

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

AURINIA PHARMACEUTICALS INC.,	:	
	:	
Plaintiff,	:	Civil Action No. 20-19805 (GC)(DEA)
	:	
v.	:	
	:	OPINION
SUN PHARMACEUTICAL INDUSTRIES, INC.,	:	
et al.	:	
	:	
Defendants.	:	

This matter comes before the Court on the following two motions: (1) a motion by Plaintiff Aurinia Pharmaceuticals Inc. (“Aurinia” or “Plaintiff”) for leave to amend its infringement contentions (ECF No. 47); and (2) a motion by Defendants Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries, Ltd. (collectively “Defendants” or “Sun”) for leave to amend their counterclaims (ECF No. 91). The Court heard oral argument on June 14, 2022. For the reasons below, Plaintiff’s motion is granted in part and denied in part, and Sun’s motion is granted.

I. Plaintiff’s Motion to Amend Its Infringement Contentions

This is a patent infringement action in which Plaintiff alleges that Defendants infringe U.S. Patent Nos. 10,265,375 (the ’375 Patent) and 10,973,871 (the ’871 patent) (together, the “Asserted Patents”) by Defendants’ commercial manufacture, use, offer to sell and sales of Defendants’ CEQUA product, a calcineurin inhibitor immunosuppressant ophthalmic solution. Pursuant to Local Patent Rule 3.7, Plaintiff moves to amend its infringement contentions. Plaintiff states that the basis for the proposed amendments are documents that were produced by

Sun after the deadline for Plaintiff's initial contentions concerning the nature and qualities of the components of Sun's allegedly infringing product.

A. Plaintiff's Opening Arguments

According to Plaintiff, on July 1, 2021, Plaintiff served its first set of requests for production of documents on Defendants, including requests for documents relating to Defendants' New Drug Application ("NDA") and product formulation and specifications for the accused product. Soon after, on July 12, 2021, Defendants demanded Plaintiff dismiss the action, alleging that CEQUA does not infringe the Asserted Patents based on third-party testing of the surfactants used in CEQUA. Defendants contended that the testing allegedly showed that the two surfactants do not have an absolute difference of greater than about 3 as required by the asserted claims.¹ Plaintiff disagreed based on publicly available information and requested from Sun complete documentation around the third-party testing.

In accordance with the Scheduling Order, Plaintiff served its disclosure of asserted claims and infringement contentions on July 27, 2021 and amended those contentions a few days later. According to Plaintiff, at that time, Sun had not produced any non-public technical documents showing "the nature and qualities of the components of their infringing CEQUA product, including without limitation, non-publicly available information contained in their NDA and product specifications or documents relating to the secret third party testing." ECF No. 47-1 at 6.

¹ The Asserted Patents independent claim limitations require "a pharmaceutical composition comprising a calcineurin inhibitor or mTOR inhibitor, a first surfactant with an HLB index greater than about 10, and a second surfactant with an HLB index of greater than about 13, wherein an absolute difference between the HLB index of the first surfactant and the HLB index of the second surfactant is greater than about 3, wherein the composition is in the form of mixed micelles having the first and second surfactants; and wherein the composition contains less than 2% by weight ethanol." ECF Nos. 1, 20. The claim limitations requiring "a first surfactant with an HLB index greater than about 10, and a second surfactant with an HLB index of greater than about 13, wherein an absolute difference between the HLB index of the first surfactant and the HLB index of the second surfactant is greater than about 3" are also required by the remaining asserted dependent claims of the Asserted Patents. *Id.*

Plaintiff states that it continued to seek production of the documents relating to the third-party testing through further correspondences and meet and confers. Defendants served their initial Non-Infringement Contentions on September 15, 2021, but, according to Plaintiff, did not provide any underlying documentation to support its assertion that the HLB limitations were absent. After further communications between the parties, on October 15, 2021, Defendants produced certain documentation related to the third-party testing. Defendants continued to supplement their production through December 7, 2021. According to Plaintiff, the December 7th supplemental production contained key information regarding Defendants' representations to the FDA regarding the nature and qualities of the surfactants used in CEQUA relevant to its infringement contentions.

On December 23, 2021, Plaintiff served Second Amended Infringement contentions, and on January 3, 2022, Defendants stated they would not consent to the amendment. This motion followed.

In its moving brief, Plaintiff argues that (1) good cause exists to permit amendment; and (2) the amendment does not prejudice Defendants. As to good cause, Plaintiff asserts it acted diligently and promptly in supplementing its infringement contentions as new, nonpublic information became available to it. Plaintiff claims it acted diligently in attempting to obtain the non-public information and, once it acquired the information, it acted promptly in seeking to amend its contentions.

As to prejudice, Plaintiff contends that Defendants cannot be surprised by the proposed amendment given that Plaintiff is citing Defendants' own information, which Defendants have had knowledge of this information in its possession and control since the outset of this case. Further, Plaintiff claims that its proposed amendment will not result in any additional burden or

costs to Defendants because it does not add new products, patents or even claims to the case. Last, Plaintiff asserts that the proposed amendment will not cause any delay in the case.

B. Defendants' Responsive Arguments

Defendants do not oppose Plaintiff amending its contentions “to only add citations to non-public documents produced by Sun after Aurinia’s initial contentions deadline.” ECF No. 53 at 2. However, Defendants oppose the motion in all other respects and argue that the amendments Plaintiff seeks “dramatically change and redo its infringement contentions.” *Id.* at 3.

According to Sun, shortly after receiving Plaintiff’s initial infringement contentions on July 27, 2021, Defendants informed Plaintiff that its contentions were deficient. Specifically, Defendants state that they pointed out “Aurinia’s failure to comply with the Local Patent Rules by (i) providing only boilerplate allegations of infringement under [the Doctrine of Equivalents] ...; (ii) failing to identify its own product that allegedly practices the alleged invention of the Asserted Patents; and (iii) failing to separately identify by production number the documents for each category of Aurinia’s contentions, as required by L. Pat. R. 3.2(g).” *Id.* Three days later, Plaintiff served its first set of Amended Contentions, but, according to Defendant, other than identifying the documents required under Local Patent Rule 3.2(g), Plaintiff did not correct any of the deficiencies identified by Sun.

Defendants allege that they continued to advise Plaintiff that its contentions were deficient under the Local Patent Rules. According to Sun, Plaintiff maintained that its contentions satisfied the Local Patent Rules and never sought to amend to address the alleged deficiencies identified by Defendants.

Sun disputes Plaintiff’s assertion that the proposed amendments are based on “new information recently identified by Aurinia during discovery.” Sun contends that Plaintiff’s

proposed amendments include much more. For example, Defendants point to, “13 pages of new practicing product allegations and tens of new [Doctrine of Equivalents] arguments” and argue that Plaintiff provides no explanation as to how any of the “new information recently identified by Aurinia during discovery” relates to these amendments. ECF No. 53 at 5-6. Defendants point to the following specific amendments that they contend are improper:

First, Defendants point to Plaintiff’s disclosure requirement regarding its own product under Local Patent Rule 3.1(g).² Sun notes that in Plaintiff’s Initial Contentions and First Amended Contentions Plaintiff’s entire disclosure pursuant to Local Patent Rule 3.1(g) regarding its own product was a single sentence: “Aurinia has had an ophthalmic pharmaceutical product in commercial development since at least 2015.” Plaintiff cited no documents (in its Initial Contentions), did no claim chart mapping, and provided no product name. Defendants allege that defense counsel repeatedly wrote to Plaintiff complaining of the deficiencies in Plaintiff’s 3.1(g) contentions, advising that Plaintiff’s failure to show how its own product mapped to the asserted claims was prejudicing Sun’s ability to prepare its case. Sun states that now, in its proposed Second Amended Contentions, Plaintiff for the first time provides 13 pages of new claim-by-claim contentions for its allegedly practicing product and cites documents allegedly in support thereof. Plaintiff, however, has provided no explanation as to why it waited so long to provide this information. Because the information about Plaintiff’s alleged practicing product has been within Plaintiff’s possession, custody, and control, Sun argues that Plaintiff has not shown good cause for this amendment. Further, Defendants contend they would be prejudiced, as they may

² Local Patent Rule 3.1(g) provides: “If a party asserting patent infringement wishes to preserve the right to rely, for any purpose, on the assertion that its own apparatus, product, device, process, method, act, or other instrumentality practices the claimed invention, the party shall identify, separately for each asserted claim, each such apparatus, product, device, process, method, act, or other instrumentality that incorporates or reflects that particular claim”.

have utilized different discovery requests or interrogatories, or developed new and/or different defenses, had they known this new information regarding the purportedly practicing product.

Second, Defendants contend that the amendments regarding Plaintiff's new Doctrine of Equivalents ("DOE") arguments should not be permitted. Sun argues that Plaintiff fails to specifically address these amendments in its briefing and does not articulate any good cause for this amendment. According to Sun, Plaintiff's Initial and First Amended Contentions included only insufficient, boilerplate DOE allegations that do not meet the requirements of this District's Local Patent Rules. Specifically, for each and every limitation, Plaintiff simply asserted that Defendants' mode of infringement was "Direct or Under the Doctrine of Equivalents". Sun notes that despite Sun's repeated complaints about this deficiency, Plaintiff waited until now to seek to amend its DOE theories. Defendants contend that the proposed DOE contentions are untimely, lack good cause, and prejudice Defendants. In particular, Sun states that the new DOE arguments do not provide a citation to any Sun document (*i.e.*, the purported justification for the proposed amendments), and do not provide a reason that these assertions could not have been made in the earlier-served contentions. As to prejudice (an issue which Defendants argue is not necessary to reach due to the lack of good cause), Sun claims to have been disadvantaged in the claim construction process, specifically in understanding how Plaintiff thought Sun's CEQUA product read on the claims.

Third, Sun alleges that Plaintiff supplemented its claim charts with citations to documents other than the new Sun documents. For example, Plaintiff also adds citations to pages in documents that it clearly was aware of because those same documents were cited in prior versions of its contentions. Defendants contend that it is too late for Plaintiff to now supplement

its contentions with citations it was aware of when it served its Initial and First Amended Contentions.

Finally, Defendants point out that Plaintiff's proposed Second Amended Contentions includes an entirely new section, "Response to Defendants' Noninfringement Contentions." Defendants maintain that this amendment is outside what the Local Patent Rules permit, and that Plaintiff has not articulated any good cause showing that this amendment is proper. Sun contends, contrary to Plaintiff's assertions, that it never kept any part of its testing to show noninfringement a "secret", and it provided Aurinia with a report reflecting its testing of the surfactants used in Sun's accused CEQUA product prior to Plaintiff's initial contentions being served.

C. Plaintiff's Reply

In response to Sun's assertions that the proposed Second Amended Contentions contain amendments not based on the new discovery produced by Sun, Plaintiff states that its proposed amendments merely "clarify and provide additional detail on Aurinia's existing infringement theories based primarily on the withheld information." ECF No. 55 at 3-4. First addressing Sun's assertions regarding Plaintiff's Rule 3.1(g) disclosures, Plaintiff takes issue with Defendants' claim that it provided only a single sentence in both sets of contentions. Plaintiff notes that in its First Amended Contentions, in addition to the single sentence pointed to by Defendants, Plaintiff also provided citations to a number of documents. Plaintiff further argues that its proposed amendment clarifies and provides greater detail on the contentions already asserted about its practicing product. It contends that the proposed amendment does not assert any new practicing products and does not add additional asserted claims, but rather "reduces the number of asserted claims and provides clarity to Aurinia's earlier contentions to avoid unnecessary disputes during

discovery.” *Id.* at 6. Plaintiff claims that contrary to the assertions by Defendants, there is no prejudice to Defendants because Plaintiff is not introducing any “new” information into the case.

Turning next to Defendants’ arguments regarding the DOE, Plaintiff contends that its earlier disclosures were not “insufficient” as alleged and, further, that its proposed amendment does not present “new” DOE theories late in the case. Plaintiff claims to be seeking “to amend its contentions to clarify and provide greater detail.” *Id.* at 10. Plaintiff asserts it “acted diligently and timely in refining its infringement contentions as new, nonpublic information was produced by Defendants in October and December, *e.g.*, the source and precise composition of the surfactants used in Defendants’ infringing product.” *Id.* For example, Plaintiff points to its DOE assertions tied to the literal infringement assertions for claim 1 of the ’375 Patent, which cite to ten documents produced by Defendants after Aurinia’s initial infringement contentions were due, six of which were produced on December 7, 2021. Plaintiff further argues that Defendants can point to no real prejudice, as Defendants identify no actual terms needing construction and fail to identify any such issue in their subsequently filed Opening Claim Construction Brief.

Addressing Sun’s assertion that Plaintiff’s responses to Defendants’ noninfringement contentions should not be permitted, Plaintiff contends this position is “without merit” because: (1) any additional page citations are not prejudicial to Sun and were in response to Defendants’ assertion that its product lacked certain claim elements; and (2) while Sun produced a 2-page report regarding alleged testing, Sun withheld the information underlying the testing for many months.

Last, Plaintiff reasserts that, overall, its proposed amendments would not prejudice Defendants in any way.

D. Sun's Sur-Reply

Sun requested leave to file a sur-reply brief, and the Court has reviewed and considered the sur-reply brief. Sun contends that Plaintiff's Reply fails to address the appropriate legal standard regarding amendment of contentions, noting, in particular, that

[d]iligence of the moving party is ... the dominant consideration in determining whether good cause exists under Rule 3.7. ... Moreover, the Court need not consider whether the non-party would suffer prejudice unless it has first found the moving party was diligent in discovering that an amendment was appropriate and then promptly moved to amend its contentions.

Razor USA LLC v. DGL Group, Ltd., No. 19-12939, 2022 WL 44627, at *6 (D.N.J. Jan. 5, 2022) (internal citations omitted). Sun points out that Plaintiff's arguments focus primarily on an alleged lack of prejudice to Sun.

As to Plaintiff's proposed amendments regarding its own practicing product, Sun disputes Plaintiff's claims that its allegations regarding its practicing product are "not new". Sun reiterates that Aurinia's initial contentions contained a single sentence disclosure regarding its practicing product and citation to five documents, and Aurinia has made no attempt to tie the alleged reason for the proposed amendment directly to the 13-page amendment of this section.

Further, Sun contends that Aurinia's allegations that its proposed amendments reduce the number of asserted claims is factually wrong, and the proposed amendments alter only the claims that Aurinia alleges are practiced by its own product. Sun states that Plaintiff's proposed amendments now asserts that its product practices two claims—claims 12 and 27 of the '375 patent—that were never previously asserted against Sun.

Sun maintains that Aurinia provides no rationale for why it should be allowed to now add new claim mapping and new documents to support its allegedly practicing product claims.

Because Aurinia cannot establish it was diligent in seeking to add these, Sun contends it should be prevented from amending its contentions pursuant to Local Patent Rule 3.1(g).

Turning to Plaintiff's proposed DOE amendments, Sun takes issue with Plaintiff's claims that its DOE theories are not new, but rather are meant to "clarify and provide greater detail." Sun notes that parties are not permitted to assert a general DOE theory and then proffer a more specific theory "when it becomes convenient". *Howmedica Osteonics Corp. v. Depuy Orthopaedics, Inc.*, No. 11-6498, 2014 WL 6675923, at *5 (D.N.J. Oct. 19, 2014) ("A patentee cannot be permitted to assert a general DOE theory of infringement and then proffer a more specific DOE theory whenever it becomes convenient for it to do so."). Further, Sun contends that Plaintiff falsely alleges that its "DOE assertions tied to Aurinia's literal infringement assertions" cite to new documents, and that a review of the redline document proves that none of Aurinia's new DOE allegations cite to any new documents, nor do they cite to the new Sun documents that provide the alleged good cause for Aurinia's amendments. Sun states that it has no objection to Aurinia's additional citations to non-public documents produced after Aurinia's contentions were due but maintains that these documents have no discernible relationship to Aurinia's DOE allegations and cannot provide good cause to amend Aurinia's DOE contentions.

Overall, Sun reasserts that the later-produced documents do not provide Aurinia good cause to for the extensive amendments sought, arguing that the good cause analysis must tie new documents directly to the proposed amendments, and that Plaintiff has failed to make this showing.

E. Analysis

Local Patent Rule 3.7 governs amendments of infringement contentions. Pursuant to Local Patent Rule 3.7, "Amendment of any contentions ... may be made only by order of the

Court upon a timely application and showing of good cause.” Local Patent Rule 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.” As relevant to the present case, these circumstances include: “... (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention; ...” 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 “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.” *Razor USA LLC v. DGL Grp., Ltd.*, No. 19-12939, 2022 WL 44627, at *3 (D.N.J. Jan. 5, 2022). The Rules “seek to balance the right to develop new information in discovery with the need for certainty as to legal theories.” *Nautilus Neurosciences, Inc. v. Wockhardt USA LLC*, No. 11-1997, 2013 WL 7901901, at *2 (D.N.J. Jan. 23, 2013). Courts have noted that, unlike the liberal standard for amending pleadings under Federal Rule of Civil Procedure 15(a), Patent Rule 3.7 implements a “conservative” approach to amending contentions, “designed to prevent the ‘shifting sands’ approach to claim construction.” *King Pharm., Inc. v. Sandoz Inc.*, No. 08-5974, 2010 WL 2015258 at *4 (D.N.J. May 20, 2010). Satisfying the requirements of Rule 3.7 “is not a simple undertaking and requires the movant to overcome a substantial preference against granting the amendment.” *Nautilus Neurosciences*, 2013 WL 7901901, at *2. Even so, the rule “is not a straitjacket into which litigants are locked from the moment their contentions are served,” but rather allows “a modest degree of flexibility, at least near the outset.” *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, No. 12-3289, 2014 WL 1494592, at *8 (D.N.J. Apr. 16, 2014).

Under Patent Rule 3.7, the Court may grant leave to amend infringement contentions upon a showing 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. *Razor USA*, 2022 WL 44627, at *4 (citing *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197, 2015 WL 4138982, at *4 (D.N.J. July 9, 2015)). The burden is on the moving party to demonstrate these criteria are met. *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, No. 10-6108, 2013 WL 785067, at *2-3 (D.N.J. Feb. 28, 2013).

It is Plaintiff's burden to establish the three necessary elements to grant this motion. First is whether the application is timely. To the extent that Plaintiff's proposed Second Amended Contentions include the addition of citations to non-public documents produced by Sun after Plaintiff's initial contention deadline, those proposed amendments are timely. However, the vast majority of the proposed amendments are not based upon these new documents. For example, with respect to its own practicing product (for which Plaintiff itself presumably has possessed the relevant information), Plaintiff proposes 13-pages of amendments that it claims "clarifies and provides greater detail on the contentions already asserted about its practicing product." Plaintiff also claims the amendments "clarify" its DOE assertions and, overall, "clarify" its infringement contentions. But absent a connection to the new information purportedly relied upon, such a "clarification" is untimely. The Court agrees with Defendants that Plaintiff has not made that connection.

Turning to the second factor, Plaintiff also must show that good cause exists for the amendment. Here again, Plaintiff points to the new information produced by Defendants in discovery as purportedly establishing good cause. However, as noted, Plaintiff has not shown there is a link between the amendments and the non-public documents produced by Defendants

after Plaintiff served its initial contentions. As such, good cause has not been established. The amendments are extensive, and Plaintiff has failed to draw a clear connection to most of the proposed amendments and the new information received.

Overall, Plaintiff's arguments focus heavily on the third prong of the analysis, *i.e.*, its assertion that there will be no prejudice to Sun by the proposed amendments. Sun, on the other hand, argues it would suffer prejudice if the amendments are permitted. However, the Court need not resolve that question. "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 evaluated unless the moving party has shown it was diligent in discovering that an amendment was appropriate and promptly moved to amend its contentions." *Razor USA LLC v. DGL Grp., Ltd.*, No. 19-12939, 2022 WL 714736, at *6 (D.N.J. Mar. 10, 2022). Plaintiff has failed to establish the first two factors of the analysis, therefore the Court does not consider the third factor.

In sum, the Court finds that, with limited exception, Plaintiff's proposed Second Amended Contentions are neither timely nor supported by good cause. Plaintiff's motion, therefore, is denied in all aspects but one. The Court will permit the proposed amendment only to the extent citations were added to documents produced by Sun after Aurinia's initial contentions deadline. The motion for leave to amend is denied in all other respects.

II. Sun's Motion to Amend Its Counterclaims to Add Inequitable Conduct

Sun seeks to amend its counterclaims to allege that the Asserted Patents are unenforceable under the doctrine of inequitable conduct. Specifically, Sun's proposed counterclaim alleges that Aurinia and its attorneys committed inequitable conduct by failing to include Dr. Kishore Cholkar as an inventor on the '375 and '871 Patents.

Dr. Cholkar was a Ph.D. student at University of Missouri-Kansas City (“UMKC”) working with Dr. Ashim K. Mitra, a named inventor listed on the Asserted Patents, beginning in approximately April 2008. According to Sun, Dr. Cholkar worked to develop stable ophthalmic compositions with calcineurin inhibitors or mTOR inhibitors for treating ocular diseases and conditions, including with voclosporin. Sun asserts that as a result of Dr. Cholkar’s extensive studies, conception, and experimentation, each independent claim of the Asserted Patents contains the limitation, “wherein the composition contains less than 2% by weight ethanol.”

According to Defendants, in 2018, Dr. Cholkar was in communication with Aurinia and worked with the attorneys prosecuting U.S. Application No. 14/627,063 (the “’063 Application”) that issued as the ’375 Patent. Sun states that Dr. Cholkar worked with Aurinia and its attorneys to draft a declaration in support of the patentability of the ’063 Application. In particular, Mr. Michael Martin, who is the current Chief Business Officer of Aurinia, approached Dr. Cholkar to discuss the declaration. Sun alleges that Mr. Martin met in-person with Dr. Cholkar and during the meeting stated to Dr. Cholkar that he knew Dr. Cholkar should have been named as a coinventor on the ’063 Application. On May 11, 2018, Dr. Cholkar submitted the signed declaration in support of the invention disclosed in the ’063 Application under 37 C.F.R. § 1.132. However, according to Sun, despite Mr. Martin’s acknowledgement of Dr. Cholkar’s contribution to the claimed subject matter of the ’063 Application, Dr. Cholkar was not named as a co-inventor.

On March 23, 2022, Sun served a subpoena to UMKC seeking documents related to the research and development work for the subject matter of the Asserted Patents. Sun received responsive documents from UMKC and produced them to Aurinia on April 13, 2022. Sun claims the documents that UMKC provided showed that Dr. Cholkar was involved with key studies

contributing to the alleged invention of the Asserted Patents. According to Sun, once Defendants fully learned the facts and circumstances detailed in its proposed Counterclaims, Sun notified Aurinia of its intention to amend its pleading. Plaintiff opposes the amendment.

A. Legal Standard

Pursuant to Federal Rule of Civil Procedure 15, leave to amend the pleadings is to be granted freely “when justice so requires.” The Federal Rules of Civil Procedure allow for amendments to be granted liberally in light of the “principle that the purpose of pleading is to facilitate a proper decision on the merits.” *Foman v. Davis*, 371 U.S. 178, 182 (1962) (citation and internal quotation marks omitted). Nevertheless, the Court may deny a motion to amend where there is “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment.” *Id.* However, where there is an absence of these factors, a motion for leave to amend a pleading should be liberally granted. *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004).

Plaintiff contends that leave to amend should be denied on the basis of futility, undue delay, and prejudice. The Court addresses each below.

B. Futility

The futility analysis on a motion to amend is essentially the same as a Rule 12(b)(6) motion. *See In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1332 (3d Cir. 2002). The proposed amended claim “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable

for the misconduct alleged.” *Id.* “[G]iven the liberal standard for the amendment of pleadings, ‘courts place a heavy burden on opponents who wish to declare a proposed amendment futile.’” *Brainbuilders, LLC v. Optum, Inc.*, No. 18-638, 2019 WL 2315389, at *5 (D.N.J. May 31, 2019). Therefore, “[i]f a proposed amendment is not clearly futile, then denial of leave to amend is improper.” *Id.*

“Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). A claim for inequitable conduct requires that (1) “the patentee acted with the specific intent to deceive the [Patent and Trademark Office (“PTO”)],” and (2) the material withheld from the PTO satisfies “but-for materiality,” that is, the PTO would not have allowed a claim had it been aware of the undisclosed material. *Therasense*, 649 F.3d at 1290-91. A party claiming inequitable conduct ordinarily must show that the patentee “withheld or misrepresented information that, in the absence of the withholding or misrepresentation, would have prevented a patent claim from issuing.” *Ohio Willow Wood Co. v. Alsp S., LLC*, 735 F.3d 1333, 1345 (Fed. Cir. 2013).

A counterclaim or affirmative defense of inequitable conduct sounds in fraud and therefore is subject to the heightened pleading standard of Fed. R. Civ. P. 9(b). “Whether inequitable conduct has been pleaded with particularity under Rule 9(b) is a question governed by Federal Circuit law.” *Sanders v. The Mosaic Co.*, 418 F. App'x 914, 918 (Fed. Cir. 2011) (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009)). “To plead inequitable conduct, ‘the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.’” *Id.* (quoting *Exergen*).

Plaintiff first alleges that the proposed amendment fails to meet the materiality standard because Sun fails to plead plausible facts that Dr. Cholkar was an inventor. Plaintiff points to Sun's assertions that Dr. Cholkar allegedly (1) contributed to conception of the patent claim limitation "wherein the composition contains less than 2% by weight ethanol"; (2) "examined the method of mixing the formulation to 95% ethanol to form an ethanolic solution and then evaporating the ethanolic solution to form a near-solid matter[, resulting] in near-solid matter that was essentially free of ethanol (about <2% ethanol)"; and (3) joined the laboratory of Dr. Mitra at UMKC beginning in April 2008 where his alleged work and contributions subsequently were allegedly performed. According to Plaintiff, however, the alleged conception (1) of being essentially free of ethanol (less than 2% ethanol) and (2) of mixing 95% ethanol to form an ethanolic solution and then evaporating the ethanolic solution to form a near-solid matter, was disclosed in Aurinia's provisional patent application (Aurinia's Provisional Application No. 60/997,796, dated October 8, 2007) six months before Dr. Cholkar joined UMKC.

Plaintiff also contends that the first example in the October 2007 provisional application specifically describes protocols for experiments of the same subject matter six months before Dr. Cholkar even joined UMKC to start work. As such, Plaintiff claims that Defendants' allegation that Dr. Cholkar contributed to the conception of less than 2% ethanol is not plausible under the Rule 12(b)(6) standards.

Plaintiff maintains that other allegations confirm the lack of plausibility of the inequitable conduct defense. First, they point to Defendants' citations to nine documents produced by UMKC to support the allegation that Dr. Cholkar contributed to the claim limitation, even though, according to Plaintiff, 8 out of these 9 documents are stand-alone documents that do not

mention Dr. Cholkar's name. And the one that does mention his name allegedly makes no specific attribution to Dr. Cholkar as conceiving of a less than 2% ethanol subject matter.

Second, Plaintiff notes that Dr. Cholkar did not represent himself to the Patent Office to be an inventor even though he knew and understood fully Aurinia's patent application. Defendants' proposed amended pleading references Dr. Cholkar's May 11, 2018 expert declaration filed by Aurinia in the Patent Office in support of the patentability of the '063 Application. This declaration avers that (1) he was fully aware of the contents of Aurinia's patent application disclosing the same less than 2% subject matter, (2) that he was not listed as an inventor on the application and (3) had no financial interest in the outcome of the '063 Application.

Third, Plaintiff contends that even if Dr. Cholkar should have been named as an inventor, such failure does not support a claim of inequitable conduct. Plaintiff points out that some courts have held that improper inventorship does not meet the "but-for" materiality requirement under *Therasense*. See, e.g., *Auxilium Pharms., Inc. v. Watson Lab'ys, Inc.*, No. CIV.A. 12-3084, 2014 WL 9859224, at *35 (D.N.J. Dec. 16, 2014) ("[I]ncorrect inventorship evidence is not but-for material under *Therasense*.").

Plaintiff further argues that Defendants' Proposed Amendment fails to meet the *Exergen* standard of specifically alleging the who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. As to the "who," Plaintiff asserts that it is insufficient for Defendants to allege that "Aurinia and its attorneys" had a duty of candor and good faith in dealing with the USPTO. While Plaintiff concedes that Defendants' Proposed Amendment does mention Mr. Michael Martin's name, Plaintiff claims that Defendants plead no facts beyond the conclusory allegation that Mr. Martin allegedly stated that he knew Dr. Cholkar

should have been named as a co-inventor on the '063 Application. Plaintiff maintains that this allegation is belied by Dr. Cholkar's averment of non-inventorship to the Patent Office and is not plausible.

Further, Defendants allege Mr. Martin met with Dr. Cholkar for purposes of discussing an expert declaration when he made this alleged statement. Plaintiffs point out that with this supposed knowledge, Dr. Cholkar then avers he is properly not listed as an inventor even though Dr. Cholkar avers he fully understood the subject matter of the Aurinia patent application. Plaintiff characterizes Defendants' allegations as asking the Court to leap to an inference of specific intent to deceive the PTO based on an inventorship allegation by a non-attorney without pleading any facts about (1) whether Mr. Martin knew the legal requirements for an inventor under the patent law, (2) whether he was using the term "inventor" colloquially or in accordance with the patent law, and (3) whether he intentionally caused his attorneys not to list Dr. Cholkar on the list of inventors when filing and maintaining the '063 Application. Thus, Plaintiff contends that Defendants have failed to plead facts "from which a court may reasonably infer that a party acted with the requisite state of mind." *Exergen*, 575 F.3d at 1327.

Finally, Plaintiff argues that Sun appears to be taking the position that because inventorship may be material to the PTO examination, it is sufficient to support an inference of intent to deceive. Plaintiff contends that under *Therasense*, courts "may not infer intent solely from materiality" and that "[i]ntent and materiality are separate requirements." *Therasense*, 649 F.3d at 1290.

In response, Sun asserts that Plaintiff's arguments, although couched in terms of plausibility, are in reality factual disputes. For example, Sun claims that the provisional patent application Plaintiff points to is not dispositive of the inventorship issue, but rather highlights the

factual disputes that exist between the parties related to the allegations in Sun's proposed amended pleading. Although Plaintiff asserts that the provisional application shows that Dr. Cholkar could not have invented the alcohol limitations recited in the ultimately issued patent claims, Sun states that the application specifically does not claim any subject matter related to the use of alcohol. Defendants, in fact, contend that differences between the disclosure in the provisional application and the language that ultimately appears in the issued patent claims is a result of Dr. Cholkar conducting numerous studies. As such, Sun asserts Dr. Cholkar conceived of part of the claimed invention.

Sun further argues that Plaintiff's additional points also relate to factual disputes between the parties and do not touch on the plausibility of the proposed counterclaims. Aurinia attaches a number of documents to its Opposition that Sun received from UMKC in response to Sun's document subpoena. These documents allegedly reflect studies and results from Dr. Cholkar's work on the project that led to the claimed invention. While Aurinia points out that Dr. Cholkar's name is not recorded on these documents, Sun argues this is inapposite. Sun states that it is not uncommon that an investigator's name is not included on raw data documenting work product, and further, that Plaintiff presents no evidence that these documents do not demonstrate Dr. Cholkar's work.

Sun also points to the declaration of Dr. Cholkar's relied on by Plaintiff that was submitted during the prosecution of the '375 Patent in support of its patentability. Plaintiff argues this declaration shows that Dr. Cholkar did not claim to be a coinventor, but Sun contends that Aurinia mischaracterizes this declaration as a disavowal of inventorship by Dr. Cholkar. Sun notes that in the declaration Dr. Cholkar merely recognizes that he "is not a listed inventor" on the pending patent application and goes on to provide information in support of patentability.

Sun argues that its proposed amended pleading properly alleges the who, what, when, where, and how of the material misrepresentation or omission committed by Aurinia before the U.S. Patent and Trademark Office. As to who, Sun's proposed amended pleading goes beyond merely alleging wrongdoing by an organization and its attorneys, and specifically alleges wrongdoing by Aurinia's current Chief Business Officer, Mr. Michael Martin. To the extent that Aurinia asserts that Mr. Martin may not have fully understood the legal requirements of inventorship and may have been using the term inventor "colloquially," Sun maintains that this merely highlights a potential fact dispute between the parties.

Sun points to a district court decision outside of this district that, contrary to the district court decision cited by Plaintiff, found that inventorship is a critical requirement for obtaining a patent, and can be considered "but for" material. *Imprenta Servs., Inc. v. Karll*, No. 22-6177, 2021 WL 4555333, at *3 (C.D. Cal. July 13, 2021) ("[A] full and accurate disclosure" of correct inventorship "is a critical requirement for obtaining a patent . . . [i]nventorship, then, is but-for material."). Sun also contends that purposefully omitting a coinventor during prosecution can qualify as egregious misconduct, since incorrect inventorship directly affects the validity of a patent. *See Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) ("When the patentee has engaged in affirmative acts of egregious misconduct . . . the misconduct is material.").

According to Sun, Aurinia also incorrectly claims that Sun infers deceptive intent only from its allegations of materiality. Defendants claim such an argument ignores the other allegations in Sun's amended counterclaims. Sun contends that, when the factual allegations in its proposed amended pleading are taken as a whole, a reasonable fact finder could infer deceptive intent to support a claim of inequitable conduct from the facts alleged by Sun.

The futility analysis requires to the Court to evaluate whether a claim is clearly futile on its face. While Plaintiff clearly disagrees with the assertions in Sun’s proposed inequitable conduct claim and raises a number of merits-based challenges to the facts asserted, such disagreement does not render the claim implausible for the purposes of a Rule 15 analysis. The Court agrees with Sun that much of Plaintiff’s futility argument highlights factual and legal disputes on the issues rather than plausibility. As the Hon. Mark Falk, U.S.M.J, observed in *High 5 Games, LLC v. Marks*:

these claims are lathered in fact disputes that are inappropriate to conclusively resolve in the context of a motion to amend. Amendment to the pleadings is a fairly basic practice that does not rise to the level of dispositive motion practice. And delving into the morass of fact questions inherent in these claims usurps dispositive motion practice and amounts to making embedded factual findings and dispositive decisions in the non-dispositive amendment context.

High 5 Games, LLC v. Marks, No. 13-7161, 2017 WL 349375, at *5 (D.N.J. Jan. 24, 2017).

Indeed, a motion for leave to amend under Rule 15 “does not require the parties to engage in the equivalent of substantive motion practice upon the proposed new claim or defense; this does require, however, that the newly asserted defense appear to be sufficiently well-grounded in fact or law that it is not a frivolous pursuit.” *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 469 (D.N.J. 1990). Here, the Court finds the proposed amendment to be sufficiently well-grounded as not to be frivolous, and it is not legally insufficient on its face. Under the liberal standards of Rule 15, the Court is satisfied the amendment is not futile.

C. Timeliness

The Court has discretion to deny a motion for leave to amend based upon undue delay. Notably, delay alone is insufficient grounds to deny an amendment. *Cornell and Co., Inc. v. Occupational Safety and Health Review Commission*, 573 F.2d 820, 823 (3d Cir. 2001). However, “at some point, the delay will become ‘undue,’ placing an unwarranted burden on the

court, or will become ‘prejudicial,’ placing an unfair burden on the opposing party.” *Adams v. Gould*, 739 F.2d 858, 868 (3d Cir. 1984). In fact, prejudice “is the touchstone for the denial of an amendment,” and a finding of unfair or substantial prejudice is sufficient ground for denial. *Cornell and Co., Inc.*, 573 F.2d at 823; *Lorenz v. CSX Corporation*, 1 F.3d 1406, 1414 (3d Cir. 1993). In evaluating the extent of any alleged prejudice, the Court looks to the hardship on the non-moving party if the amendment were granted. *Cureton v. NCAA*, 252 F.3d 267, 273 (3d Cir. 2001).

Plaintiff contends that Sun’s motion is untimely because Defendants knew of the facts underlying their inequitable conduct claims as early as February 2019 yet did not move to amend until May 2022. Plaintiff claims that Defendants learned of Dr. Cholkar’s work in February 2019, when UMKC filed a lawsuit against Sun and other parties, alleging Dr. Cholkar was an inventor to one of Sun’s patents. Plaintiff also notes that Sun had the belief that Dr. Cholkar was an inventor to the Asserted Patents when Defendants asserted an implied license defense in their Answer, which is dated June 2, 2021. When asked by Plaintiff about the factual basis for that assertion, Defendants in their interrogatory responses dated May 11, 2022, explain the factual basis for this defense as follows: “The alleged invention claimed in the Asserted Patents, on which Dr. Cholkar is an unnamed co-inventor, is encompassed within the General Release Agreement’s definition of Product and/or Related Product. Therefore, through the transfer and assignment of rights from Dr. Cholkar to Sun recited in the General Release Agreement, Sun acquired rights to the Asserted Patents and cannot infringe the Asserted Patents.” ECF No. 89-11 at 29. Thus, Plaintiff argues, Sun improperly delayed seeking to amend, and the motion should be denied as untimely.

In response, Sun argues first that its motion comes within the time set by the Scheduling Order. Sun also claims it required the documents it received from UMKC in late March “to corroborate any claim of inventorship.” Sun states that inequitable conduct is a “serious allegation and Sun does not make it lightly”, and it could not have made it without the corroborating documents.

Sun disputes Plaintiff’s allegation that Sun’s implied license defense pled in its Answer demonstrates that Sun knew the facts supporting its counterclaim at a much earlier time. Sun claims (1) it had to plead all possible defenses in its answer to Aurinia’s complaint or risk waiving its defenses; and (2) Sun pleading its implied license defense in its Answer is not akin to Sun having discovered all of the facts and circumstances supporting its inequitable conduct claims.

Sun contends that its knowledge that UMKC and Dr. Cholkar had previously alleged Dr. Cholkar was a co-inventor of a different set of patents, is irrelevant. According to Sun, the research work underlying those patents, which cover a different drug and different formulation, had nothing to do with the research work that led to Aurinia’s presently Asserted Patents.

“[T]he question of undue delay requires that [the Court] focus on the movant’s reasons for not amending sooner.” *Cureton v. Nat’l Collegiate Athletic Ass’n*, 252 F.3d 267, 273 (3d Cir. 2001). While it appears that Sun had formed a belief early in this litigation that Dr. Cholkar was a co-inventor, Sun maintains that it was not possible to assert an inequitable conduct claim until it received documents from UMKC in March 2022 allegedly corroborating its belief. Plaintiff disputes this, arguing that 8 of the 9 documents produced by UMKC do not even mention Dr. Cholkar’s name, and that the 9th document does not suggest that Dr. Cholkar is a co-inventor.

Sun responds that it is not uncommon for an investigator's name to be left off of work product and, in any event, Plaintiff's argument raises a question of fact.

Indeed, what the documents establish as to Dr. Cholkar is a question of fact that is not for the Court to determine on this motion for leave to amend. There does not appear to be a dispute that the documents, at least in part, relate to Dr. Cholkar. As such, the Court credits Sun's assertion that it was not until it received the UMKC documents that it felt it was appropriate to seek leave to amend to add the inequitable conduct claim. Moreover, while certainly not dispositive of the issue of timeliness, the motion for leave to amend was filed within the time set by the Scheduling Order. Taking all of these factors into consideration, the Court does not find there was undue delay by Defendants in seeking leave to amend.

D. Prejudice

As to prejudice, Plaintiff claims allowing the proposed amendment enlarges the litigation, imposing additional costs and likely delay as Defendants argue for more discovery. Plaintiff also argues it allegedly forces Aurinia to choose between maintaining its trial date and perhaps foregoing certain discovery or agreeing to push even further out its trial date while Defendants continue to infringe Aurinia's patents.

Sun, on the other hand, claims that Aurinia has not made any convincing showing of any prejudice it would face if Sun's proposed amended pleading is permitted because Sun's counterclaims do not add any new patents to this case. Additionally, Sun points out that Sun's allegations involve Mr. Michael Martin who was already listed in Aurinia's Rule 26 disclosures as early as July 2021. Mr. Martin was also already listed as one of Aurinia's ESI discovery custodians, and Sun has already noticed Mr. Martin for deposition.

As noted above, “prejudice to the non-moving party is the touchstone for the denial of an amendment.” *Lorenz v. CSX Corp.*, 1 F.3d 1406,1414 (3d Cir. 1993). In its evaluation of prejudice to the non-moving party in the context of a motion to amend, courts consider whether amendment would impair the non-moving party’s “ability to present its case.” *Diebler v. SanMedica Int’l, LLC*, No. 19-20155, 2021 WL 5013617, at *4 (D.N.J. Oct. 28, 2021). Importantly, “incidental prejudice to the opponent is not a sufficient basis for denial of an amendment; such prejudice becomes “undue” when the opponent shows it would be “unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered....” *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990). In determining whether undue prejudice will result if leave is granted, courts consider whether the assertion of any new claim will: “(i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction.” *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004).

The Court is not persuaded that permitting amendment at this point in the case would significantly delay the resolution of this matter or deny Plaintiff the opportunity to present facts or evidence to defend against Defendants’ claims. The amendment adds no new patents to the case. Discovery is ongoing, and discovery involving Mr. Martin has already been noticed by Defendants. The law requires leave to amend be liberally granted, and in its assessment of any potential prejudice, the Court finds no basis to deny such leave.

III. Conclusion

This matter is before the Court a motion by Plaintiff for leave to amend its infringement contentions (ECF No. 47); and a motion by Defendants for leave to amend their counterclaims

(ECF No. 91). For the reasons above, Plaintiff's motion is granted in part and denied in part, and Sun's motion is granted. An appropriate Order accompanies this Opinion.

s/ Douglas E. Arpert

DOUGLAS E. ARPERT
United States Magistrate Judge

Dated: August 2, 2022