the reasons outlined in *Synopsys*

and *Shaw*, that fact does not evidence bad faith on the part of *Purdue*. At best, the post IPR viability of Purdue's §§ 102 and 103 defenses in light of the Federal Circuit's decisions in *Synopsys* and *Shaw* may impact the Court's decisions going forward regarding whether matters should be stayed pending IPR. It does not, however, convince the Court that Purdue should be judicially estopped from raising any defenses in this litigation.

III. Conclusion

For the reasons states above, Purdue's motion to amend its Invalidity Contentions pursuant to L.Pat.R. 3.3 and 3.4 is GRANTED and Depomed's cross motion to strike is DENIED. An appropriate Order follows.

Dated: November 4, 2016

Tonianne J. Bongiovanni
HONORABLE TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE