

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

<p>ASTRAZENECA AB, et al.</p> <p style="text-align: center;">Plaintiffs,</p> <p style="text-align: center;">v.</p> <p>DR. REDDY'S LABORATORIES INC. et al.</p> <p style="text-align: center;">Defendants.</p>	<p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p> <p>:</p>	<p>Civil Action No. 11-2317 (JAP)</p> <p>Consolidated for discovery purposes with: Civil Action Nos. 11-4275, 11-6348, 13-0091</p> <p style="text-align: center;">OPINION</p>
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PISANO, District Judge

In this Hatch Waxman patent infringement action Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively, "Plaintiffs") have moved for summary judgment that the claims of U.S. Patent No. 6,926,907 (the "907 patent") are not invalid. Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd. (collectively, "Defendants" or "DRL") have opposed the motion. Also pending before the Court are two related motions: (1) DRL's motion to strike Plaintiffs' validity contentions; and (2) Plaintiffs' motion to amend their responses to DRL's invalidity contentions. For the reasons set forth below, Plaintiffs' motions are denied. DRL's motion is granted.

I. BACKGROUND

There are two separate civil actions relevant to the instant motion, both Hatch Waxman patent infringement actions relating to Plaintiffs' product Vimovo, a drug that is a combination

of a nonsteroidal anti-inflammatory drug and a proton pump inhibitor. These two actions are as follows:

DRL I: Civil Action No. 11-2317

On or about March 11, 2011, DRL provided notice to Plaintiffs that it filed an Abbreviated New Drug Application (“ANDA”) relating to Plaintiffs’ drug product Vimovo seeking approval to market a generic version of Vimovo prior to expiration of the associated patents. Thereafter, Plaintiff filed a patent infringement lawsuit alleging, as relevant to the instant motion, that DRL infringed claims of the ‘907 patent. *See* Civil Action No. 11-2317 (“*DRL I*”). The relief sought by Plaintiff in *DRL I* includes a request for a judgment declaring that the ‘907 patent is valid and enforceable. D.I. 42 at 22; 226 at 12. DRL asserted in its Answer an affirmative defense of invalidity and, further, counterclaimed for entry of judgment that the ‘907 patent is invalid. Thereafter, in accordance with this district’s Local Patent Rules, DRL served their invalidity contentions (“Invalidity Contentions”). Plaintiffs served their response to DRL’s Invalidity Contentions (the “First Response”), but later moved to amend their First Response. That motion was denied by Magistrate Judge Arpert. *See* Memorandum Opinion and Order at D.I. 134 in Civ. Action No. 11-2317. Six months later, Plaintiffs again filed their motion to amend their First Response, citing the filing of a second infringement action against DRL (namely, *DRL II*, discussed below) as the basis for their motion. That motion is decided herein.

DRL II: Civil Action No. 13-0091

On November 20, 2012, DRL provided notice to Plaintiffs that it filed a second ANDA relating to the Vimovo product. As it had done with respect to the earlier ANDA, DRL provided to the Food and Drug Administration (“FDA”) a Paragraph IV certification in which it certified

to FDA that the '907 patent was "invalid, unenforceable or will not be infringed" by DRL's generic Vimovo product. It does not appear to be disputed that along with DRL's notice to Plaintiff DRL raised, among other things, the issue of invalidity of the '907 patent. Based on this ANDA filing, Plaintiffs brought a second patent infringement action against DRL, *see* Civil Action No. 13-0091 ("*DRL II*"), alleging that DRL has infringed the '907 patent. As in *DRL I*, the relief sought by Plaintiff in *DRL II* includes a request for a judgment declaring that the '907 patent is valid and enforceable. D.I. 1 at 19; 62 at 10. Also like in *DRL I*, in its Answer DRL asserted invalidity of the '907 patent as an affirmative defense. DRL, however, did not assert an invalidity counterclaim. Further, when the appropriate time came under the Local Patent Rules and/or the relevant scheduling order, DRL did not serve invalidity contentions with respect to the '907 patent.¹ Nevertheless, even though DRL did not propound invalidity contentions, Plaintiffs served invalidity responses ("Second Response") or "validity contentions." According to Plaintiffs, the Second Response is substantially the same as the amended First Response Plaintiff sought (but was denied) leave to file in *DRL I*. DRL has now moved to strike the Second Response.

Plaintiffs have moved in *DRL II* for summary judgment that the claims of the '907 patent are not invalid. Plaintiffs argue that judgment should be entered declaring the patent to be not invalid because DRL, having failed to propound invalidity contentions, can present no evidence of invalidity. DRL opposes the motion claiming that the Court lacks subject matter jurisdiction with respect to the issue of invalidity in *DRL II*. According to DRL, the court lacks such

¹ Rather, DRL states that it has chosen not to pursue a defense of invalidity in *DRL II* "because non-infringement provides a complete defense." D.I. 164 at 5. According to DRL, it has developed a different formulation for its second generic Vimovo ANDA product that is designed specifically to avoid (and thus not infringe) the claims of the '907 patent. Therefore, according to DRL, the issue to be litigated in *DRL II* relating to the '907 patent should center only on non-infringement.

jurisdiction because DRL has abandoned its invalidity defense in *DRL II*² (although it continues to assert it in *DRL I*).

II. ANALYSIS

1. Plaintiffs' Motion for Summary Judgment of Validity

Federal courts have limited subject matter jurisdiction and possess “only the power that is authorized by Article III of the Constitution and the statutes enacted by Congress pursuant thereto.” *Bender v. Williamsport Area School Dist.*, 475 U.S. 534, 541, 106 S.Ct. 1326, 89 L.Ed.2d 501 (1986). Article III limits this Court's jurisdiction to actual “cases” and “controversies.” U.S. Const. art. III, § 2. Here, DRL claims that there is no case or controversy in *DRL II* with respect to the validity of the ‘907 patent because DRL has chosen not to pursue invalidity as a defense in the case. Plaintiffs, however, contend that the case or controversy requirement is fulfilled here because Plaintiffs themselves have sought judgment regarding the validity of the ‘907 patent claims and, accordingly, the issue of validity is in dispute in *DRL II*. In the *DRL II* complaint (as in the *DRL I* complaint), Plaintiffs requested judgment that the ‘907 patent claims are valid and enforceable. Although DRL initially asserted an affirmative defense of invalidity, DRL has since abandoned this defense in *DRL II*. It is Plaintiffs’ position that regardless of DRL’s decision to abandon its invalidity defense, Plaintiffs may still pursue their declaratory judgment claim for a judgment of validity in *DRL II*.

Under the Declaratory Judgment Act, a Court “may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.” 28 U.S.C. § 2201(a). A justiciable declaratory judgment action occurs where “the facts alleged, under all the circumstances, show that there is a substantial controversy, between

² DRL states that it has offered to withdraw its invalidity affirmative defense but Plaintiffs have declined the offer. D.I. 164 at 6.

parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127, 127 S.Ct. 764, 771 (2007). The dispute must be “‘definite and concrete, touching the legal relations of parties having adverse legal interests’; ... ‘real and substantial’ and ‘admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.’ *Id.* (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 57 S.Ct. 461, 81 L.Ed. 617 (1937)).

Even when a suit satisfies the subject matter jurisdiction prerequisites, “district courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act.” *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289, 115 S.Ct. 2137, 132 L.Ed.2d 214 (1995). As the Supreme Court has stated

The Declaratory Judgment Act provides that a court “*may* declare the rights and other legal relations of any interested party,” 28 U.S.C. § 2201(a) (emphasis added), not that it must do so. This text has long been understood “to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants.” *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286, 115 S.Ct. 2137, 132 L.Ed.2d 214 (1995); *see also* *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95, n. 17, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993); *Brillhart v. Excess Ins. Co. of America*, 316 U.S. 491, 494–496, 62 S.Ct. 1173, 86 L.Ed. 1620 (1942). We have found it “more consistent with the statute,” however, “to vest district courts with discretion in the first instance, because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp.” *Wilton, supra*, at 289, 115 S.Ct. 2137.

MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 136, 127 S.Ct. 764, 776 (2007).

As stated earlier, to the extent that DRL’s pleading in *DRL II* includes an invalidity defense, DRL plainly has abandoned that defense. As a result, Plaintiffs cite to, among other things, *DRL I* as evidence that the requisite controversy exists between the parties to support a declaratory judgment claim. However, Plaintiffs’ entire argument that the Court has subject matter jurisdiction to decide the validity of the ‘907 patent in *DRL II* rests on the threshold

premise that Plaintiff's request for a declaratory judgment of validity is a valid cause of action. While invalidity of a patent is an available affirmative defense in a patent infringement action, Plaintiff cites nothing to support the notion that a patentee has an affirmative cause of action to seek a declaration that a patent is valid. Indeed, the opposite appears to be true. *See Semiconductor Energy Laboratory Co., Ltd. v. Nagata*, 706 F.3d 1365, 1370 (Fed. Cir. 2013) (“The relief requested ... is akin to seeking a declaratory judgment of patent validity, which is not a viable cause of action.”); *Brooks Mfg. Co. v. Dis-Tran Wood Products, LLC*, 2012 WL 1099760, (W.D. Wash. 2012) (dismissing action seeking declaratory judgment that a patent is valid and stating as follows: “[T]he court has reviewed cases where plaintiffs have sought a declaration of invalidity, noninfringement, or future infringement. ... [T]he court has uncovered no case in which a patentee seeks a declaration of validity. Indeed, [the] patent is presumed valid. ... Therefore, [Plaintiff] essentially seeks a declaration as to the status quo.”). Therefore, there is no basis upon which the Court may enter the judgment Plaintiffs seek in *DRL II*.

The Court recognizes that there exists an ongoing dispute between the parties as the validity of the '907 patent. However, that issue is being litigated in a separate (but related and partially consolidated³) action in which the defense of invalidity has been asserted by DRL. The parties have each served their contentions regarding validity in that action. Consequently, even if subject matter jurisdiction existed in *DRL II* over the parties' validity dispute, the Court would, in its discretion under the Declaratory Judgment Act, not address the issue in *DRL II* and deny Plaintiffs' summary judgment motion. In light of *DRL I*, there simply is no reason to address validity in *DRL II* at this time, particularly given the stage of this case and the procedural posture in which the issue has been presented to the Court. It is plain that the parties' positions and actions on the issue of validity in *DRL II* are being driven not with an eye toward efficient

³ The cases have been consolidated for discovery purposes.

resolution of the issue on the merits, but rather by Plaintiffs' desire to inject into the litigation contentions that they were denied leave to raise in *DRL I*, as well as by DRL's desire to prevent Plaintiffs from raising such contentions. As Magistrate Judge Arpert earlier advised the parties, the issues regarding Plaintiffs' "validity contentions" are more appropriately addressed by way of a motion seeking leave to amend Plaintiffs' First Response to the Invalidity Contentions, which the Court decides below.

For all of the reasons above, Plaintiffs' motion for summary judgment of validity of the '907 patent is denied.

2. Motion to Strike Validity Contentions in *DRL II*

DRL has moved to strike the invalidity response (Second Response) served by Plaintiffs in *DRL II*. DRL argues that Local Patent Rule 3.6(i) permits a party alleging infringement to serve only a response to an accused infringer's invalidity contentions and DRL has not propounded invalidity contentions in *DRL II*. Plaintiffs oppose the motion, stating that they put forth their validity contentions in support of their request for a declaratory judgment of validity. However, for the reasons stated above, not the least of which is that there does not appear to exist a valid cause of action for a declaration of patent validity, the validity of the '907 patent is not at issue in *DRL II*.

Furthermore, the Court is not persuaded by arguments that *DRL I* and *DRL II* are essentially the same case and will be tried together, or that any decision regarding invalidity in *DRL I* necessarily impacts *DRL II*. Plaintiff has already served invalidity responses in *DRL I* and serving another "response" in *DRL II* when there have been no additional invalidity contentions would be either superfluous or simply an attempt to raise the additional contentions that Plaintiffs were not permitted to serve in *DRL I*.

