

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**EPITOPIX, LLC d/b/a
VAXXINOVA US,**

Plaintiff,

v.

ZOETIS INC.,

Defendant.

Civil Action No.: 23-2467 (BRM) (JSA)

**MEMORANDUM OPINION
AND ORDER**

JESSICA S. ALLEN, U.S.M.J.

This is a patent infringement case. Plaintiff, Epitopix, LLC d/b/a Vaxxinova US (“Plaintiff”), alleges that Defendant, Zoetis, Inc. (“Defendant”), has infringed U.S. Patent No. 8,637,048 (“the ’048 patent”). Before the Court is Defendant’s motion to amend its invalidity contentions. (ECF Nos. 128, 137). Plaintiff opposes the motion. (ECF No. 134). No oral argument was heard. *See* Fed. R. Civ. P. 78. For the reasons stated below, and for good cause shown, Defendant’s motion is **DENIED**.

I. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND¹

Plaintiff produces lines of vaccine products utilizing SRP² technology covered by the ’048 patent (as well as other non-asserted patents), including vaccines for cattle, poultry and swine. (Compl., ¶¶ 1, 16). Plaintiff’s vaccines target bacteria such as *E. coli*, *Salmonella*, *Klebsiella*, and *Pasteurella*. (*Id.*, ¶ 16). Defendant is a former subsidiary of Pfizer Inc. that became an

¹ The parties are familiar with the factual background and procedural history. Only what is relevant to decide Defendant’s motion is recited herein.

² “SRP” is shorthand for “siderophore receptor protein.” (Compl., ¶ 8).

independent company in 2013. (*Id.*, ¶ 3). Plaintiff and Pfizer had a prior business relationship including a license agreement. (*Id.*, ¶ 27). However, Plaintiff contends that Defendant “proceeded to use [Plaintiff’s] patented SRP technology in new products beyond the scope of the limited commercialization rights,” including in Defendant’s *Enviracor J-5* product, an *E. coli* bacterin recommended for use in cattle. (*Id.*, ¶¶ 28-33).

The Complaint was filed on May 4, 2023. (ECF No. 1).³ A Pretrial Scheduling Order was entered on September 11, 2023. (ECF No. 28). Defendant served its invalidity contentions on or about December 13, 2023, which contained, among other things, several theories of indefiniteness, pursuant to 35 U.S.C. § 112. (*See* ECF No. 134 at 1).⁴

On February 8, 2024, the parties exchanged their preliminary proposed claim constructions and supporting evidence. (*See* ECF No. 39). The parties completed claim-construction briefing on June 17, 2024. (*See* ECF Nos. 62, 64). On October 30, 2024, the Honorable Brian R. Martinotti, U.S.D.J. conducted a *Markman* hearing. (*See* ECF No. 81). On January 23, 2025, Judge Martinotti issued a *Markman* Opinion and Order construing the disputed claim terms. (*See* ECF Nos. 89-90). On February 21, 2025, Judge Martinotti entered a stipulation that reduced the number of remaining claims at issue in the case to four (4). (*See* ECF No. 99).⁵

On May 2, 2025, Defendant purported to serve Plaintiff with supplemental invalidity contentions asserting two new theories of indefiniteness under 35 U.S.C. § 112. (*See* ECF No.

³ The '048 patent expired on or about January 3, 2022. (Compl., ¶ 15).

⁴ A claim is indefinite, and thus invalid under 35 U.S.C. § 112, if the claim “read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

⁵ Claims 21, 22, 47, and 50 of the '048 patent (the “asserted claims”).

129 at 4, at times, “the supplemental contentions”). According to Defendant, the new indefiniteness theories identified in the supplemental contentions are based on “grammatical errors” in Claims 21 and 22 that allegedly render the asserted claims in ’048 patent “unintelligible.” (ECF No. 129 at 5). In response, Plaintiff objected to the supplemental contentions as being impermissibly served without leave of Court in violation of Local Patent Rule 3.7. (See ECF No. 126).

On August 13, 2025, the Court held a case management conference and advised Defendant that its supplemental contentions could not be unilaterally served pursuant to the Local Patent Rules. (See ECF No. 126). Accordingly, the Court directed the parties to informally address the issue and, if it could not be resolved, for Defendant to file a motion to amend its invalidity contentions. (*Id.*) Ultimately, the parties were unable to resolve their dispute. (See ECF No. 127). Defendant’s motion to amend its invalidity contentions followed. (See ECF Nos. 128, 134, 137).

II. DISCUSSION

A. Legal Standard

“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 case.” *Amgen Inc. v. Kashiv Biosciences LLC*, 2019 WL 5445974, at *1 (D.N.J. Oct. 24, 2019). The Patent Rules “are designed to require the parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.” *Id.* (internal quotation omitted).

Pursuant to Local Patent Rule 3.3, a party opposing an assertion of patent infringement must serve on all parties its “Invalidity Contentions,” which shall contain, among other things, the

following information: (a) the identity of each item of prior art that allegedly anticipates each asserted claim or renders it obvious, (b) an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness, (c) a chart identifying where specifically in each alleged item of prior art each limitation of each asserted claim is found, and (d) a detailed explanation of the bases for the asserted grounds of invalidity based on enablement or written description under 35 U.S.C. § 112. *Id.*; *see also Jazz Pharma. Ireland Ltd. v. Lupin, Inc.*, 2026 WL 191182, at *4 (D.N.J. Jan. 26, 2026).

Local Patent Rule 3.7 provides that any “[a]mendment of any contentions . . . pursuant to these Local Patent Rules may be made only by order of the Court upon a *timely application and showing of good cause.*” L. Pat. R. 3.7 (emphasis added).

In seeking leave to amend, the party applying for leave must demonstrate that (1) the application is timely; (2) there is good cause for the amendment; and (3) the adverse party will not suffer undue prejudice if leave to amend is granted. *See Celgene Corp. v. Natco Pharma Ltd.*, 2015 WL 4138982, at *4 (D.N.J. July 9, 2015). The Patent Rules are not “a straitjacket into which litigants are locked from the moment their contentions are served,” *Abraxis BioScience, LLC v. Actavis, LLC*, 2017 WL 2079647, at *2 (D.N.J. May 15, 2017), and there is “unquestionably . . . a modest degree of flexibility with regard to amendments of contentions, at least near the outset of a case.” *Horizon Pharma AG v. Watson Labs, Inc.*, 2015 WL 12850575, at *3 (D.N.J. Feb. 24, 2015) (internal cites omitted). At the same time, motions to amend invalidity contentions “are not granted as liberally as motions to amend pleadings . . . because the philosophy behind amending claim charts is decidedly conservative and designed to prevent the shifting sands approach to a party’s contentions.” *Nautilus Neurosciences, Inc. v. Wockhardt USA, LLC*, 2013

WL 7901901, at *7 (D.N.J. Jan. 23, 2013) (internal quotes and cites omitted). Accordingly, “[s]ufficiently satisfying the elements set forth in Rule 3.7 is not a simple undertaking and requires the movant to overcome a substantial preference against granting the amendment.” *Razr USA LLC v. DGL Grp. Ltd.*, 2022 WL 714736, at *3 (D.N.J. Mar. 10, 2022).

In assessing a request to amend, courts first look at timeliness. *See, e.g., AS America, Inc. v. Masco Corp. of Indiana*, 2013 WL 4084237, at *2 (D.N.J. Aug. 13, 2013). Courts have equated timeliness with the diligence of the moving party. *See, e.g., id.; Warner Chilcott Co., LLC v. Lupin Ltd.*, 2013 U.S. Dist. LEXIS 116988, at *5 (D.N.J. Aug. 19, 2013) (diligence equates to timeliness under Rule 3.7). Courts have interpreted diligence as requiring a “showing that the party seeking leave to amend acted . . . promptly [in] moving to amend when new evidence is revealed in discovery.” *Warner Chilcott*, 2013 U.S. Dist. LEXIS 116988, at *5 (citing *O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc.*, 467 F. 3d 1355, 1366 (Fed. Cir. 2006)). The diligence requirement has two aspects: “One is whether the moving party acted diligently to discover that a supplement or amendment was appropriate. The second aspect is whether the moving party promptly moved to amend its contentions after it learned an amendment was necessary.” *AS America*, 2013 WL 4084237, at *2.

As it relates to good cause, Rule 3.7 provides a “non-exhaustive” list of examples that may, absent undue prejudice to the adverse party, support a finding of good cause: “(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 searches; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of Infringement contentions; (d) disclosure of an infringement contention by a

Hatch–Waxman Act party asserting infringement ... that requires response by the adverse party because it was not previously presented or reasonably anticipated” *Id.*⁶

While lack of prejudice to the non-moving party must also be established to obtain leave to amend under Rule 3.7, this requirement need not be considered unless the moving party has first shown it was diligent in discovering that an amendment was appropriate and promptly moved to amend its contentions. *See Jazz Pharms., Inc. v. Roxane Labs., Inc.*, 2013 WL 785067, at *5 (D.N.J. Feb. 28, 2013) (“Only if the moving party is able to show diligence may the court consider the prejudice to the non-moving party.”) (citing *CBS Interactive, Inc. v. Etilize, Inc.*, 257 F.R.D. 195, 201 (N.D. Cal. 2009)). As addressed below, the Court finds that Defendant did not act diligently or timely move to amend, and thus, need not reach the issue of prejudice to the non-moving party.

B. Parties’ Arguments

Defendant candidly acknowledges that its request to amend “does not fit neatly into any of the circumstances for good cause listed in Rule 3.7” (ECF No. 129 at 4). However, Defendant maintains that it should nevertheless be permitted to serve its supplemental contentions because it has met the “spirit” of the timeliness requirement in Local Patent Rule 3.7. (*Id.* at 3). Specifically, Defendant contends that, during the *Markman* hearing, Judge Martinotti deferred questions of indefiniteness until summary judgment motion practice. (*Id.* at 5). Defendant thus

⁶ Some courts also consider the following in assessing whether there is good cause: “(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.” *AS America*, 2013 WL 4084237, at *2; *see also Oy Ajat, Ltd. v. Vatech Amer., Inc.*, 2012 WL 1067900, at *20 (D.N.J. March 29, 2012).

argues that because Judge Martinotti has deferred indefiniteness issues until the summary judgment phase, the new indefiniteness theories in the supplemental contentions are “timely” for purposes of Patent Rule 3.7. (*Id.*)

In opposition, Plaintiff contends that Defendant’s proposed supplemental contentions, alleging “grammatical” inconsistencies in two claims, are based solely on the face of the patent’s claims and thus could have been raised by Defendant since the outset of the litigation. (ECF No. 134 at 10). Plaintiff continues that Defendant does not explain or identify any reason why the new indefiniteness theories could not have been included in its initial invalidity contentions served in December 2023. Thus, according to Plaintiff, Defendant has not been diligent in seeking leave to amend and has failed to establish good cause. (*Id.* at 10-12). Plaintiff further submits that Judge Martinotti’s decision to defer questions of indefiniteness to summary judgment motion practice is not a “free pass” to untimely amend invalidity contentions and does not excuse Defendant’s lack of diligence. (*Id.* at 6). Finally, Plaintiff contends that prejudice should not be considered since Defendant did not meet the threshold showing of diligence, but nevertheless contends it would be prejudiced if the amendments were allowed. (*Id.* at 12-14).

C. Analysis

It is undisputed that Defendant’s motion seeks to introduce two new theories of indefiniteness through the supplemental contentions. The Court concludes that Defendant has untimely moved to amend and that good cause has not been shown.

Indefiniteness is a relatively basic concept—that is, a patent is supposed to identify to a person of skill in the art the distinction between what is claimed and what is not. *See 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.” *Auxilium Pharma., Inc. v. Watson Labs, Inc.*, 2013 WL 12149760, at *7 (D.N.J. June 6, 2013). “Of particular importance for this analysis is that a court looks to the disclosure of the patent, and the intrinsic evidence, to decide indefiniteness.” *Id.* Indefiniteness arguments are thus often readily discernable and must be included in invalidity contentions. *See* L. Pat. R. 3.3(d) (invalidity contentions must contain “[a]ny grounds of invalidity based on ... indefiniteness under 53 U.S.C. § 112(1)”).

Here, Defendant’s proposed new indefiniteness theories contained in the supplemental contentions are based on the plain language of the ’048 patent. Defendant indisputably has had the ’048 patent since at least May 2023, when the Complaint was filed—and likely long before then. Defendant’s invalidity contentions were served in December 2023, and those contentions included certain indefiniteness arguments. (*See* ECF No. 134 at 1). Defendant’s motion papers provide no explanation as to why it could not, despite exercising due diligence, assert these completely new indefiniteness arguments in its original contentions. The present record before this Court demonstrates that the new indefiniteness arguments are not based on any newly discovered evidence, claim construction ruling, or any other intervening circumstance that might constitute good cause. Rather, it appears that Defendant has simply re-evaluated the asserted claims and seeks to add new arguments. This amounts to a litigation strategy, which is not akin to showing good cause. Defendant’s new theories are based on the plain language of the patent that has been publicly available and unchanged since the patent issued. Thus, the time to add

these new arguments has passed. Accordingly, the Court finds that Defendant's motion, which comes nearly twenty months after its initial invalidity contentions were served, is untimely, devoid of demonstrating due diligence, and lacks good cause. *See, e.g., Nautilus Neurosciences, Inc.*, 2013 WL 7901901, at *7 ([B]y failing to sufficiently explain why they were unable to uncover . . . the defense of indefiniteness prior to submitting their contentions, Defendants fail to carry their burden of demonstrating they acted diligently."); *Auxilium*, 2013 WL 12149760, at *8 (request to amend to include indefiniteness arguments not timely when movant "could have reviewed" the patent and disclosure and considered indefiniteness months earlier).

Defendant contends that Judge Martinotti's decision to defer consideration of indefiniteness issues until dispositive motion practice renders its application timely. (*See* ECF No. 129 at 5). However, that is a non sequitur, as timeliness is measured by a party's diligence. *See Warner Chilcott Co.*, 2013 U.S. Dist. LEXIS 11698, at *5. And here, Defendant has not been diligent because Defendant's proposed new indefiniteness positions are not based on the substance of the Court's *Markman* Opinion, but rather, are grammatical and based on the face of the patent that has been available for years. *See, e.g., Nautilus Neurosciences, Inc.*, 2013 WL 7901901, at *7.

For the foregoing reasons, Defendant has failed to show that its motion to amend is timely or establish good cause pursuant to Rule 3.7. The absence of diligence and lack of good cause is fatal to Defendant's motion. Accordingly, the Court need not address whether Plaintiff would be unfairly prejudiced by the amendment. *See, e.g., Horizon*, 2015 WL 12850575, at *5 ("Ordinarily the Court will only consider prejudice to the non-moving party if the moving party has made the requisite showing of diligence."); *Auxilium*, 2013 WL 12149760, at *8 (declining to evaluate

prejudice when movant did not establish good cause).

III. CONCLUSION

For the reasons stated above, Defendant's motion for leave to amend its invalidity contentions, (ECF No. 128), is **DENIED**.

SO ORDERED.

s/Jessica S. Allen
Hon. Jessica S. Allen
United States Magistrate Judge

Dated: February 27, 2026

cc: Hon. Brian R. Martinotti, U.S.D.J.