The Court, therefore, shall grant DRL's motion and strike the validity contentions.

3. Motion to Amend Invalidity Responses in *DRL I*

This district's Local Patent Rules permit contentions to be amended "by order of the Court upon a timely application and showing of good cause." Local Patent Rule 3.7. Pursuant to Rule 3.7, a court may permit a party to amend its invalidity contentions provided the following three elements are established: (1) the moving party makes a timely application to the court; (2) there is good cause for the amendment; and (3) there is no undue prejudice to the adverse party.⁴ *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 10-6108, 2012 WL 3133943 at *2 (D.N.J. July 30, 2012). The rule provides a "non-exhaustive" list of examples of circumstances that may support a finding of good cause including:

(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.

Local Patent Rule 3.7.

The Local Patent 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 Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). However, while amendments to contentions are not granted as liberally as requests for amendments to pleadings, the Patent Rules retain some degree of flexibility and are not intended

⁴ The Court may only consider prejudice to the non-moving party if the moving party is able to demonstrate diligence. See Opinion at D.I. 134 (citing *Apple v. Samsung*, 2012 U.S. Dist. LEXIS 83115, at *13 (N.D. Cal. Mar. 27, 2012) (collecting cases)).

to be “a straitjacket into which litigants are locked from the moment their contentions are served.” *Id.*

This is Plaintiffs’ second motion to amend their invalidity responses in *DRL I*. The first was filed August 17, 2012. On March 18, 2013, Magistrate Judge Arpert denied the motion, finding that Plaintiffs failed to establish the requisite timeliness, good cause and lack of prejudice to permit the amendment. *See* D.I. 173. The Court first rejected Plaintiffs’ argument that they had good cause to amend because, as a result of inadvertence, Plaintiffs’ original invalidity responses neglected to address particular patent claims and, further, Plaintiffs’ had changed counsel: “Given the sophistication and number of attorneys involved, the Court is not persuaded that Plaintiffs were diligent in either discovering prior errors or omissions, or moving to amend their responses until seven months after they were first submitted.” D.I. 173 at 6. The Court further rejected Plaintiffs’ arguments regarding “inadvertent omissions,” finding: “The length and nature of Plaintiffs’ proposed amendments, moreover, do not suggest inadvertent omission. To the contrary, they are more in line with changes that reflect a shift in theory or position by Plaintiffs.” *Id.* at 7. Additionally, the Court found that allowing Plaintiffs’ amended invalidity contention responses would prejudice DRL because of “the additional resources DRL would need to expend in order to defend against the new theories and defenses introduced by Plaintiffs” and “this proceeding is no longer in its early stages.” *Id.* at 9. Finally, the Court also rejected Plaintiffs’ argument that they should be allowed to “conform” their responses to DRL to responses in a related case, with which *DRL I* has been consolidated for purposes of discovery. *Id.* at 8.

Less than six months after Magistrate Judge Arpert issued his decision, Plaintiffs filed the instant motion to amend. In this second motion, Plaintiffs are seeking to file substantially the

same amended invalidity responses as they sought in the earlier motion. Plaintiffs now claim that the filing of *DRL II* provides good cause for granting this motion in *DRL I*. According to Plaintiffs, the “changed procedural and scheduling posture due to DRL’s second ANDA and the effect an in validity holding in *DRL I* will have on *DRL II*” provides good cause for the requested amendment. However, Plaintiffs never really explain exactly how the filing of *DRL II* is such a change in circumstances that it would justify altering the earlier ruling. Indeed, the filing of *DRL II* or a change in the litigation schedule cannot, for example, remedy the lack of diligence or the lack of “inadvertence” found by Magistrate Judge Arpert. Here, Plaintiffs appear to simply be attempting to take a second bite at the proverbial apple.

Consequently, the Court finds Plaintiffs’ motion to be without merit, and the motion is denied.

III. CONCLUSION

For the reasons above, Plaintiffs’ motion for summary judgment and motion to amend it invalidity responses are denied. DRL’s motion to strike is granted. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge